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Annex 1. Additional comments

Annex 2. Overview of nomenclature systems for medical devices in WHO Member States
Acknowledgements

In order to respond to the World Health Assembly resolution 60.29 on health technologies, particularly medical devices, Adriana Velazquez Berumen, Team Lead for medical devices and in vitro Diagnostics, developed the concept and coordinated the work on the first Baseline country survey on medical devices (under the Global Initiative on Health Technologies) as well as the resulting Global Atlas of medical devices in 2010. Since then, to keep the data up-to-date, she coordinated various re-launches of the survey whose results were published as country profiles in book form and/or digital form on the WHO website\(^1\) in 2015 and 2017 and this present publication on 2022. The statistics are also found in the Global Health Observatory, where data has been updated after every edition. She worked in 2021, under the guidance from Dr Clive Ondari director of the Health Product Policy and Standards Department, and the leadership of Dr Mariangela Simao, Assistant Director General of the Access to Medicines and Health Products Division.

WHO acknowledges and is most grateful to the consultants, country focal points in the Ministries of Health and WHO staff at regional and country offices who dedicated their time and expertise to provide country data on medical devices. The survey was managed by Ricardo X. Martínez with the support of Heike Hufnagel and Valeria Montant. The analysis, evaluation, compilation, and verification of response data was coordinated and implemented by Ricardo X. Martínez with the assistance of Heike Hufnagel, Lucero López, Lucia Jiménez, Juan J. López, David López, and Artiom Schepilov.

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## Acronyms and abbreviations

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<td>CSoMD21</td>
<td>Country survey on medical devices 2020-2021</td>
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<td>FY21</td>
<td>Fiscal Year 2021</td>
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<td>EMDN</td>
<td>European Medical Device Nomenclature</td>
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<td>GII</td>
<td>Global Innovation Index</td>
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<td>GNI</td>
<td>gross national income</td>
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<td>GHO</td>
<td>WHO Global Health Observatory</td>
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<td>GMDN</td>
<td>Global Medical Device Nomenclature</td>
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<td>HDI</td>
<td>Human Development Index</td>
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<td>HTA</td>
<td>health technology assessment</td>
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<td>IAEA</td>
<td>International Atomic Energy Agency</td>
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<td>information, and communication technology</td>
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<td>ICT Development Index</td>
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<td>ITU</td>
<td>International Telecommunication Union</td>
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<td>IHDI</td>
<td>inequality adjusted Human Development Index</td>
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<td>IVDs</td>
<td>in vitro diagnostics</td>
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<td>MOH</td>
<td>Ministry of Health</td>
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<td>POP</td>
<td>population</td>
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<td>SDGs</td>
<td>Sustainable Development Goals</td>
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<td>UHC</td>
<td>Universal Health Coverage</td>
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<td>UMDNS</td>
<td>Universal Medical Device Nomenclature System</td>
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<td>UN</td>
<td>United Nations</td>
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<td>UN POP</td>
<td>United Nations Population Division of the Department of Economic and Social Affairs</td>
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<td>WB</td>
<td>World Bank</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>WIPO</td>
<td>World Intellectual Property Organization</td>
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Preface

Health technologies are essential for a functioning health system. Medical devices in particular are crucial in the prevention, diagnosis, and treatment of illness and disease as well as patient rehabilitation. Recognizing this important role of health technologies, the World Health Assembly adopted resolution WHA60.29 in May 2007.

To determine the key areas that require support for the development or improvement of health technology programs in countries and regions, the first WHO Baseline country survey on medical devices was launched in February 2010 by the WHO Department of Essential Health Technologies and resulted in the first set of country profiles conveying the situation of medical devices globally. The country profiles were updated with a re-launch of the survey in November 2013 and since then, every 3 years, updates of the global medical device data have been published. In 2017 the Global Atlas of medical devices' book was published containing 177 country profiles, an introduction to the medical device topics covered by the survey, and the corresponding facts, figures, and maps. From November 2020 until March 2021, the latest complete re-launch of the survey was carried out and its results are presented in this publication containing all 194 country profiles. It should be noted that the COVID-19 situation alerted the challenges presented by lack of priority or basic medical devices.

This publication is intended for use as a reference by decision-makers in ministries of health, nongovernmental organizations and academic institutions involved in health technology at the district, national, regional or global levels. For a deeper understanding of the importance and standing in the health care domain of each of the survey's topics please refer to the document “Global Atlas of medical devices - WHO medical devices technical series 2017” that addresses these in separate chapters.
Methodology

The 2020 re-launch of the 2010 Baseline country survey on medical devices was conceptualized and realized by the medical devices team. The appointed health technology focal points of 177 Member States\(^1\) and more than 500 country contacts, as well as WHO contacts and related contacts in the 17 countries without appointed focal points, were contacted by email in 4 different languages with a request to support and coordinate either the update of the information already available in the previous atlas data or - in case of countries that had not answered the previous surveys - their first participation in the survey. Additionally, the medical devices team with the help of consultants, performed a web-based desk review of all countries to verify, update or newly include valid links to national websites regarding regulation, health technology assessment, and nomenclature.

These efforts resulted in the final collection of all countries, either directly via nominated official health technology focal points i.e. 179 countries or indirectly via specific medical device country focal points. Results were analyzed, evaluated, compiled, and are now presented in this document in country profiles, together with additional information regarding the global and national medical device situations. The country profiles incorporate facts indicating the national status of medical devices in areas such as: medical device policies, regulations, incorporation, lists, inventories, production, nomenclature, health technology assessment, consumption, access, availability, management, and their use by health care health workers, patients, academia and biomedical engineering resources.

The focus of the 2021 edition of the Global Atlas is to point out how the status of medical device topics supports or hinders the accomplishment of the Sustainable Development Goals (SDGs) and collaborates to the progress of the country-specific Universal Health Coverage (UHC) path.

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\(^1\) The countries' health technology focal points were nominated and their roles established in a two year effort upon the initiative of the WHO medical devices team in 2010.
Sources of the country profile’s indicators

In the country profile there are four sections that contain indicators that may be taken from another source other than the Baseline Country Survey of Medical Devices 2020-2021 (BCSoMD21) consultation. Among these sources we have the following: International Atomic Energy Agency: IAEA; Organisation for Economic Co-operation and Development OECD; and WHO Global Health Observatory: GHO. Here we specified each of the indicators, as well as their definition, details and sources.

Country indicators section


**World Bank income group classification:** (WB Income Classification) The World Bank assigns the world’s economies to four income groups—low, lower-middle, upper-middle, and high-income countries. The classifications are updated each year on July 1 and are based on GNI per capita in current USD (using the Atlas method exchange rates) of the previous year (i.e. 2019 in this case). In this publication the classification used corresponds to the fiscal year of 2021: WB FY21 2019 (accessed June 2021: the link provided updates the year classification each 1st of July, if it is the case you must refer to the historical WB income classification to find the fiscal year of 2021: FY21).

**Life expectancy at birth (years):** The average number of years of life expected by a hypothetical cohort of individuals who would be subject during all their lives to the mortality rates of a given period. It is expressed as years. UNDP WPP 2019 (MOR) (accessed June 2021).

**Under-five mortality rate (SDG 3.2):** probability of dying by age 5 per 1000 live births. WHO Global Health Observatory (GHO) data. WHO GHO 2019 (accessed June 2021).

**Probability of dying 30-70 of NCDs (SDG 3.4.1):** probability of dying between age 30 and exact age 70 years from any of cardiovascular disease, cancer, diabetes, or chronic respiratory disease. WHO Global Health Observatory (GHO) data. WHO GHO 2016 (accessed January 2021).

**Human Development Index (HDI):** This a summary measure of average achievement in key dimensions of human development: a long and healthy life (life expectancy at birth), being knowledgeable (education dimension measured by mean of years of schooling for adults aged years and more and expected years of schooling for children of school entering age), and have a decent standard of living (measured by gross national income per capita). **Inequality adjusted HDI (IHDI):** adjusts the HDI for inequality in the distribution of each of the three dimensions across the population. UNDP 2019 (accessed June 2021). HDI and IHDI technical notes

**Information, communication technology (ICT) Development Index (IDI):** is a composite index combining eleven indicators into one benchmark measure that serves to monitor and compare developments in ICT between countries and over time. It is composed by 3 ICT related components: readiness (infrastructure, access), use (intensity), and capability (skills). ITU 2017 (accessed June 2021). IDI methodology.
Service coverage Index (SDG 3.8.1): average coverage of essential services based on tracer interventions that include reproductive, maternal, newborn and child health, infectious diseases, non-communicable diseases and service capacity and access, among the general and the most disadvantaged population. WHO Global Health Observatory (GHO) data. WHO GHO 2017 (accessed June 2021).

Percentage of the population with out-of-pocket health spending exceeding 10% or 25% of the household expenditure/budget/income: (SDG 3.8.2). WHO Global Health Observatory (GHO) data. 10%: WHO GHO 2010-2018 and 25%: WHO GHO 2010-2018 (accessed January 2021).

Global Innovation Index (GII): is an annual ranking of countries by their capacity for, and success in, innovation. It is computed by taking a simple average of the scores in two sub-indices, the Innovation Input Index and Innovation Output Index, which are composed of five and two pillars respectively. Each of these pillars describes an attribute of innovation. Each pillar is divided into three sub-pillars, each of which is composed of individual indicators, a total of 80 indicators are in GII 2020 exploring a broad vision of innovation, including political environment, education, infrastructure and business sophistication. WIPO 2020 (accessed June 2021). GII Conceptual framework.

High-technology exports (% of manufactured exports): are products with high R&D intensity, such as in aerospace, computers, pharmaceuticals, scientific instruments, and electrical machinery. Joint UN and World Bank 2017-2019 (accessed June 2021).

National health technology assessment unit section

Designated unit/department for health technology assessment (HTA): states if the country have a systematic formal process by which information is gathered to support healthcare decision-making at a national level (options: Yes or No). Latest country data during the period 2015 to 2021 from one of the following sources: 2021 WHO HTA/Health Benefit Package (HBP) Survey; WHO Country Survey BCSoMD21; and 2015 WHO HTA Global Survey.

Medical equipment section

Density of magnetic resonance imaging units (per million population): number of Magnetic Resonance (MRI) units from the public and private sectors, per million population (UNDP WPP 2019 (2020 POP)). Latest country data during the period 2013 to 2021 from one of the following sources: BCSoMD21; MRI: WHO GHO 2013-17 (accessed June 2021); and OECD database 2017-19 (accessed June 2021).

Density of computed tomography units (per million population): number of Computed tomography (CT) scan units from the public and private sectors, per million population (UNDP WPP 2019 (2020 POP)). Latest country data during the period 2013 to 2021 from one of the following sources: BCSoMD21; CT: WHO GHO 2013-17 (accessed June 2021); and OECD database 2017-19 (accessed June 2021).

Density of positron emission tomography units (per million population): number of Positron emission tomography (PET) units from the public and private sectors, per million population (UNDP WPP 2019 (2020 POP)). Latest country data during the period 2013 to 2021 from one of the following sources: BCSoMD21; PET: WHO GHO 2013-17 (accessed June 2021); and OECD database 2017-19 (accessed June 2021).

Density of gamma camera or nuclear medicine units (per million population): number of Gamma camera or Nuclear medicine units from the public and private sectors, per million population (UNDP WPP 2019 (2020 POP)). Latest country data during the period 2013 to 2021 from one of the following sources: BCSoMD21; GC&NM: WHO GHO 2013-17 (accessed June 2021); and OECD database 2017-19 (accessed June 2021).
Density of mammographs (per million females aged between 50 and 69 years old): Number of mammographs units from the public and private sectors, per million population (UNDP WPP 2019 (2020 POP)). Latest country data during the period 2013 to 2021 from one of the following sources: BCSoMD21; MAM: WHO GHO 2013-17 (accessed June 2021); and OECD database 2017-19 (accessed June 2021).

Density of radiotherapy units (per million population): number of radiotherapy units (RU) including the following: circular and linear accelerators (LINAC), Radionuclide teletherapy units, Brachytherapy units, proton ion therapy or particle accelerators, and X-Ray generators (as defined by IAEA); per million population (UNDP WPP 2019 (2020 POP)). Latest country data during the period 2013 to 2021 from the latest available of the following sources: BCSoMD21; RU: WHO GHO 2013-17 (accessed June 2021); and IAEA’s database (2017-21) (accessed June 2021).

Healthcare facility section

The information for every indicator was maintained, from previous Surveys and then was updated with the new information provided by the Ministry of Health or public institutions sent officially to WHO when completing the survey.

Density of Health posts (per 100,000 population): Number of health posts from the public and private sectors, per 100,000 population. Health posts are either community centres or health environments with a very limited number of beds with limited curative and preventive care resources normally assisted by health workers or nurses. Latest country data during the period 2013 to 2021 from the latest available of the following sources: BCSoMD21; and HP: WHO GHO 2013-17 (accessed June 2021).

Density of Health centres (per 100,000 population): Number of health centres from the public and private sectors, per 100,000 population. Latest country data during the period 2013 to 2021 from the latest available of the following sources: BCSoMD21; and HC: WHO GHO 2013-17 (accessed June 2021).

Density of general/district/rural hospitals (per 100,000 population): Number of general, district, and rural hospitals from the public and private sectors, per 100,000 population. Latest country data during the period 2013 to 2021 from the latest available of the following sources: BCSoMD21; and HG: WHO GHO 2013-17 (accessed June 2021).

Density of specialized hospitals (per 100,000 population): Number of specialized hospitals delivering mainly tertiary care from the public and private sectors, per 100,000 population. It includes regional/specialized/teaching and research hospitals available in the country. Latest country data during the period 2013 to 2021 from the latest available of the following sources: BCSoMD21; and HS: WHO GHO 2013-17 (accessed June 2021).

Medical devices workforce section

Density of medical doctors (per 10 000 population): Number of medical doctors, per 10,000 population. It includes generalists, specialist medical practitioners and medical doctors not further defined, in the given national and/or subnational area. Latest country data during the period 2010 to 2018 from the latest available of the following source: MD: WHO GHO 2010-18 (accessed June 2021).

Number of biomedical/clinical engineers professionals in the country: Number of biomedical engineers (holding the corresponding university degree) and biomedical technicians. It includes generalists, specialist medical practitioners and medical doctors not further defined, in the given national and/or subnational area. Latest country data during the period 2014 to 2021 from the latest available of the following sources: BCSoMD21; and BE: WHO GHO 2014-17 (accessed June 2021).
Country profiles
### Afghanistan

#### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):&lt;sup&gt;a&lt;/sup&gt;</th>
<th>38,928 (37)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years):&lt;sup&gt;c&lt;/sup&gt;</td>
<td>68.3</td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births):&lt;sup&gt;d&lt;/sup&gt;</td>
<td>60.3</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):&lt;sup&gt;e&lt;/sup&gt;</td>
<td>29.80%</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank&lt;sup&gt;f&lt;/sup&gt;</td>
<td>0.51 (—); low</td>
</tr>
<tr>
<td>ICT Development Index (rank)&lt;sup&gt;g&lt;/sup&gt;</td>
<td>2 (159)</td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births):&lt;sup&gt;a&lt;/sup&gt;</td>
<td>60.3</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):&lt;sup&gt;h&lt;/sup&gt;</td>
<td>37</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):&lt;sup&gt;i&lt;/sup&gt;</td>
<td>14.6% (2.0%)</td>
</tr>
<tr>
<td>Global innovation index (rank):&lt;sup&gt;j&lt;/sup&gt;</td>
<td>— (—)</td>
</tr>
<tr>
<td>ICT Development Index (rank):&lt;sup&gt;g&lt;/sup&gt;</td>
<td>—</td>
</tr>
<tr>
<td>ICT Development Index (rank):&lt;sup&gt;g&lt;/sup&gt;</td>
<td>—</td>
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</tr>
<tr>
<td>Global innovation index (rank):&lt;sup&gt;j&lt;/sup&gt;</td>
<td>— (—)</td>
</tr>
<tr>
<td>ICT Development Index (rank):&lt;sup&gt;g&lt;/sup&gt;</td>
<td>—</td>
</tr>
</tbody>
</table>

#### National policy on health technology

- **Health technology (medical device) national policy:** No
- **Policy is part of the National Health Program/Plan:** No
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

#### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
- **Lists available:** Yes, but it is only a recommendation
- **Unit:** —
- **Website:** —
- **Nomenclature systems used for devices and tests:** —

**National list for different types of healthcare facilities (hospitals, laboratories, etc):**
- **Lists available:** No
- **Website - hospitals:** —
- **Website - IVD:** —
- **Nomenclature systems used for devices and tests:** —

**National list for specific clinical interventions/emergencies:**
- **Lists available:** No
- **Website:** —

#### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):**<sup>a</sup> No
- **National unit/department that includes HTA for medical devices:** No
- **Website(s):** —
- **Contact:** — Email: —
- **Committee includes a biomedical or clinical engineer:** —

#### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** Yes
- **Name of regulatory agency:** General Directorate Pharmaceutical Affairs, Ministry of Public Health (MoPH).
- **Contact:** Mr. Abdul Hafiz Quraishi Email: —
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** —
- **Other agency’s website:** —

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<sup>a</sup> Annually unless otherwise stated. 
<sup>b</sup> Low: Rank 1-10, Low-Middle: Rank 11-30, Middle-High: Rank 31-100, High: Rank 101+. 
<sup>c</sup> Years 2018-2020 estimated. 
<sup>d</sup> Number of deaths under age 5 per 1000 live births. 
<sup>e</sup> Percentage of all deaths due to NCDs in those aged 30-70 years. 
<sup>f</sup> 0-1 = very high, 1-2 = high, 2-3 = middle, 3-4 = low, 4-5 = very low. 
<sup>g</sup> Rank 1 = highest, 1-100. 
<sup>h</sup> UHC - Service coverage index (1-100). 
<sup>i</sup> UHC - Population with household spending >10% (>25%) of corresponding income (%). 
<sup>j</sup> Global innovation index (rank). 

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The National HTA unit is not yet established.
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation
Policy or guideline: No  Website: —
National level procurement: No  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*a</td>
<td>3</td>
<td>0.1</td>
<td>*</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*a</td>
<td>6</td>
<td>0.2</td>
<td>*</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*a</td>
<td>0</td>
<td>0</td>
<td>*</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*a</td>
<td>0</td>
<td>0</td>
<td>*</td>
</tr>
<tr>
<td>Mammograph:*a</td>
<td>0</td>
<td>0</td>
<td>*</td>
</tr>
<tr>
<td>Radiotherapy:*a</td>
<td>0</td>
<td>0</td>
<td>*</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Radiology, Ministry of Public Health.  Unit website: —
Contact name: Mr. Mirza Said Hashimi  Contact email: moph.ird@gmail.com
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population):* 2.78
Number of biomedical/clinical engineers professionals in the country:* <10

Contacts
MOH focal point
Name: Dr. Asheq Khan Sadaty
Department: General Directorate of Curative Medicine/MoPH.
Email: moph.dds@gmail.com

Other country focal point
Name: Mr. Mirza Said Hashimi
Email: moph.ird@gmail.com

WHO health products focal point:
Name: Dr. Najibullah Safi
Email: safin@who.int

WHO Representative/WHO Liaison Officer:
Name: Dr. Dapeng Luo
Email: luod@who.int

General comments (...Annex 1): Concerning the HT national policy, it can be found the following document, within the provided website: ley-18211-dec-5-2007 SNIS.pdf.
Country indicators

Population 000s (rank): a 2,878 (137)
World Bank income group: b Upper-Middle

Life expectancy at birth (years): c

| Under-five mortality (per 1000 live births): d | 9.7 |
| UHC - Service coverage index (1-100): e | 59 |
| Probability of dying aged 30-70 yrs of NCDs (%): f | 17.00% |
| UHC - Population with household spending >10% (>25%) of corresponding income (%): g | 16.7% (5.0%) |
| Human Development Index (inequality adjusted HDI): rank: h | 0.8 (0.71); high |
| Global innovation index (rank): i | 27.1 (83) |
| ICT Development Index (rank): j | 5.1 (89) |
| High-technology exports (% of manufacture exports): k | 0.00% |

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Language(s): English and Albanian
MOH responsible for health technology policy implementation: Unit for the Management of Medical Devices.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (…Annex 1):
There is not yet an HTA national unit but it has been acknowledged at a political level by the MoH. There is a centralized system for managing health products pricing and reimbursement via the Ministry of Health, the National Agency for Drugs and Device, and the Drug Price Commission.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: National Agency for Drugs and Medical Devices (AKBPM).
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: Agencia Kombetare e Barnave dhe Pajisjeve Mjekesore (National Agency for Drugs and Medical Devices).
Other agency’s website: http://ak bpm.gov.al/?lang=en

National regulatory comments (…Annex 1):
—
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: For procurement purposes
Website: —

Medical device incorporation

Procurement  Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: —

Donations  Policy or guideline: Yes  Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>5</td>
<td>1.58</td>
<td>Health posts</td>
<td>415</td>
<td>13.08</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>17</td>
<td>5.36</td>
<td>Health centres</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals</td>
<td>23</td>
<td>0.72</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals</td>
<td>9</td>
<td>0.28</td>
</tr>
<tr>
<td>Mammograph</td>
<td>18</td>
<td>54.4</td>
<td>Estimation % of health facilities with none or very limited oxygen supply</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>6</td>
<td>2.08</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical device management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Unit for the Management of Medical Devices  Unit website: —
Contact name: Ms. Ledina Picari  Contact email: {picari@moh.gov.al}
Website with publically available technical specifications: —
Number of regional/state offices/units: 4

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes  Software name: Clingo.

Medical devices workforce

Density of medical doctors (per 10 000 population):* 16.47
Number of biomedical/clinical engineers professionals in the country:* 55

Contacts

MOH focal point
Name: Ms. Ledina Picari
Department: —
Email: {picari@moh.gov.al}

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Gerald Rockenschaub
Email: rockenschaubg@who.int

General comments (...Annex 1): Concerning the HT national policy, it was provided the following document: http://www.who.int/medical_devices/survey_resources/health_technology_national_policy_albania.pdf

Software comments (...Annex 1): The inventory system is called CLINGO. The National Biomedical Centre manages the system. Each hospital (13 regional hospitals are involved) is in charge of adding their own data. It doesn’t cover all the hospitals and other public health institutions.
Algeria

Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population (000s) (rank):</td>
<td>43,851 (33)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td></td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>23.3</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%)</td>
<td>14.20%</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank</td>
<td>0.75 (0.6); high</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>4.7 (102)</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>78</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%)</td>
<td>— (—)</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>19.5 (121)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>1.00%</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: No
Language(s): Français
MOH responsible for health technology policy implementation: Direction Générale de la Pharmacie.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —
HTA unit comments (...Annex 1): Adopted EMA (European Medicines Agency) and ICH (International Council for Harmonisation for Pharmaceuticals) guidelines. Inspector General Office performs health economics HTA. Within the MoH HTA is focused on pharmaceutics but not in medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Ministère de la santé, de la Population et de la Réforme Hospitalière.
Website(s): [www.sante.gov.dz](http://www.sante.gov.dz)
Contact: Dr. Hamou Hafed Email: dgpharmacie@sante.dz
Name(s) of other regulatory agency eg. for radiation equipment etc.: Algerian Atomic Energy Commission (Comена).
National regulatory comments (...Annex 1):
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation

Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td></td>
<td>49</td>
<td>—</td>
<td></td>
<td>1.12</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: —  Professionally trained biomedical/clinical engineers: No
Unit/Department: Sous direction de l’enregistrement des produits pharmaceutiques.  Unit website: www.sante.gov.dz
Contact name: Dr. Soumia Yahiaoui  Contact email: bensoumi20@yahoo.com
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —  Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 17.19
Number of biomedical/clinical engineers professionals in the country: <10

Contacts
MOH focal point
Name: —
Department: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Bla Francois Nguessan
Email: nguessanf@who.int

Other country focal point
Name: Dr. Soumia Yahiaoui
Email: bensoumi20@yahoo.com

WHO health products focal point:
Name: —
Email: —

General comments (...Annex 1): —

WHO African Region
WHO Representative/WHO Liaison Officer:
Name: Dr. Bla Francois Nguessan
Email: nguessanf@who.int

Medical equipment

Density per 1,000,000, population

Magnetic Resonance Imaging:*  n/a  n/a
Computerized Tomography Scanner:*  n/a  n/a
Positron Emission Tomography Scanner:*  n/a  n/a
Gamma camera or nuclear medicine:*  n/a  n/a
Mammograph:*  n/a  n/a
Radiotherapy:*  49  1.12

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: —  Professionally trained biomedical/clinical engineers: No
Unit/Department: Sous direction de l’enregistrement des produits pharmaceutiques.  Unit website: www.sante.gov.dz
Contact name: Dr. Soumia Yahiaoui  Contact email: bensoumi20@yahoo.com
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —  Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 17.19
Number of biomedical/clinical engineers professionals in the country: <10

Contacts
MOH focal point
Name: —
Department: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Bla Francois Nguessan
Email: nguessanf@who.int

Other country focal point
Name: Dr. Soumia Yahiaoui
Email: bensoumi20@yahoo.com

WHO health products focal point:
Name: —
Email: —

General comments (...Annex 1): —
### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>77 (184)</th>
<th>World Bank income group:</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Life expectancy at birth (years):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Under-five mortality (per 1000 live births): | 3 |
| Probability of dying aged 30-70 yrs of NCDs (%) | — |
| Human Development Index (inequality adjusted HDI): rank | 0.87 (—): very high |
| ICT Development Index (rank): | 7.7 (30) |
| UHC - Service coverage index (1-100): | — |
| UHC - Population with household spending >10% (>25%) of corresponding income (%) | — (—) |
| Global innovation index (rank): | — (—) |
| High-technology exports (% of manufacture exports): | 28.50% |

### National policy on health technology

Health technology (medical device) national policy: —
Policy is part of the National Health Program/Plan: —
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
Lists available: —
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

**National list for different types of healthcare facilities (hospitals, laboratories, etc):**
Lists available: —
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

**National list for specific clinical interventions/emergencies:**
Lists available: —
Website: —

### National health technology assessment unit

Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

### National regulatory authority

Presence of national authority responsible for regulating medical devices: —
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

Approved devices lists comments (...Annex 1):

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):

HTA unit comments (...Annex 1):
There are identified HTA activities but not a national unit.

National regulatory comments (...Annex 1): —
Medical device nomenclature system
Official nomenclature system for medical devices: — Type: — Use: — Website: —

Medical device incorporation
Procurement
Policy or guideline: — Website: —
National level procurement: — Website: —
Donations
Policy or guideline: — Website: —
Technical specifications
Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:α</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:α</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Postitron Emission Tomography Scanner:α</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:α</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:α</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
<td></td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
</tr>
<tr>
<td>Radiotherapy:β</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

α Density per 1,000,000 females aged 50-69 old.

Medical equipment management unit
Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —
Website: —
Use of management software: — Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 33.33
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: —
Email: —

General comments (Annex 1): —
Angola

Country indicators

Population 000s (rank): 32,866 (44)
World Bank income group: Lower-Middle
Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Year</th>
<th>Angola</th>
<th>World</th>
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</thead>
<tbody>
<tr>
<td>2000</td>
<td>45.3</td>
<td>51.3</td>
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<tr>
<td>2005</td>
<td>46.3</td>
<td>52.3</td>
</tr>
<tr>
<td>2010</td>
<td>47.3</td>
<td>53.3</td>
</tr>
<tr>
<td>2015</td>
<td>48.3</td>
<td>54.3</td>
</tr>
<tr>
<td>2020</td>
<td>49.3</td>
<td>55.3</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 74.7
UHC - Service coverage index (1-100): 40
Probability of dying aged 30-70 yrs of NCDs (%): 16.50%
UHC - Population with household spending >10% (>25%) of corresponding income (%):

<table>
<thead>
<tr>
<th>Year</th>
<th>People spending &gt;10% of income</th>
<th>People spending &gt;25% of income</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2020</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Human Development Index (inequality adjusted HDI): 0.58 (0.4); rank: medium
Global innovation index (rank): — (—)
ICT Development Index (rank): 1.9 (160); High-technology exports (% of manufacture exports): 5.80%

National policy on health technology
Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices
National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —
National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —
National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Approved devices lists comments (...Annex 1):
Health care facilities lists comments (...Annex 1):
Specific lists comments (...Annex 1):

National health technology assessment unit
Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

National regulatory authority
Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Agência Reguladora de Medicamentos e Tecnologias de Saúde (ARMED)
Website(s): —
Contact: Dr. Boaventura Moura Email: boaventura.a@gmail.com
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

National regulatory comments (...Annex 1):
June 4, 2021: With Presidential Decree 136/21 the extinction of the Direcção Nacional de Medicamentos e Equipamentos is announced and the Regulatory Agency for Medicines and Health Technologies (ARMED) is created, which will have its headquarters in Luanda, Angola and will be supervised by the Ministry of Health.
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified  Website: —

Medical device incorporation

Procurement
Policy or guideline: No  Website: —  National level procurement: Yes  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No  Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging: α</td>
<td>1</td>
<td>0.05</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner: α</td>
<td>9</td>
<td>0.42</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner: α</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine: α</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph: α</td>
<td>5</td>
<td>6.33</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy: γ</td>
<td>4</td>
<td>0.12</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

α Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: —  Professionally trained biomedical/clinical engineers: No  Unit Department: —  Unit website: —  Contact name: Mr. Elisio de Carvalho  Contact email: oisile2000@yahoo.com.br  Website with publically available technical specifications: —  Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —  Website: —  Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): ε 2.15  Number of biomedical/clinical engineers professionals in the country: γ —

Contacts
MOH focal point
Name: Mr. Elisio de Carvalho  Department: —  Email: oisile2000@yahoo.com.br  Contact name: Mr. Elisio de Carvalho  Contact email: oisile2000@yahoo.com.br  Website with publically available technical specifications: —  Number of regional/state offices/units: —  Contact name: Mr. Elisio de Carvalho  Contact email: oisile2000@yahoo.com.br  Website with publically available technical specifications: —  Number of regional/state offices/units: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Djamila Khady Cabral  Email: cabrald@who.int

General comments (...Annex 1): —

Other country focal point
Name: —  Email: —

WHO health products focal point:
Name: —  Email: —

Medical devices workforce
Density of medical doctors (per 10 000 population): ε 2.15  Number of biomedical/clinical engineers professionals in the country: γ —

Medical equipment incorporation

Procurement
Policy or guideline: No  Website: —  National level procurement: Yes  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No  Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging: α</td>
<td>1</td>
<td>0.05</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner: α</td>
<td>9</td>
<td>0.42</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner: α</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine: α</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph: α</td>
<td>5</td>
<td>6.33</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy: γ</td>
<td>4</td>
<td>0.12</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

α Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: —  Professionally trained biomedical/clinical engineers: No  Unit Department: —  Unit website: —  Contact name: Mr. Elisio de Carvalho  Contact email: oisile2000@yahoo.com.br  Website with publically available technical specifications: —  Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —  Website: —  Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): ε 2.15  Number of biomedical/clinical engineers professionals in the country: γ —

Contacts
MOH focal point
Name: Mr. Elisio de Carvalho  Department: —  Email: oisile2000@yahoo.com.br  Contact name: Mr. Elisio de Carvalho  Contact email: oisile2000@yahoo.com.br  Website with publically available technical specifications: —  Number of regional/state offices/units: —  Contact name: Mr. Elisio de Carvalho  Contact email: oisile2000@yahoo.com.br  Website with publically available technical specifications: —  Number of regional/state offices/units: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Djamila Khady Cabral  Email: cabrald@who.int

General comments (...Annex 1): —

Other country focal point
Name: —  Email: —

WHO health products focal point:
Name: —  Email: —

Medical devices workforce
Density of medical doctors (per 10 000 population): ε 2.15  Number of biomedical/clinical engineers professionals in the country: γ —

Contacts
MOH focal point
Name: Mr. Elisio de Carvalho  Department: —  Email: oisile2000@yahoo.com.br  Contact name: Mr. Elisio de Carvalho  Contact email: oisile2000@yahoo.com.br  Website with publically available technical specifications: —  Number of regional/state offices/units: —  Contact name: Mr. Elisio de Carvalho  Contact email: oisile2000@yahoo.com.br  Website with publically available technical specifications: —  Number of regional/state offices/units: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Djamila Khady Cabral  Email: cabrald@who.int

General comments (...Annex 1): —

Other country focal point
Name: —  Email: —

WHO health products focal point:
Name: —  Email: —
Antigua and Barbuda

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):*</th>
<th>98 (183)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:Ⅲ</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):&quot;</td>
<td>72.1</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births):α  6.6

Probability of dying aged 30-70 yrs of NCDs (%):α  22.60%

Human Development Index (inequality adjusted HDI): rankα  0.78 (—): high

ICT Development Index (rank):α  5.7 (76)

High-technology exports (% of manufacture exports):α  0.60%

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

List of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):§
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

National regulatory comments (...Annex 1): —
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Nomenclature comments (...Annex 1):

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

![Medical equipment](image)

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:α</td>
<td>1</td>
<td>11.11</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:β</td>
<td>2</td>
<td>22.23</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:γ</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:δ</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>1</td>
<td>1.11</td>
</tr>
<tr>
<td>Mammograph:ε</td>
<td>2</td>
<td>272.15</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Radiotherapy:γ</td>
<td>1</td>
<td>10.2</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: —  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): ε 27.67
Number of biomedical/clinical engineers professionals in the country: γ —

Contacts

MOH focal point
Name: Mr. St. Clair A. Soleyn
Department: Ministry of Health
Email: stclairsoleyn@gmail.com

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: Ms. Anneque Wilson
Email: wilsonan@ecc.paho.org

WHO Representative/WHO Liaison Officer:
Name: —
Email: —

General comments (...Annex 1): —

Antigua and Barbuda
Argentina

Country indicators

Population 000s (rank): 45,196 (32)
World Bank income group: Upper-Middle

Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Year</th>
<th>Life Expectancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1950</td>
<td>71</td>
</tr>
<tr>
<td>1970</td>
<td>73.7</td>
</tr>
<tr>
<td>1990</td>
<td>76.4</td>
</tr>
<tr>
<td>2010</td>
<td>77.1</td>
</tr>
<tr>
<td>2020</td>
<td>76.4</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 9.3
UHC - Service coverage index (1-100): 76

Probability of dying aged 30-70 yrs of NCDs (%): 15.80%
UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)

Human Development Index (inequality adjusted HDI): 0.85 (0.75): very high
Global innovation index (rank): 28.3 (80)

ICT Development Index (rank): 6.8 (51)
High-technology exports (% of manufacture exports): 5.20%

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, Unidad Coordinadora de Evaluación y Ejecución de Tecnologías en Salud.
Website(s): https://www.argentina.gob.ar/noticias/sobre-los-procesos-de-control-de-dispositivos-medicos; http://www.iecs.org.ar
Contact: Dra. Analía del Carmen Amarilla Email: aamarilla@msal.gov.ar
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Instituto Nacional de Productos Médicos - ANMAT.
Website(s): https://www.argentina.gob.ar/anmat/regulados/productos-medicos
Contact: Lic. Andrea Bodnar Email: andrea.bodnar@anmat.gob.ar
Name(s) of other regulatory agency eg. for radiation equipment etc.: Autoridad Regulatoria Nuclear (ARN)
Other agency’s website: https://www.argentina.gob.ar/arn

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: https://www.argentina.gob.ar/anmat
Language(s): Español
MOH responsible for health technology policy implementation: Secretaría de Calidad en Salud - Ministerio de Salud

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes
Unit: Instituto Nacional de Productos Médicos - ANMAT
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: https://www.argentina.gob.ar/sssalud/hospitales
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: Yes
Website: https://www.argentina.gob.ar/salud/calidadatencionmedica

Approved devices lists comments (...Annex 1):
Existe una base de datos que contiene a las tecnologías sanitarias (denominados productos médicos) registradas y disponibles en el sitio -ver tercera liga web- (accesible con colocar nombre genérico de producto (por ej: apósito) o con su identificación (Nº de PM).

Health care facilities lists comments (...Annex 1):
Cirugía, diagnóstico por imágenes, laboratorio, terapia intensiva.

Specific lists comments (...Annex 1):
Actualmente existen lineamientos para la elaboración de guías. Disponible en la segunda página web proporcionada.

HTA unit comments (...Annex 1):
—

National regulatory comments (...Annex 1):
—
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Based on UMDNS  Use: For regulatory purposes
Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: http://www.anmat.gov.ar/webanmat/productos_medicos/recomendaciones_compraprod.medicos.asp
National level procurement: Yes  Website: http://www.anmat.gov.ar/webanmat/productos_medicos/recomendaciones_compraprod.me dicos.asp
Donations
Policy or guideline: Yes  Website: https://www.argentina.gob.ar/anmat/regulados/productosmedicos/requisitos-para-el-ingreso-al-pais-de-productos-donados

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: Yes
Website: https://www.argentina.gob.ar/anmat/regulados/productosmedicos/requisitos-para-el-ingreso-al-pais-de-productos-donados

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>179</td>
<td>3.96</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: —  Professionally trained biomedical/clinical engineers: —
Unit/Department: Unidad Coordinadora de Evaluación y Ejecución de Tecnologías en Salud.
Unit website: https://www.argentina.gob.ar/anmat
Contact name: Dra. Analia del Carmen Amarilla  Contact email: pngc@msal.gov.ar
Website with publically available technical specifications: https://www.argentina.gob.ar/anmat
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: None
Website: —
Use of management software: —  Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population):* 39.9
Number of biomedical/clinical engineers professionals in the country:* 1500

Contacts
MOH focal point
Name: Dra. Analia del Carmen Amarilla
Department: Ministerio de Salud
Email: amariella@msal.gov.ar
Other country focal point
Name: —  Email: —

WHO health products focal point:
Name: —  Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Eva Jané Llopis  Email: janellopis@paho.org

General comments (...Annex 1): The MoH wants to push awareness/surveillance about health technology quality, technical specifications, etc.
## Armenia

### Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>2,963 (134)</td>
<td></td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
<td></td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>68.4 to 61.7</td>
<td>Armenia (72.1) to World (77.2)</td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>11.8</td>
<td></td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>22.30%</td>
<td></td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank:</td>
<td>0.78 (0.7): high</td>
<td></td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>5.8 (75)</td>
<td></td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>11.8</td>
<td></td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>22.30%</td>
<td></td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank:</td>
<td>0.78 (0.7): high</td>
<td></td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>5.8 (75)</td>
<td></td>
</tr>
</tbody>
</table>

### National policy on health technology

- **Policy technology (medical device) national policy:** No
- **Policy is part of the National Health Program/Plan:** No
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: No
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —
- **National list for different types of healthcare facilities (hospitals, laboratories, etc)**
  - Lists available: Yes
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —
- **National list for specific clinical interventions/emergencies:**
  - Lists available: No
  - Website: —

### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):** Yes
- **National unit/department that includes HTA for medical devices:** Yes, Health Project Implementation Unit and Scientific Centre of Drug and Medical Technology Expertise.
- **Contact:** Mr. Armen Madantsyan  Email: healthpiu@gmail.com
- **Committee includes a biomedical or clinical engineer:** —

### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** Yes
- **Name of regulatory agency:** Ministry of Health (MoH).
- **Website(s):** [https://www.moh.am/#3/27](https://www.moh.am/#3/27)
- **Contact:** Mr. Armen Karapeyan  Email: skarapetyan@moh.am
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** Armenian Nuclear Regulatory Authority (ANRA).

### Approved devices lists comments

(...Annex 1):

- —

### Health care facilities lists comments

(...Annex 1):

- —

### Specific lists comments

(...Annex 1):

- —

### HTA unit comments

(...Annex 1):

Informing decisions of the cited institutions are not specifically HTA. Alternative email: info@healthpiu.am.

### National regulatory comments

(...Annex 1):

- "National Institute of Metrology";
- "National Institute of Standards";
- "ArmAtomInspection"; and "Scientific Center of Drug and Medical Technology Expertise".
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Nomenclature comments (...Annex 1):

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>7</td>
<td>2.35</td>
<td>Health posts</td>
<td>238</td>
<td>8</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>9</td>
<td>3.02</td>
<td>Health centres</td>
<td>16</td>
<td>0.54</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals</td>
<td>54</td>
<td>1.81</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>4</td>
<td>1.34</td>
<td>Specialized/regional/national hospitals</td>
<td>19</td>
<td>0.64</td>
</tr>
<tr>
<td>Mammograph</td>
<td>7</td>
<td>22.5</td>
<td>Estimation % of health facilities with none or very limited oxygen supply</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>5</td>
<td>1.69</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Health Project Implementation Unit (HPIU).  Unit website: http://www.pharm.am/
Contact name: Mr. Armen Madantsyan.  Contact email: Healthpiu@gmail.com

Inventories and medical equipment management software

Type of inventories available: —
Website: http://www.pharm.am/
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): 44.02
Number of biomedical/clinical engineers professionals in the country: —

Contacts

MOH focal point
Name: Mr. Armen Madantsyan
Department: Health Project Implementation Unit of Ministry of Health
Email: healthpiu@gmail.com
Other country focal point
Name: —
Email: Healthpiu@gmail.com

General comments (...Annex 1):

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liason Officer:
Name: Dr. Jihane F. Tawilah
Email: tawilahj@who.int

WHO European Region

General comments (...Annex 1): —

Medical device incorporation comments (...Annex 1): The technical specifications are developed by the Health Project Implementation Unit (HPIU) biomedical engineer in cooperation with international consultants.
Country indicators

Population 000s (rank): 25,500 (55)
World Bank income group: High

Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Year</th>
<th>Age</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020</td>
<td>100</td>
<td>84.2</td>
<td>86.9</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 3.6
UHC - Service coverage index (1-100): 87

Probability of dying aged 30-70 yrs of NCDs (%): 9.10%
UHC - Population with household spending >10% (>25%) of corresponding income (%): 3.7% (0.5%)

Human Development Index (inequality adjusted HDI): 0.94 (0.87); very high
Global innovation index (rank): 48.4 (23)

ICT Development Index (rank): 8.2 (14)
High-technology exports (% of manufacture exports): 21.50%

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

Approved devices lists comments (...Annex 1):
—

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: —
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, Pharmaceutical Benefits Advisory Committee / Medical Services Advisory Committee / Prostheses List Advisory Committee / Therapeutic Goods Administration.

Contact: — Email: hta@health.gov.au
Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (...Annex 1):
The Therapeutic Goods Administration (TGA), the Medical Services Advisory Committee (MSAC), the Pharmaceutical Advisory Committee (PBAC), and the Prostheses List Advisory Committee (PLAC) perform Health Technology Assessment (HTA) processes to provide advice to the Australian Government Department of Health.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Australian Therapeutic Goods Administration (TGA).
Website(s): http://www.tga.gov.au/medical-devices-ivds
Contact: Dr. Larry Kelly Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).
Other agency’s website: https://www.arpansa.gov.au/
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Based on GMDN  Use: Not specified  Website: —

Medical device incorporation

Procurement
Policy or guideline: —  Website: —
National level procurement: —  Website: —

Donations
Policy or guideline: —  Website: —

Technical specifications
Technical specifications to support procurement or donations: —
Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical Device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>375</td>
<td>14.71</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>1782</td>
<td>69.88</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>102</td>
<td>4</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>483</td>
<td>18.94</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>589</td>
<td>201.23</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>237</td>
<td>9.29</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: — Professionally trained biomedical/clinical engineers: —  Unit/Department: — Unit website: —  Contact name: — Contact email: —  Website with publically available technical specifications: —  Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —  Website: —  Use of management software: — Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population):* 37.6  Number of biomedical/clinical engineers professionals in the country: 320

Contacts
MOH focal point
Name: Mr. Chris Bedford  Department: —  Email: chris.bedford@health.gov.au
Other country focal point
Name: —  Email: —
WHO health products focal point
Name: —  Email: —

WHO Representative/WHO Liaison Officer
Name: —  Email: —

General comments (Annex 1): —

Software comments (Annex 1): —

Medical devices workforce

Magnetic Resonance Imaging:* 375 14.71  Health posts: n/a n/a
Computerized Tomography Scanner:* 1782 69.88  Health centres: n/a n/a
Positron Emission Tomography Scanner:* 102 4  General/district hospitals: n/a n/a
Gamma camera or nuclear medicine:* 483 18.94  Specialized/regional/national hospitals: n/a n/a
Mammograph:* 589 201.23  Estimation % of health facilities with none or very limited oxygen supply: n/a
Radiotherapy:* 237 9.29

* Density per 1,000,000 females aged from 50-69 old.
### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>9,006 (96)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>81.4</td>
</tr>
</tbody>
</table>

| Under-five mortality (per 1000 live births): | 3.5 |
| Probability of dying aged 30-70 yrs of NCDs (%): | 11.40% |
| Human Development Index (inequality adjusted HDI): rank | 0.92 (0.86); very high |
| ICT Development Index (rank): | 8 (21) |
| UHC - Service coverage index (1-100): | 79 |
| UHC - Population with household spending >10% (>25%) of corresponding income (%): | — (—) |
| Global innovation index (rank): | 50.1 (19) |

### National policy on health technology

**Health technology (medical device) national policy:** Yes

**Policy is part of the National Health Program/Plan:** Yes

**Website:** [https://www.sozialministerium.at/en.html](https://www.sozialministerium.at/en.html)

**Language(s):** German

**MOH responsible for health technology policy implementation:** —

### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**

- **Lists available:** Yes
- **Unit:** Hauptverband der österreichischen Sozialversicherungsträger
- **Website:** —
- **Nomenclature systems used for devices and tests:** —

**National list for different types of healthcare facilities (hospitals, laboratories, etc):**

- **Lists available:** Yes
- **Website - hospitals:** [https://www.sozialministerium.at/public.html](https://www.sozialministerium.at/public.html)
- **Website - IVD:** [https://www.sozialministerium.at/public.html](https://www.sozialministerium.at/public.html)
- **Nomenclature systems used for devices and tests:** —

**National list for specific clinical interventions/emergencies:**

- **Lists available:** Yes
- **Website:** [https://www.sozialministerium.at/public.html](https://www.sozialministerium.at/public.html)

### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** Yes

**National unit/department that includes HTA for medical devices:** Yes, GOEG/BIQG

**Website(s):** [http://www.goeg.at](http://www.goeg.at); [https://aihta.at](https://aihta.at); [http://www.sozialversicherung.at](http://www.sozialversicherung.at)

**Contact:** Ms. Eva Kernstock  Email: eva.kernstock@goeg.at

**Committee includes a biomedical or clinical engineer:** —

### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes

**Name of regulatory agency:** Austrian Medicines and Medical Devices Agency (BASG).


**Contact:** Dr. Martin Renhardt  Email: martin.renhardt@bmg.gv.at

**Name(s) of other regulatory agency eg. for radiation equipment etc.:** Austrian Federal Office for Safety in Health Care/Bundesamt für Sicherheit im Gesundheitswesen (BASG); International Atomic Energy Agency (IAEA).

**Other agency’s website:** [https://www.basg.gv.at](https://www.basg.gv.at); [https://www-pub.iaea.org/MTCD/Publications/PDF/CSPS-7-P.pdf](https://www-pub.iaea.org/MTCD/Publications/PDF/CSPS-7-P.pdf)
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Based on UMDNS  Use: For regulatory purposes
Website: https://goeg.at/Medizinproduktregister

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: http://www.hauptverband.at/
National level procurement: No  Website: —

Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>208</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>255</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>24</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>93</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>190</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>76</td>
</tr>
</tbody>
</table>

Healthcare facility
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>n/a</td>
</tr>
<tr>
<td>Health centres:</td>
<td>n/a</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>n/a</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
</tr>
<tr>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Abteilung Medizinprodukte within MoH (BMSPGK).  Unit website: http://www.bmg.gv.at
Contact name: Dr. Martin Renhardt  Contact email: martin.renhardt@bmg.gv.at
Website with publically available technical specifications: https://www.sozialministerium.at/Themen/Gesundheit/Medizin-und-Gesundheitsberufe/Medizin/Medizinprodukte/Erlaesse-und-Richtlinien-im-Bereich-Medizinprodukte.html
Number of regional/state offices/units: 9

Inventories and medical equipment management software
Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: https://www.sozialministerium.at/
Use of management software: Yes  Software name: Various: MTECS, Visual FM, SAP, etc.

Medical devices workforce
Density of medical doctors (per 10 000 population):* 52.11
Number of biomedical/clinical engineers professionals in the country:* 800

Contacts
MOH focal point
Name: Dr. Martin Renhardt
Department: Department III/3 Pharmaceuticals and Medical Devices (MoH)
Email: martin.renhardt@bmg.gv.at
Other country focal point
Name: —
Email: —

General comments (…Annex 1):

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: —
Email: —

General comments (…Annex 1): —
Azerbaijan

Country indicators

Population 000s (rank): 10,139 (89)
World Bank income group: Upper-Middle

Life expectancy at birth (years):

Under-five mortality (per 1000 live births): 20.4
UHC - Service coverage index (1-100): 65

Probability of dying aged 30-70 yrs of NCDs (%): 22.20%
UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)

Human Development Index (inequality adjusted HDI): 0.76 (0.68): high
Global innovation index (rank): 27.2 (82)

ICT Development Index (rank): 6.2 (65)
High-technology exports (% of manufacture exports): 5.00%

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: Health Organization Department.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes, but it is only a recommendation
Unit: Medical Technical Department of the Innovation and Supply Centre.
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Approved devices lists comments
(…Annex 1):
—

Health care facilities lists comments
(…Annex 1):
—

Specific lists comments (…Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes
Website(s): https://www.isim.az/en/main
Contact: Mr. Kerimov Ramiz Talat  Email: kerimov62@hotmail.com
Committee includes a biomedical or clinical engineer: —

HTA unit comments (…Annex 1):
The HTA activities in pharmaceutics are not specifically for medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: Analytical Expertise Center (MMA).
Website(s): http://www.pharma.az/
Contact: —  Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: State Agency for Normal and Radiological Activity Regulation (Ministry of Emergency Situations of the Republic of Azerbaijan).
Other agency’s website: https://www.nuve.fhn.gov.az/organizations.php?aze-7

National regulatory comments
(…Annex 1):
—
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: Yes  Website: https://apps.who.int/iris/bitstream/handle/10665/44568/9789241501408_eng.pdf?sequence=1

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>14</td>
<td>1.38</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>51</td>
<td>5.03</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>2</td>
<td>0.2</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph</td>
<td>25</td>
<td>22.5</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>12</td>
<td>1.18</td>
</tr>
</tbody>
</table>

Healthcare facility

<table>
<thead>
<tr>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Health centres</td>
<td>700</td>
<td>6.9</td>
</tr>
<tr>
<td>General/district hospitals</td>
<td>500</td>
<td>4.93</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Estimation % of health facilities with none or very limited oxygen supply: n/a</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Medical equipment management unit

Unit present: —  Professionally trained biomedical/clinical engineers: No
Unit/Department: Innovation and Supply Centre  Unit website: —
Contact name: Mr. Ramiz Kerimov  Contact email: kerimov62@hotmail.com
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): a 34.46
Number of biomedical/clinical engineers professionals in the country: —

Contacts

WHO Representative/WHO Liaison Officer:
Name: Dr. Fatos Hande Harmanci
Email: harmancih@who.int

General comments (...Annex 1): —

Medical device incorporation comments (...Annex 1):

The Procurement guidelines are under development. For donations guidelines the WHO are the ones used. The corresponding technical specifications are under the responsibility of the Innovation and Supply Centre.

Software comments (...Annex 1):

—

Azerbaijan
**Bahamas**

### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>393 (170)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>79.1</td>
</tr>
</tbody>
</table>

#### Under-five mortality (per 1000 live births):
- 12.6

#### UHC - Service coverage index (1-100):
- 75

#### Probability of dying aged 30-70 yrs of NCDs (%):
- 15.50%

#### UHC - Population with household spending >10% (>25%) of corresponding income (%):
- 2.7% (0.2%)

#### Human Development Index (inequality adjusted HDI): rank
- 0.81 (→): very high

#### Global innovation index (rank):
- (→)

#### ICT Development Index (rank):
- 6.5 (57)

#### High-technology exports (% of manufacture exports):
- 2.00%

### National policy on health technology

**Health technology (medical device) national policy:** No

**Policy is part of the National Health Program/Plan:** No

**Website:** —

**Language(s):** —

**MOH responsible for health technology policy implementation:** —

### National lists of medical devices

#### National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
- Lists available: No
- Unit: —
- Website: —
- Nomenclature systems used for devices and tests: —

#### National list for different types of healthcare facilities (hospitals, laboratories, etc)
- Lists available: No
- Website - hospitals: —
- Website - IVD: —
- Nomenclature systems used for devices and tests: —

#### National list for specific clinical interventions/emergencies:
- Lists available: No
- Website: —

### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** No

**National unit/department that includes HTA for medical devices:** No

**Website(s):** —

**Contact:** —  Email: —

**Committee includes a biomedical or clinical engineer:** —

### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** No

**Name of regulatory agency:** Ministry of Health (MoH).

Medical device nomenclature system

| Official nomenclature system for medical devices: | No |
| Use: | Not specified |

Website: —

Medical device incorporation

Procurement

Policy or guideline: No  National level procurement: Yes  Website: http://www.phabahamas.org/

Donations

Policy or guideline: No  Website: —

Technical specifications

Technical specifications to support procurement or donations: No  Publically available: —

Website: —

Medical equipment

| Magnetic Resonance Imaging:* | 1 | 2.54 |
| Computerized Tomography Scanner:* | 5 | 12.72 |
| Positron Emission Tomography Scanner* | 0 | 0 |
| Gamma camera or nuclear medicine* | 0 | 0 |
| Mammograph:* | 4 | 95.1 |
| Radiotherapy* | 2 | 5.09 |

Healthcare facility

| Total | Density per 1,000,000 population |
| Health posts: | 150 | 38.17 |
| Health centres: | 0 | 0 |
| General/district hospitals: | 0 | 0 |
| Specialized/regional/national hospitals: | 1 | 0.25 |

Estimation % of health facilities with none or very limited oxygen supply: n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Supplies Management Agency  Unit website: —

Contact name: Mr. Audley Bain  Contact email: abain1@pmh.phabahamas.org

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None

Website: —

Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): 19.39

Number of biomedical/clinical engineers professionals in the country: —

Contacts

MOH focal point

Name: Dr. Anthone Ward  Department: Public Hospitals Authority  Email: award@phabahamas.org

Other country focal point

Name: —  Email: —

WHO health products focal point

Name: —  Email: —

General comments (...Annex 1): —

Medical device incorporation comments (...Annex 1):

The Public Hospitals Authority, the corporate entity of the Ministry of Health, is responsible for managing the three Public Hospitals within the Bahamas. It uses the services of the ECRI Institute to assist in the procurement of medical devices.

Medical devices workforce

Density of medical doctors (per 10,000 population): 19.39

Number of biomedical/clinical engineers professionals in the country: —

Contacts

MOH focal point

Name: Dr. Anthone Ward  Department: Public Hospitals Authority  Email: award@phabahamas.org

Other country focal point

Name: —  Email: —

WHO health products focal point

Name: —  Email: —

General comments (...Annex 1): —
## Bahrain

### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>1,702 (148)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Life expectancy at birth (years):</th>
<th>77.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>1970</td>
<td>63.7</td>
</tr>
<tr>
<td>1990</td>
<td>72.3</td>
</tr>
<tr>
<td>2010</td>
<td>77.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births):</th>
<th>6.9</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Probability of dying aged 30-70 yrs of NCDs (%):</th>
<th>11.30%</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Human Development Index (inequality adjusted HDI):</th>
<th>0.85 (very high)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rank:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICT Development Index (rank):</th>
<th>7.6 (31)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>UHC - Service coverage index (1-100):</th>
<th>77</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</th>
<th>— (—)</th>
</tr>
</thead>
</table>

### National policy on health technology

**Health technology (medical device) national policy:**

- Policy is part of the National Health Program/Plan: —
- Website: —
- Language(s): —
- MOH responsible for health technology policy implementation: —

### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**

- Lists available: —
- Unit: —
- Website: —
- Nomenclature systems used for devices and tests: —

**National list for different types of healthcare facilities (hospitals, laboratories, etc):**

- Lists available: —
- Website - hospitals: —
- Website - IVD: —
- Nomenclature systems used for devices and tests: —

**National list for specific clinical interventions/emergencies:**

- Lists available: —
- Website: —

### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):**

- No

**National unit/department that includes HTA for medical devices:**

- No

**Website(s):**

- —

**Contact:**

- Email: —

**Committee includes a biomedical or clinical engineer:**

- —

### National regulatory authority

**Presence of national authority responsible for regulating medical devices:**

- —

**Name of regulatory agency:** National Health Regulatory Authority, Kingdom of Bahrain.

**Website(s):**

- [https://www.nhra.bh/](https://www.nhra.bh/)

**Contact:**

- Email: —

**Name(s) of other regulatory agency eg. for radiation equipment etc.:** Ministry of Health; Supreme Council for Environment.

**Other agency’s website:**

- ECD;

### Approved devices lists comments

(...Annex 1): —

### Health care facilities lists comments

(...Annex 1): —

### Specific lists comments

(...Annex 1): —

### HTA unit comments

(...Annex 1): There are identified HTA activities but not a national unit.

### National regulatory comments

(...Annex 1): —
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Many co-existence of nomenclatures  Use: For regulatory and procurement purposes
Website: [https://www.nhra.bh/Departments/MDR/](https://www.nhra.bh/Departments/MDR/)MediaHandler/GenericHandler/documents/departments/MDR/guidelines/MDR_Guideline_Medical%20Device%20Registration%20Form%20%2020%20Dec%202020.pdf]

Nomenclature comments (...Annex 1):
It is needed the GMDN code for registration of medical devices, as well as the HS code.

Medical device incorporation

**Procurement**
Policy or guideline: —  Website: —
National level procurement: —  Website: —

**Donations**
Policy or guideline: —  Website: —

**Technical specifications**
Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Posterton Emission Tomography Scanner:</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Radiotherapy: 2 1.18

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: —  Professionally trained biomedical/clinical engineers: —
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —
Website: —
Use of management software: —  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 9.26
Number of biomedical/clinical engineers professionals in the country: <10

Contacts
**MOH focal point**
Name: —
Department: —
Email: —

**WHO health products focal point**
Name: —
Email: —

**WHO Representative/WHO Liason Officer**
Name: Dr. Tasnim Atatraht
Email: atatraht@who.int

General comments (...Annex 1): —
### Bangladesh

#### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>164,689 (8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>77.3</td>
</tr>
</tbody>
</table>

#### National policy on health technology

- Health technology (medical device) national policy: No
- Policy is part of the National Health Program/Plan: No
- Website: —
- Language(s): —

MOH responsible for health technology policy implementation: Health Services Division.

#### National lists of medical devices

- Approved devices lists comments: (...Annex 1):

- Lists available: Yes
  - Unit: Directorate General of Drug Administration (DGDA).

Nomenclature systems used for devices and tests: National.

#### National list for different types of healthcare facilities (hospitals, laboratories, etc)

- Health care facilities lists comments: (...Annex 1):

- Lists available: Yes

Nomenclature systems used for devices and tests: —

#### National list for specific clinical interventions/emergencies:

- Specific lists comments: (...Annex 1):

- Lists available: No
  - Website: —

#### National health technology assessment unit

- HTA unit comments: (...Annex 1):

- Designated unit/department for health technology assessment (HTA): No
- National unit/department that includes HTA for medical devices: No
- Website(s): —
  - Contact: —
  - Email: —
  - Committee includes a biomedical or clinical engineer: —

#### National regulatory authority

- National regulatory comments: (...Annex 1):

- Presence of national authority responsible for regulating medical devices: Yes
- Name of regulatory agency: Directorate General of Drug Administration (DGDA).
- Website(s): [https://www.dgda.gov.bd/](https://www.dgda.gov.bd/)
- Contact: Ms S. M. Sabrina Yesmin — Email: sabrinayesmin22@gmail.com; sabrina@dgda.gov.bd

Name(s) of other regulatory agency eg. for radiation equipment etc.: Bangladesh Atomic Energy Regulatory Authority - Government of the People's Republic of Bangladesh; National Electro-Medical Equipment Maintenance Workshop and Training Center-Ministry of Health and Family Welfare.


---

| Under-five mortality (per 1000 live births): | 30.8 |
| Probability of dying aged 30-70 yrs of NCDs (%): | 21.60% |
| Human Development Index (inequality adjusted HDI): rank: | 0.63 (0.48): medium |
| ICT Development Index (rank): | 2.5 (147) |

| UHC - Service coverage index (1-100): | 48 |
| UHC - Population with household spending >10% (>25%) of corresponding income (%): | 24.7% (9.5%) |
| Global innovation index (rank): | 20.4 (16) |
| High-technology exports (% of manufacture exports): | — |
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified  Website: —

Medical device incorporation
Procurement

Donations
Policy or guideline: Yes  Website: —

Technical specifications

Medical equipment
<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>80</td>
<td>0.49</td>
<td>Health posts:</td>
<td>12477</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>50</td>
<td>0.3</td>
<td>Health centres:</td>
<td>27</td>
<td>0.02</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:</td>
<td>15</td>
<td>0.09</td>
<td>General/district hospitals:</td>
<td>59</td>
<td>0.04</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>14</td>
<td>0.09</td>
<td>Specialized/regional/national hospitals:</td>
<td>—</td>
<td>0</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>12</td>
<td>1.12</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>—</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>43</td>
<td>0.26</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —
Website: —
Use of management software: —  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): * 6.37
Number of biomedical/clinical engineers professionals in the country: <10

Contacts
MOH focal point
Name: Mr. Salah Uddin
Department: Directorate General of Drug Administration (DGDA)
Email: salahuddin733@yahoo.com

WHO health products focal point
Name: —
Email: —

WHO Representative/WHO Liaison Officer
Name: Dr. Bardan Jung Rana
Email: ranab@who.int

General comments (...Annex 1): —
### Barbados

#### Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>287 (173)</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>— (—)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>79.9</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>12.7</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>77</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>16.20%</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>16.4% (3.8%)</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI):</td>
<td>0.81 (0.68); very high</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>— (—)</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>7.3 (34)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>13.70%</td>
</tr>
</tbody>
</table>

#### National policy on health technology

Health technology (medical device) national policy: **No**
Policy is part of the National Health Program/Plan: **No**
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

#### National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: **No**
Unit: —
Website: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: **No**
Website - hospitals: —
Website - IVD: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

#### National health technology assessment unit

Designated unit/department for health technology assessment (HTA): **No**
National unit/department that includes HTA for medical devices: **No**
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

#### National regulatory authority

Presence of national authority responsible for regulating medical devices: **No**
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:α</td>
<td>0</td>
<td>0</td>
<td>Health posts:</td>
<td>11</td>
<td>3.86</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:α</td>
<td>2</td>
<td>7.03</td>
<td>Health centres:</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:α</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:α</td>
<td>1</td>
<td>3.51</td>
<td>Specialized/regional/national hospitals:</td>
<td>1</td>
<td>0.35</td>
</tr>
<tr>
<td>Mammograph:α,β</td>
<td>1</td>
<td>28.96</td>
<td>Estimation % of health facilities with none or very limited oxygen supply: n/a</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:γ</td>
<td>2</td>
<td>6.97</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

α Density per 1,000,000 females aged from 50-69 old.

Medical device management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: Yes  Software name: Equipment Management Software.

Medical devices workforce

Density of medical doctors (per 10,000 population): 24.88
Number of biomedical/clinical engineers professionals in the country: <10

Contacts

MOH focal point
Name: Mr. Dwayne Smith
Department: Office of the Senior Medical Officer of Health (South)
Email: lordmonkman@yahoo.com
Other country focal point
Name: Dr. Joy St. John
Email: cmo@health.gov.bb

WHO health products focal point
Name: Dr. Gabriel Vivas
Email: vivasgab@ecc.paho.org

WHO Representative/WHO Liaison Officer
Name: Dr. Yitades Gebre
Email: gebrey@paho.org

General comments (...Annex 1): Concerning the Healthcare Infrastructure section: there are many single and grouped medical centres and general practice clinics/offices which perform primary care that includes emergency services. Some medical centres of the private sector perform secondary care services as well.
Belarus

Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>9,449 (95)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td></td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%)</td>
<td>23.70%</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): (rank)</td>
<td>0.82 (0.77); very high</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>7.6 (32)</td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>3.2</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>76</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>9.2% (0.7%)</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Language(s): Russian
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes
Unit: Department of Medical Technology of the Ministry of Health (MoH).
Website: http://www.pravo.by/
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: https://www.rceth.by/; http://minzdrav.gov.by/upload/dadvfiles/%D0%BF%D1%80%D0%B8%D0%BB%D0%BE%D0%B6%D0%B5%D0%BD%D0%B8%D1%8F%20%D0%BA%201180.pdf
Website - IVD: https://www.rceth.by/
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: Yes

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, the Republican Scientific and Practical Center for Medical Technologies, Informatization, Administration and Management of Health (BELC__) and Center for expertise and tests in healthcare (RCETH).
Contact: — Email: rceth@rceth.by
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Ministry of Health: Center of Expertise and Testing in Health Care; Department of Medical Equipment, Logistical Support, and Construction.
Website(s): http://www.rceth.by
Contact: A. Y. Stolyarov Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: Department of Nuclear and Radiation Safety of the Ministry of Emergency Situations of the Republic of Belarus.
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: Not specified
Website: https://www.rceth.by/Documents/3mz3prN132420141216.pdf

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: http://minzdrav.gov.by/en/ministerstvo/tsentralizovannyye-zakupki.php

Donations
Policy or guideline: Yes  Website: http://minzdrav.gov.by/upload/dadvfiles/250.pdf

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging*a</td>
<td>24</td>
<td>2.57</td>
<td>Health posts:</td>
<td>1437</td>
<td>15.36</td>
</tr>
<tr>
<td>Computerized Tomography Scanner*a</td>
<td>58</td>
<td>6.2</td>
<td>Health centres:</td>
<td>268</td>
<td>2.86</td>
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<tr>
<td>Positron Emission Tomography Scanner*a</td>
<td>0</td>
<td>0</td>
<td>General district hospitals:</td>
<td>385</td>
<td>4.11</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine*a</td>
<td>24</td>
<td>2.57</td>
<td>Specialized/regional/national hospitals:</td>
<td>51</td>
<td>0.55</td>
</tr>
<tr>
<td>Mammograph*a</td>
<td>23</td>
<td>17.48</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy*b</td>
<td>61</td>
<td>6.46</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Contact name: Mr. V. A. Hodzhaev  Contact email: info@belmt.by
Website with publically available technical specifications: —
Number of regional/state offices/units: 7

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Use of management software: Yes  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): ε 51.91
Number of biomedical/clinical engineers professionals in the country: γ —

Contacts
MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: Mr. V. A. Hodzhaev
Email: info@belmt.by

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liason Officer:
Name: Dr. Viatcheslav Grankov AI
Email: eurowhoblr@who.int

General comments (...Annex 1): —

WHO European Region

A1B2
C3D4

Medical device incorporation comments (...Annex 1):
Public procurement of medical devices and their specifications for each procurement procedure can be found in our website.

Nomenclature comments (...Annex 1):
State register of medical equipment and medical supplies of Belarus.

Software comments (...Annex 1):
Go to website (first link) and find the document titled "mfindr".

* Density per 1,000,000 females aged 50-69 old.
## National policy on health technology

**Health technology (medical device) national policy:** Yes

Policy is part of the National Health Program/Plan: Yes


**Language(s):** Français et Néerlandais

**MOH responsible for health technology policy implementation:** Agence Fédérale des Médicaments et des Produits de Santé pour les dispositifs médicaux et les dispositifs médicaux implantables actifs et l'Institut Scientifique de Santé Publique - Section de Biologie clinique pour les dispositifs médicaux de diagnostic in vitro.

## National lists of medical devices

### National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

- **Lists available:** Yes, but it is only a recommendation
- **Unit:** Institut National d’Assurance Maladie Invalidité (INAMI).
- **Website:** [https://www.riziv.fgov.be/fr/Pages/default.aspx](https://www.riziv.fgov.be/fr/Pages/default.aspx)
- **Nomenclature systems used for devices and tests:** —

### National list for different types of healthcare facilities (hospitals, laboratories, etc.):

- **Lists available:** Yes
- **Website - hospitals:** [https://www.ejustice.just.fgov.be/cgi_loi/loi_a.pl?language=fr&caller=list&cn=20011114466&la=fr&printtab=loi&sql=dt%3D%27arrete%20royal%27&tri=dd+as+rank&rech=1&numero=1](https://www.ejustice.just.fgov.be/cgi_loi/loi_a.pl?language=fr&caller=list&cn=20011114466&la=fr&printtab=loi&sql=dt%3D%27arrete%20royal%27&tri=dd+as+rank&rech=1&numero=1)
- **Nomenclature systems used for devices and tests:** —

### National list for specific clinical interventions/emergencies:

- **Lists available:** Yes
- **Website:** —

### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** Yes

**National unit/department that includes HTA for medical devices:** Yes, Health Care Knowledge Center (KCE).


**Contact:** Email: info@kce.fgov.be

**Committee includes a biomedical or clinical engineer:** —

### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes

**Name of regulatory agency:** Agence Fédérale des Médicaments et des Produits de Santé (AFMPS).

**Website(s):** [https://www.afmps.be/fr](https://www.afmps.be/fr)

**Contact:** Ms. Frédérique Meulders Email: frederique.meulders@afmps.be

**Name(s) of other regulatory agency eg. for radiation equipment etc.:** Competent Authority for in vitro diagnostic medical devices. Scientific Institute of Public Health - Dept. Clinical Biology Anne Van Nerom - and Agence Fédérale de Contrôle Nucléaire.

**Other agency’s website:** [https://afcn.fgov.be/fr](https://afcn.fgov.be/fr)

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### Population and Health Indicators

| Indicator | Value
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>11,590 (80)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>84</td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>3.4</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>11.40%</td>
</tr>
<tr>
<td>Human Development Index (rank):</td>
<td>0.93 (0.86); very high</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>7.8 (25)</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>84</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>11.5% (1.4%)</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>49.1 (22)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>12.00%</td>
</tr>
</tbody>
</table>

---

### Approved devices lists comments

Ces listes existent indirectement par le remboursement de certains dispositifs médicaux et/ou le remboursement de certains tests cliniques effectués. Les dispositifs médicaux implantables et invasifs à long terme doivent se trouver dans ce listing de l’INAMI pour pouvoir être facturés par l’hôpital aux patients. La liste est disponible sur internet via le lien signalé. Approvement for reimbursement by type of IVD device or analysis, not a product-specific list.

### Health care facilities lists comments

Ces listes existent indirectement par le remboursement de certains dispositifs médicaux et/ou le remboursement de certains tests cliniques effectués.

### HTA unit comments

The assessment includes pre-market clinical evaluation of innovative high-risk medical devices.

### National regulatory comments

Agence Fédérale de Contrôle Nucléaire en ce qui concerne les dispositifs médicaux repris sous le point 3 de l’annexe XII de l’Arrêté royal du 18/03/1999, qui veille au contrôle et à l’application du Règlement Général de la Protection de la population, des travailleurs et de l’environnement contre le danger des Rayonnements Ionisants (le RGPRI: AR du 20 juillet 2001), dans lequel sont stipulées des conditions / exigences en ce qui concerne les dispositifs médicaux relevant de sa compétence.

SPF Economie, PME, Classes Moyennes et Energie; Les Directions Générales Energie, Qualité & Sécurité et Contrôle & Médiation.
### Medical device nomenclature system

**Official nomenclature system for medical devices:** Yes  **Type:** Based on GMDN  **Use:** For regulatory purposes  

### Medical device incorporation

**Procurement**  
**Policy or guideline:** Yes  **Website:** https://www.afmps.be/fr; https://www.sciensano.be/en  
**National level procurement:** No  **Website:** https://www.afmps.be/fr; https://www.sciensano.be/en

**Donations**  
**Policy or guideline:** No  **Website:** —

**Technical specifications**  
**Technical specifications to support procurement or donations:** Yes  
**Publically available:** Yes  

### Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging&lt;sup&gt;a&lt;/sup&gt;</td>
<td>133</td>
<td>11.48</td>
<td>Health posts: n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner&lt;sup&gt;a&lt;/sup&gt;</td>
<td>272</td>
<td>23.47</td>
<td>Health centres: n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner&lt;sup&gt;a&lt;/sup&gt;</td>
<td>30</td>
<td>2.59</td>
<td>General/district hospitals: n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine&lt;sup&gt;a&lt;/sup&gt;</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals: n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph&lt;sup&gt;a&lt;/sup&gt;&lt;sup&gt;*,&lt;/sup&gt;</td>
<td>416</td>
<td>280.08</td>
<td>Estimation % of health facilities with none or very limited oxygen supply: n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy&lt;sup&gt;a&lt;/sup&gt;</td>
<td>125</td>
<td>10.79</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> Density per 1,000,000 females aged from 50-69 old.

### Medical equipment management unit

**Unit present:** —  **Professionally trained biomedical/clinical engineers:** —  
**Unit/Department:** —  **Unit website:** —  
**Contact name:** —  **Contact email:** —  
**Website with publically available technical specifications:** —  
**Number of regional/state offices/units:** 0

### Inventories and medical equipment management software

**Type of inventories available:** None  
**Website:** —  
**Use of management software:** —  
**Software name:** —

### Medical devices workforce

**Density of medical doctors (per 10 000 population):** 59.56  
**Number of biomedical/clinical engineers professionals in the country:** 500

### Contacts

**MOH focal point**  
**Name:** Ms. Frédérique Meulders  
**Department:** DG Post: Health Products Division, Medical Devices Cell.  
**Email:** frederique.meulders@afmps.be  
**Other country focal point**  
**Name:** Mr. Tom Clarijs  
**Email:** —

**WHO health products focal point:**  
**Name:** —  
**Email:** —  
**WHO Representative/WHO Liaison Officer:**  
**Name:** —  
**Email:** weu@who.int

### General comments (...Annex 1):

L’Agence fédérale de Contrôle nucléaire (AFCN) est en train de réviser les inventaires des dispositifs médicaux émettant des rayonnements ionisants présents en Belgique. Cet inventaire provient en partie de données fournies par les Organismes Agréés (AV Controlatom, TechniTest, ...). COCIR (European Coordination Committee of the Radiological, Electromedical and Medical

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### Belgium

**latest (2015 - 2021):** WHO HTA/HBP 2021 survey or WHO HTA 2015 survey or WHO 2021 survey


**latest (2013 - 2021):** WHO GHO 2021 survey or IAEA (2017 - 2021)

**latest (2010 - 2018):** WHO GHO 2010 - 2018

**n/a not applicable/not available**
### Belize

#### Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>398 (169)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>73.5</td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>12.3</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>22.10%</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI):</td>
<td>0.72 (0.55): high</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>3.7 (120)</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>64</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>— (—)</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>— (—)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>0.10%</td>
</tr>
</tbody>
</table>

#### National policy on health technology

- **Health technology (medical device) national policy:** No
- **Policy is part of the National Health Program/Plan:** No
- **Website:** —
- **Language(s):** English
- **MOH responsible for health technology policy implementation:** Regulatory Unit.

#### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - **Lists available:** No
  - **Unit:** —
  - **Website:** —
  - **Nomenclature systems used for devices and tests:** —

- **National list for different types of healthcare facilities (hospitals, laboratories, etc)**
  - **Lists available:** Yes
  - **Website - hospitals:** —
  - **Website - IVD:** —
  - **Nomenclature systems used for devices and tests:** —

- **National list for specific clinical interventions/emergencies:**
  - **Lists available:** No
  - **Website:** —

#### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):** No
- **National unit/department that includes HTA for medical devices:** No
- **Website(s):** —
- **Contact:** — Email: —
  - Committee includes a biomedical or clinical engineer: —

#### Health care facilities lists comments

- **(...)Annex 1):** Policy Analysis & Planning Unit, Ministry of Health.

#### HTA unit comments

- **(...)Annex 1):** HTA activities have been identified, but there is not a specific national unit.

#### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** No
- **Name of regulatory agency:** —
- **Website(s):** —
- **Contact:** — Email: —
  - Name(s) of other regulatory agency eg. for radiation equipment etc.: —
  - Other agency’s website: —

- **National regulatory comments ((...)Annex 1):** —
Medical device nomenclature system
Official nomenclature system for medical devices: No Type: None Use: Not specified Website: —

Nomenclature comments (...Annex 1):
—

Medical device incorporation
Procurement
Policy or guideline: No Website: —
National level procurement: No Website: —

Donations
Policy or guideline: No Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: — Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>1</td>
<td>3.01</td>
<td>Health posts:</td>
<td>40</td>
<td>12.05</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>4</td>
<td>12.05</td>
<td>Health centres:</td>
<td>40</td>
<td>12.05</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>4</td>
<td>1.21</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>2</td>
<td>0.6</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>4</td>
<td>258</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>0</td>
<td>0</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: — Professionally trained biomedical/clinical engineers: No
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 3

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population):* 10.78
Number of biomedical/clinical engineers professionals in the country:* <10

Contacts
MOH focal point
Name: Mr. Tony Nijssen
Department: N.E.M.C.
Email: mohnemc@gmail.com

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —

General comments (...Annex 1):
—

WHO Region of the Americas

WHO Representative/WHO Liaison Officer:
Name: Dr. Jack Noreen
Email: jackn@paho.org

General comments (...Annex 1):
The NEMC is trying to standardize equipment, and has suggested to set up a procurement committee. There is no follow up.

Belize

Medical device incorporation comments (...Annex 1):
The NEMC is in the process of updating the Inventory, only for the public health facilities. The Karl Heusner Memorial Hospital (KHMH) has its own Inventory System.

WHO GHO 2010-2018
n/a not applicable/not available
Benin

Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population (000s)</td>
<td>12,123 (76)</td>
</tr>
<tr>
<td>Life expectancy at birth (years)</td>
<td>63.9</td>
</tr>
<tr>
<td>World Bank income group</td>
<td>Lower-Middle</td>
</tr>
</tbody>
</table>

National policy on health technology

- Health technology (medical device) national policy: Yes
- Policy is part of the National Health Program/Plan: No
- Website: —
- Language(s): —
- MOH responsible for health technology policy implementation: —

National lists of medical devices

- National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
  - Lists available: Yes
  - Unit: Agence Béninoise de Régulation Pharmaceutique (ABRP)
  - Website: [https://www.abrp.bj/](https://www.abrp.bj/) (Annex 1)
  - Nomenclature systems used for devices and tests: —

- National list for different types of healthcare facilities (hospitals, laboratories, etc)
  - Lists available: Yes
  - Nomenclature systems used for devices and tests: —

- National list for specific clinical interventions/emergencies:
  - Lists available: No
  - Website: —

National health technology assessment unit

- Designated unit/department for health technology assessment (HTA): Yes
- National unit/department that includes HTA for medical devices: Yes, Direction de la programmation et de la prospective (DPP)
- Website(s): [https://sante.gouv.bj/](https://sante.gouv.bj/) (Annex 1)
- Contact: — Email: —
- Committee includes a biomedical or clinical engineer: —

National regulatory authority

- Presence of national authority responsible for regulating medical devices: Yes
- Name of regulatory agency: Agence Béninoise de Régulation Pharmaceutique (ABRP)
- Website(s): [https://www.abrp.bj/](https://www.abrp.bj/) (Annex 1)
- Contact: Mr. Isaac Houinsou Hans Email: ihhans@yahoo.fr
- Name(s) of other regulatory agency eg. for radiation equipment etc.: International Atomic Energy Agency (IAEA)
### Medical device nomenclature system

**Official nomenclature system for medical devices:** No  
**Type:** None  
**Use:** Not specified  
**Website:** [http://www.sante.gouv.bj/](http://www.sante.gouv.bj/)

### Medical device incorporation

#### Procurement

**Policy or guideline:** No  
**Website:** —

**National level procurement:** Yes  
**Website:** —

#### Donations

**Policy or guideline:** No  
**Website:** —

#### Technical specifications

**Technical specifications to support procurement or donations:** Yes  
**Publically available:** Yes  
**Website:** [https://www.abrp.bj/](https://www.abrp.bj/)

### Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging: α</td>
<td>0</td>
<td>0</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner: α</td>
<td>3</td>
<td>0.29</td>
<td>Health centres:</td>
<td>563</td>
<td>5.45</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner: α</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>26</td>
<td>0.25</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine: α</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>11</td>
<td>0.11</td>
</tr>
<tr>
<td>Mammograph: α, β</td>
<td>7</td>
<td>16.09</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Radiotherapy: α</td>
<td>0</td>
<td>0</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

### Medical equipment management unit

**Unit present:** Yes  
**Professionally trained biomedical/clinical engineers:** —  
**Unit/Department:** Agence des Infrastructure Sanitaire de l’Equipement et de la Maintenance (AISEM)  
**Unit website:** —  
**Contact name:** Mr. Laurent Houndeton  
**Contact email:** houndetonlaurent@hotmail.com  
**Website with publically available technical specifications:** —  
**Number of regional/state offices/units:** 2

### Inventories and medical equipment management software

**Type of inventories available:** National inventory only for high cost technologies (such as MRI, CT or PET scanners)  
**Website:** —  
**Use of management software:** Yes  
**Software name:** Le fichier excel est utilisé dans certains cas. En outre, le logiciel G-MAINT, développé au Bénin, est en cours d’expérimentation dans certains hôpitaux.

### Medical devices workforce

**Density of medical doctors (per 10 000 population):** 0.65

**Number of biomedical/clinical engineers professionals in the country:** 16

### Contacts

**MOH focal point**

**Name:** —  
**Department:** —  
**Email:** —

**Other country focal point**

**Name:** Mr. Laurent Houndeton  
**Email:** houndetonlaurent@hotmail.com

**WHO health products focal point**

**Name:** —  
**Email:** —  
**WHO Representative/WHO Liaison Officer:**

**Name:** Dr. Mamoudou Harouna Djingarey  
**Email:** dingareyh@who.int

### General comments

*Density per 1,000,000 females aged from 50-69 old.

**Use of management software:** Yes  
**Software name:** Le fichier excel est utilisé dans certains cas. En outre, le logiciel G-MAINT, développé au Bénin, est en cours d’expérimentation dans certains hôpitaux.
**Country indicators**

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>772 (160)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>71.3 (72.1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births):</th>
<th>28.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>62</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Probability of dying aged 30-70 yrs of NCDs (%):</th>
<th>23.30%</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>0.65 (0.48): medium</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>— (—)</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>3.7 (121)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>—</td>
</tr>
</tbody>
</table>

**National policy on health technology**

<table>
<thead>
<tr>
<th>Health technology (medical device) national policy:</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy is part of the National Health Program/Plan:</td>
<td>Yes</td>
</tr>
<tr>
<td>Website:</td>
<td>—</td>
</tr>
<tr>
<td>Language(s):</td>
<td>—</td>
</tr>
<tr>
<td>MOH responsible for health technology policy implementation:</td>
<td>—</td>
</tr>
</tbody>
</table>

**National lists of medical devices**

<table>
<thead>
<tr>
<th>National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:</th>
<th>Lists available: Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit: Health Care Diagnostic Division, Department of Medical Services.</td>
<td></td>
</tr>
<tr>
<td>Website: <a href="http://www.moh.gov.bt/">http://www.moh.gov.bt/</a></td>
<td></td>
</tr>
<tr>
<td>Nomenclature systems used for devices and tests:</td>
<td>—</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>National list for different types of healthcare facilities (hospitals, laboratories, etc)</th>
<th>Lists available: Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Website - hospitals: <a href="http://www.moh.gov.bt/">http://www.moh.gov.bt/</a></td>
<td></td>
</tr>
<tr>
<td>Nomenclature systems used for devices and tests:</td>
<td>—</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>National list for specific clinical interventions/emergencies:</th>
<th>Lists available: No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Website: <a href="http://www.moh.gov.bt/">http://www.moh.gov.bt/</a></td>
<td></td>
</tr>
</tbody>
</table>

**National health technology assessment unit**

<table>
<thead>
<tr>
<th>Designated unit/department for health technology assessment (HTA):</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>National unit/department that includes HTA for medical devices:</td>
<td>Yes, Essential Medicine &amp; Technology Division.</td>
</tr>
<tr>
<td>Contact: Ms. Deepika Adhikari Email: <a href="mailto:emtd@health.gov.bt">emtd@health.gov.bt</a></td>
<td></td>
</tr>
<tr>
<td>Committee includes a biomedical or clinical engineer:</td>
<td>—</td>
</tr>
</tbody>
</table>

**National regulatory authority**

<table>
<thead>
<tr>
<th>Presence of national authority responsible for regulating medical devices:</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of regulatory agency: Drug Regulatory Authority (DRA).</td>
<td></td>
</tr>
<tr>
<td>Website(s):</td>
<td><a href="http://www.dra.gov.bt/">http://www.dra.gov.bt/</a></td>
</tr>
<tr>
<td>Contact: — Email: —</td>
<td></td>
</tr>
<tr>
<td>Name(s) of other regulatory agency eg. for radiation equipment etc.:</td>
<td>—</td>
</tr>
<tr>
<td>Other agency’s website:</td>
<td>—</td>
</tr>
</tbody>
</table>

**Approved devices lists comments**

(...Annex 1): We have a list for each level of health centre used for annual identification for non drug items which includes equipments but we have not uploaded it in a website.

**Health care facilities lists comments**

(...Annex 1): —

**Specific lists comments**

(...Annex 1): At present we do not have national lists of recommended medical devices but we are developing a standard list of Equipment and non-drug items for each level of health facilities in Bhutan (national, regional, district hospital, Basic health unit I and Basic health unit II). The standard list of equipment will be based on the standard services that will be provided at each level of the health centre. The standard list is available since 2012.

**HTA unit comments**

(...Annex 1): HTA is focused on pharmaceutics and vaccines but not in medical devices.

**National regulatory comments**

(...Annex 1): The DRA has no assigned responsibilities for regulating medical devices.
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: http://www.mof.gov.bt/
National level procurement: Yes  Website: http://www.moh.gov.bt/
Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment Type</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>1</td>
<td>1.33</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>1</td>
<td>1.33</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Healthcare facility

<table>
<thead>
<tr>
<th>Healthcare facility Type</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>192</td>
<td>25.47</td>
</tr>
<tr>
<td>Health centres:</td>
<td>12</td>
<td>1.59</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>10</td>
<td>1.33</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>1</td>
<td>0.13</td>
</tr>
</tbody>
</table>
| Estimation % of health facilities with none or very limited oxygen supply: n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Drug Vaccine and Equipment Division  Unit website: —
Contact name: Ms. Soira Sonam Tamang  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population):* 4.6
Number of biomedical/clinical engineers professionals in the country: <10

Contacts
MOH focal point
Name: Ms. Deepika Adhikari
Department: Essential medicine & Technology Div., Dept. Medical Services, MoH
Email: emtd@health.gov.bt
Other country focal point
Name: Ms. Soira Sonam Tamang
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Rui Paulo de Jesus
Email: jesusr@who.int

General comments (...Annex 1): Concerning the Infrastructure section: there is 1 National Referral Hospital with 350 beds, 2 Regional referral hospitals with 150 beds each, 10 district hospitals with 60 to 40 beds. 12 district hospitals with 20 beds. Out of 192 health posts, 18 are Basic Health Unit grade I with 10 beds, and the remaining 174 health centres with 2 to 5 beds are Basic Health Unit grade II.

Medical device incorporation comments (...Annex 1):
All medical devices are procured by the Ministry of Health (MoH) following the Procurement Rules and Regulations of the Ministry of Finance Bhutan (see: procurementmanual1.pdf). Drug Vaccine and Equipment Division (DVED) is the agency in the MoH that does the procurement of drugs and medical devices for the whole country.

Software comments (...Annex 1):
The Biomedical Engineering Division under the Department of Medical Services has maintained an Inventory of equipment above 25,000 rupees only.

* Density per 1,000,000 females aged from 50-69 old.
Bolivia (Plurinational State of)

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):*</th>
<th>11,673 (79)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank group:*</td>
<td>Lower-Middle</td>
</tr>
</tbody>
</table>

Population

- Life expectancy at birth (years):  
  - Male: 71.3
  - Female: 71.1

Health indicators

- Under-five mortality (per 1000 live births): 26
- Probability of dying aged 30-70 yrs of NCDs (%): 17.20%
- Human Development Index (inequality adjusted HDI): 0.72 (0.55) - high
- ICT Development Index (rank): 4.3 (112)
- Under-five mortality (per 1000 live births): 26
- Probability of dying aged 30-70 yrs of NCDs (%): 17.20%
- Human Development Index (inequality adjusted HDI): 0.72 (0.55) - high
- ICT Development Index (rank): 4.3 (112)

GDP and innovation

- Global innovation index (rank): 22.4 (105)
- Human Development Index (inequality adjusted HDI): 0.72 (0.55) - high
- ICT Development Index (rank): 4.3 (112)

Other indicators

- Probability of dying aged 30-70 yrs of NCDs (%): 17.20%
- Human Development Index (inequality adjusted HDI): 0.72 (0.55) - high
- ICT Development Index (rank): 4.3 (112)

National policy on health technology

- Health technology (medical device) national policy: Yes
- Policy is part of the National Health Program/Plan: Yes
- Website: http://www.who.int/medical_devices/survey_resources/health_technology_national_policy_bolivia.pdf
- Language(s): Español
- MOH responsible for health technology policy implementation: Unidad de Medicamentos y Tecnología en Salud, Unidad de Servicios de Salud.

National lists of medical devices

- National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
  - Lists available: No
  - Unit: —
  - Website: https://www.minsalud.gob.bo/
  - Nomenclature systems used for devices and tests: —
- National list for different types of healthcare facilities (hospitals, laboratories, etc)
  - Lists available: Yes
  - Website - hospitals: https://www.minsalud.gob.bo/
  - Nomenclature systems used for devices and tests: —
- National list for specific clinical interventions/emergencies:
  - Lists available: Yes
  - Website: https://www.minsalud.gob.bo/

National health technology assessment unit

- Designated unit/department for health technology assessment (HTA):* Yes
- National unit/department that includes HTA for medical devices: Yes, Unidad de Medicamentos y Tecnología en Salud.
- Contact: — Email: —
- Committee includes a biomedical or clinical engineer: —

National regulatory authority

- Presence of national authority responsible for regulating medical devices: Yes
- Name of regulatory agency: Unidad de Medicamentos y Tecnologia en Salud.
- Website(s): https://www.minsalud.gob.bo/
- Contact: Ms. Wilma Teran Carreon Email: wilteranc@yahoo.es
- Name(s) of other regulatory agency eg. for radiation equipment etc.: Unidad de Seguros Publicos de Salud.
- Other agency’s website: https://aben.gob.bo/
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Based on UMDNS  Use: Not specified

Website: https://www.agemed.gob.bo/

Medical device incorporation

Procurement

Policy or guideline: No  Website: —

National level procurement: No  Website: —

Donations

Policy or guideline: Yes  Website: https://www.minsalud.gob.bo/

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: Yes

Website: https://www.minsalud.gob.bo/

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility†</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>1472</td>
<td>13.79</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>937</td>
<td>8.78</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>83</td>
<td>0.78</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>31</td>
<td>0.29</td>
</tr>
<tr>
<td>Mammograph</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>13</td>
<td>1.11</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

† Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: —  Professionally trained biomedical/clinical engineers: No

Unit/Department: Unidad de Seguros Publicos  Unit website: —

Contact name: Mr. Dante Ergueta and Ms. Mari Tejerina  Contact email: danteergueta@gmail.com

Website with publically available technical specifications: —

Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: https://www.minsalud.gob.bo/

Use of management software: No  Software name: —

Software comments (...Annex 1):

El inventario de equipos y la aplicación del plan para la adquisición de equipo médico solo se realizó para los departamentos de Oruro, Beri y Pando.

Medical devices workforce

Density of medical doctors (per 10 000 population):* 10.3

Number of biomedical/clinical engineers professionals in the country:* 45

Contacts

MOH focal point

Name: —

Department: —

Email: —

Other country focal point

Name: Mr. Dante Ergueta and Ms. Mari Tejerina

Email: danteergueta@gmail.com

WHO health products focal point:

Name: Dr. Victoria de Urioste

Email: durioste@bol.ops-oms.org

WHO Representative/WHO Liaison Officer:

Name: Ms. Alma Fabiola Morales Salinas

Email: moraleaf@paho.org

General comments (...Annex 1): —

* Density per 1,000,000 females aged from 50-69 old.
Country indicators

Population 000s (rank): 3,281 (132)
World Bank income group: Upper-Middle

Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Year</th>
<th>Bosnia and Herzegovina</th>
<th>World</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990</td>
<td>72.0</td>
<td>75.5</td>
</tr>
<tr>
<td>2000</td>
<td>73.6</td>
<td>76.7</td>
</tr>
<tr>
<td>2020</td>
<td>76.3</td>
<td>79.1</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 5.9
UHC - Service coverage index (1-100): 61

Probability of dying aged 30-70 yrs of NCDs (%): 17.80%
UHC - Population with household spending >10% (>25%) of corresponding income (%): 8.2% (1.4%)

Human Development Index (inequality adjusted HDI): 0.78 (0.67): high
Global innovation index (rank): 29 (74)

ICT Development Index (rank): 5.4 (83)
High-technology exports (% of manufacture exports): 5.30%

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Language(s): Bosnian, Croatian, Serbian (local), and English
MOH responsible for health technology policy implementation: Health Sector.

National lists of medical devices

Approved devices lists comments (...Annex 1):
There are the lists of medical devices for procurement regarding the each general hospital as well as clinical centres (situation analysis of health care institutions). At the primary health care level, there is a list of medical equipments that is necessary for family medicine.

Health care facilities lists comments (...Annex 1):
The Rulebook on Normative Standards for Establishment of Health Institutions.

Specific lists comments (...Annex 1):
There are documents that regulate the necessary knowledge, skills, procedures and equipment (definition of medical technology) which are used by those group of diseases. Also, there are Guides for specific medical conditions, and there are adequate contingency plans for responding for public health threats as needed. The Rulebook on National Standards for Establishment of Health Institutions, Standards for Primary Care and Hospitals.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: No
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Agency for Medical Products and Medical Devices (ALMBiH); Institute for standardization of Bosnia and Herzegovina (ISBIH).
Website(s): http://www.almbih.gov.ba/
Contact: Mr. Ph. Tanja Savanović Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: Bosnia and Herzegovina State Regulatory Agency for Radiation Safety and Nuclear Safety.
Other agency’s website: http://www.darns.gov.ba/en/EnglishDARNS/AboutAs

Approved devices lists comments (...Annex 1):
There are the lists of medical devices for procurement regarding the each general hospital as well as clinical centres (situation analysis of health care institutions). At the primary health care level, there is a list of medical equipments that is necessary for family medicine.

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HTA unit comments (...Annex 1):
The HTA is acknowledged in decentralized legislation, and present at a national level.

National regulatory comments (...Annex 1):
For the Republika Srpska: Regarding the procurement of various medical devices, the company that generally provides the medical device must ensure capable suppliers who can implement a proper assessment and who can carry out the certification of medical devices.
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: Many co-existence of nomenclatures  Use: Not specified

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: http://www.almbih.gov.ba/
National level procurement: Yes  Website: http://www.almbih.gov.ba/
Donations
Policy or guideline: Yes  Website: —
Technical specifications
Technical specifications to support procurement or donations: No
Publicly available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*a</td>
<td>21</td>
<td>5.48</td>
<td>Health posts:</td>
<td>1610</td>
<td>42.04</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*a</td>
<td>63</td>
<td>16.45</td>
<td>Health centres:</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*a</td>
<td>1</td>
<td>0.26</td>
<td>General/district hospitals:</td>
<td>1</td>
<td>0.03</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*a</td>
<td>6</td>
<td>1.57</td>
<td>Specialized/regional/national hospitals:</td>
<td>5</td>
<td>0.13</td>
</tr>
<tr>
<td>Mammograph:*a</td>
<td>88</td>
<td>182.72</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Radiotherapy:*a</td>
<td>13</td>
<td>3.96</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical device management unit
Unit present: —  Professionally trained biomedical/clinical engineers: No
Unit/Department: Agency for Medical Products and Medical Devices.  Unit website: http://www.almbih.gov.ba/
Contact name: Dr. Tanja Savanović.  Contact email: t.savanovic@almbih.gov.ba
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 21.62
Number of biomedical/clinical engineers professionals in the country: 50

Contacts
MOH focal point
Name: Ms. Sabina Sahman
Department: Ministry of Civil Affairs of Bosnia and Herzegovina, Department of Health
Email: sabina.sahman@mcp.gov.ba
Other country focal point
Name: Dr. Tanja Savanović
Email: t.savanovic@almbih.gov.ba

WHO health products focal point
Name: —
Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Erwin Aime Willy D. Cooreman
Email: cooremane@who.int

General comments (...Annex 1): —

Medical device incorporation comments (...Annex 1):
Responsible authority in both entities. Ministry of Health of Republika Srpska is responsible for the procurement of high-cost technologies while the Health Care Institutions can provide procurement of other medical equipment.

WHO European Region

Nomenclature comments (...Annex 1):
Our nomenclature is based on GMDN and EDMA codes. In our instructions we ask for our manufacturer and representative of manufacturers to use GMDN or EDMA codes for making generic name. We have free access to GMDN base, and we found a new version of EDMA codes in internet.
Botswana

Country indicators

| Population 000s (rank):| 2,352 (141) |
| World Bank income group: Upper-Middle |
| Life expectancy at birth (years): |

Under-five mortality (per 1000 live births): 41.6
UHC - Service coverage index (1-100): 61

Probability of dying aged 30-70 yrs of NCDs (%): 20.30%
UHC - Population with household spending >10% (>25%) of corresponding income (%): — —

Human Development Index (inequality adjusted HDI): 0.74 (—); high
Global innovation index (rank): 25.4 (89)

ICT Development Index (rank): 4.6 (105)
High-technology exports (% of manufacture exports): 0.40%

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: No
Website: [https://www.who.int/medical_devices/survey_resources/health_technology_national_policy_botswana.pdf](https://www.who.int/medical_devices/survey_resources/health_technology_national_policy_botswana.pdf)
Language(s): English
MOH responsible for health technology policy implementation: Biomedical Engineering Services.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

Approved devices lists comments (...Annex 1):
—

Health care facilities lists comments (...Annex 1):
Documents are in constant revision and update.

Specific lists comments (...Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No, Clinical Services.
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
It is needed to strengthen the research to improve the HTA capacity.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Botswana Medicines Regulatory Authority (BoMRA).
Website(s): [https://www.bomra.co.bw/index.php/news-updates](https://www.bomra.co.bw/index.php/news-updates)
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: Radiation Protection Inspectorate.

National regulatory comments (...Annex 1):
There is a drug regulatory unit. It has a draft for an Act that will regulate medicines and medical devices.
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Based on UMDNS  Use: For procurement purposes
Website: https://www.bomra.co.bw/index.php/news-updates

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: https://ipms.ppadb.co.bw/login
National level procurement: Yes  Website: https://ipms.ppadb.co.bw/login
Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:</td>
<td>1</td>
<td>0.49</td>
<td>Health posts:</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:</td>
<td>2</td>
<td>0.99</td>
<td>Health centres:</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>16</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>3</td>
</tr>
<tr>
<td>Mammograph:</td>
<td>2</td>
<td>19.1</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:</td>
<td>3</td>
<td>1.28</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical device incorporation comments (...Annex 1):

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Clinical Services  Unit website: —
Contact name: Bs. Tlhomelang  Contact email: bstlhomelang@gov.bw
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes  Software name: Customized Solution.

Medical devices workforce
Density of medical doctors (per 10,000 population): 2.89
Number of biomedical/clinical engineers professionals in the country: 52

Contacts
MOH focal point
Name: Dr. Ndwapi Ndwapi
Department: Ministerial Strategy Office of the MoH
Email: ndwapi@gov.bw
Other country focal point
Name: Bs. Tlhomelang
Email: bstlhomelang@gov.bw
WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Josephine Namboze
Email: nambozej@who.int

General comments (...Annex 1): Concerning the Infrastructure section: there are 800 clinics, healthposts and mobile clinics.

WHO African Region

Botswana
## Brazil

### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank): a</th>
<th>212,559 (6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group: b</td>
<td>Upper-Middle</td>
</tr>
</tbody>
</table>

| Life expectancy at birth (years): c | 75.6 |

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births): d</th>
<th>13.9</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Service coverage index (1-100): e</td>
<td>79</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Probability of dying aged 30-70 yrs of NCDs (%): f</th>
<th>16.60%</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%): g</td>
<td>— (—)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Human Development Index (inequality adjusted HDI): rank h</th>
<th>0.77 (0.57): high</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global innovation index (rank): i</td>
<td>31.9 (62)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICT Development Index (rank): j</th>
<th>6.1 (66)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-technology exports (% of manufacture exports): k</td>
<td>13.30%</td>
</tr>
</tbody>
</table>

### National policy on health technology

**Health technology (medical device) national policy:** Yes
- Policy is part of the National Health Program/Plan: Yes
- Website: [https://www.gov.br/saude/pt-br](https://www.gov.br/saude/pt-br)
- Language(s): Portugues
- MOH responsible for health technology policy implementation: Secretariat of Science, Technology and Strategic Inputs.

### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
- Lists available: Yes
  - Unit: —
  - Website: —

**National list for different types of healthcare facilities (hospitals, laboratories, etc):**
- Lists available: No
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

**National list for specific clinical interventions/emergencies:**
- Lists available: Yes
  - Website: [https://www.gov.br/saude/pt-br](https://www.gov.br/saude/pt-br)

### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** Yes
- National unit/department that includes HTA for medical devices: Yes, DECIT and National Committee for Health Technology Incorporation (CONITEC).
- Contact: Dr. Leonor Pacheco Email: leonor.santos@saude.gov.br
- Committee includes a biomedical or clinical engineer: —

### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes
- Name of regulatory agency: Brazilian Health Surveillance Agency (ANVISA)/General Office of Medical Devices.
- Website(s): [http://antigo.anvisa.gov.br/](http://antigo.anvisa.gov.br/)
- Contact: Mrs. Maria Fonseca Veloso Email: rel@anvisa@anvisa.gov.br
- Name(s) of other regulatory agency eg. for radiation equipment etc.: Comissão Nacional de Energia Nuclear.

### Approved devices lists comments

- Lists for diseases are Health Attention Secretariat (SAS) unit competence. Other lists are not available for the moment.

### Health care facilities lists comments

- Competencia de la Health Attention Secretariat (SAS).

### Specific lists comments

### HTA unit comments

- HTA for medical devices, medicines, interventions, etc. There exist several agencies (see third link).

### National regulatory comments

- —
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Based on GMDN  Use: For regulatory purposes
Website: https://www.anvisa.gov.br/datavisa/nomestecnicosggtps/consulta_ggtps.asp

Medical device incorporation

Procurement
Policy or guideline: Yes  Website: http://portalsaude.saude.gov.br/portalsaude/
National level procurement: Yes  Website: http://portalsaude.saude.gov.br/portalsaude/gestor/area.cfm?id_area1504

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy*</td>
<td>541</td>
<td>2.55</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Department of Science and Technology (DECIT).  Unit website: http://portal.saude.gov.br
Contact name: Dr. Leonor Santos Pacheco  Contact email: leonor.santos@saude.gov.br
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: Yes  Software name: Locally developed.

Medical devices workforce

Density of medical doctors (per 10,000 population): 23.11
Number of biomedical/clinical engineers professionals in the country: 600

Contacts

MOH focal point
Name: Dr. Leonor Maria Pacheco Santos
Department: Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Ministério da Saúde - MS
Email: leonor.santos@saude.gov.br
Other country focal point
Name: Dr. Mario César Muñiz Ferrer
Email: mario@cecmed.cu

WHO health products focal point:
Name: —
Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Socorro Gross Galiano
Email: grosssoc@paho.org

General comments (...Annex 1): —
Brunei Darussalam

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>437 (168)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>69.5</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: bme@moh.gov.bn
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
It is a established system for setting healthcare priorities, which involves HTA.

National regulatory authority

Presence of national authority responsible for regulating medical devices: —
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

National regulatory comments (...Annex 1):
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: No  Website: —

Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publicly available: No
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>1</td>
<td>2.39</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>3</td>
<td>7.18</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>3</td>
<td>91.93</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>2</td>
<td>4.58</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Healthcare facility

<table>
<thead>
<tr>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>14</td>
<td>3.35</td>
</tr>
<tr>
<td>Health centres:</td>
<td>2</td>
<td>0.48</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>3</td>
<td>0.72</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>1</td>
<td>0.24</td>
</tr>
</tbody>
</table>

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Biomedical Engineering Unit (BME). Unit website: —
Contact name: —  Contact email: bme@moh.gov.bn
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): 16.09
Number of biomedical/clinical engineers professionals in the country: —

Contacts

MOH focal point
Name: Mr. Abidin Bin Haji Othman
Department: Healthcare Technology Department
Email: abidin.othman@moh.gov.bn

WHO Representative/WHO Liaison Officer:
Name: —
Email: wpmyswr@who.int

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —

General comments (...Annex 1): —


Brunei Darussalam
### Bulgaria

#### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>6,948 (105)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td></td>
</tr>
</tbody>
</table>

#### National policy on health technology

**Health technology (medical device) national policy:** No  
**Policy is part of the National Health Program/Plan:** No  
**Website:** —  
**Language(s):** —  
**MOH responsible for health technology policy implementation:** —

#### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**  
**Lists available:** Yes  
**Unit:** National Health Insurance Fund.  
**Website:** —  
**Nomenclature systems used for devices and tests:** —

**National list for different types of healthcare facilities (hospitals, laboratories, etc):**  
**Lists available:** No  
**Website - hospitals:** —  
**Website - IVD:** —  
**Nomenclature systems used for devices and tests:** —

**National list for specific clinical interventions/emergencies:**  
**Lists available:** No  
**Website:** —

#### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** Yes  
**National unit/department that includes HTA for medical devices:** No  
**Contact:** Email: —  
**Committee includes a biomedical or clinical engineer:** —

#### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes  
**Name of regulatory agency:** Bulgarian Drug Agency (BDA).  
**Website(s):** [https://www.bda.bg](https://www.bda.bg), [http://mh.government.bg](http://mh.government.bg), [https://mi.government.bg/bg](https://mi.government.bg/bg)  
**Contact:** Email: medical@bda.bg  
**Name(s) of other regulatory agency eg. for radiation equipment etc.:** Nuclear Regulatory Agency.  
**Other agency’s website:** [http://www.bnra.bg/](http://www.bnra.bg/)

### Approved devices lists comments (...Annex 1): —

### Health care facilities lists comments (...Annex 1): —

### Specific lists comments (...Annex 1): —

### HTA unit comments (...Annex 1):  
It exists a limited number of trained HTA experts. Relevant health economic education is available at several universities in the region, and HTA experts or health economists work as consultants for the government (more info see third link).

### National regulatory comments (...Annex 1): —
Medical device nomenclature system

Official nomenclature system for medical devices: No
Type: Many co-existence of nomenclatures
Use: Not specified

Nomenclature comments (...Annex 1): Use of GMDN and UMDNS.

Medical device incorporation

Procurement
Policy or guideline: Yes

National level procurement: Yes
Website: http://www.mh.government.bg/

Donations
Policy or guideline: No
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Equipment Type</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging(a)</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner(a)</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner(a)</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine(a)</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph(a)</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy(b)</td>
<td>54</td>
<td>7.77</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical device incorporation comments (...Annex 1):
Only for the devices which are supplied through a centralized procedure accomplished by the Ministry of Health.

Medical equipment management unit
Unit present: —
Professionally trained biomedical/clinical engineers: —
Unit/Department: —
Contact name: —
Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: None
Website: —
Use of management software: —
Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 42.07
Number of biomedical/clinical engineers professionals in the country: 35

Contacts
MOH focal point
Name: Mr. Todor Darakchiev
Department: Market Supervision and Inspections
Email: todor.darakchiev@bda.bg

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liason Officer:
Name: Dr. Skender Syla.
Email: sylas@who.int

General comments (...Annex 1): —
Burkina Faso

Country indicators

Population 000s (rank): 20,903 (58)
World Bank income group: Low
Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births)</th>
<th>87.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%)</td>
<td>21.70%</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI)</td>
<td>0.45 (0.32): low</td>
</tr>
<tr>
<td>ICT Development Index (rank)</td>
<td>1.9 (162)</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100)</td>
<td>40</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%)</td>
<td>3.1% (0.4%)</td>
</tr>
<tr>
<td>Global innovation index (rank)</td>
<td>20 (118)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports)</td>
<td>25.80%</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: https://www.sante.gov.bf/accueil
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

Health care facilities lists comments (...Annex 1): —

Specific lists comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: National Regulatory Authority for Radiation Protection and Nuclear Safety
Other agency’s website: https://www-pub.iaea.org/mtcd/meetings/PDFplus/2009/CN166/CN166_Presentations/Session%20B/006%20Belemsaga.pdf

National regulatory comments (...Annex 1):
The RPNS within the NRA is in the process of institutionalization.
Medical device nomenclature system

Official nomenclature system for medical devices:
No  Type: None  Use: Not specified
Website: —

Medical device incorporation

Procurement

Policy or guideline:
No  Website: —
National level procurement: Yes  Website: —
Donations

Policy or guideline:
No  Website: —

Technical specifications

Technical specifications to support procurement or donations:
No
Publically available:
—  Website: —

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers:
Yes
Unit/Department:
Department of medical Products (DMP).
Unit website: —
Contact name: Mr. Hamidou Sama  Contact email: —
Website with publically available technical specifications:
—
Number of regional/state offices/units: 13

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment
Use of management software: Yes  Software name: PLAMAHS (Heart Consultancy).
Website: —

Medical devices workforce

Density of medical doctors (per 10,000 population):
ε 0.94
Number of biomedical/clinical engineers professionals in the country: γ <10

Contacts

MOH focal point
Name: Mr. O. Emmanuel Zida  Department of Health
Email: ezida2002@yahoo.fr

Other country focal point
Name: Ms. Micheline Ouédraogo
Email: mkonkobo1@yahoo.fr

WHO health products focal point:
Name: Dr. Daogo Sosthène Zombre  Email: zombres@who.int

WHO Representative/WHO Liaison Officer:
Name: Dr. Amata J. Diarra  Email: diarraal@who.int

General comments

Concerning the HT national policy, a 2010 version was provided. Concerning the section infrastructure: There are CRO and Hospital national.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Website: —

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment
Use of management software: Yes  Software name: PLAMAHS (Heart Consultancy).
Website: —

Medical equipment Total

Density per 1,000,000 population
Healthcare facility
γ Total
Healthcare facility
γ Total

Magnetic Resonance Imaging:
α 2
0.1
Health posts:
140 0.67
Computerized Tomography Scanner:
α 15 0.72
Health centres:
2468 11.89
Positron Emission Tomography Scanner:
α 0 0
General/district hospitals:
180 0.86
Gamma camera or nuclear medicine:
α 1 0.05
Specialized/regional/national hospitals:
9 0.05
Mammograph:
α, * 13 15.49
Estimation % of health facilities with none or very limited oxygen supply: 75%
Radiotherapy:
β 0 0

* Density per 1,000,000 females aged from 50 -69 old.

Software comments

Inventaire technique au niveau national a été fait par la DGIEM en 2003 avec l’appui de la GTZ; un inventaire non technique a été fait par la DAF en 2007 suivant une procédure du Ministère de l’Economie et des Finances. La mise à jour de ces inventaires n’est pas effective. Il y a les deux types d’inventaire: national fonctionnel pour certain équipement médicale et non-fonctionnel pour d’autres.

Software comments

Les achats se font selon plusieurs procédures en fonction de la source de financement (les projets font des appels d’offres de façon indépendante, les hôpitaux exécutent en interne une partie du budget achat, les achats groupés au niveau national sont en train d’être expérimentés par la CAMEG: Centrale d’Achat des Médicaments Génériques); des appels d’offres internationaux sont quelque fois lancés par les projets.
Burundi

Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>11,891 (77)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>66.7</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: Autorité Burundaise de Régulation des Médicaments et des Aliments

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes
Unit: Direction des Infrastructures Sanitaires et des Equipements (DISE)
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: Yes
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: —, Département des Infrastructures sanitaires et des équipements (DISE)
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Autorité Burundaise de Régulation des Médicaments et des Aliments
Website(s): —
Contact: Mr. Emmanuel Bamenyekanye Email: bamenyekanye@hotmail.com
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>56.5</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>22.90%</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank:</td>
<td>0.43 (0.3): low</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>1.5 (172)</td>
</tr>
<tr>
<td>Global innovation exports (% of manufacture exports):</td>
<td>1.50%</td>
</tr>
</tbody>
</table>

Approved devices lists comments (...Annex 1):
Nous avons des listes prédéfinies suivant le type de catégories conformes aux normes en vigueur au MoH.

Health care facilities lists comments (...Annex 1):
Nous avons également de la documentation sur la normalisation des équipements par structures de soins.

Specific lists comments (...Annex 1):
Lists available for communicable and non communicable diseases, injuries, and public health emergency situations.

HTA unit comments (...Annex 1): —

National regulatory comments (...Annex 1): —
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation

Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical device incorporation comments (...Annex 1):
Procédé aux achats/Système d’appel d’offres ouvert national/international. Il existe des entreprises nationales spécialisées dans la vente de ces produits.

Medical device incorporation

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment Type</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility Type</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:a</td>
<td>0</td>
<td>0</td>
<td>Health posts:</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:a</td>
<td>2</td>
<td>0.2</td>
<td>Health centres:</td>
<td>509</td>
<td>5.01</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:a</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>33</td>
<td>0.32</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:a</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>3</td>
<td>0.03</td>
</tr>
<tr>
<td>Mammograph:a</td>
<td>1</td>
<td>2.69</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:a</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*a Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: —
Unit/Department: Direction des Infrastructures Sanitaires et des Equipements (DISE)  Unit website: —
Contact name: Mr. Eugène Mujambere  Contact email: mujambereeugene@yahoo.fr
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): 1
Number of biomedical/clinical engineers professionals in the country: <10

Contacts

MOH focal point
Name: Mr. Déo Niyonkuru
Department: —
Email: niyonkurunew@yahoo.fr

Other country focal point
Name: Mr. Eugène Mujambere
Email: mujambereeugene@yahoo.fr

WHO health products focal point
Name: Dr. Donatien Bigirimana
Email: bigirimanad@who.int

General comments (...Annex 1): —

WHO Representative/WHO Liaison Officer:
Name: Dr. Xavier Crespin
Email: cxavier@who.int

General comments (...Annex 1): —
Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):*</th>
<th>16,719 (70)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):#</td>
<td>69.4</td>
</tr>
</tbody>
</table>

| Under-five mortality (per 1000 live births):# | 26.6 |
| UHC - Service coverage index (1-100):# | 60 |
| Probability of dying aged 30-70 yrs of NCDs (%)#: | 21.10% |
| UHC - Population with household spending >10% (>25%) of corresponding income (%):# | 15.3% (5.2%) |
| Human Development Index (inequality adjusted HDI): rank,* | 0.59 (0.48): medium |
| Global innovation index (rank):| 21.5 (110) |
| ICT Development Index (rank):| 3.3 (128) |
| High-technology exports (% of manufacture exports):| 1.20% |

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: —
Language(s): Khmer and English
MOH responsible for health technology policy implementation: Hospital Services and Biomedical Engineering Bureau, Department of Hospital Services, Ministry of Health.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests:

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests:

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No, Department of Hospital Service.
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: —
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

Population 000s (rank): 16,719 (70)
World Bank income group: Lower-Middle
Life expectancy at birth (years): 69.4

Under-five mortality (per 1000 live births): 26.6
UHC - Service coverage index (1-100): 60
Probability of dying aged 30-70 yrs of NCDs (%): 21.10%
UHC - Population with household spending >10% (>25%) of corresponding income (%): 15.3% (5.2%)
Human Development Index (inequality adjusted HDI): rank, 0.59 (0.48): medium
Global innovation index (rank): 21.5 (110)
ICT Development Index (rank): 3.3 (128)
High-technology exports (% of manufacture exports): 1.20%
Medical device nomenclature system
Official nomenclature system for medical devices: Yes
Type: Nationally developed
Use: For procurement purposes
Website: —

Medical device incorporation
Procurement
Policy or guideline: No
Website: —
National level procurement: Yes
Website: —
Donations
Policy or guideline: No
Website: —
Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>1</td>
<td>0.07</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>18</td>
<td>1.19</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mammograph</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>3</td>
<td>0.18</td>
</tr>
</tbody>
</table>

Healthcare facility

<table>
<thead>
<tr>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts</td>
<td>113</td>
<td>0.75</td>
</tr>
<tr>
<td>Health centres</td>
<td>992</td>
<td>6.55</td>
</tr>
<tr>
<td>General/district hospitals</td>
<td>61</td>
<td>0.4</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals</td>
<td>9</td>
<td>0.06</td>
</tr>
</tbody>
</table>

Estimation % of health facilities with none or very limited oxygen supply: n/a

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes
Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Department of Planning and Health Information
Contact name: —
Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: Yes
Software name: MEDEMIS.

Software comments (...Annex 1):
The software was originally developed by the Ministry of Health (MoH). The Department of Hospital service is managing inventories for medical equipment of four National hospitals and 18 CPA3 level hospitals. The Controlled medical equipment requires management (monitoring), maintenance and repair.

Medical devices workforce

Density of medical doctors (per 10,000 population): 1.93
Number of biomedical/clinical engineers professionals in the country: —

Contacts

MOH focal point
Name: Dr. Cheu Sivuthy
Department: Department of Hospital Services
Email: cheusivuthy@gmail.com

WHO Representative/WHO Liason Officer
Name: Dr. Ailan Li
Email: lia@who.int

Other country focal point
Name: —
Email: —

WHO health products focal point
Name: —
Email: —

General comments (...Annex 1): —

a UN POP/WPP 2019 (2020 POP)
b WB FY21 2019
c UN POP/WPP 2019 (1990-2020 MOR)
d WHO GHO 2019
e WHO GHO 2016
f UNDP 2019
g ITU 2017
h WHO GHO 2017
i WHO GHO 2010-2018
j WIPO 2020
k UN and WB 2017-2019
l Latest (2015-2021); WHO HTA/HBP 2021 survey or WHO HTA 2015 survey or WHO 2021 survey
m Latest (2013-2021); WHO GHO 2021 survey or OECD (2017-2019)

Medical device incorporation comments (...Annex 1):
Procurement: Health Sector Support Program (HSSP2) is the implementation project team under the direction of Health Sector Strategic Plan (HSP2) of the Ministry of Health. Medical Equipment standard list for CPA1,2,3 referral hospitals.
### Cameroon

#### Country indicators

- **Population 000s (rank):** 26,546 (52)
- **World Bank income group:** Lower-Middle

#### National policy on health technology

- **Health technology (medical device) national policy:** Yes
- **Policy is part of the National Health Program/Plan:** Yes
- **Language(s):** Français et Anglais
- **MOH responsible for health technology policy implementation:** Direction de l’Organisation des Soins et de la Technologie Sanitaire.

#### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: No
  - Website: —
  - Nomenclature systems used for devices and tests: —

- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - Lists available: Yes
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

- **National list for specific clinical interventions/emergencies:**
  - Lists available: No
  - Website: —

#### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):** No
- **National unit/department that includes HTA for medical devices:** No
- **Website(s):** —
- **Contact:** — Email: —

- **HTA unit comments:** (...Annex 1):
  - —

#### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** Yes
- **Name of regulatory agency:** —
- **Website(s):** —
- **Contact:** — Email: —
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** National Radiation Protection Agency (NRPA).
- **Other agency’s website:** https://gnssn.iaea.org/main/ANNuR/Activity%20Documents%20%20Public/Regional%20Workshop%20on%20Management%20of%20Safe%20Disposal%20of%20Radioactive%20Waste/CAMEROON.pdf

- **National regulatory comments:** (...Annex 1):
  - Il existe un organisme chargé de la réglementation concernant les équipements qui émettent les rayonnements ionisants. L’Agence Nationale de Radioprotection. Contact: Dr Simo Augustin, e-mail: augsimox@yahoo.fr.
  - We added a website link that directs the user to an NRPA presentation.

#### Approved devices lists comments

(...Annex 1):

- —

#### Health care facilities lists comments

(...Annex 1):

- —

#### Specific lists comments

(...Annex 1):

- —

#### Human Development Index (inequality adjusted HDI): 0.56 (0.38): medium

#### ICT Development Index (rank): 2.4 (149)

#### Under-five mortality (per 1000 live births): 74.8

#### Probability of dying aged 30-70 yrs of NCDs (%): 21.60%

#### UHC - Service coverage index (1-100): 46

#### UHC - Population with household spending >10% (>25%) of corresponding income (%): 10.8% (3.0%)

#### Global innovation index (rank): 20 (119)

#### High-technology exports (% of manufacture exports): 6.00%
Medical device nomenclature system

Official nomenclature system for medical devices: No
Type: None
Use: Not specified
Website: —

Medical device incorporation

Policy or guideline: Yes
National level procurement: Yes
Website: —

Donations

Policy or guideline: No
Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging a</td>
<td>1</td>
<td>0.04</td>
<td>Health posts:</td>
<td>1653</td>
<td>7.43</td>
</tr>
<tr>
<td>Computerized Tomography Scanner a</td>
<td>14</td>
<td>0.63</td>
<td>Health centres:</td>
<td>141</td>
<td>0.63</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner a</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>150</td>
<td>0.67</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine a</td>
<td>1</td>
<td>0.04</td>
<td>Specialized/regional/national hospitals:</td>
<td>9</td>
<td>0.04</td>
</tr>
<tr>
<td>Mammograph a β</td>
<td>15</td>
<td>17.4</td>
<td>Estimation % of health facilities with none or very limited oxygen supply: n/a</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiotherapy a β</td>
<td>1</td>
<td>0.04</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes
Professionally Trained biomedical/clinical engineers: Yes
Unit/Department: Studies and Project Division (DEP). Unit website: http://www.minsante.cm/
Contact name: —
Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 10

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No
Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): 0.88
Number of biomedical/clinical engineers professionals in the country: 19

Contacts

MOH focal point
Name: Mr. Vincent Ngaleu Toko
Department: Consultant MoH
Email: vngaleutoko@yahoo.fr
Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: Dr. Samuel Besong
Email: besongs@who.int

WHO Representative/WHO Liaison Officer:
Name: Dr. Phanuel Habimana
Email: habimanap@who.int

General comments (...Annex 1): L’étude devrait inclure la formation dans le domaine. Le Cameroun dispose d’un cycle de formation de techniciens en maintenance hospitalière qui fonctionne depuis deux ans dans trois lycées techniques, le diplôme de sortie délivré au bout de trois ans est équivalent du baccalauréat. Il existe également des cycles de formation dans le domaine en enseignement supérieur.
Canada

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank): a</th>
<th>37,742 (39)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group: b</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years): c</td>
<td></td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No

Website: [http://www.cadth.ca/media/policy_forum_section/1_health_tech_strategy_1.0_nov-2004_e.pdf](http://www.cadth.ca/media/policy_forum_section/1_health_tech_strategy_1.0_nov-2004_e.pdf)

Language(s): English and Français

MOH responsible for health technology policy implementation: Canadian Agency for Drugs and Technologies in Health (CADTH).

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - IVD: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): d Yes

National unit/department that includes HTA for medical devices: Yes, Canadian Agency for Drugs and Technologies in Health (CADTH).

Website(s): [https://www.cadth.ca/](https://www.cadth.ca/); [https://www.ihe.ca/](https://www.ihe.ca/); [https://www.INESSS.QC.CA/EN/Home.HTML](https://www.INESSS.QC.CA/EN/Home.HTML); [https://www.hqontario.ca/](https://www.hqontario.ca/)

Contact: — Email: —

Committee includes a biomedical or clinical engineer: Yes

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Health Canada, Health Products and Food Branch, Medical Devices Directorate


Contact: David Boudreau Email: david.boudreau@hc-sc.gc.ca

Name(s) of other regulatory agency eg. for radiation equipment etc.: Consumer and Clinical Radiation Protection Bureau

Other agency’s website: [https://nuclearsafety.gc.ca/eng/](https://nuclearsafety.gc.ca/eng/)

Under-five mortality (per 1000 live births): d 4.9

UHC - Service coverage index (1-100): e 89

Probability of dying aged 30-70 yrs of NCDs (%): f 9.80%

UHC - Population with household spending >10% (>25%) of corresponding income (%): f 2.6% (0.5%)

Human Development Index (inequality adjusted HDI): rank: g 0.93 (0.85); very high

Global innovation index (rank): h 52.3 (17)

ICT Development Index (rank): i 7.8 (29)

High-technology exports ( % of manufacture exports): j 16.50%

Population 000s (rank): a 37,742 (39)

World Bank income group: b High

Life expectancy at birth (years): c

Under-five mortality (per 1000 live births): d 4.9

UHC - Service coverage index (1-100): e 89

Probability of dying aged 30-70 yrs of NCDs (%): f 9.80%

UHC - Population with household spending >10% (>25%) of corresponding income (%): f 2.6% (0.5%)

Human Development Index (inequality adjusted HDI): rank: g 0.93 (0.85); very high

Global innovation index (rank): h 52.3 (17)

ICT Development Index (rank): i 7.8 (29)

High-technology exports ( % of manufacture exports): j 16.50%
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  
Type: Many co-existence of nomenclatures  
Use: For regulatory purposes  

Medical device incorporation

Procurement

Policy or guideline: No  
Website: —

Donations

Policy or guideline: No  
Website: —

Technical specifications

Technical specifications to support procurement or donations: No  
Publically available: —  
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>389</td>
<td>10.31</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>557</td>
<td>14.76</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>56</td>
<td>1.48</td>
<td>General/district hospitals:</td>
<td>299 0.79</td>
<td></td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>588</td>
<td>15.58</td>
<td>Specialized/regional/national hospitals:</td>
<td>46 0.12</td>
<td></td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>669</td>
<td>134.45</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>351</td>
<td>9.3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  
Professionally trained biomedical/clinical engineers: Yes

Unit/Department: —  
Contact name: —  
Contact email: —  
Website with publically available technical specifications: —  
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment  
Website: —  
Use of management software: —  
Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): 24.43  
Number of biomedical/clinical engineers professionals in the country: 642

Contacts

MOH focal point

Name: Mr. David Boudreau  
Department: Strategic Policy Branch, Health Canada  
Email: —

Other country focal point

Name: Dr. Lesley Dunfield  
Email: lesleyd@cadth.ca

WHO health products focal point:

Name: —  
Email: —

WHO Representative/WHO Liaison Officer:

Name: Ms. Mary Lou Valdez  
Email: valdezmar@paho.org

General comments: In several survey’s sections (e.g. section health policy), we were not able to reflect the shared governance approach that Canada has evolved towards as several as the key organisations, namely, the Canadian Agency for Drugs and Technology in Health are neither national nor provincial but entities whose governance and financing is shared among the Deputy Minister of Health of Canada’s 14 jurisdictions (e.g. Federal, 10 provinces and 3 Territories). In addition, the survey did not allow for the identification of existing provincial capacities which would have resulted in having to fill 13 separate surveys to accurately reflect Canada’s reality. Concerning HT national policy, it was provided the following document: [http://www.who.int/medical_devices/survey_resources/health_technology_national_canada](http://www.who.int/medical_devices/survey_resources/health_technology_national_canada)
Cape Verde

Country indicators

Population 000s (rank): 556 (165)
World Bank income group: Lower-Middle
Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Year</th>
<th>Cape Verde</th>
<th>World</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020</td>
<td>72.1</td>
<td>72.1</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 14.9
Probability of dying aged 30-70 yrs of NCDs (%): 17.20%
Human Development Index (inequality adjusted HDI): 0.67 (medium)
ICT Development Index (rank): 4.9 (93)

Health technology (medical device) national policy:
Yes
Policy is part of the National Health Program/Plan:
Yes
Website: http://www.minsaude.gov.cv
Language(s): Portuguese
MOH responsible for health technology policy implementation: General Directorate of Planning, Budgeting and Management

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: https://www.who.int/medical_devices/survey_resources/medical_devices_by_facility_cape_verde.pdf
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):
Yes
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Health Regulatory Independent Entity (ERIS)
Website(s): http://www.eris.cv
Contact: Ms. Edith Santos Email: edith.santos@gov.cv
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

Approved devices lists comments (...Annex 1):

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):
No, it is done according to the needs and the procedures of our action plan for the next years.

HTA unit comments (...Annex 1):
HTA is focused on pharmaceutics but not in medical devices.

National regulatory comments (...Annex 1):
There is a department in charge of medical devices, but there is no legislation nor registration of medical devices yet.
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: http://www.minsaude.gov.cv

Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>3</td>
<td>5.4</td>
<td>Health posts:</td>
<td>148</td>
<td>26.62</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>8</td>
<td>14.39</td>
<td>Health centres:</td>
<td>39</td>
<td>7.01</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>4</td>
<td>0.72</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>2</td>
<td>0.36</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>5</td>
<td>124.25</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally Trained biomedical/clinical engineers: Yes
Unit/Department: Health Infrastructure and Equipment Maintenance and Management Service  Unit website: —
Contact name: Ms. Margarida Cardoso  Contact email: margarida.cardoso@gov.cv
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: None
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 7.81
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: Ms. Margarida Cardoso
Email: margarida.cardoso@gov.cv

WHO health products focal point:
Name: —
Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Daniel A. Kertesz
Email: kertesz@who.int

General comments (...Annex 1): In conclusion, there is a need to organize the park of medical devices. We would like to make a national inventory for medical equipment, assess the needs, and organizing technical guidelines for procurement to elaborate a clear plan of medical devices management. We think it is time to develop legislation for medical devices.
Central African Republic

Country indicators

- Population 000s (rank): 4,830 (122)
- World Bank income group: Low
- Life expectancy at birth (years): 51.7

National policy on health technology

- Health technology (medical device) national policy: No
- Policy is part of the National Health Program/Plan: No
- Website: —
- Language(s): —
- MOH responsible for health technology policy implementation: —

National lists of medical devices

- National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
  - Lists available: Yes
  - Unit: Unité de cession des médicaments et équipements médicaux.
  - Website: —
  - Nomenclature systems used for devices and tests: —

- National list for different types of healthcare facilities (hospitals, laboratories, etc)
  - Lists available: Yes
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

- National list for specific clinical interventions/emergencies:
  - Lists available: Yes
  - Website: —

National health technology assessment unit

- Designated unit/department for health technology assessment (HTA): No
- National unit/department that includes HTA for medical devices: No
- Website(s): —
- Contact: — Email: —
- Committee includes a biomedical or clinical engineer: —

Approved devices lists comments
(Annex 1):
En concernant acquisition il y a une longue durée entre la commande et la réception.

Health care facilities lists comments
(Annex 1):
—

Specific lists comments
(Annex 1):

HTA unit comments
(Annex 1):
—

National regulatory authority

- Presence of national authority responsible for regulating medical devices: Yes
- Name of regulatory agency: Direction des Infrastructures Sanitaires.
- Website(s): —
- Contact: Mrs. Claudine Kaya Email: nzoulouc@yahoo.fr
- Name(s) of other regulatory agency eg. for radiation equipment etc.: —
- Other agency’s website: —

National regulatory comments
(Annex 1):
—

Under-five mortality (per 1000 live births): 110.1
UHC - Service coverage index (1-100): 33
Probability of dying aged 30-70 yrs of NCDs (%): 23.10%
UHC - Population with household spending >10% (>25%) of corresponding income (%): —
Human Development Index (inequality adjusted HDI): rank: 0.4 (0.23) low
Global innovation index (rank): —
ICT Development Index (rank): 1 (175)
High-technology exports (% of manufacture exports): 29.00%

ICT Development Index (rank): 1 (175)

Population 000s (rank): 4,830 (122)

World Bank income group: Low

Life expectancy at birth (years): 51.7

Probability of dying aged 30-70 yrs of NCDs (%): 23.10%

Human Development Index (inequality adjusted HDI): rank: 0.4 (0.23) low

ICT Development Index (rank): 1 (175)

High-technology exports (% of manufacture exports): 29.00%
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation

Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation

Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation

Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation

Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation

Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation

Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>0</td>
<td>0</td>
<td>Health posts:</td>
<td>562</td>
<td>12.17</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>Health centres:</td>
<td>92</td>
<td>1.99</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>13</td>
<td>0.28</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>4</td>
<td>0.09</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>1</td>
<td>4.68</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Inventories and medical equipment management software
Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medicine devices workforce
Density of medical doctors (per 10 000 population): * 0.72
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: Mr. Leppa
Email: —

WHO health products focal point
Name: Dr. Florentine Sylvie Mberyo Yaah
Email: mberyos@who.int

WHO Representative/WHO Liaison Officer:
Name: Dr. Ngoy Nsenga
Email: nsengan@who.int

General comments (...Annex 1): Concerning the HT national policy it is stated in the following document 
POLITINACIONALSAUDE_VERSAOVALIDADA 2020.
### Chad

#### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>16,426 (71)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.1</td>
</tr>
</tbody>
</table>

#### National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: Direction Générale Technique Pharmacie, Médicament et Laboratoire (DGTPML)

#### National lists of medical devices

**National list of approved priority/essential medical devices (including IVDs), for procurement or reimbursement:**
- Lists available: Yes
- Unit: Direction Générale Technique Pharmacie, Médicament et Laboratoire (DGTPML)
- Website: —
- Nomenclature systems used for devices and tests: —

**National list for different types of healthcare facilities (hospitals, laboratories, etc)**
- Lists available: Yes
- Website - hospitals: —
- Website - IVD: —
- Nomenclature systems used for devices and tests: —

**National list for specific clinical interventions/emergencies:**
- Lists available: No
- Website: —

**Approved devices lists comments**
(...Annex 1):
It is needed to revise the list

**Health care facilities lists comments**
(...Annex 1):
—

**Specific lists comments**
(...Annex 1):
—

#### National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: No
- Website(s): —
- Contact: — Email: —
- Committee includes a biomedical or clinical engineer: —

#### HTA unit comments
(...Annex 1):
—

#### National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

**Name of regulatory agency:** Direction Générale Technique Pharmacie, Médicament et Laboratoire (DGTPML)
- Website(s): —
- Contact: — Email: —

**Name(s) of other regulatory agency eg. for radiation equipment etc.:** The Chadian Agency of Radiation Protection and Nuclear Security (ATRSN).
### Medical device nomenclature system

**Official nomenclature system for medical devices:** No  **Type:** None  **Use:** Not specified  
**Website:** —

### Medical device incorporation

**Procurement**

**Policy or guideline:** Yes  **Website:** —  
**National level procurement:** Yes  **Website:** —

**Donations**

**Policy or guideline:** Yes  **Website:** —

**Technical specifications**

**Technical specifications to support procurement or donations:** No  
**Publically available:** —  
**Website:** —

### Medical equipment

<table>
<thead>
<tr>
<th>Medical device Incorporation</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>1</td>
<td>0.06</td>
<td>Health posts:</td>
<td>1823</td>
<td>11.1</td>
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<tr>
<td>Computerized Tomography Scanner:*</td>
<td>3</td>
<td>0.18</td>
<td>Health centres:</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>120</td>
<td>0.73</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mammographe:*</td>
<td>2</td>
<td>3.57</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

### Medical equipment management unit

**Unit present:** Yes  **Professionally trained biomedical/clinical engineers:** Yes  
**Unit/Department:** Centrale Pharmaceutique d’Achats (CPA)- Division Approvisionnement and Division Assurance Qualité  
**Unit website:** —  
**Contact name:** —  
**Contact email:** —  
**Website with publically available technical specifications:** —  
**Number of regional/state offices/units:** 0

### Inventories and medical equipment management software

**Type of inventories available:** Periodic  
**Website:** —  
**Use of management software:** Yes  **Software name:** G-Stock/MSPSN (2014-2015)

### Medical devices workforce

**Density of medical doctors (per 10 000 population):** 0.54  
**Number of biomedical/clinical engineers professionals in the country:** 12

### Contacts

**MOH focal point**

**Name:** Mr. Ngardibaye Madjimbaye  
**Department:** Division Equipement Maintenace  
**Email:** madjimbayen@yahoo.fr

**Other country focal point**

**Name:** Mr. Djémian Mongbe  
**Email:** —

**WHO health products focal point**

**Name:** —  
**Email:** —

**WHO Representative/WHO Liaison Officer:**

**Name:** Dr. Jean-Bosco Ndihokubwayo  
**Email:** ndihokubwayoj@who.int

**General comments (...Annex 1):** The lack of a national policy in matters of health technology does not allow access to information on medical devices that could support the action plan with regards to training of users, specialists and maintenance technicians.
Chile

Country indicators

<table>
<thead>
<tr>
<th>National policy on health technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health technology (medical device) national policy: No</td>
</tr>
<tr>
<td>Policy is part of the National Health Program/Plan: No</td>
</tr>
<tr>
<td>Website: —</td>
</tr>
<tr>
<td>Language(s): —</td>
</tr>
<tr>
<td>MOH responsible for health technology policy implementation: —</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>National lists of medical devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:</td>
</tr>
<tr>
<td>Lists available: Yes, but it is only a recommendation</td>
</tr>
<tr>
<td>Unit: Sección dispositivos médicos - Instituto de Salud Pública de Chile.</td>
</tr>
<tr>
<td>Website: <a href="http://www.ispch.cl/dispositivos-medicos">http://www.ispch.cl/dispositivos-medicos</a></td>
</tr>
<tr>
<td>Nomenclature systems used for devices and tests: —</td>
</tr>
<tr>
<td>National list for different types of healthcare facilities (hospitals, laboratories, etc)</td>
</tr>
<tr>
<td>Lists available: No</td>
</tr>
<tr>
<td>Website - hospitals: —</td>
</tr>
<tr>
<td>Website - IVD: —</td>
</tr>
<tr>
<td>Nomenclature systems used for devices and tests: —</td>
</tr>
<tr>
<td>National list for specific clinical interventions/emergencies:</td>
</tr>
<tr>
<td>Lists available: No</td>
</tr>
<tr>
<td>Website: —</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>National health technology assessment unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designated unit/department for health technology assessment (HTA): Yes</td>
</tr>
<tr>
<td>National unit/department that includes HTA for medical devices: Yes, Institute of Public Health and MoH.</td>
</tr>
<tr>
<td>Website(s): <a href="https://www.ispch.cl/">https://www.ispch.cl/</a>; <a href="http://redetsa.org/wp/?page_id=322">http://redetsa.org/wp/?page_id=322</a></td>
</tr>
<tr>
<td>Contact: — Email: —</td>
</tr>
<tr>
<td>Committee includes a biomedical or clinical engineer: Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>National regulatory authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presence of national authority responsible for regulating medical devices: Yes</td>
</tr>
<tr>
<td>Name of regulatory agency: Instituto de Salud Pública de Chile, Agencia Nacional de Dispositivos Médicos, Innovación y Desarrollo (ANDID).</td>
</tr>
<tr>
<td>Website(s): <a href="https://www.ispch.cl/andid/">https://www.ispch.cl/andid/</a></td>
</tr>
<tr>
<td>Contact: Ms. Ana Maria Concha Email: <a href="mailto:amconcha@ispch.cl">amconcha@ispch.cl</a></td>
</tr>
<tr>
<td>Name(s) of other regulatory agency eg. for radiation equipment etc.: Comisión Chilena de Energía Nuclear.</td>
</tr>
<tr>
<td>Other agency’s website: <a href="https://www.cchen.cl/">https://www.cchen.cl/</a></td>
</tr>
</tbody>
</table>
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: http://www.minsal.cl

Donations
Policy or guideline: No  Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility*</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>226</td>
<td>11.82</td>
<td>Health posts:</td>
<td>1883</td>
<td>10.69</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>446</td>
<td>23.33</td>
<td>Health centres:</td>
<td>21</td>
<td>0.12</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>100</td>
<td>0.57</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>62</td>
<td>0.35</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>58</td>
<td>32.18</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>56</td>
<td>2.93</td>
<td>—</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: —
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): 51.82
Number of biomedical/clinical engineers professionals in the country: 650

Contacts

MOH focal point
Name: Mr. Luis Vera Benavides
Department: Departamento de calidad y seguridad del paciente y Unidad de Evaluación de Tecnologías Sanitarias
Email: lvera@minsal.cl

Other country focal point
Name: Mr. Luis Ampuero Velásquez
Email: lampuero@minsal.cl

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liason Officer:
Name: Dr. Luis Fernando Leanes
Email: leanesf@paho.org

General comments (...Annex 1): Concerning the Infrastructure section: Los 21 centros de salud están incorporados en los 100 hospitales distritales/rurales. Los Centros de Referencia de Salud (CRS) = 7 considera a los Hospitales de Chile denominados de Mediana Complejidad y que se ubican en la región metropolitana y demás regiones del país. También existen también los hospitales de Chile denominados de Alta Complejidad. Se ubican en la región metropolitana y demás regiones del país. Estos hospitales tienen la calidad de “Establecimientos Auto-gestionados en red”, incluyendo los...
China

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank): a</th>
<th>1,439,324 (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group: b</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years): c</td>
<td>76.6</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Language(s): —
MOH responsible for health technology policy implementation: Department of Planning and Finance, State Food and Drug Administration.

National lists of medical devices

National list of approved priority/essential medical devices (including IVDs), for procurement or reimbursement:
- Lists available: Yes
- Unit: —
- Website: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
- Lists available: Yes
- Website - hospitals: —
- Website - IVD: http://app1.nmpa.gov.cn/data_nmpa-face3/base.jsp?tableId=105&tableName=TABLE105&title=%CC%E5%CD%E2%D5%EF%B6%CF%CA%4%BC%CB%B7%D6%0D%4%6%E7%BC%A3%AB2013%B0%E6%A9&bcId=1529044584537669180366272682
- Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
- Lists available: —
- Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): a Yes
National unit/department that includes HTA for medical devices: Yes, Department of planning and finance MoH; China National Health Development Research Center (CNHDC); Fudan University (Key Lab of Health Technology Assessment: KLHTA).
Website(s): http://www.futurehealthsystems.org/cnhdc; https://chta.fudan.edu.cn/upload/%E6%96%87%E5%9B%BB%E5%85%AC%E5%91%A8/%E5%B7%A5%E4%BD%9C%E7%AE%80%E8%AE%AF/WHOCC-CHN86_HTA%20policy%20brief_2018_issue201.pdf
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Ministry of Health, State Food and Drug Administration.
Contact: Ms. Yasha Huang Email: huangys@cfda.gov.cn
Name(s) of other regulatory agency eg. for radiation equipment etc.: China Atomic Energy Authority; National Health Commission of the People's Republic of China.
Medical device nomenclature system
Official nomenclature system for medical devices: Yes Type: Based on UMDNS Use: Not specified
Website: https://www.nmpa.gov.cn/
http://english.nmpa.gov.cn/2019-12/14/c_432228.htm

Medical device incorporation
Procurement
Policy or guideline: Yes Website: —
National level procurement: Yes Website: http://en.nhc.gov.cn/
https://www.nmpa.gov.cn/
Donations
Policy or guideline: Yes Website: http://en.nhc.gov.cn/; https://www.nmpa.gov.cn/
Technical specifications
Technical specifications to support procurement or donations: Yes
Publicly available: —

Medical equipment
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>1818</td>
<td>1.26</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Department of Technology and Education. Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: —
Use of management software: — Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 19.8
Number of biomedical/clinical engineers professionals in the country: 661030

Contacts
MOH focal point
Name: —
Department: —
Email: —
Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: Ms. Jianrong Qiao
Email: qiaoj@who.int
WHO Representative/WHO Liaison Officer:
Name: Dr. Gauden Galea
Email: galeag@who.int

General comments (Annex 1): —

Medical device incorporation comments (Annex 1): —

Medical device comments (Annex 1): —

Medical equipment comments (Annex 1): —

Medical equipment T otal Density per 1,000,000 population Healthcare facility γ Total Density per 100,000 population

Magnetic Resonance Imaging: a n/a n/a Health posts: n/a n/a
Computerized Tomography Scanner: a n/a n/a Health centres: n/a n/a
Positron Emission Tomography Scanner: a n/a n/a General/district hospitals: n/a n/a
Gamma camera or nuclear medicine: a n/a n/a Specialized/regional/national hospitals: n/a n/a
Mammograph:* n/a n/a Estimation % of health facilities with none or very limited oxygen supply: n/a
Radiotherapy:* 1818 1.26

a Density per 1,000,000 females aged from 50-69 old.

WHO Western Pacific Region
WHO health products focal point:
Name: Ms. Jianrong Qiao
Email: qiaoj@who.int
WHO Representative/WHO Liaison Officer:
Name: Dr. Gauden Galea
Email: galeag@who.int

General comments (Annex 1): —
### Colombia

#### Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population (000s) (rank):</td>
<td>50,883 (29)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.3</td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>13.8</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>15.8%</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI) (rank):</td>
<td>0.77 (0.6): high</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>5.4 (84)</td>
</tr>
</tbody>
</table>

#### National policy on health technology

- **Health technology (medical device) national policy:** Yes
- **Policy is part of the National Health Program/Plan:** Yes
- **Website:** [https://www.who.int/medical_devices/survey_resources/health_technology_national_policy_colombia.pdf](https://www.who.int/medical_devices/survey_resources/health_technology_national_policy_colombia.pdf)
- **Language(s):** Español
- **MOH responsible for health technology policy implementation:** Dirección de Medicamentos y Tecnologías en Salud.

#### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: Yes
  - Unit: Dirección de Medicamentos y Tecnologías en Salud
  - Website: [https://www.minsalud.gov.co/salud/MT/Paginas/dispositivos-medicos-equipos-biomedicos.aspx](https://www.minsalud.gov.co/salud/MT/Paginas/dispositivos-medicos-equipos-biomedicos.aspx)

- **Nomenclature systems used for devices and tests:** —

- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - Lists available: Yes
  - Website - hospitals: —

- **Nomenclature systems used for devices and tests:** —

- **National list for specific clinical interventions/emergencies:**
  - Lists available: No
  - Website: —

#### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):** Yes
- **National unit/department that includes HTA for medical devices:** Yes, INVIMA.
- **Website(s):** [https://www.invima.gov.co/](https://www.invima.gov.co/), [https://www.iets.org.co/](https://www.iets.org.co/)
- **Contact:** Mr. Julio César Aldana Bula  Email: invimagd@invima.gov.co

- **Committee includes a biomedical or clinical engineer:** —

#### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** Yes
- **Name of regulatory agency:** Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA).
- **Website(s):** [http://www.invima.gov.co](http://www.invima.gov.co)
- **Contact:** Ms. Lucia Ayala Rodríguez  Email: layalar@invima.gov.co
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA); Ministerio de Minas y Energía.

### Under-five mortality (per 1000 live births): 13.8

### UHC - Service coverage index (1-100): 76

### Probability of dying aged 30-70 yrs of NCDs (%): 15.8%

### UHC - Population with household spending >10% (>25%) of corresponding income (%): 8.2% (2.2%)

### Human Development Index (inequality adjusted HDI) (rank): 0.77 (0.6): high

### Global innovation index (rank): 30.8 (68)

### ICT Development Index (rank): 5.4 (84)

### High-technology exports (% of manufacture exports): 9.10%

---

**Approved devices lists comments** (...Annex 1): No existe un listado oficial. El acuerdo No.008 de La Comisión de Regulación en Salud (CRES) establece que los dispositivos médicos usados en los procedimientos listados son reembolsados dentro del Plan de Beneficios en Salud.

**Health care facilities lists comments** (...Annex 1): —

**Specific lists comments** (...Annex 1): —

**HTA unit comments** (...Annex 1): The INVIMA (Instituto Nacional de Vigilancia en Medicamentos y alimentos) and the IETS (Instituto de Evaluación Tecnológica en Salud) perform HTA.

**National regulatory comments** (...Annex 1): El INVIMA tiene dos dependencias relacionadas, la Subdirección de Registros Sanitarios que tiene un grupo funcional específico de dispositivos médicos y se encarga de la evaluación y autorización pre-mercado de los dispositivos médicos; y la Subdirección de Insumos para la Salud que se encarga de la vigilancia posmercado y de auditar sistemas de calidad de los fabricantes y condición de calidad de los importadores de los dispositivos médicos en Colombia. También existe la Dirección de Dispositivos Médicos y otras Tecnologías.
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: For regulatory and procurement purposes
Website: https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/resolucion-2535-de-2013.pdf

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: No  Website: —

Donations
Policy or guideline: Yes  Website: https://www.invima.gov.co/en/

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: Yes
Website: https://www.minsalud.gov.co/Normatividad_Nuevo/Forms/DispForm.aspx?ID=5524

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>12</td>
<td>0.24</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanners:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammography:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>121</td>
<td>2.38</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Inventories and medical equipment management software

Type of inventories available: None
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): 38.44
Number of biomedical/clinical engineers professionals in the country: 2000

Contacts

MOH focal point
Name: Ms. Marleny Montenegro Guerrero
Department: Dirección de Medicamentos y Tecnologías en Salud
Email: mmontenegro@minsalud.gov.co

Other country focal point

General comments (...Annex 1): Actualmente se tiene reglamentado y en fase de implementación el Programa Nacional de Tecnovigilancia Post-mercado liderado por el Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA) (importantes para la gestión y manejo de los dispositivos médicos), también es importante establecer normas sobre los
## Country indicators

<table>
<thead>
<tr>
<th>Global Health Technology Classification</th>
<th>Comoros</th>
<th>World Bank income group:</th>
<th>Lower-Middle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>870 (158)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>World Bank income group:</td>
<td></td>
<td>Lower-Middle</td>
<td></td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>62.9</td>
<td>UHC - Service coverage index (1-100):</td>
<td>52</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>22.90%</td>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>8.8% (1.6%)</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank:</td>
<td>0.55 (0.3): medium</td>
<td>Global innovation index (rank):</td>
<td>— (—)</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>1.8 (164)</td>
<td>High-technology exports (% of manufacture exports):</td>
<td>3.00%</td>
</tr>
</tbody>
</table>

### National policy on health technology

**Health technology (medical device) national policy:** No  
**Policy is part of the National Health Program/Plan:** No  
**Website:** —  
**Language(s):** —  
**MOH responsible for health technology policy implementation:** —

### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**  
**Lists available:** No  
**Unit:** —  
**Website:** —  
**Nomenclature systems used for devices and tests:** —

**National list for different types of healthcare facilities (hospitals, laboratories, etc):**  
**Lists available:** Yes  
**Website - hospitals:** Liste nationale des medicaments essentiels adultes et pediatriques 2020  
**Website - IVD:** —  
**Nomenclature systems used for devices and tests:** —

**National list for specific clinical interventions/emergencies:**  
**Lists available:** No  
**Website:** —

### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** Yes  
**National unit/department that includes HTA for medical devices:** No  
**Website(s):** —  
**Contact:** —  
**Email:** —  
**Committee includes a biomedical or clinical engineer:** —

### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes  
**Name of regulatory agency:** Direction des Etablissements de soins Publics et Privés.  
**Website(s):** —  
**Contact:** Dr. Ahamada Said Fazul  
**Email:** —  
**Name(s) of other regulatory agency eg. for radiation equipment etc.:** —  
**Other agency’s website:** —

### Approved devices lists comments

(...Annex 1): —

### Health care facilities lists comments

(...Annex 1): —

### Specific lists comments

(...Annex 1): —

### HTA unit comments

(...Annex 1): —

### National regulatory comments

Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: —
Donations
Policy or guideline: No  Website: —
Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>0</td>
<td>0</td>
<td>Health posts:</td>
<td>69</td>
<td>7.93</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>1</td>
<td>1.15</td>
<td>Health centres:</td>
<td>18</td>
<td>2.07</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>17</td>
<td>1.95</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>—</td>
<td>0</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>1</td>
<td>24.28</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>75%</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>0</td>
<td>0</td>
<td>—</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: None
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population): 1.7
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: Dr. Ahamada Said Fazul
Department: Direction des Etablissement des Soins Publics et Privés, Ministère de la Santé, de la Solidarité et de la Promotion du Genre
Email: sfazul@yahoo.fr
Other country focal point
Name: Dr. Ahamada Said Fazul, Ministère de la santé
Email: —

WHO health products focal point:
Name: —
Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Abdoulaye Diarra
Email: diarraa@who.int

General comments (Annex 1): —

Medical device incorporation comments (Annex 1):
La Evaluación de Tecnologías se reglamentó en el año 2011 mediante la Ley 1438, la cual será competencia del Instituto Nacional de Evaluación de Tecnologías que está en proceso de creacion.
Congo

Country indicators

| Population 000s (rank):\textsuperscript{a} | 5,518 (115) |
| Life expectancy at birth (years):\textsuperscript{c} | 64.2 |

Global atlas of medical devices 2022

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):\textsuperscript{a} No
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Direction des laboratoires.
Website(s): —
Contact: Mr. Arthur Ngole Email: arthurngolet@gmail.com
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

| Probability of dying aged 30-70 yrs of NCDs (%)\textsuperscript{d} | 16.70% |
| Human Development Index (inequality adjusted HDI): rank\textsuperscript{c} | 0.57 (0.45): medium |
| ICT Development Index (rank)\textsuperscript{d} | — (—) |

| Under-five mortality (per 1000 live births):\textsuperscript{b} | 47.8 |
| UHC - Service coverage index (1-100):\textsuperscript{h} | 39 |
| UHC - Population with household spending >10% (>25%) of corresponding income (%):\textsuperscript{b} | 4.6% (0.7%) |
| Global innovation index (rank):\textsuperscript{j} | — (—) |
| High-technology exports (% of manufacture exports):\textsuperscript{a} | 6.70% |

| Under-five mortality (per 1000 live births):\textsuperscript{b} | 47.8 |
| UHC - Service coverage index (1-100):\textsuperscript{h} | 39 |
| UHC - Population with household spending >10% (>25%) of corresponding income (%):\textsuperscript{b} | 4.6% (0.7%) |
| Global innovation index (rank):\textsuperscript{j} | — (—) |
| High-technology exports (% of manufacture exports):\textsuperscript{a} | 6.70% |

| UHC - Service coverage index (1-100):\textsuperscript{h} | 39 |
| UHC - Population with household spending >10% (>25%) of corresponding income (%):\textsuperscript{b} | 4.6% (0.7%) |
| Global innovation index (rank):\textsuperscript{j} | — (—) |
| High-technology exports (% of manufacture exports):\textsuperscript{a} | 6.70% |

| UHC - Service coverage index (1-100):\textsuperscript{h} | 39 |
| UHC - Population with household spending >10% (>25%) of corresponding income (%):\textsuperscript{b} | 4.6% (0.7%) |
| Global innovation index (rank):\textsuperscript{j} | — (—) |
| High-technology exports (% of manufacture exports):\textsuperscript{a} | 6.70% |

| UHC - Service coverage index (1-100):\textsuperscript{h} | 39 |
| UHC - Population with household spending >10% (>25%) of corresponding income (%):\textsuperscript{b} | 4.6% (0.7%) |
| Global innovation index (rank):\textsuperscript{j} | — (—) |
| High-technology exports (% of manufacture exports):\textsuperscript{a} | 6.70% |

| UHC - Service coverage index (1-100):\textsuperscript{h} | 39 |
| UHC - Population with household spending >10% (>25%) of corresponding income (%):\textsuperscript{b} | 4.6% (0.7%) |
| Global innovation index (rank):\textsuperscript{j} | — (—) |
| High-technology exports (% of manufacture exports):\textsuperscript{a} | 6.70% |
Medical device nomenclature system
Official nomenclature system for medical devices: No
Type: Many co-existence of nomenclatures
Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: No
Website: —
National level procurement: Yes
Website: —
Donations
Policy or guideline: Yes
Website: —
Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Total</th>
<th>Medical equipment</th>
<th>Total</th>
<th>Healthcare facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Density per</td>
<td>Magnetic Resonance Imaging</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>1,000,000 population</td>
<td>Computerized Tomography Scanner</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td>Positron Emission Tomography Scanner</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td>Gamma camera or nuclear medicine</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td>Mammograph</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td>Radiotherapy</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical device incorporation comments (...Annex 1):
L’achat des dispositifs médicaux est décentralisé. Il peut se faire au niveau national comme à l’étranger.

Medical device nomenclature system comments (...Annex 1):
La Nomenclature officiel n’existe pas. Mais sinon, on utilise ce qui peut être à la portée de la main et selon les circonstances.

Medical equipment management unit
Unit present: Yes
Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Direction des laboratoires
Contact name: Mr. Arthur Ngolet
Contact email: arthurngolet@gmail.com
Website: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —
Use of management software: No
Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 1.06
Number of biomedical/clinical engineers professionals in the country: <10

Contacts
MOH focal point
Name: Mr. Arthur Ngolet
Department: Direction des laboratoires, Ministere de la santé et de la population
Email: arthurngolet@gmail.com
Other country focal point
Name: —
Email: —

WHO health products focal point
Name: Dr. Ray Mankele
Email: mankele@cg.afro.who.int
WHO Representative/WHO Liason Officer
Name: Dr. Lucien Alexis Manga
Email: mangal@who.int

General comments (...Annex 1): —
## Cook Islands

### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):a</th>
<th>18 (191)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:b</td>
<td>—</td>
</tr>
<tr>
<td>Life expectancy at birth (years):c</td>
<td><a href="Image">Graph</a></td>
</tr>
</tbody>
</table>

### Under-five mortality (per 1000 live births):d 7.6

### Probability of dying aged 30-70 yrs of NCDs (%):e —

### Human Development Index (inequality adjusted HDI): rank:f — (—)

### ICT Development Index (rank):g — (—)

### UHC - Service coverage index (1-100):h —

### UHC - Population with household spending >10% (>25%) of corresponding income (%):i — (—)

### Global innovation index (rank):j — (—)

### ICT Development Index (rank):g — (—)

### High-technology exports (% of manufacture exports):k —

### National policy on health technology

#### Health technology (medical device) national policy: —
- Policy is part of the National Health Program/Plan: —
- Website: —
- Language(s): —
- MOH responsible for health technology policy implementation: —

### National lists of medical devices

#### National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
- Lists available: —
- Unit: —
- Website: —

#### Nomenclature systems used for devices and tests: —

#### National list for different types of healthcare facilities (hospitals, laboratories, etc)
- Lists available: —
- Website - hospitals: —
- Website - IVD: —

#### Nomenclature systems used for devices and tests: —

#### National list for specific clinical interventions/emergencies:
- Lists available: —
- Website: —

### National health technology assessment unit

#### Designated unit/department for health technology assessment (HTA):d No
- National unit/department that includes HTA for medical devices: No
- Website(s): —
- Contact: — Email: —
- Committee includes a biomedical or clinical engineer: —

### National regulatory authority

#### Presence of national authority responsible for regulating medical devices: —
- Name of regulatory agency: —
- Website(s): —
- Contact: — Email: —
- Name(s) of other regulatory agency eg. for radiation equipment etc.: —
- Other agency’s website: —

### Approved devices lists comments (...Annex 1): —

### Health care facilities lists comments (...Annex 1): —

### Specific lists comments (...Annex 1): —

### HTA unit comments (...Annex 1):
- There are identified HTA activities but not a national unit.

### National regulatory comments (...Annex 1): —
Medical device nomenclature system
Official nomenclature system for medical devices: — Type: — Use: — Website: —

Medical device incorporation
Procurement
Policy or guideline: — Website: —
National level procurement: — Website: —
Donations
Policy or guideline: — Website: —
Technical specifications
Technical specifications to support procurement or donations: —
Publicly available: —
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging: α</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts: n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner: β</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres: n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner: γ</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals: n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine: δ</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/ regional/ national hospitals: n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph: ε</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply: n/a</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiotherapy: θ</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —
Website: —
Use of management software: — Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): α 14.12
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: —
Email: —

Who health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Mark Andrew Jacobs
Email: jacobsma@who.int

General comments (...Annex 1): —
Costa Rica

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank): a</th>
<th>5,094 (119)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group: b</td>
<td>Upper-Middle</td>
</tr>
</tbody>
</table>

Life expectancy at birth (years): c

Under-five mortality (per 1000 live births): d 8.6

Probability of dying aged 30-70 yrs of NCDs (%): e 11.50%

Human Development Index (inequality adjusted HDI) rank: f 0.81 (0.66): very high

ICT Development Index (rank): g 6.4 (60)

UHC - Service coverage index (1-100): h 77

UHC - Population with household spending >10% (>25%) of corresponding income (%): i 9.8% (1.7%)

Global innovation index (rank): j 33.5 (56)

High-technology exports (% of manufacture exports): k 17.60%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: http://www.ccss.sa.cr


Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: http://www.ccss.sa.cr

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): a No

National unit/department that includes HTA for medical devices: Yes, Dirección de Desarrollo Científico y Tecnológico en Salud (DDCTS) MoH and Caja Costarricense de Seguro Social (CCSS).

Website(s): https://www.ccss.sa.cr/; http://www.ministeriodesalud.go.cr

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Ministerio de Salud.

Website(s): http://www.ministeriodesalud.go.cr/index.php/

Contact: Ms. Giselle Rodriguez Email: grodriguez@ministeriodesalud.go.cr

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency’s website: https://www.sicop.go.cr/index.jsp

Approved devices lists comments (...Annex 1):

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):

Existen protocolos y procedimientos para las enfermedades y situaciones de emergencias en mención, pero no existen listas de dispositivos médicos como tales.

HTA unit comments (...Annex 1):

Two entities perform HTA: Caja Costarricense de Seguro Social (CCSS) and DDCTS. The extension of the HTA entities is at subnational level, not at national level.

National regulatory comments (...Annex 1):

El Ministerio de Salud tiene a su cargo el registro y control del equipo y material biomédico mediante el Reglamento Nº 34482-S para el uso, registro, clasificación, importación y control de equipo y material biomédico. El Sistema Integrado de Compras Públicas sigue la regulación vigente para hacer sus respectivas compras de productos de salud.

Global innovation index (rank): 33.5 (56)

ICT Development Index (rank): 6.4 (60)

High-technology exports (% of manufacture exports): 17.60%

Population 000s (rank): a 5,094 (119)

World Bank income group: b Upper-Middle

Life expectancy at birth (years): c

Under-five mortality (per 1000 live births): d 8.6

Probability of dying aged 30-70 yrs of NCDs (%): e 11.50%

Human Development Index (inequality adjusted HDI) rank: f 0.81 (0.66): very high

ICT Development Index (rank): g 6.4 (60)

UHC - Service coverage index (1-100): h 77

UHC - Population with household spending >10% (>25%) of corresponding income (%): i 9.8% (1.7%)

Global innovation index (rank): j 33.5 (56)

High-technology exports (% of manufacture exports): k 17.60%
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Nationally developed

Use: For regulatory and procurement purposes

Website: https://www.ministeriodesalud.go.cr/index.php/acceso-a-sistemas-de-informacion

Medical device incorporation

Procurement

Policy or guideline: No  Website: —

National level procurement: Yes  Website: https://www.ccss.sa.cr/

Donations

Policy or guideline: Yes  Website: https://www.ministeriodesalud.go.cr/index.php/registro-de-productos-de-interes-sanitario?id=637

Technical specifications

Technical specifications to support procurement or donations: Yes

Publicly available: Yes

Website: https://www.ministeriodesalud.go.cr/index.php/registro-de-productos-de-interes-sanitario?id=637

Medical equipment

<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>4</td>
<td>0.82</td>
<td>Health posts:</td>
<td>103</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>25</td>
<td>5.13</td>
<td>Health centres:</td>
<td>34</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>1</td>
<td>0.21</td>
<td>General/district hospitals:</td>
<td>13</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>6</td>
<td>1.23</td>
<td>Specialized/regional/national hospitals:</td>
<td>14</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>60</td>
<td>150.26</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>7</td>
<td>1.37</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Software comments (...Annex 1):

El Ministerio de Salud cuenta con la base de datos de los productos de equipo y material biomédico registrados para el país. Para cualquier adquisición dentro del país es necesario contar con su registro, pero no es del tipo inventario pues no se contabiliza; el registro tiene cinco años de vigencia. En el caso de la CCSS (ver https://www.ccss.sa.cr/) se tiene un inventario por establecimiento (en los tres niveles de atención) tanto a nivel hospitalario como en clinicas y áreas de salud. Del sector privado se ha reportado que cuentan con inventarios de equipos por institución, sin embargo no se tiene acceso a ese inventario pues se maneja como

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes


Unit website: —

Contact name: Ms. Ana Eduviges Sancho Jiménez  Contact email: esancho@ministeriodesalud.go.cr

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: http://www.ccss.sa.cr


Medical devices workforce

Density of medical doctors (per 10 000 population): 28.94

Number of biomedical/clinical engineers professionals in the country: 85

Contacts

MOH focal point

Name: —

Department: —

Email: —

Other country focal point

Name: Ms. Ana Eduviges Sancho Jiménez  Email: esancho@ministeriodesalud.go.cr

WHO health products focal point:

Name: Lic. Hernán Luque

Email: luqueher@corps-oms.org

WHO Representative/WHO Liaison Officer:

Name: Dr. María Dolores Perez-Rosas

Email: perezmd@paho.org

General comments (...Annex 1):

Es difícil que las instituciones den cierta información que consideran es confidencial, por el ejemplo: el acceso a sus inventarios de equipo. En el caso de la Caja Costarricense de Seguro Social, que es el mayor prestador de servicios de salud del país, se pudo obtener dicha información con las autoridades correspondientes, pero resulta complicado.
## Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>26,378 (53)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>67.2</td>
</tr>
</tbody>
</table>

### National policy on health technology
- **Health technology (medical device) national policy:** Yes
- **Policy is part of the National Health Program/Plan:** Yes
- **Website:** —
- **Language(s):** Français
- **MOH responsible for health technology policy implementation:** Direction des Infrastructures, de l’Equipement et de la Maintenance.

### National lists of medical devices
- **National list of approved priority/essential medical devices (including IVDs), for procurement or reimbursement:**
  - Lists available: Yes, but it is only a recommendation
  - Unit: Direction des Infrastructures, de l’Equipement et de la Maintenance (DIEM).
  - Website: —
  - Nomenclature systems used for devices and tests: —
- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - Lists available: Yes
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —
- **National list for specific clinical interventions/emergencies:**
  - Lists available: —
  - Website: —

### National health technology assessment unit
- **Designated unit/department for health technology assessment (HTA):** Yes
- **National unit/department that includes HTA for medical devices:** No
- **Website(s):** —
- **Contact:** — Email: rachdunc2002@yahoo.fr
- **Committee includes a biomedical or clinical engineer:** —

### National regulatory authority
- **Presence of national authority responsible for regulating medical devices:** Yes
- **Name of regulatory agency:** Direction des Infrastructures, de l’Equipement, du Matériel et de la Maintenance.
- **Website(s):** —
- **Contact:** Dr. Duncan Rachel  Email: rachdunc2002@yahoo.fr
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** —
- **Other agency’s website:** —

### Global innovation index (rank)
- **21.2 (112)**

### ICT Development Index (rank)
- **3.1 (131)**

### Under-five mortality (per 1000 live births)
- **81**

### UHC - Service coverage index (1-100)
- **47**

### Probability of dying aged 30-70 yrs of NCDs (%)
- **29.10%**

### UHC - Population with household spending >10% (>25%) of corresponding income (%)
- **12.4% (3.4%)**

### Human Development Index (rank)
- **0.54 (0.35): low**

### Global innovation index (rank)
- **21.2 (112)**

### High-technology exports (% of manufacture exports)
- **11.20%**

### Approved devices lists comments
- Les listes d’acquisition proviennent du Plan National de développement Sanitaire PNDS.

### Health care facilities lists comments
- Document de travail de la Direction des Infrastructures, de l’Equipement et de la Maintenance (DIEM): ListeTypeEquip CHR_HG_CSU_CSR.

### Specific lists comments
- Les procédures et directives sont dans le manuel de directives à l’attention du personnel des des établissements de soins. Il n’existe pas de liste spécifique à un domaine ou un programme de santé.

### HTA unit comments
- —

### National regulatory comments
- —
Medical device nomenclature system
Official nomenclature system for medical devices: No Type: None Use: Not specified Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes Website: —
National level procurement: No Website: —

Donations
Policy or guideline: No Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: — Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>3</td>
<td>0.15</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>14</td>
<td>0.69</td>
<td>Health centres:</td>
<td>2404</td>
<td>11.83</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>235</td>
<td>1.16</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>20</td>
<td>0.1</td>
</tr>
<tr>
<td>Mammograph</td>
<td>0</td>
<td>0</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>2</td>
<td>0.08</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Direction des infrastructures de l'équipement et de la maintenance. Unit website: —
Contact name: Mr. Tra Bi Irié Contact email: trabidenis@yahoo.fr
Website with publically available technical specifications: —
Number of regional/state offices/units: 6

Inventories and medical equipment management software
Type of inventories available: None
Website: —
Use of management software: No Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 1.62
Number of biomedical/clinical engineers professionals in the country: 50

Contacts
MOH focal point
Name: Dr. Tra Bi Yrié
Department: Direction des infrastructures, de l'Equipement et de la Maintenance (DIEM)
Email: denis.trabi@yahoo.fr
Other country focal point
Name: — Email: —

WHO health products focal point:
Name: Dr. Théodore Yao Kouadio
Email: yaot@ci.afro.who.int

WHO Representative/WHO Liaison Officer:
Name: Dr. Jean-Marie Vianny Yameogo
Email: yameogoj@who.int

Medecine and Health Care in Côte d’Ivoire

WHO African Region

Croatia

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>4,105 (127)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.3</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 4.8

Probability of dying aged 30-70 yrs of NCDs (%): 16.7%

Human Development Index (inequality adjusted HDI): 0.85 (0.78); very high

ICT Development Index (rank): 7.2 (36)

UHC - Service coverage index (1-100): 71

UHC - Population with >10% (<25%) of corresponding income (%): 2.8% (0.3%)

Global innovation index (rank): 37.3 (41)

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Language(s): Croatian
MOH responsible for health technology policy implementation: Agency for Quality and Accreditation in Health.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - IVD: [https://www.halmed.hr/en/Medicinski-proizvodi/Baza-medicinskih-proizvoda/Pretraga-po-proizvodima/#rezultati](https://www.halmed.hr/en/Medicinski-proizvodi/Baza-medicinskih-proizvoda/Pretraga-po-proizvodima/#rezultati)
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No, Agency for Quality and Accreditation in Health.
Website(s): [http://aaz.hr/sites/default/files/hrvatske_smjernice_za_procjenu_zdravstvenih_technologija.pdf](http://aaz.hr/sites/default/files/hrvatske_smjernice_za_procjenu_zdravstvenih_technologija.pdf); [http://www.miz.hr/](http://www.miz.hr/); [http://www.hzzo.hr](http://www.hzzo.hr); [http://www.hzjz.hr/english/](http://www.hzjz.hr/english/);
Contact: Mr. Renato Mittermayer Email: renato.mittermayer@aaz.hr
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Agency for Medical Products and Medical Devices, Subunit for Medical Devices.
Website(s): —
Contact: Mr. Krunoslav Kranjcec Email: krunoslav.kranjcec@almp.hr
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: [http://narodne-novine.nn.hr/](http://narodne-novine.nn.hr/)

Approved devices lists comments (…Annex 1):
—

Health care facilities lists comments (…Annex 1):
—

Specific lists comments (…Annex 1):
In 2007 the Ministry of Health and Social Welfare issued Ordinance on the organization and work procedures of the Ministry of Health and Social Welfare’s Crisis Headquarters (http://narodne-novine.nn.hr/clanci/sluzbeni/2007_05_46_1563.html) which determines organization scheme and work procedure of the Ministry of Health and Social Welfare’s Crisis Headquarters as well as actions of other health care institutions and private health workers in case of major crisis. Major crisis is described as any event which constitutes a serious threat to health of a certain community and results (or

HTA unit comments (…Annex 1):
HTA is focused on pharmaceutics, not specifically in medical devices. HTA has three partners: the MoH, Health Insurance Fund (HIF) and Croatian Institute of Public Health (CIPH). However systematic use of HTA to support healthcare decision-making is in still in process, but expected over the next years.

National regulatory comments (…Annex 1):
—

Population 000s (rank): 4,105 (127)
World Bank income group: High
Life expectancy at birth (years): 72.3

Under-five mortality (per 1000 live births): 4.8

Probability of dying aged 30-70 yrs of NCDs (%): 16.7%

Human Development Index (inequality adjusted HDI): 0.85 (0.78); very high

ICT Development Index (rank): 7.2 (36)

UHC - Service coverage index (1-100): 71

UHC - Population with >10% (<25%) of corresponding income (%): 2.8% (0.3%)

Global innovation index (rank): 37.3 (41)

Language(s): Croatian
MOH responsible for health technology policy implementation: Agency for Quality and Accreditation in Health.
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: https://www.halmed.hr/ Medicinski-proizvodi/Upute-za-podnositelje-zahtjeva-41/Proizvodnja-medicinskih-proizvoda/

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: http://www.zdravlje.hr/
National level procurement: Yes  Website: http://www.zdravlje.hr/
Donations
Policy or guideline: Yes  Website: http://narodne-novine.nn.hr/clanci/sluzbeni/2009_12_151_3696.html
Technical specifications
Technical specifications to support procurement or donations: No  Publicly available: —  Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:α</td>
<td>31</td>
<td>7.23</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:α</td>
<td>64</td>
<td>14.92</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:α</td>
<td>2</td>
<td>0.47</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:α</td>
<td>26</td>
<td>6.06</td>
</tr>
<tr>
<td>Mammograph:α</td>
<td>124</td>
<td>206.54</td>
</tr>
<tr>
<td>Radiotherapy:α</td>
<td>24</td>
<td>5.85</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>36</td>
<td>0.84</td>
</tr>
<tr>
<td>Health centres:</td>
<td>13</td>
<td>0.3</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>22</td>
<td>0.51</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>15</td>
<td>0.35</td>
</tr>
</tbody>
</table>

Technical specifications
Technical specifications to support procurement or donations: No  Publicly available: —  Website: —

Medical equipment management unit
Unit present: —  Professionally trained biomedical/clinical engineers: No
Unit/Department: Directorate for Financial Affairs.  Unit website: https://zdravstvo.gov.hr/
Contact name: Ms. Antoaneta Bilic  Contact email: antoaneta.bilic@mzss.hr
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: None
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population): 29
Number of biomedical/clinical engineers professionals in the country: 250

Contacts
MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: Ms. Antoaneta Bilic
Email: antoaneta.bilic@mzss.hr

WHO health products focal point
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Iva Pejnovic Franelic
Email: pejnovici@who.int

General comments (...Annex 1):
—

Software comments (...Annex 1):
The Ministry of Health and Social Welfare has a national informal and internal inventory for medical devices in all public health institutions. This inventory is used mainly for analytical purposes and planning strategies within the Ministry. In 2008 Croatian National Institute of Public Health, as part of a pilot project under EUROSTAT guidelines, made an inventory of 10 most expensive medical devices (MRI, Computed Tomography, Linear Accelerator, etc.).
Global atlas of medical devices 2022

Cuba

Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>11,327 (82)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
</tbody>
</table>

Life expectancy at birth (years):

- Cuba: 78.7
- World: 72.3

Under-five mortality (per 1000 live births): 5.1

UHC - Service coverage index (1-100): 83

Probability of dying aged 30-70 yrs of NCDs (%): 16.40%

UHC - Population with household spending >10% (>25%) of corresponding income (%): —

Human Development Index (inequality adjusted HDI): rank: 0.78 (—): high

Global innovation index (rank): —

ICT Development Index (rank): 2.9 (137)

High-technology exports (% of manufacture exports): —

National policy on health technology

- Health technology (medical device) national policy: Yes
- Policy is part of the National Health Program/Plan: Yes
- Language(s): Español
- MOH responsible for health technology policy implementation: Ministry of Health of Cuban Republic

National lists of medical devices

- National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
  - Lists available: Yes
  - Unit: Medical Devices Department of CECMED (Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos)
  - Website: —
  - Nomenclature systems used for devices and tests: —

- National list for different types of healthcare facilities (hospitals, laboratories, etc):
  - Lists available: Yes
  - Nomenclature systems used for devices and tests: —

- National list for specific clinical interventions/emergencies:
  - Lists available: Yes
  - Website: —

National health technology assessment unit

- Designated unit/department for health technology assessment (HTA): Yes
- National unit/department that includes HTA for medical devices: Yes, CECMED/ Medical Devices Department/ Section of Conformity Assessment Medical Devices
- Website(s): [https://www.cecmed.cu/content/indicaciones-para-el-registro](https://www.cecmed.cu/content/indicaciones-para-el-registro)
- Contact: Dr. Mario César Muñiz Ferrer Email: mario@cecmed.cu
- Committee includes a biomedical or clinical engineer: Yes

National regulatory authority

- Presence of national authority responsible for regulating medical devices: Yes
- Name of regulatory agency: Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos (CECMED)
- Website(s): [https://www.cecmed.cu](https://www.cecmed.cu)
- Contact: MSc. Olga Lidia Jacobo Casanueva Email: olga@cecmed.cu
- Name(s) of other regulatory agency eg. for radiation equipment etc.: Agencia de Energía Nuclear y Tecnologías de avanzada (AENTA); Oficina Nacional de Regulación y Seguridad Ambiental (ORASEN), Centro de Protección e Higiene de las Radiaciones (CPHR)

Approved devices lists comments

(...Annex 1):

- Health care facilities lists comments
  (...Annex 1):
  - Existe un listado de modelo de equipamiento médico destinado para cada nivel de atención. No está refrendado en ninguna web (no disponible).

- Specific lists comments
  (...Annex 1):
  - Cada especialidad médica tiene establecidas normas y programas a través de las recomendaciones de los grupos nacionales y apoyo del Consejo de Sociedades Científicas. En cuanto a las listas para diferentes enfermedades y/o situaciones no están refrendadas en ninguna web (no disponible).

- HTA unit comments
  (...Annex 1):
  - It also exists the Department of Innovation and Evaluation of Health Technologies attached to the National Directorate of Science and Technology of the Ministry of Public Health (MINSAP). Evaluations are made mainly for pharmaceutics not for medical devices.

National regulatory comments

(...Annex 1):

- En el caso de los medios de diagnóstico in vitro, estos son regulados y atendidos en el Centro de Control Estatal de Medicamentos, Equipos y Dispositivos Médicos (CEMED). Evaluations are made mainly for pharmaceutics not for medical devices.
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Many co-existence of nomenclatures  Use: For procurement purposes
Website: https://www.cecmed.cu/; http://www.electromedicina.sld.cu

Medical device incorporation

Procurement
National level procurement: Yes  Website: http://www.sld.cu/

Donations

Technical specifications
Technical specifications to support procurement or donations: Yes  Publically available: No  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging&lt;sup&gt;a&lt;/sup&gt;</td>
<td>25</td>
<td>2.21</td>
</tr>
<tr>
<td>Computerized Tomography Scanner&lt;sup&gt;b&lt;/sup&gt;</td>
<td>60</td>
<td>5.3</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner&lt;sup&gt;c&lt;/sup&gt;</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine&lt;sup&gt;d&lt;/sup&gt;</td>
<td>16</td>
<td>1.41</td>
</tr>
<tr>
<td>Mammograph&lt;sup&gt;e&lt;/sup&gt;</td>
<td>30</td>
<td>18.49</td>
</tr>
<tr>
<td>Radiotherapy&lt;sup&gt;f&lt;/sup&gt;</td>
<td>33</td>
<td>2.91</td>
</tr>
</tbody>
</table>

Healthcare facility<sup>x</sup>

<table>
<thead>
<tr>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts</td>
<td>11128</td>
<td>98.24</td>
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<tr>
<td>Health centres</td>
<td>724</td>
<td>6.39</td>
</tr>
<tr>
<td>General/district hospitals</td>
<td>54</td>
<td>0.48</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals</td>
<td>96</td>
<td>0.85</td>
</tr>
</tbody>
</table>

Software comments (...Annex 1):
SUCNEM is based on UMDNS. It is also in use the GMDN.

Medical device incorporation comments (...Annex 1):
Basado en la política de salud, los equipos médicos deben contar con el Registro Sanitario para su utilización en el Sistema Nacional de Salud (see: www.bvscuba.sld.cu) y en la Gaceta Oficial de la República de Cuba (www.gacetaofical.cu). Para el proceso de importación se realiza una evaluación entre las autoridades competentes donde se efectúa previamente un análisis entre asistencia médica y electromedicina. Las fichas técnicas para facilitar el proceso de adquisición no están publicadas.

Medical devices workforce

Density of medical doctors (per 10,000 population): 92.7
Number of biomedical/clinical engineers professionals in the country: 550

Contacts

MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: —
Email: —

WHO health products focal point
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. José Gerardo Moya
Email: moyajose@paho.org

General comments (...Annex 1):
En términos de aclaración general indicamos que en Cuba, como es conocido, el Sistema de Salud tiene características de ser único, centralizado, público, gratuito y universal, refrendado en la Constitución de la República. La demanda de equipos médicos se realiza sobre la base de requerimientos acorde al desarrollo científico-técnico mundial y de los índices de consumo para los insumos y obedece a las políticas sanitarias establecidas. Con relación al 3.3.1 las Directrices se basan en la Resolución del Ministerio del Comercio Exterior No. 15 del 2006, no obstante...
### Cyprus

#### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):a</th>
<th>1,207 (154)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:b</td>
<td>High</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Life expectancy at birth (years):c</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
</tr>
<tr>
<td>1990</td>
</tr>
<tr>
<td>2000</td>
</tr>
<tr>
<td>2010</td>
</tr>
<tr>
<td>2020</td>
</tr>
<tr>
<td>CYP</td>
</tr>
<tr>
<td>World</td>
</tr>
</tbody>
</table>

#### National policy on health technology

**Health technology (medical device) national policy:** No  
**Policy is part of the National Health Program/Plan:** No  
**Website:** —  
**Language(s):** —  
**MOH responsible for health technology policy implementation:** —

#### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**  
Lists available: No  
Unit: —  
Website: —  
Nomenclature systems used for devices and tests: —

**National list for different types of healthcare facilities (hospitals, laboratories, etc)**

Lists available: No  
Website - hospitals: —  
Website - IVD: —  
Nomenclature systems used for devices and tests: —

**National list for specific clinical interventions/emergencies:**  
Lists available: No  
Website: —

#### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** Yes  
**National unit/department that includes HTA for medical devices:** No  
**Contact:** Email: —  
**Committee includes a biomedical or clinical engineer:** —

#### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes  
**Name of regulatory agency:** Cyprus Medical Devices Competent Authority.  
**Website(s):** —  
**Contact:** Ms. Androulla Stylianou  
**Email:** —  
**Name(s) of other regulatory agency eg. for radiation equipment etc.:** —  
**Other agency’s website:** —

#### Approved devices lists comments

(...Annex 1):

—

#### Health care facilities lists comments

(...Annex 1):

—

#### Specific lists comments (...Annex 1):

—

#### HTA unit comments (...Annex 1):

Pharmaceutical Services within the Ministry of Health performs HTA evaluation of pharmaceutics.

#### National regulatory comments

(...Annex 1):

—

#### Under-five mortality (per 1000 live births):d

2.3

#### UHC - Service coverage index (1-100):e

78

#### Probability of dying aged 30-70 yrs of NCDs (%):f

11.30%

#### UHC - Population with household spending >10% (>25%) of corresponding income (%):g

16.1% (1.5%)

#### Human Development Index (inequality adjusted HDI): h

0.89 (0.81); very high

#### Global innovation index (rank):i

45.7 (29)

#### ICT Development Index (rank):j

7.8 (28)

#### High-technology exports (% of manufacture exports):k

19.90%
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Many co-existence of nomenclatures  Use: Not specified

Medical device incorporation

Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>16</td>
<td>14.02</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>29</td>
<td>25.41</td>
<td>Health centres:</td>
<td>38</td>
<td>3.33</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>10</td>
<td>8.76</td>
<td>Specialized/regional/national hospitals:</td>
<td>7</td>
<td>0.61</td>
</tr>
<tr>
<td>Mammograph</td>
<td>40</td>
<td>329.64</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>—</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>10</td>
<td>8.29</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): 19.51
Number of biomedical/clinical engineers professionals in the country: 15

Contacts

MOH focal point
Name: Ms. Andoulla Stylianou
Department: Medical Devices Competent Authority, Medical and Public Health Services
Email: cymda@mpms.moh.gov.cy

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: —
Email: —

General comments (Annex 1): —
Czech Republic

Country indicators

| Population 000s (rank):[^a] | 10,709 (85) | Under-five mortality (per 1000 live births):[^c] | 3.2 | UHC - Service coverage index (1-100):[^b] | 76 |
| Life expectancy at birth (years):[^c] | 71.5 | Probability of dying aged 30-70 yrs of NCDs (%):[^c] | 15.00% | UHC - Population with household spending >10% (>25%) of corresponding income (%):[^c] | 2.2% (0.1%) |
| World Bank income group:[^h] | High | Human Development Index (inequality adjusted HDI): | 0.9 (0.86): very high | Global innovation index (rank):[^j] | 48.3 (24) |
| | | ICT Development Index (rank):[^l] | 7.2 (43) | High-technology exports (% of manufacture exports):[^k] | 20.80% |

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes
Unit: VZP CR (General Health Insurance Company).
Website: [http://www.vzp.cz/](http://www.vzp.cz/)
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: [https://www.mzcr.cz/](https://www.mzcr.cz/)
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: [https://www.mzcr.cz/doporucujici-a-interpretacni-dokumenty-meddev/](https://www.mzcr.cz/doporucujici-a-interpretacni-dokumenty-meddev/)

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[^d] Yes
National unit/department that includes HTA for medical devices: No
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments ([...Annex 1]):
There are HTA activities in pharmaceutics, not specifically for medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Ministry of Health.
Contact: Ms. Karolina Pestova Email: karolina.pestova@mzcr.cz
Name(s) of other regulatory agency eg. for radiation equipment etc.: State Institute for Drug Control.
Other agency’s website: [https://www.sujb.cz/en/](https://www.sujb.cz/en/)
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Based on UMDNS
Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: No  Website: —
National level procurement: No  Website: —
Donations
Policy or guideline: No  Website: —
Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging*</td>
<td>110</td>
<td>10.27</td>
<td>Health posts:</td>
<td>24063</td>
<td>224.84</td>
</tr>
<tr>
<td>Computerized Tomography Scanner*</td>
<td>171</td>
<td>15.97</td>
<td>Health centres:</td>
<td>17</td>
<td>0.16</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner*</td>
<td>17</td>
<td>1.59</td>
<td>General/district hospitals:</td>
<td>43</td>
<td>0.4</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine*</td>
<td>127</td>
<td>11.86</td>
<td>Specialized/regional/national hospitals:</td>
<td>27</td>
<td>0.25</td>
</tr>
<tr>
<td>Mammograph*</td>
<td>119</td>
<td>8.729</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Radiotherapy*</td>
<td>114</td>
<td>10.65</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical device incorporation comments (...Annex 1):

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): * 4116
Number of biomedical/clinical engineers professionals in the country: <10

Contacts
MOH focal point
Name: Ms. Karolina Pestova
Department: Department of Pharmacy, Ministry of Health
Email: karolina.pestova@mzcr.cz
Other country focal point
Name: Mr. Jan Zofka
Email: zofka@uzis.cz

WHO health products focal point:
Name: —
Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Srdan Matic
Email: matics@who.int

General comments (...Annex 1): —
Democratic People’s Republic of Korea

### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>25,779 (54)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.0</td>
</tr>
</tbody>
</table>

### National policy on health technology

- Health technology (medical device) national policy: Yes
- Policy is part of the National Health Program/Plan: Yes
- Website: —
- Language(s): —
- MOH responsible for health technology policy implementation: —

### National lists of medical devices

#### National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
- Lists available: Yes
- Unit: —
- Website: —
- Nomenclature systems used for devices and tests: —

#### National list for different types of healthcare facilities (hospitals, laboratories, etc)
- Lists available: Yes
- Website - hospitals: —
- Website - IVD: —
- Nomenclature systems used for devices and tests: —

#### National list for specific clinical interventions/emergencies:
- Lists available: —
- Website: —

### National health technology assessment unit

- Designated unit/department for health technology assessment (HTA): Yes
- National unit/department that includes HTA for medical devices: Yes, National Evidence-based healthcare Collaborating Agency (NECA).
- Website(s): https://portal.htai.org/index.php?q=node/379
- Contact: — Email: —
- Committee includes a biomedical or clinical engineer: —

### National regulatory authority

- Presence of national authority responsible for regulating medical devices: Yes
- Name of regulatory agency: Department of Medical Device Management and Production
- Website(s): —
- Contact: — Email: —
- Name(s) of other regulatory agency eg. for radiation equipment etc.: —
- Other agency’s website: —

### National policy on health technology indicators

- Probability of dying aged 30-70 yrs of NCDs (%): 25.60%
- UHC - Service coverage index (1-100): 71
- UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)
- Human Development Index (inequality adjusted HDI): rank: — (—)
- Global innovation index (rank): — (—)
- ICT Development Index (rank): — (—)
- High-technology exports (% of manufacture exports): —

### National regulatory comments

- Approved devices lists comments (...Annex 1): —
- Health care facilities lists comments (...Annex 1): —
- Specific lists comments (...Annex 1): —
- HTA unit comments (...Annex 1): —
- National regulatory comments (...Annex 1): —
Medical device nomenclature system
Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes Website: —
National level procurement: Yes Website: —
Donations
Policy or guideline: Yes Website: —
Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Healthcare facility
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts: 6263</td>
<td>25.16</td>
</tr>
<tr>
<td>Health centres: 974</td>
<td>3.91</td>
</tr>
<tr>
<td>General/district hospitals: 1575</td>
<td>6.33</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals: n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Estimation % of health facilities with none or very limited oxygen supply: n/a</td>
<td></td>
</tr>
</tbody>
</table>

Medical equipment management unit
Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Department of Medical Equipment Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Use of management software: — Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 36.83
Number of biomedical/clinical engineers professionals in the country: —

Contacts
**MOH focal point**
Name: —
Department: —
Email: —

**Other country focal point**
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Edwin Ceniza Salvador
Email: salvadore@who.int

General comments (Annex 1): —
Democratic Republic of the Congo

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>89,561 (16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>61.7</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 84.8

Probability of dying aged 30-70 yrs of NCDs (%): 19.40%

Human Development Index (inequality adjusted HDI): 0.48 (low)

ICT Development Index (rank): 1.6 (171)

UHC - Service coverage index (1-100): 41

UHC - Population with household spending >10% (>25%) of corresponding income (%): 4.8% (0.6%)

Global innovation index (rank): — (—)

High-technology exports (% of manufacture exports): —

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (Annex 1):

Approved devices lists comments (Annex 1):
Il existe des listes de matériel dressé au niveau périphérique approuvé (district sanitaire). Pour le niveau intermédiaire et niveau tertiaire cette liste est en élaboration.

Health care facilities lists comments (Annex 1):
—

Specific lists comments (Annex 1):
—

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: La Direction des laboratoires de Santé / Ministère de la Santé.
Website(s): https://www.minisanterdc.cd/
Contact: Mr. Daniel Ngeleka Mutolo Email: dangelmutolo@yahoo.fr
Name(s) of other regulatory agency eg. for radiation equipment etc.: Direction des laboratoires de Sante; Direction des Equipements et Materiels medicaux, and Comite National de Protection Contre les Rayonnements Ionisants (CNPRI).

National regulatory comments (Annex 1):
La Direction des laboratoires de Sante veuille surtout au respect des normes de autres équipements des laboratoires et des services d’imagerie médicales. Tandis que la Direction des Equipements et Materiels Medicaux s’occupe des autres matériels médicaux et non médicaux . Un autre organisme non du ressort de la santé, c’est le Comite National de Protection Contre les Rayonnements Ionisants (CNPRI) qui s’occupe essentiellement des équipements émettant des rayonnements non seulement médicaux mais tout. Il faut dire qu’il y a manque notoire des textes qui doivent réglementer tout ceci . C’est avec les quelques notions appris par ici et par là qu’on essaye de faire tant qu’on peut . Sinon, le secteur est très peu réglementé ou carrément non réglementé.
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: No  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>0</td>
<td>0</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>5</td>
<td>0.07</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>290</td>
<td>0.43</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>1</td>
<td>0.01</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>2</td>
<td>0.74</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>1</td>
<td>0.01</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Direction des Equipements et Matériels Médicaux.  Unit website: —
Contact name: Mr. Ngilo Eagbali  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 1

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population):* 0.9
Number of biomedical/clinical engineers professionals in the country:* 100

Contacts

MOH focal point
Name: Mr. Malaba Munyyanjie Cleophas If
Department: Direction des Laboratoires de Santé
Email: malabac@yahoo.fr
Other country focal point
Name: Mr. Ngilo Eagbali
Email: Ngilozagbali@yahoo.fr

WHO health products focal point:
Name: Dr. Anastasie Mulumba M.
Email: mulumbaa@who.int
WHO Representative/WHO Liaison Officer:
Name: Dr. Yokouidé Allarangar
Email: afwoccd@who.int

General comments (...Annex 1): En tant pays post-conflit, dans le processus de l'organisation de son système national de santé, le gouvernement dispose déjà d'une stratégie de renforcement du système de santé qui est une stratégie sectorielle. Ensuite, le pays vient de se doter d'un plan stratégique de développement sanitaire pour 5 ans avec un cadre des dépenses à moyen terme ou toutes ces technologies sont planifiées.

Software comments (...Annex 1):
On est dans le processus de créer de pool de maintenance avec des ingénieurs sanitaires et de rehabiliter les ateliers qui existent. Il y a un programme de formation des ingénieurs et des utilisateurs.

Medical device incorporation comments (...Annex 1):
En R.D.Congo, les achats se font à tous les niveaux. L'Etat n'a pas pu reglementer ce secteur les achats se font à tous les niveaux et surtout les bailleurs de fonds pour leurs programmes spécifiques qu'ils appuient. Le directives à ce niveau sont fonction d'un appel offre, c'est en ce moment que celui qui lance l'offre dresse un certains critères des dispositifs qu'il veut acquier.
Denmark

**Country indicators**

- **Population 000s (rank):** 5,792 (113)
- **World Bank income group:** High
- **Life expectancy at birth (years):**

<table>
<thead>
<tr>
<th>Year</th>
<th>Denmark</th>
<th>World</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>74.7</td>
<td>70.4</td>
</tr>
<tr>
<td>2010</td>
<td>76.7</td>
<td>72.7</td>
</tr>
</tbody>
</table>

**Under-five mortality (per 1000 live births):** 3.8
**UHC - Service coverage index (1-100):** 81

| Probability of dying aged 30-70 yrs of NCDs (%) | 11.30% |
| UHC - Population with household spending >10% (>25%) of corresponding income (%) | 2.9% (0.5%) |
| Human Development Index (inequality adjusted HDI): rank | 0.94 (0.88); very high |
| Global innovation index (rank) | 57.5 (6) |
| ICT Development Index (rank) | 8.7 (4) |
| High-technology exports (% of manufacture exports) | 12.00% |

**National policy on health technology**

- **Health technology (medical device) national policy:** Yes
- **Policy is part of the National Health Program/Plan:** No
- **Website:** —
- **Language(s):** Danish
- **MOH responsible for health technology policy implementation:** Lægemiddelstyrelsen (Danish Medicines Agency).

**National lists of medical devices**

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: No
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —

- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - Lists available: No
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

- **National list for specific clinical interventions/emergencies:**
  - Lists available: No
  - Website: —

**National health technology assessment unit**

- **Designated unit/department for health technology assessment (HTA):** Yes
- **National unit/department that includes HTA for medical devices:** Yes, HTA unit within the Danish Health Authority.
- **Website(s):** https://www.sst.dk/en; https://laegemiddelstyrelsen.dk/en/
- **Contact:** Email: eje@dkma.dk
- **Committee includes a biomedical or clinical engineer:** Yes

**National regulatory authority**

- **Presence of national authority responsible for regulating medical devices:** Yes
- **Name of regulatory agency:** Lægemiddelstyrelsen / Danish Medicines Agency.
- **Website(s):** https://laegemiddelstyrelsen.dk/
- **Contact:** Ms. Ellen Jespersen Email: eje@dkma.dk
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** The Danish Health and Medicines Authority.
- **Other agency’s website:** https://www.sst.dk/da/Opgaver/Straalebeskyttelse

- **Approved devices lists comments** (...Annex 1):
  - —

- **Health care facilities lists comments** (...Annex 1):
  - —

- **Specific lists comments** (...Annex 1):
  - In the case of lists for different diseases and situations, there are some more general plans, but no specific medical devices recommended.

- **HTA unit comments** (...Annex 1):
  - —

- **National regulatory comments** (...Annex 1):
  - —
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Based on GMDN  Use: Not specified
Website: https://laegemiddelstyrelsen.dk/

Medical device incorporation
Policy or guideline: No  Website: —
National level procurement: No  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No  Publically available: —  Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>77</td>
<td>13.7</td>
<td>Health posts</td>
<td>3881</td>
<td>69.07</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>236</td>
<td>40.75</td>
<td>Health centres</td>
<td>251</td>
<td>4.47</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>48</td>
<td>8.29</td>
<td>General/district hospitals</td>
<td>29</td>
<td>0.52</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>85</td>
<td>14.68</td>
<td>Specialized/regional/national hospitals</td>
<td>5</td>
<td>0.09</td>
</tr>
<tr>
<td>Mammograph</td>
<td>88</td>
<td>119.43</td>
<td>Estimation % of health facilities with none or very limited oxygen supply</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>71</td>
<td>12.26</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —  Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: www.sis.dk
Use of management software: Yes  Software name: Several systems: MEDUSA, MERIDA, QAMAP, REMEDY and more.

Medical devices workforce
Density of medical doctors (per 10,000 population): 42.25
Number of biomedical/clinical engineers professionals in the country: 450

Contacts
<table>
<thead>
<tr>
<th>MOH focal point</th>
<th></th>
<th>WHO health products focal point:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: Ms. Nina Moss</td>
<td>Department: Ministry of Interior and Health</td>
<td>Name: —</td>
</tr>
<tr>
<td>Email: <a href="mailto:nmo@sum.dk">nmo@sum.dk</a></td>
<td>Email: —</td>
<td>Email: <a href="mailto:eurordletters@who.int">eurordletters@who.int</a></td>
</tr>
</tbody>
</table>

Other country focal point
Name: Mr. Mads Frellsen
Email: maf@sst.dk

WHO Representative/WHO Liason Officer:
Name: Dr. Hans Kluge
Email: eurordletters@who.int

General comments (...Annex 1): The National Board of Health is issuing some Health Technology Assessments, including but not limited to medical devices. Only a minority of technologies are handled, so this is regarded as being outside the scope of the Policy section.
### Djibouti

#### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):(^n)</th>
<th>988 (156)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:(^m)</td>
<td>Lower-Middle</td>
</tr>
</tbody>
</table>

| Life expectancy at birth (years):\(^c\) | 63.7 (Only) |

| Under-five mortality (per 1000 live births):\(^d\) | 57.5 |
| UHC - Service coverage index (1-100):\(^b\) | 47 |
| Probability of dying aged 30-70 yrs of NCDs (%):\(^a\) | 19.60% |
| UHC - Population with household spending >10% (>25%) of corresponding income (%):\(^*\) | — (—) |
| Human Development Index (inequality adjusted HDI): rank\(^b\) | 0.52 (—): low |
| Global innovation index (rank):\(^i\) | — (—) |
| ICT Development Index (rank):\(^d\) | 2 (158) |
| High-technology exports (% of manufacture exports):\(^a\) | — |

#### National policy on health technology

**Health technology (medical device) national policy:** —

Policy is part of the National Health Program/Plan: —

Website: —

Language(s): —

MOH responsible for health technology policy implementation: —

#### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**

Lists available: —

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

**National list for different types of healthcare facilities (hospitals, laboratories, etc)**

Lists available: —

Website - hospitals: —

Website - IVD: —

Nomenclature systems used for devices and tests: —

**National list for specific clinical interventions/emergencies:**

Lists available: —

Website: —

#### National health technology assessment unit

Designated unit/department for health technology assessment (HTA):\(^4\) No

National unit/department that includes HTA for medical devices: No

Website(s): https://sante.gouv.dj/

Contact: —  Email: —

Committee includes a biomedical or clinical engineer: —

**HTA unit comments (…Annex 1):**

The development of the HTA unit is in progress, as well as the human resources to fill the workforce gap within the MoH.

#### National regulatory authority

Presence of national authority responsible for regulating medical devices: —

**Name of regulatory agency:** —

Website(s): —

Contact: —  Email: —

**Name(s) of other regulatory agency eg. for radiation equipment etc.:** —

Other agency’s website: —

**National regulatory comments (…Annex 1):**

—
Medical device nomenclature system

Official nomenclature system for medical devices: _ Type:_ _ Use:_ 
Website: —

Medical device incorporation

Procurement
Policy or guideline: — Website: —
National level procurement: — Website: —

Donations
Policy or guideline: — Website: —

Technical specifications
Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging: α</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner: β</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner: γ</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine: δ</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph: ε</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy: φ</td>
<td>n/a</td>
<td>n/a</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: — Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population):² 2.24
Number of biomedical/clinical engineers professionals in the country: γ <10

Contacts

MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: —
Email: —

WHO health products focal point
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Reinhilde Therese Van De Weerdt
Email: vanr@who.int

General comments (...Annex 1): —
Dominica

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>72 (185)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.3</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): no, Biomedical Department, PMH.
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
HTA activities have been identified, but there is not a specific national unit.

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

Approved devices lists comments (...Annex 1):

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):

HTA unit comments (...Annex 1):
National regulatory comments (...Annex 1):
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified  Website: —

Medical device incorporation

Procurement

Policy or guideline: No  Website: —

National level procurement: No  Website: —

Donations

Policy or guideline: No  Website: —

Technical specifications

Technical specifications to support procurement or donations: No  Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>0</td>
<td>0</td>
<td>Health posts:</td>
<td>61</td>
<td>84.72</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>1</td>
<td>13.89</td>
<td>Health centres:</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>2</td>
<td>2.78</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>2</td>
<td>206.69</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Central Medical Stores.  Unit website: —

Contact name: Mrs. Theresa Shillingford.  Contact email: cms@cwdom.dm

Website with publically available technical specifications: —

Number of regional/state offices/units: 3

Inventories and medical equipment management software

Type of inventories available: None  Website: —

Use of management software: Yes  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population):† 11.03

Number of biomedical/clinical engineers professionals in the country: —

Contacts

MOH focal point

Name: Dr. Ruby Josephine Blanc  Department: Princess Margaret Hospital  Email: blancruby@hotmail.com

WHO health products focal point:

Name: —  Email: —

WHO Representative/WHO Liaison Officer:

Name: Dr. Yitades Gebre  Email: gebrey@paho.org

Other country focal point

Name: Mrs. Theresa Shillingford  Email: cms@cwdom.dm

General comments (...Annex 1): A manual exists in draft form to govern issues related to medical devices. It is still supposed to have a final review to begin the process of it's adoption and implementation.
# Dominican Republic

## Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>10,848 (84)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>73.1</td>
</tr>
</tbody>
</table>

## National policy on health technology

- **Health technology (medical device) national policy:** No
- **Policy is part of the National Health Program/Plan:** No
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

## National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: No
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —

- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - Lists available: No
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

- **National list for specific clinical interventions/emergencies:**
  - Lists available: No
  - Website: —

## National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):** Yes
- **National unit/department that includes HTA for medical devices:** Yes, Superintendencia de Salud y Riesgos Laborales (SISALRIL) y Electromedicina MoH.
- **Website(s):** [https://www.sisalril.gob.do/](https://www.sisalril.gob.do/); [http://redetsa.org/wp/?page_id=322](http://redetsa.org/wp/?page_id=322)
- **Contact:** — Email: —
- **Committee includes a biomedical or clinical engineer:** —

## National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** Yes
- **Name of regulatory agency:** Viceministerio de Garantía de la Calidad.
- **Website(s):** [https://digemaps.msp.gob.do/menu/](https://digemaps.msp.gob.do/menu/); [https://www.msp.gob.do/web/](https://www.msp.gob.do/web/)
- **Contact:** Ms. Cristina Hernández Email: —
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** Ministerio de Salud Pública.
- **Other agency’s website:** [https://www.msp.gob.do/web/](https://www.msp.gob.do/web/)

## Approved devices lists comments

(...Annex 1): —

## Health care facilities lists comments

(...Annex 1): —

## Specific lists comments

(...Annex 1): —

## HTA unit comments

(...Annex 1): —

## National regulatory comments

(...Annex 1): La Ley General de Salud 42-01 y el Reglamento de Medicamentos Decreto 246-06 son el marco legal que fundamenta el accionar del Viceministerio de Garantía de la Calidad.

## Under-five mortality

- **(per 1000 live births):** 28

## UHC - Service coverage index (1-100): 74

## Probability of dying aged 30-70 yrs of NCDs (%): 19.00%

## UHC - Population with household spending >10% (>25%) of corresponding income (%): —

## Human Development Index (inequality adjusted HDI): 0.76 (0.6): high

## Global innovation index (rank): 25.1 (90)

## ICT Development Index (rank): 4.5 (106)

## High-technology exports (% of manufacture exports): 7.00%
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified  Website: —

Medical device incorporation

Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: https://msp.gob.do/web/

Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: No  Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>27</td>
<td>2.49</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Healthcare facility

<table>
<thead>
<tr>
<th>Facility Type</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes  Unit/Department: Electromedicina.  Unit website: —
Contact name: Mr. Juan del Rosario  Contact email: juan23955@hotmail.com  Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None  Website: —  Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): 14.52
Number of biomedical/clinical engineers professionals in the country: 100

Contacts

MOH focal point
Name: —  Department: —  Email: —

Other country focal point
Name: Mr. Juan del Rosario  Email: juan23955@hotmail.com

WHO health products focal point:
Name: Ms. Dalia Castillo de Lebron  Email: dcastill@dor.ops-oms.org

WHO Representative/WHO Liaison Officer:
Name: Dr. Olivier Ronveaux  Email: ronveauoli@paho.org

General comments (...Annex 1): —
Country indicators

Population 000s (rank): 17,643 (66)

World Bank income group: Upper-Middle

Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Year</th>
<th>1990</th>
<th>2000</th>
<th>2010</th>
<th>2020</th>
</tr>
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<tbody>
<tr>
<td>ECU</td>
<td>63.7</td>
<td>67.2</td>
<td>73.8</td>
<td>76.7</td>
</tr>
<tr>
<td>World</td>
<td>69.1</td>
<td>72.8</td>
<td>77.1</td>
<td>78.2</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births):

- Ecuador: 14
- World: 13.00%

UHC - Service coverage index (1-100):

- Ecuador: 77
- World: 10.3% (2.4%)

Probability of dying aged 30-70 yrs of NCDs (%):

- Ecuador: 13.00%

Human Development Index (inequality adjusted HDI): rank: 0.76 (0.62): high

Global innovation index (rank): 24.1 (99)

ICT Development Index (rank): 4.8 (97)

High-technology exports (% of manufacture exports): 5.50%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Language(s): Español

MOH responsible for health technology policy implementation: Dirección de Inteligencia en Salud.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

- Lists available: No
- Unit: —
- Website: [https://www.salud.gob.ec/ecuador-cuenta-con-lista-y-aplicativo-para-la-adquisicion-de-dispositivos-medicos-de-calidad-seguros-y-eficaces/](https://www.salud.gob.ec/ecuador-cuenta-con-lista-y-aplicativo-para-la-adquisicion-de-dispositivos-medicos-de-calidad-seguros-y-eficaces/)

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

- Lists available: Yes
- Website - hospitals: [https://www.salud.gob.ec/](https://www.salud.gob.ec/)
- Website - IVD: [https://www.salud.gob.ec/](https://www.salud.gob.ec/)
  [https://www.controlsanitario.gob.ec/base-de-datos/](https://www.controlsanitario.gob.ec/base-de-datos/)

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

- Lists available: Yes
- Website: [http://www.investigacionesalud.gob.ec/](http://www.investigacionesalud.gob.ec/)

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes

National unit/department that includes HTA for medical devices: Yes, Coordinación General de Desarrollo Estratégico en Salud (Dirección Nacional de Inteligencia de la Salud).

Website(s): [https://www.salud.gob.ec/direccion-de-inteligencia-de-la-salud/](https://www.salud.gob.ec/direccion-de-inteligencia-de-la-salud/)

Contact: Ms. Ruth Lucio  Email: ruth.lucio@msp.gob.ec
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Coordinación Nacional de Desarrollo Estratégico, Dirección de Inteligencia and Instituto Nacional de Higiene y Medicina Tropical.

Website(s): [https://www.salud.gob.ec/](https://www.salud.gob.ec/)
  [https://www.controlsanitario.gob.ec/](https://www.controlsanitario.gob.ec/)

Contact: Ms. Ruth Lucio  Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: Agencia Nacional de Regulación, Control y Vigilancia Sanitaria.
Other agency’s website: [https://www.controlsanitario.gob.ec/](https://www.controlsanitario.gob.ec/)

Population 000s (rank): 17,643 (66)

World Bank income group: Upper-Middle

Under-five mortality (per 1000 live births): 14

UHC - Service coverage index (1-100): 77

Probability of dying aged 30-70 yrs of NCDs (%): 13.00%

UHC - Population with household spending >10% (>25%) of corresponding income (%): 10.3% (2.4%)

Human Development Index (inequality adjusted HDI): rank: 0.76 (0.62): high

Global innovation index (rank): 24.1 (99)

ICT Development Index (rank): 4.8 (97)

High-technology exports (% of manufacture exports): 5.50%
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: https://www.salud.gob.ec/direccion-nacional-de-medicamentos-y-dispositivos-medicos/
Donations
Policy or guideline: Yes  Website: https://www.salud.gob.ec/direccion-nacional-de-medicamentos-y-dispositivos-medicos/

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Equipment Type</th>
<th>Total</th>
<th>Dens. per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Dens. per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>2</td>
<td>0.13</td>
<td>Health posts</td>
<td>458</td>
<td>2.91</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>25</td>
<td>1.59</td>
<td>Health centres</td>
<td>56</td>
<td>0.36</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>2</td>
<td>0.13</td>
<td>General/district hospitals</td>
<td>8</td>
<td>0.05</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>2</td>
<td>0.13</td>
<td>Specialized/regional/national hospitals</td>
<td>15</td>
<td>0.1</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>28</td>
<td>1.59</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Red de Hospitales  Unit website: https://www.salud.gob.ec/
Contact name: Dr. Luis Paredes  Contact email: luis.paredes@msp.gob.ec
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population): 22.2
Number of biomedical/clinical engineers professionals in the country: 126

Contacts
WHO health products focal point:
Name: Dr. Víctor Arauz
Email: arauzvic@paho.org
WHO Representative/WHO Liaison Officer:
Name: Dr. Oscar Martín Barreneche
Email: barreneosc@paho.org


WHO Region of the Americas
World Health Organization

Ecuador

WHO GHO 2010-2018
n/a not applicable/not available
Egypt

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):*</th>
<th>102,334 (14)</th>
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<tbody>
<tr>
<td>World Bank income group:*</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):*</td>
<td>71.7</td>
</tr>
</tbody>
</table>

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: —
Language(s): Arabic and English
MOH responsible for health technology policy implementation: Geographical Unit of Health Information (GIS), Aantrz
National Health Information: administration of medical devices.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: Yes
Website: https://www.care.gov.eg/

Approved devices lists comments (...Annex 1):
—

Health care facilities lists comments (...Annex 1):
Were counted by the sector ministry and therapeutic medicine, the National Information Center Ministry

Specific lists comments (...Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):* No
National unit/department that includes HTA for medical devices: No
Website(s): https://gah.gov.eg/indexenglish.php
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
A pharmacoeconomics unit was officially established in 2011 under the Central Administration of Pharmaceutical Affairs within the Ministry of Health, but HTA is not obligatory for pricing or reimbursement. However, the recent universal health insurance law from 2018 mandates the representation of health economists in the governing boards of the new Universal Health Insurance Authority and the health care provider body.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: —
Website(s): https://www.care.gov.eg/
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: Egyptian Nuclear and Radiological Regulatory Authority (ENRRA).
Other agency’s website: https://gnssn.iaea.org/main/ANNuR/Activity%20Documents%20Public/6th%20ANNuR%20Plenary%20Meeting/Egypt1.pdf

National regulatory comments (...Annex 1):
—

Under-five mortality (per 1000 live births):* 20.3
UHC - Service coverage index (1-100):* 68
Probability of dying aged 30-70 yrs of NCDs (%):* 27.70%
UHC - Population with household spending >10% (>25%) of corresponding income (%):* 26.2% (3.9%)
Human Development Index (inequality adjusted HDI):* 0.71 (0.5); high
Global innovation index (rank):* 24.2 (96)
ICT Development Index (rank):* 4.6 (103)
High-technology exports (% of manufacture exports):* 2.30%

Population 000s (rank):* 102,334 (14)
World Bank income group:* Lower-Middle
Life expectancy at birth (years):* 71.7

Under-five mortality (per 1000 live births):* 20.3
UHC - Service coverage index (1-100):* 68
Probability of dying aged 30-70 yrs of NCDs (%):* 27.70%
UHC - Population with household spending >10% (>25%) of corresponding income (%):* 26.2% (3.9%)
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Human Development Index (inequality adjusted HDI):* 0.71 (0.5); high
Global innovation index (rank):* 24.2 (96)
ICT Development Index (rank):* 4.6 (103)
High-technology exports (% of manufacture exports):* 2.30%
Medical device nomenclature system
Official nomenclature system for medical devices: Yes
Type: Nationally developed
Use: Not specified
Website: https://www.edaegypt.gov.eg/

Medical device incorporation
Policy or guideline: Yes
Website: —
National level procurement: Yes
Website: —
Donations
Policy or guideline: Yes
Website: —
Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:</td>
<td>143</td>
</tr>
</tbody>
</table>

Healthcare facility
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>314</td>
</tr>
<tr>
<td>Health centres:</td>
<td>208</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>407</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>99</td>
</tr>
</tbody>
</table>

Nomenclature comments (...Annex 1):
Used in the database of geographical information system health.

Medical device incorporation comments (...Annex 1):
Management of medical equipment and hospital management. Curative medicine sector and management of medical devices.

Medical equipment management unit
Unit present: Yes
Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Quality Management
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes
Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population): 7.46
Number of biomedical/clinical engineers professionals in the country: 1000

Contacts
MOH focal point
Name: Dr. Sohier Saad Botrous Attalla
Department: Central Administration of National Information Center for Health - Ministry of Health
Email: ssb_attalla@yahoo.com

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liason Officer:
Name: Dr. Naeema Al Gasseer
Email: algasseern@who.int

General comments (...Annex 1): Concerning the Infrastructure section: the proposed names are not totally compatible with ours. Thus, the number of units is under the Ministry of Health only and is not confined to Tfsalia to the private sector in 2010.
El Salvador

Country indicators

- Population 000s (rank): 6,486 (110)
- World Bank income group: Lower-Middle

Life expectancy at birth (years): 73.3

National policy on health technology

- Health technology (medical device) national policy: No
- Policy is part of the National Health Program/Plan: No
- Website: —
- Language(s): —
- MOH responsible for health technology policy implementation: —

National lists of medical devices

- Approved devices lists comments (...Annex 1):
- Required for procurement or reimbursement: —

National list of priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc.

Lists available: Yes

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: http://asp.salud.gob.sv/; http://www.salud.gob.sv/

National health technology assessment unit

- Designated unit/department for health technology assessment (HTA): Yes
- National unit/department that includes HTA for medical devices: Yes, Dirección de Desarrollo de Infraestructura Sanitaria a través de la Unidad de Proyectos.

Website(s): —
Contact: Mr. Luis Escobar Email: lescobar@salud.gob.sv
Committee includes a biomedical or clinical engineer: —

National regulatory authority

- Presence of national authority responsible for regulating medical devices: Yes
- Name of regulatory agency: Dirección Nacional de Medicamentos
Website(s): https://www.medicamentos.gob.sv/index.php/es/servicios-m/descargables/unidad-de-registro-de-dispositivos-medicos
Contact: Lic. Francisco Bosco Cortez Morales Email: insomos.medicos@medicamentos.gob.sv
Name(s) of other regulatory agency eg. for radiation equipment etc.: Dirección de Protección Radiológica (DPR).
Other agency’s website: https://www.salud.gob.sv/direccion-de-proteccion-radiologica/

National regulatory comments (...Annex 1):

El departamento está a cargo del Dr. Rivera, Director de Regulación y Legislación en Salud del Ministerio de Salud.
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: For procurement purposes
Website: —

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: No  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging*</td>
<td>7</td>
</tr>
<tr>
<td>Computerized Tomography Scanner*</td>
<td>30</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner*</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine*</td>
<td>6</td>
</tr>
<tr>
<td>Mammograph*</td>
<td>30</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>11</td>
</tr>
</tbody>
</table>

Healthcare facility

<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts</td>
<td>624</td>
</tr>
<tr>
<td>Health centres</td>
<td>3</td>
</tr>
<tr>
<td>General/district hospitals</td>
<td>25</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals</td>
<td>3</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Unidad Nacional de Radiaciones Ionizantes  Unit website: —
Contact name: Ms. Carolina de Rivera  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 5

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: https://www.salud.gob.sv/direccion-de-proteccion-radiologica/; https://www.medicamentos.gob.sv/index.php/es/servicios-m/descargables/urim-m
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): 28.7
Number of biomedical/clinical engineers professionals in the country: 231

Contacts

MOH focal point
Name: Lic. Sulay Stefanni Mejía Campos
Department: Cooperation unit and strategic alliances
Email: cooperacion@medicamentos.gob.sv

WHO health products focal point:
Name: Dr. Laura Ramírez
Email: lramirez@paho.org

WHO Representative/WHO Liason Officer:
Name: Dr. Giovanni Escalante Guzman
Email: gescalante@paho.org

General comments
Las respuestas proporcionadas corresponden exclusivamente a la información disponible en la Unidad de Proyectos del Ministerio de Salud Pública y Asistencia Social. Agradecemos permitirnos participar de tan importante encuesta que nos permite establecer un enlace que estamos seguros contribuirá a mejorar nuestra gestión en la planificación, evaluación, adquisición y mantenimiento de los dispositivos médicos de nuestro sistema nacional de salud; así como a contribuir en el desarrollo de una política nacional de tecnología sanitaria en El Salvador. Este trabajo...
Equatorial Guinea

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>1,403 (149)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
</tbody>
</table>

Life expectancy at birth (years):

| Under-five mortality (per 1000 live births): | 81.9 |
| Probability of dying aged 30-70 yrs of NCDs (%): | 22.00% |
| Human Development Index (inequality adjusted HDI): | 0.59 (medium) |
| ICT Development Index (rank): | 1.9 (163) |
| UHC - Service coverage index (1-100): | 45 |
| UHC - Population with household spending >10% (>25%) of corresponding income (%): | — (—) |
| Global innovation index (rank): | — (—) |
| High-technology exports (% of manufacture exports): | — |

National policy on health technology

Health technology (medical device) national policy:

Policy is part of the National Health Program/Plan:

Website:

Language(s):

MOH responsible for health technology policy implementation:

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available:

Unit:

Website:

Nomenclature systems used for devices and tests:

National list for different types of healthcare facilities (hospitals, laboratories, etc):

Lists available:

Website - hospitals:

Website - IVD:

Nomenclature systems used for devices and tests:

National list for specific clinical interventions/emergencies:

Lists available:

Website:

Approved devices lists comments (...Annex 1):

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):

No

National unit/department that includes HTA for medical devices:

No

Website(s):

Contact:

Email:

Committee includes a biomedical or clinical engineer:

HTA unit comments (...Annex 1):

There are identified HTA activities but not a national unit.

National regulatory authority

Presence of national authority responsible for regulating medical devices:

Name of regulatory agency:

Website(s):

Contact:

Email:

Name(s) of other regulatory agency eg. for radiation equipment etc.:

Other agency’s website:

National regulatory comments (...Annex 1):

—
Medical device nomenclature system
Official nomenclature system for medical devices: __ Type: __ Use: __
Website: —

Medical device incorporation
Procurement
Policy or guideline: — Website: —
National level procurement: — Website: —
Donations
Policy or guideline: — Website: —
Technical specifications
Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —
Website: —
Use of management software: — Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population): 4.02
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: —
Department: —
Email: —
Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. George Fom Ameh
Email: amehg@who.int

General comments (...Annex 1): —

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*a Latest (2015-2021); WHO HTA/HBP 2021 survey or WHO HTA 2015 survey or WHO 2021 survey
*b Latest (2013-21); WHO GHO 2021 survey or IAEA (2017-2021)
*c Latest (2011-2015); WHO GHO/2021 survey or IAEA (2017-2021)
*d Latest (2010-2018); WHO GHO 2016
*e WHO GHO 2010-2018
*f Latest (2012-2019); UNDP 2019
*g Latest (1990-2020); UN 2019
*h Latest (2015-2018); ITU 2017
*i Latest (2016-2018); WHO GHO 2017
*j Latest (2016-2018); WHO GHO 2010-2018
*k Latest (2016-2018); WIPO 2020
*l Latest (2016-2018); UN and WB 2017-2019

** Density per 1,000,000 females aged from 50-69 old.

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WHO African Region
Equatorial Guinea
Eritrea

**Country indicators**

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>3,546 (130)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>65.3</td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>40.5</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>38</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>23.90%</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>— (—)</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank:</td>
<td>low</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>— (—)</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>1 (176)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacturing exports):</td>
<td>—</td>
</tr>
</tbody>
</table>

**National policy on health technology**

- Health technology (medical device) national policy: Yes
- Policy is part of the National Health Program/Plan: Yes
- Website: —
- Language(s): English
- MOH responsible for health technology policy implementation: Department of Regulatory Services, Medicine and Medical Devices Control Division.

**National lists of medical devices**

- National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
  - Lists available: No
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —

- National list for different types of healthcare facilities (hospitals, laboratories, etc)
  - Lists available: Yes
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

- National list for specific clinical interventions/emergencies:
  - Lists available: No
  - Website: —

**National health technology assessment unit**

- Designated unit/department for health technology assessment (HTA): Yes
- National unit/department that includes HTA for medical devices: No
- Website(s): —
- Contact: — Email: —
- Committee includes a biomedical or clinical engineer: —

**National regulatory authority**

- Presence of national authority responsible for regulating medical devices: Yes
- Name of regulatory agency: Ministry of Health, Department of Regulatory Services.
- Website(s): —
- Contact: Mr. Eyassu Bahta Email: bahtassy@gmail.com
- Name(s) of other regulatory agency eg. for radiation equipment etc.: —
- Other agency’s website: —
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: https://shabait.com/

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging: a</td>
<td>1</td>
<td>0.16</td>
<td>Health posts:</td>
<td>185</td>
<td>2.92</td>
</tr>
<tr>
<td>Computerized Tomography Scanner: b</td>
<td>2</td>
<td>0.32</td>
<td>Health centres:</td>
<td>56</td>
<td>0.88</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner: c</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>16</td>
<td>0.25</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine: d</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>1</td>
<td>0.02</td>
</tr>
<tr>
<td>Mammograph: e, f</td>
<td>4</td>
<td>16.56</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Radiotherapy: g</td>
<td>0</td>
<td>0</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Department of Health services. Unit website: —
Contact name: Dr. Brhane Debru  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 6

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): ε 0.79
Number of biomedical/clinical engineers professionals in the country: γ —

Contacts

**MOH focal point**
Name: Mr. Gherezghier Habtu
Department: NMFA Division in the Ministry of Health
Email: wedirebi22@gmail.com

**Other country focal point**
Name: Dr. Brhane Debru
Email: —

**WHO health products focal point**
Name: —
Email: —

**WHO Representative/WHO Liaison Officer**
Name: Dr. Martins Ovberedjo
Email: ovberedjom@who.int

General comments (...Annex 1): —

Software comments (...Annex 1): National medical devices inventory on the six zones has started in 2008 and, currently, it is in the process of finalization (only one zone is partially remaining).
**Estonia**

### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):*</th>
<th>1,327 (151)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:*</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):*</td>
<td>[Graph showing life expectancy over time]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births):*</th>
<th>2.4</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Service coverage index (1-100):*</td>
<td>75</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):*</td>
<td>17.00%</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):*</td>
<td>— (—)</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank*</td>
<td>0.89 (0.83): very high</td>
</tr>
<tr>
<td>Global innovation index (rank):*</td>
<td>48.3 (25)</td>
</tr>
<tr>
<td>ICT Development Index (rank):*</td>
<td>8.1 (17)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):*</td>
<td>9.30%</td>
</tr>
</tbody>
</table>

### National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**

- Lists available: Yes
- Unit: —

**Nomenclature systems used for devices and tests:** —

**National list for different types of healthcare facilities (hospitals, laboratories, etc)**

- Lists available: Yes
- Website - hospitals: [https://www.riigiteataja.ee/ert/act.jsp?id=13252715](https://www.riigiteataja.ee/ert/act.jsp?id=13252715)
- Website - IVD: [https://www.riigiteataja.ee/aktilisa/1300/4201/4006/SOM_m26_lisa.pdf#](https://www.riigiteataja.ee/aktilisa/1300/4201/4006/SOM_m26_lisa.pdf#)

**National list for specific clinical interventions/emergencies:**

- Lists available: Yes
- Website: [https://www.riigiteataja.ee/ert/act.jsp?id=13252715](https://www.riigiteataja.ee/ert/act.jsp?id=13252715)

### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** Yes

**National unit/department that includes HTA for medical devices:** Yes, University of Tartu: Public Health Department.


**Contact:** — Email: dph@ut.ee

Committee includes a biomedical or clinical engineer: —

### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes

**Name of regulatory agency:** Health Board, Medical Devices Department.


**Contact:** Mr. Andrei Knuut Email: mso@terviseamet.ee

**Name(s) of other regulatory agency eg. for radiation equipment etc.:** —

**Other agency’s website:** [https://www.riigiteataja.ee/index.html](https://www.riigiteataja.ee/index.html)

---

Approved devices lists comments

(...Annex 1):
The list about reimbursed medical devices used in outpatient conditions is available on web-site (second link). Medical devices used in inpatient conditions are financed though the prices of healthcare services (these prices include also costs of workforce, area, etc.). List of healthcare services is available on web-site (third link).

Health care facilities lists comments

(...Annex 1):

Specific lists comments

(...Annex 1):
Recommended medical devices for specific procedures are described in diagnostic (and treatment) guidelines. They are composed and/or approved by specialists organizations.

HTA unit comments

(...Annex 1):
The HTA for medical products, mainly pharmaceutics, and treatments. There is mention of medical equipment too.

National regulatory comments

(...Annex 1):
—
### Medical device nomenclature system

**Official nomenclature system for medical devices:** Yes  
**Type:** Nationally developed  
**Use:** Not specified  

### Medical device incorporation

**Procurement**  
**Policy or guideline:** Yes  
**Website:** [https://www.riigiteataja.ee/ert/act.jsp?id=13191371](https://www.riigiteataja.ee/ert/act.jsp?id=13191371)  
**National level procurement:** No  
**Donations**  
**Policy or guideline:** No  
**Website:** —

#### Technical specifications

**Technical specifications to support procurement or donations:** No  
**Publically available:** —  
**Website:** —

### Medical equipment

<table>
<thead>
<tr>
<th>Equipment Type</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:</td>
<td>18</td>
<td>13.56</td>
<td>Health posts:</td>
<td>485</td>
<td>37.68</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:</td>
<td>25</td>
<td>18.84</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:</td>
<td>3</td>
<td>2.26</td>
<td>General/district hospitals:</td>
<td>18</td>
<td>1.4</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:</td>
<td>3</td>
<td>2.26</td>
<td>Specialized/regional/national hospitals:</td>
<td>3</td>
<td>0.23</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>14</td>
<td>76.94</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>9</td>
<td>6.78</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*a Density per 1,000,000 females aged from 50-69 old.

### Medical equipment management unit

**Unit present:** Yes  
**Professionally trained biomedical/clinical engineers:** Yes  
**Unit/Department:** Department of Public Health, University of Tartu  
**Unit website:** [http://www.arth.ut.ee/](http://www.arth.ut.ee/)  
**Contact name:** —  
**Contact email:** —  
**Website with publically available technical specifications:** [http://www.arth.ut.ee/](http://www.arth.ut.ee/)  
**Number of regional/state offices/units:** 0

### Inventories and medical equipment management software

**Type of inventories available:** None  
**Website:** —  
**Use of management software:** No  
**Software name:** —

### Medical devices workforce

**Density of medical doctors (per 10 000 population):** 34.63  
**Number of biomedical/clinical engineers professionals in the country:** 60

### Contacts

**MOH focal point**  
**Name:** Ms. Tairi Välinurm  
**Department:** Medicines Department  
**Email:** tairivalinurm@sm.ee  
**Other country focal point**  
**Name:** —  
**Email:** —

**WHO health products focal point**  
**Name:** —  
**Email:** —  
**WHO Representative/WHO Liaison Officer**  
**Name:** Ms. Kristina Köhler  
**Email:** kohlerk@who.int

---

*a Density per 1,000,000 females aged from 50-69 old.

b Latest (2015-2021); WHO HTA/HBP 2021 survey or WHO HTA 2015 survey or WHO 2021 survey  
c Latest (2013-2021); WHO GHO/2021 survey or OECD (2017-2019)  
d Latest (2015-2021); WHO HTA/HBP 2021 survey or OECD (2017-2019)  
e Latest (2014-2021); WHO GHO/2021 survey

---

**Medical device incorporation comments (...Annex 1):** The procurement of medical devices is regulated by the Public procurement law, as well as all other commodities (see specified website: riigiteataja).
**Eswatini**

### Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>1,160 (155)</td>
<td></td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Lower-Middle</td>
<td></td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>63</td>
<td></td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>49.4</td>
<td></td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>26.70%</td>
<td></td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI):</td>
<td>0.61 (0.45): medium</td>
<td></td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>— (—)</td>
<td></td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>63</td>
<td></td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>— (—)</td>
<td></td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>— (—)</td>
<td></td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>0.30%</td>
<td></td>
</tr>
</tbody>
</table>

### National policy on health technology

- **Health technology (medical device) national policy:** No
- **Policy is part of the National Health Program/Plan:** No
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: No
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —

- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - Lists available: No
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

- **National list for specific clinical interventions/emergencies:**
  - Lists available: No
  - Website: —

### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):** Yes
- **National unit/department that includes HTA for medical devices:** —
- **Website(s):** —
- **Contact:** — Email: —
- **Committee includes a biomedical or clinical engineer:** —

### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** No
- **Name of regulatory agency:** Pharmaceuticals & Medicines, Ministry of Health.
- **Contact:** — Email: —
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** —
- **Other agency’s website:** —

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**Approved devices lists comments (...Annex 1):** —

**Health care facilities lists comments (...Annex 1):** —

**Specific lists comments (...Annex 1):** The list is still being developed by the Emergency Preparedness Group.

**HTA unit comments (...Annex 1):** There is no HTA national unit per se. However, and adaptive HTA has been used to inform in areas such as benefits package in health interventions prioritisation packages.

**National regulatory comments (...Annex 1):** —
### Medical device nomenclature system

Official nomenclature system for medical devices: No  
Type: None  
Use: Not specified  
Website: —

### Medical device incorporation

**Procurement**

Policy or guideline: No  
Website: —

**Donations**

Policy or guideline: Yes  
Website: —

### Technical specifications

Technical specifications to support procurement or donations: No  
Publically available: —  
Website: —

### Medical equipment

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>0</td>
<td>0</td>
<td>Health posts: 162</td>
<td>12.97</td>
<td></td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>3</td>
<td>2.4</td>
<td>Health centres: 8</td>
<td>0.64</td>
<td></td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals: 2</td>
<td>0.16</td>
<td></td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals: 2</td>
<td>0.16</td>
<td></td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>2</td>
<td>33.62</td>
<td>Estimation % of health facilities with none or very limited oxygen supply: n/a</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

### Medical equipment management unit

Unit present: Yes  
Professionally trained biomedical/clinical engineers: Yes  
Unit/Department: Biomedical unit  
Unit website: —  
Contact name: Mr. Leornad Zwane  
Contact email: magmu@realnet.co.sz  
Website with publically available technical specifications: —  
Number of regional/state offices/units: 0

### Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment  
Website: —  
Use of management software: No  
Software name: —

### Medical devices workforce

Density of medical doctors (per 10,000 population): 0.96  
Number of biomedical/clinical engineers professionals in the country: <10

### Contacts

**MOH focal point**

Name: Dr. Samuel Vusi Magagula  
Department: MoH  
Email: magagulasam@gov.sz

**Other country focal point**

Name: Mr. Leornad Zwane  
Email: magmu@realnet.co.sz

**WHO health products focal point**

Name: —  
Email: —

**WHO Representative/WHO Liason Officer**

Name: Dr. Cornelia Atsyor  
Email: atsyorc@who.int

**General comments**

Concerning the Infrastructure section: In Swaziland Health Centres may have more than 20 beds. The referral levels are being defined by the ongoing essential health care package that is being developed.
Ethiopia

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>114,964 (12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>66.3</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: Federal Ministry of Health (FMOH).

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes, but it is only a recommendation
Unit: Pharmaceutical and Medical Device Directorate, FMOH.
Website: www.moh.gov.et
Nomenclature systems used for devices and tests: Several of the ones mention above.

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: www.moh.gov.et
Website - IVD: —
Nomenclature systems used for devices and tests: Use of several nomenclatures.

National list for specific clinical interventions/emergencies:
Lists available: No

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No, Pharmaceutical and medical equipment directorate
Website(s): —
Contact: Mr. Regasa Bayisa Email: regasa.bayisa@moh.gov.et
Committee includes a biomedical or clinical engineer: No

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Ethiopian Food and Drug Administration (EFDA).
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: Radiation & Protection Authority; Ethiopian standard Agency (ESA)
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  
**Type:** Nationally developed  
**Use:** For various purposes above-mentioned  

---

Medical device incorporation

**Procurement**

Policy or guideline: No  
Website: —  
National level procurement: Yes  
Website: http://www.moh.gov.et/ejcc/en  

**Donations**

Policy or guideline: Yes  
Website: www.fmhaca.gov.et  

**Technical specifications**

Technical specifications to support procurement or donations: Yes  
Publically available: Yes  

---

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>18</td>
<td>0.16</td>
<td>Health posts:</td>
<td>17154</td>
<td>14.92</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>48</td>
<td>0.42</td>
<td>Health centres:</td>
<td>4063</td>
<td>3.53</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>338</td>
<td>0.29</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>1</td>
<td>0.01</td>
<td>Specialized/regional/national hospitals:</td>
<td>25</td>
<td>0.03</td>
</tr>
<tr>
<td>Mammograph</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>75%</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>10</td>
<td>0.09</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

Medical equipment management unit

Unit present: Yes  
Professionally trained biomedical/clinical engineers: Yes  
Unit/Department: Public Health Infrastructure Directorate; Pharmaceutical and Medical Device Directorate.  
Contact name: Mr. Regasa Bayisa  
Contact email: regasa.bayisa@moh.gov.et  
Number of regional/state offices/units: 12  

---

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment  
Website: —  
Use of management software: Yes  
Software name: MEMIS (Medical Equipment Management Information System).  

---

Medical devices workforce

Density of medical doctors (per 10 000 population): 0.77  
Number of biomedical/clinical engineers professionals in the country: 1000  

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Contacts

**MOH focal point**

Name: Mr. Regasa Bayisa  
Department: PMED, FMOH  
Email: regasa.bayisa@moh.gov.et  

**WHO health products focal point**

Name: Mr. Mulugeta Mideksa  
Email: mulugetamideksa@yahoo.com  

**WHO Representative/WHO Liaison Officer**

Name: Dr. Boureima Hama Sambo  
Email: sambob@who.int  

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General comments (...Annex 1): Concerning National policy on health technology: National Medical device strategy under development (draft) and National Medical device directive (final draft) will approved within 3 or 4 months. Concerning the HT national policy, it is stated in the corresponding National Health Policy document. Concerning the Infrastructure section: the targets of the government are to expand the current infrastructure capacity.
Fiji

Country indicators

Population 000s (rank): 896 (157)
World Bank income group: Upper-Middle

Life expectancy at birth (years):

Under-five mortality (per 1000 live births): 25.7
UHC - Service coverage index (1-100): 64

Probability of dying aged 30-70 yrs of NCDs (%): 30.60%
UHC - Population with household spending >10% (>25%) of corresponding income (%):

Human Development Index (inequality adjusted HDI): 0.74 (<—): high
Global innovation index (rank): — (—)

ICT Development Index (rank): 4.5 (107)
High-technology exports (% of manufacture exports): 3.90%

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: http:/ /www.health.gov.fj
Language(s): English
MOH responsible for health technology policy implementation: Clinical Services MoH HQ.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes
Unit: Biomedical Engineering Units.
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: http:/ /www.health.gov.fj/
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: Yes
Website: http:/ /www.health.gov.fj

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
—

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Biomedical Engineering, CWMH.
Website(s): —
Contact: Mr. Virendra Deo Singh Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: Ministry of Health & Medical Services.
Other agency's website: http:/ /www.health.gov.fj/

Approved devices lists comments (...Annex 1): The biomedical catalogue for procurement can be obtained by the Fiji Health Sector Improvement Program (FHSIP).

Health care facilities lists comments (...Annex 1): CSN & CSP lists can be obtained from ministry of health, HQ.

Specific lists comments (...Annex 1): CSN & CSP. Can be obtained from Ministry of Health, HQ.

HTA unit comments (...Annex 1):
—

National regulatory comments (...Annex 1):
Also, supported by the divisional biomedical engineering units.
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: http://www.health.gov.fj/

Nomenclature comments (Annex I): —

Medical device incorporation

Procurement
Policy or guideline: Yes  Website: http://www.health.gov.fj/
National level procurement: Yes  Website: http://www.health.gov.fj/

Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: Yes
Website: http://www.health.gov.fj

Medical device incorporation comments (Annex I):
Mainly standardization of all medical equipment as per the national biomedical catalogue. Also, supported by the Ministry of Health central procurement centre at Fiji Pharmaceutical Services.

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>1</td>
<td>1.13</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>3</td>
<td>3.4</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>2</td>
<td>28.83</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
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<tr>
<td>Radiotherapy:*</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Biomedical Engineering. Unit website: —
Contact name: Mr. Mohammed Ifraz  Contact email: mohammed.ifraz@health.gov.fj
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Medical equipment management unit comments (Annex I):
BME Equipment Inventory. The inventory has more than 8,600 items.

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: Yes  Software name: EMS, EPICOR.

Software comments (Annex I):

Medical devices workforce

Density of medical doctors (per 10,000 population):* 8.6
Number of biomedical/clinical engineers professionals in the country:* <10

Medical devices workforce comments (Annex I):

Contacts

MOH focal point
Name: Mr. Virendra Deo Singh
Department: Biomedical Engineering, CWMH
Email: virendra.singh@health.gov.fj

Other country focal point
Name: Mr. Mohammed Ifraz
Email: mohammed.ifraz@health.gov.fj

General comments (Annex I): —

WHO health products focal point:
Name: Dr. Wendy Snowdon
Email: snowdonw@who.int

WHO Representative/WHO Liaison Officer:
Name: Dr. Mark Andrew Jacobs
Email: jacobsma@who.int

General comments (Annex I): —

b  WB FY1 2019  g  ITU 2017  e  WHO GHO 2019
b' Latest (2013-21), WHO GHO 2021 survey or IAEA (2017-2021)
d  WHO GHO 2019  i  WHO GHO 2010-2018  ε  WHO GHO 2010-2018
j  WHO GHO 2010-2018  n/a not applicable/not available
k  UN and WB 2017-2019

n/a not applicable/not available
Finland

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):*</th>
<th>5,541 (114)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:†</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):‡</td>
<td></td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births):§ 2.4

Probability of dying aged 30-70 yrs of NCDs (%):¶ 10.20%

Human Development Index (inequality adjusted HDI): rank:¶ 0.94 (0.89); very high

ICT Development Index (rank):** 7.9 (22)

UHC - Service coverage index (1-100):†† 78

UHC - Population with household spending >10% (>25%) of corresponding income (%):†† 6.4% (1.0%)

Global innovation index (rank):‡‡ 57 (7)

High-technology exports (% of manufacture exports):‡‡ 9.20%

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

Approved devices lists comments (...Annex 1):

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):‡ Yes
National unit/department that includes HTA for medical devices: Yes, FinCCHTA.
Contact: — Email: —
Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (...Annex 1):

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Finnish Medicines Agency (FIMEA).
Website(s): http://www.fimea.fi; http://www.valvira.fi
Contact: Mr. Heikki Mattlar Email: heikki.mattlar@fimea.fi
Name(s) of other regulatory agency eg. for radiation equipment etc.: Radiation and Nuclear Safety Authority (STUK); Ministry of Social Affairs and Health (Radiation Protection).
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  
Type: Based on EMDN  
Use: For regulatory purposes  
Website: https://www.fimea.fi/web/en/medical-devices

Medical device incorporation
Procurement
Policy or guideline: No  
National level procurement: No  
Website: —

Donations
Policy or guideline: No  
Website: —

Technical specifications
Technical specifications to support procurement or donations: No  
Publically available: —  
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:a</td>
<td>159</td>
<td>28.7</td>
<td>Health posts:</td>
<td>2200</td>
<td>39.7</td>
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<tr>
<td>Computerized Tomography Scanner:a</td>
<td>91</td>
<td>16.42</td>
<td>Health centres:</td>
<td>194</td>
<td>3.5</td>
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<tr>
<td>Positron Emission Tomography Scanner:a</td>
<td>15</td>
<td>2.71</td>
<td>General/district hospitals:</td>
<td>23</td>
<td>0.42</td>
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<tr>
<td>Gamma camera or nuclear medicine:a</td>
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<td>7.5</td>
<td>Specialized/regional/national hospitals:</td>
<td>5</td>
<td>0.09</td>
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<tr>
<td>Mammograph:a</td>
<td>156</td>
<td>214.37</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Radiotherapy:a</td>
<td>57</td>
<td>10.29</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
</tbody>
</table>

*a Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: —  
Professionally trained biomedical/clinical engineers: No
Unit/Department: —  
Unit website: —
Contact name: —  
Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No  
Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population): 46.4
Number of biomedical/clinical engineers professionals in the country: 850

Contacts
MOH focal point
Name: Ms. Mari Laurén-Häussler
Department: Department for Safety, Security and Health / Biotechnology and Medicines Unit
Email: mari.lauren-haussler@stm.fi

Other country focal point
Name: Mrs. Ritva Bly
Email: —

General comments (...Annex 1): —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: —
Email: —

Nomenclature comments (...Annex 1):
Finland CA will implement the European Medical Device Nomenclature (EMDN) used by manufacturers/ARs when registering their medical devices in the EUDAMED database. The EMDN system will be based on the Italian CND nomenclature system. This will be the only official nomenclature system for medical devices in Finland. Also, some other commercial nomenclature systems are used in healthcare organizations and health technology companies. Healthcare organizations use these nomenclatures in, for example, public procurement, product information retrieval, ERP, and cost accounting.

Medical device incorporation comments (...Annex 1): —

Software comments (...Annex 1): —

General comments (...Annex 1): —

Medical devices workforce
Density of medical doctors (per 10,000 population): 46.4
Number of biomedical/clinical engineers professionals in the country: 850

Contacts
MOH focal point
Name: Ms. Mari Laurén-Häussler
Department: Department for Safety, Security and Health / Biotechnology and Medicines Unit
Email: mari.lauren-haussler@stm.fi

Other country focal point
Name: Mrs. Ritva Bly
Email: —

General comments (...Annex 1): —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: —
Email: —

Nomenclature comments (...Annex 1):
Finland CA will implement the European Medical Device Nomenclature (EMDN) used by manufacturers/ARs when registering their medical devices in the EUDAMED database. The EMDN system will be based on the Italian CND nomenclature system. This will be the only official nomenclature system for medical devices in Finland. Also, some other commercial nomenclature systems are used in healthcare organizations and health technology companies. Healthcare organizations use these nomenclatures in, for example, public procurement, product information retrieval, ERP, and cost accounting.

Medical device incorporation comments (...Annex 1): —

Software comments (...Annex 1): —

General comments (...Annex 1): —

Medical devices workforce
Density of medical doctors (per 10,000 population): 46.4
Number of biomedical/clinical engineers professionals in the country: 850

Contacts
MOH focal point
Name: Ms. Mari Laurén-Häussler
Department: Department for Safety, Security and Health / Biotechnology and Medicines Unit
Email: mari.lauren-haussler@stm.fi

Other country focal point
Name: Mrs. Ritva Bly
Email: —

General comments (...Annex 1): —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: —
Email: —

Nomenclature comments (...Annex 1):
Finland CA will implement the European Medical Device Nomenclature (EMDN) used by manufacturers/ARs when registering their medical devices in the EUDAMED database. The EMDN system will be based on the Italian CND nomenclature system. This will be the only official nomenclature system for medical devices in Finland. Also, some other commercial nomenclature systems are used in healthcare organizations and health technology companies. Healthcare organizations use these nomenclatures in, for example, public procurement, product information retrieval, ERP, and cost accounting.

Medical device incorporation comments (...Annex 1): —

Software comments (...Annex 1): —

General comments (...Annex 1): —
Country indicators

Population 000s (rank): 65,274 (22)

World Bank income group: High

Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Year</th>
<th>France</th>
<th>Global</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990</td>
<td>78.1</td>
<td>78.3</td>
</tr>
<tr>
<td>2000</td>
<td>81.3</td>
<td>81.9</td>
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<tr>
<td>2010</td>
<td>83.2</td>
<td>83.8</td>
</tr>
<tr>
<td>2020</td>
<td>84.7</td>
<td>85.3</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 4.5

Probability of dying aged 30-70 yrs of NCDs (%): 10.6%

Human Development Index (inequality adjusted HDI): 0.9 (0.82); very high

ICT Development Index (rank): 8.2 (15)

UHC - Service coverage index (1-100): 78

UHC - Population with household spending >10% (>25%) of corresponding income (%): 1.4% (0.2%)

Global innovation index (rank): 53.7 (12)

High-technology exports (% of manufacture exports): 27.00%

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes

Website: https://solidarites-sante.gouv.fr/soins-et-maladies/autres-produits-de-sante/dispositifs-medicaux/

Language(s): Français

MOH responsible for health technology policy implementation: Direction Générale de la Santé et Direction Générale de l’Offre de Soins.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Ministère chargé de la santé et de la sécurité sociale.


Nomenclature systems used for devices and tests:

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: http://www.ameli.fr/


Nomenclature systems used for devices and tests:

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes

National unit/department that includes HTA for medical devices: Yes, Haute Autorité de Santé.

Website(s): https://www.has-sante.fr/icms/c_2883073/fr/evaluation-des-technologies-de-sante-a-la-places-de-la-qualite-de-vie; https://www.has-sante.fr/icms/c_821871/fr/securite-du-patient-guides-et-outils; https://www.has-sante.fr/icms/c_428381/fr/accreditation-des-medecins-et-equipe-medicales

Contact: Mr. Jean-Patrick Sales Email: jp.sales@has-sante.fr

Committee includes a biomedical or clinical engineer: —

HTA unit comments (…Annex 1):

There are three commissions: La commission de la transparence (CT); la commission nationale d’évaluation des dispositifs médicaux et des technologies de santé (CNEDIMTS), and the commission évaluation économique et de santé publique (CEESP).

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Ministère du Travail, de l’Emploi et de la Santé.

Website(s): http://www.sante.gouv.fr/

Contact: Ms. Emmanuelle Barsky - Adjointe au chef de bureau Email: emmanuelle.barsky@sante.gouv.fr

Name(s) of other regulatory agency eg. for radiation equipment etc.: Ministère du Travail, de l’Emploi et de la Santé.

Medical device nomenclature system
Official nomenclature system for medical devices: Yes  
Type: Nationally developed  
Use: For various purposes above-mentioned  
Website: http://www.legifrance.gouv.fr; https://www.gmdnagency.org/

Medical device incorporation
Procurement
Policy or guideline: No  
Website: —

Donations
Policy or guideline: No  
Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes  
Publicly available: Yes  
Website: https://www.ameli.fr/professionnel-de-la-lpp/exercice-professionnel/facturation/liste-des-produits-et-prestations-lpp/liste-produits-prestations-lpp

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>1034</td>
<td>15.84</td>
<td>Health posts</td>
<td>n/a</td>
<td>n/a</td>
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<tr>
<td>Computerized Tomography Scanner</td>
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<td>18.72</td>
<td>Health centres</td>
<td>n/a</td>
<td>n/a</td>
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<tr>
<td>Positron Emission Tomography Scanner</td>
<td>167</td>
<td>2.56</td>
<td>General/district hospitals</td>
<td>n/a</td>
<td>n/a</td>
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<tr>
<td>Gamma camera or nuclear medicine</td>
<td>462</td>
<td>7.08</td>
<td>Specialized/regional/national hospitals</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>599</td>
<td>9.18</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  
Professionally trained biomedical/clinical engineers: Yes  
Unit/Department: Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS).  
Unit website: —

Contact name: Mr. Jean-Claude Ghislain  
Contact email: Jean-Claude.GHISLAIN@ansm.sante.fr

Website with publically available technical specifications: —

Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —

Website: —

Use of management software: —  
Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 65.34  
Number of biomedical/clinical engineers professionals in the country: 600

Contacts
MOH focal point
Name: Ms. Geraldine Bonnin  
Department: Bureau international Santé et protection sociale, Delegation aux affaires europeennes et internationales, Ministère des Affaires sociales et de la santé  
Email: Geraldine.BONNIN@sante.gouv.fr

Other country focal point
Name: Mr. Jean-Claude Ghislain  
Email: Jean-Claude.GHISLAIN@ansm.sante.fr

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: —
Email: —

General comments (...Annex 1): Dans cette enquête, nous avons mentionné la HAS et l’ANSM qui sont deux agences qui sont chargées: HAS: Agence d’évaluation des dispositifs médicaux ANSM : Agence nationale de sécurité du médicament qui est chargée de la sécurité sanitaire des dispositifs médicaux.
### Gabon

#### Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>2,226 (142)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### National policy on health technology

- **Health technology (medical device) national policy:** No
- **Policy is part of the National Health Program/Plan:** No
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

#### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: No
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —
- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - Lists available: Yes
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —
- **National list for specific clinical interventions/emergencies:**
  - Lists available: No
  - Website: —

#### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):** Yes
- **National unit/department that includes HTA for medical devices:** No
- **Website(s):** —
- **Contact:** — Email: —
- **Committee includes a biomedical or clinical engineer:** —

#### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** No
- **Name of regulatory agency:** —
- **Website(s):** —
- **Contact:** — Email: —
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** —
- **Other agency’s website:** —

### Approved devices lists comments

- Approved devices lists comments (...Annex 1):
  - 

### Health care facilities lists comments

- Health care facilities lists comments (...Annex 1):
  - 

### Specific lists comments (...Annex 1):

- Specific lists comments (...Annex 1):
  - 

### HTA unit comments (...Annex 1):

- HTA unit comments (...Annex 1):
  - HTA activities have been identified, but there is not a specific national unit per se. Currently, the HTA unit is in progress towards the Universal Health Care (UMC) country goal.

### National regulatory comments (...Annex 1):

- National regulatory comments (...Annex 1):
  - 

#### Economic and social indicators

- **Population 000s (rank):** 2,226 (142)
- **World Bank income group:** Upper-Middle
- **Life expectancy at birth (years):** 83.7
  - 2020: 80.8
  - 2010: 66.1

#### Health care indicators

- **Under-five mortality (per 1000 live births):** 42.5
- **UHC - Service coverage index (1-100):** 49
- **Probability of dying aged 30-70 yrs of NCDs (%):** 14.40%
- **UHC - Population with household spending >10% (>25%) of corresponding income (%):** —
- **Global innovation index (rank):**
  - **High-technology exports (% of manufacture exports):** —
  - **Human Development Index (rank):**
    - 0.7 (0.54)
      - High
  - **ICT Development Index (rank):**
    - 4.1 (114)
  - **Probability of dying aged 30-70 yrs of NCDs (%):** 14.40%
  - **UHC - Service coverage index (1-100):** 49
- **Global innovation index (rank):** —
- **High-technology exports (% of manufacture exports):** —

#### Other indicators

- **Under-five mortality (per 1000 live births):** 42.5
  - UHC - Service coverage index (1-100): 49

---

*Note: Annex 1 contains additional information and definitions.*
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: https://www.sante.gov.ma/Pages/ADM_Centrale/DMP.aspx

Medical device incorporation
Procurement
Policy or guideline: No  Website: —
National level procurement: No  Website: —

Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
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</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>2</td>
<td>1.2</td>
<td>Health posts</td>
<td>492</td>
<td>29.43</td>
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<tr>
<td>Computerized Tomography Scanner</td>
<td>6</td>
<td>3.59</td>
<td>Health centres</td>
<td>37</td>
<td>2.21</td>
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<tr>
<td>Positron Emission Tomography Scanner</td>
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<td>0</td>
<td>General/district hospitals</td>
<td>41</td>
<td>2.45</td>
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<tr>
<td>Gamma camera or nuclear medicine</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals</td>
<td>6</td>
<td>0.36</td>
</tr>
<tr>
<td>Mammograph</td>
<td>6</td>
<td>73.12</td>
<td>Estimation % of health facilities with none or very limited oxygen supply</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>2</td>
<td>0.9</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Direction Générale de la Planification, des infrastructures et des Équipements.  Unit website: —
Contact name: Mr. Martin Essono  Contact email: martessono@yahoo.fr
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 6.82
Number of biomedical/clinical engineers professionals in the country: —

Contacts

**MOH focal point**
Name: Mr. Martin Essono
Department: Ministère de la Santé/ Direction Générale de la Planification, des Infrastructures et des Équipements
Email: martessono@yahoo.fr
Other country focal point
Name: Mr. Martin Essono
Email: martessono@yahoo.fr

**WHO health products focal point**
Name: Dr. Aboubacar Inoua
Email: inouaa@who.int

**WHO Representative/WHO Liaison Officer**
Name: Dr. Magaran Monzon Bagayoko
Email: bagayokom@who.int

General comments (...Annex 1): —
### Gambia

#### Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
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<tr>
<td>Population 000s (rank):</td>
<td>2,417 (140)</td>
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<tr>
<td>World Bank income group:</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td></td>
</tr>
</tbody>
</table>

#### National policy on health technology

| Policy on health technology (medical device) national policy: | No          |
| Policy is part of the National Health Program/Plan:         | No          |
| Website:                                                     | —           |
| Language(s):                                                 | —           |
| MOH responsible for health technology policy implementation: | Médecines Control Agency |

#### National lists of medical devices

| National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement: | Lists available: No |
| Unit:                                                          | — |
| Website:                                                       | — |
| Nomenclature systems used for devices and tests:              | — |

| National list for different types of healthcare facilities (hospitals, laboratories, etc): | Lists available: No |
| Website - hospitals:                                         | — |
| Website - IVD:                                               | — |
| Nomenclature systems used for devices and tests:             | — |

| National list for specific clinical interventions/emergencies: | Lists available: No |
| Website:                                                     | — |

#### National health technology assessment unit

| Designated unit/department for health technology assessment (HTA): | No          |
| Current HTA unit comments:                                      | (Annex 1): |

| National unit/department that includes HTA for medical devices: | No           |
| Website(s):                                                   | —           |
| Contact:                                                      | — Email:    |
| Committee includes a biomedical or clinical engineer:         | —           |

#### National regulatory authority

| Presence of national authority responsible for regulating medical devices: | Yes          |
| Name of regulatory agency: MÉDECINES CONTROL AGENCY               | —           |
| Website(s):                                                       | www.mca.gm  |
| Contact:                                                          | — Email:    |
| Name(s) of other regulatory agency eg. for radiation equipment etc.: | International Atomic Energy Agency (IAEA). |
| Other agency’s website:                                           | https://www.iaea.org/newscenter/news/iaea-advises-the-gambia-on-strengthening-regulatory-infrastructure |

#### Approved devices lists comments

Approved devices lists comments (...Annex 1): —

#### Health care facilities lists comments

Health care facilities lists comments (...Annex 1): —

#### Specific lists comments

Specific lists comments (...Annex 1): —

#### HTA unit comments

HTA unit comments (...Annex 1): —

#### National regulatory comments

National regulatory comments (...Annex 1): —

### National health technology assessment unit comments

HTA activities have been identified, but there is not a specific National unit. Currently, the HTA unit is in progress towards the Universal Health Care (UHC) country goal.

### National regulatory authority comments

—
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Based on UMDNS  Use: Not specified
Website: http://www.mrc.gm/

Medical device incorporation
Procurement
Policy or guideline: No  Website: —
National level procurement: No  Website: —
Donations
Policy or guideline: Yes  Website: —
Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:α</td>
<td>1</td>
<td>0.54</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:α</td>
<td>3</td>
<td>1.24</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:α</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:α</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mammograph:α,β</td>
<td>4</td>
<td>43.89</td>
</tr>
<tr>
<td>Radiotherapy:α</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Healthcare facility*
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>939</td>
</tr>
<tr>
<td>Health centres:</td>
<td>46</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>4</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>2</td>
</tr>
</tbody>
</table>

Estimation % of health facilities with none or very limited oxygen supply: n/a

Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Royal Victoria Teaching Hospital  Unit website: —
Contact name: Mr. Michael Gomez  Contact email: michael.gomez63@yahoo.com
Website with publically available technical specifications: —
Number of regional/state offices/units: 2

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes  Software name: AIMS Program.

Medical devices workforce
Density of medical doctors (per 10 000 population):* 1.07
Number of biomedical/clinical engineers professionals in the country: <10

Contacts
MOH focal point
Name: Mr. Andrew Demba
Department: Ministry of Health and Social Welfare
Email: anthems81@yahoo.com

Other country focal point
Name: Mr. Michael Gomez
Email: michael.gomez63@yahoo.com

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Desta Alamerew Tiruneh
Email: tirunehd@who.int

General comments (...Annex I):
Concerning the Infrastructure section: the private sector section correspond to the responses for the Medical Research Council (UK) the Gambia; Concerning HT nactional policy we provide the following doc.: Medical Equipment and Devices Policy 2010 March.doc. Concerning Section Infrastructure: We have 3 CHU and 1 Hôpital national.

Software comments (...Annex I):
Recently inventories have been compiled for the National Laboratory Services. However, those for Hospital/Clinical equipment are not available yet. The Medical Research Council (UK) the Gambia has a full inventory of its biomedical equipment. It is comprised of 1,500 devices including minor clinical equipment, high-cost diagnostic and research laboratory equipment. We use a proprietary equipment management program from Phoenix Data Systems Inc. called AIMS (www.goaims.com).
Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):*</th>
<th>3,989 (129)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>73.5</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 9.6
Probability of dying aged 30-70 yrs of NCDs (%): 24.90%
Human Development Index (inequality adjusted HDI): rank: 0.81 (0.72); very high
ICT Development Index (rank): 5.8 (74)

National policy on health technology

Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

List of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):* Yes
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: State Regulation Agency for Medical Activities, Ministry of Labour, Health and Social Affairs.
Website(s): http://rama.moh.gov.ge
Contact: Mr. Ivane Pockhverashvili Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: Georgian National Agency For Standards, Technical Regulations and Metrology.
Other agency's website: —

Approved devices lists comments (...Annex 1):
—

Health care facilities lists comments (...Annex 1):
—

Specific lists comments (...Annex 1):

HTA unit comments (...Annex 1):
State Regulation Agency for Medical Activities is in charge of HTA but not for medical devices.

National regulatory comments (...Annex 1):
Georgian National Agency For Standards, Technical Regulations and Metrology is responsible for standardization and metrology as well as calibration and accreditation of facilities, providing inspection of medical devices.

Population 000s (rank):* 3,989 (129)
World Bank income group:* Upper-Middle
Life expectancy at birth (years): 73.5

Under-five mortality (per 1000 live births): 9.6
Probability of dying aged 30-70 yrs of NCDs (%): 24.90%
Human Development Index (inequality adjusted HDI): rank: 0.81 (0.72); very high
ICT Development Index (rank): 5.8 (74)

UHC - Service coverage index (1-100):* 66
UHC - Population with household spending >10% (>25%) of corresponding income (%): 29.2% (9.0%)
Global innovation index (rank): 31.8 (63)
High-technology exports (% of manufacture exports): 2.60%

Georgia
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: https://matsne.gov.ge/ru

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: http://www.moh.gov.ge

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility*</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*a</td>
<td>0</td>
<td>0</td>
<td>Health posts:</td>
<td>599</td>
<td>13.8</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*a</td>
<td>38</td>
<td>8.75</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*a</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*a</td>
<td>3</td>
<td>0.69</td>
<td>Specialized/regional/national hospitals:</td>
<td>96</td>
<td>2.21</td>
</tr>
<tr>
<td>Mammograph:*a</td>
<td>23</td>
<td>40.74</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*a</td>
<td>21</td>
<td>5.26</td>
<td>—</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*a Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: https://www.moh.gov.ge/
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): 70.78
Number of biomedical/clinical engineers professionals in the country: 250

Contacts

MOH focal point
Name: Ms. Eka Paatashvili
Department: Health Care Department, Ministry of Labour, Health and Social Affairs of Georgia
Email: epaatashvili@moh.gov.ge

Other country focal point
Name: Mr. Nikoloz Pruidze
Email: kokap@moh.gov.ge

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Silviu Domente
Email: domentes@who.int

General comments (...Annex 1): —


WHO European Region

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Silviu Domente
Email: domentes@who.int

General comments (...Annex 1): —

WHO European Region

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Silviu Domente
Email: domentes@who.int

General comments (...Annex 1): —
Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>83,784 (19)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>81.1</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) and DAHTA (previous DIMDI).
Contact: — Email: —
Committee includes a biomedical or clinical engineer: Yes

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Federal Ministry of Health (BMG) - Unit Medical Devices.
Website(s): http://www.bmg.bund.de
Contact: Dr. Matthias Neumann Email: matthias.neumann@bmg.bund.de
Name(s) of other regulatory agency eg. for radiation equipment etc.: Federal Institute for Drugs and Medical Devices (BfArM); Central Authority of the Laender for Health Protection with Regard to Medicinal Products and Medical devices (ZLG).

Approved devices lists comments (...Annex 1):

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):

HTA unit comments (...Annex 1):

National regulatory comments (...Annex 1):
There are more than 30 regional Competent Authorities.
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Based on UMDNS  Use: Not specified
Website: http://www.dimdi.de

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: —  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>2869</td>
<td>34.24</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>2904</td>
<td>34.66</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>895</td>
<td>10.68</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: —  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population):* 42
Number of biomedical/clinical engineers professionals in the country:* 2050

Contacts

MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: —
Email: —

General comments (...Annex 1): Germany does not complete the whole survey because of their federal system, which will imply to make the whole survey in their 16 states. Regarding the Regulations section: they follow the EU system, other matters are state’s competency.
Ghana

Country indicators

<table>
<thead>
<tr>
<th>Term</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>31,073 (47)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td></td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): English
MOH responsible for health technology policy implementation: Clinical Engineering Department and the Biomedical Engineering Unit.

National lists of medical devices

National list of approved priority/essential medical devices (including IVDs), for procurement or reimbursement:
Lists available: Yes, but it is only a recommendation
Unit: Clinical Engineering Department.
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
There are identified HTA activities but there is not a national unit per se. HTA structures (Steering Committee, Technical Working Group and Secretariat) in the MOH have been set up and a national HTA strategy developed and yet to be launched. In progress towards the Universal Health Care country goal.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Food and Drug Board.
Website(s): https://www.fdaghana.gov.gh/
Contact: Ernest Afesey Email: safesey@yahoo.com
Name(s) of other regulatory agency eg. for radiation equipment etc.: Radiation Protection Institute.
Other agency's website: https://rpi.gaecgh.org/; https://gnra.org.gh/

Approved devices lists comments (...Annex 1):
The standard list serves as a guide. The actual procurement is based on the need of health facility, availability of utilities, and availability of professional user staff.

Health care facilities lists comments (...Annex 1):
—

Specific lists comments (...Annex 1):
—

HTA unit comments (...Annex 1):
—

National regulatory comments (...Annex 1):
The Radiation Protection Institute is responsible for the regulation of equipment with radiation sources such as X-Ray machines.
Medical device nomenclature system
Official nomenclature system for medical devices: No
Type: None
Use: Not specified

Medical device incorporation
Procurement
Policy or guideline: Yes
Website: https://pcghana.org/
National level procurement: Yes
Website: https://www.moh.gov.gh/procurement-supply/

Donations
Policy or guideline: Yes
Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Name</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>7</td>
<td>0.23</td>
<td>Health posts:</td>
<td>287</td>
<td>1.11</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>11</td>
<td>0.35</td>
<td>Health centres:</td>
<td>2364</td>
<td>9.13</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>336</td>
<td>1.3</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>2</td>
<td>0.08</td>
<td>Specialized/regional/national hospitals:</td>
<td>9</td>
<td>0.03</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>8</td>
<td>0.26</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical device workforce
Density of medical doctors (per 10,000 population): 1.06
Number of biomedical/clinical engineers professionals in the country: 450

Inventories and medical equipment management software
Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: —
Use of management software: No
Software name: —

Medical equipment management unit
Unit present: Yes
Professionally trained biomedical/clinical engineers: —
Unit/Department: Biomedical Engineering Department
Unit website: https://www.moh.gov.gh/
Contact name: Dr. Nichodemus Kafui Gebe
Contact email: —
Website with publically available technical specifications: https://www.fdaghana.gov.gh/img/organisation/GUIDELINE%20FOR%20LICENSING%20OF%20PREMISES%20FOR%20MANUFACTURING%20OF%20MEDICAL%20DEVICES.pdf
Number of regional/state offices/units: 10

Contacts
MOH focal point
Name: Dr. Nicholas Adjabu
Department: Clinical Engineering Department
Email: adjabu95@yahoo.com

Other country focal point
Name: Dr. Nichodemus Kafui Gebe
Email: —

General comments (...Annex 1): There is no written nor published national health technology policy yet but there are policies available that have been established by the systems and structures unit for health technology in Ghana. Ghana Health Service has drafted its operational policy for healthcare equipment and needs to be finalized.
### Greece

#### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>10,423 (86)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
</tbody>
</table>

| Life expectancy at birth (years): | 82.9 |

#### National policy on health technology

- **Health technology (medical device) national policy:** Yes
- **Policy is part of the National Health Program/Plan:** Yes
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

#### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - **Lists available:** No
  - **Unit:** —
  - **Website:** —
  - **Nomenclature systems used for devices and tests:** —

- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - **Lists available:** No
  - **Website - hospitals:** —
  - **Website - IVD:** —
  - **Nomenclature systems used for devices and tests:** —

- **National list for specific clinical interventions/emergencies:**
  - **Lists available:** No
  - **Website:** —

#### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):** Yes
- **National unit/department that includes HTA for medical devices:** Yes, National Evaluation Center of Quality and Technology in Health (EKAPTY).
- **Contact:** Email: info@ekapty.gr
- **Committee includes a biomedical or clinical engineer:** Yes

#### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** Yes
- **Name of regulatory agency:** National Organization for Medicines.
- **Website(s):** [www.eof.gr](http://www.eof.gr)
- **Contact:** Email: —
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** Greek Atomic Energy Commission
- **Other agency’s website:** [www.eeae.gr](http://www.eeae.gr)

#### Approved devices lists comments (...Annex 1):

#### Health care facilities lists comments (...Annex 1):

#### Specific lists comments (...Annex 1):

#### HTA unit comments (...Annex 1):

Various HTA institutions are performing a variety of domains including medical devices.

#### National regulatory comments (...Annex 1):

#### Under-five mortality (per 1000 live births): 3.8

#### Probability of dying aged 30-70 yrs of NCDs (%): 12.40%

#### Human Development Index (inequality adjusted HDI):
  - **Rank:** 0.89 (0.79); very high

#### ICT Development Index (rank): 7.2 (38)

#### UHC - Service coverage index (1-100): 75

#### UHC - Population with household spending >10% (>25%) of corresponding income (%): 16.9% (1.6%)

#### Global innovation index (rank): 36.8 (43)

#### Global innovation index (rank): 36.8 (43)

#### High-technology exports (% of manufacture exports): 12.50%
**Medical device nomenclature system**

Official nomenclature system for medical devices: Yes  
Type: Based on GMDN  
Use: Not specified  
Website: [https://www.gmdnagency.org/](https://www.gmdnagency.org/)

**Medical device incorporation**

**Procurement**
Policy or guideline: Yes  
Website: —
National level procurement: No  
Website: —

**Donations**
Policy or guideline: Yes  
Website: [www.eof.gr](http://www.eof.gr)

**Technical specifications**
Technical specifications to support procurement or donations: Yes  
Publically available: Yes  
Website: [https://www.moh.gov.gr/](https://www.moh.gov.gr/)

**Medical equipment**

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>315</td>
<td>30.22</td>
<td>Health posts:</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>436</td>
<td>41.83</td>
<td>Health centres:</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>13</td>
<td>1.25</td>
<td>General/district hospitals:</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>144</td>
<td>13.82</td>
<td>Specialized/regional/national hospitals:</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>708</td>
<td>492.19</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>69</td>
<td>6.62</td>
<td></td>
</tr>
</tbody>
</table>

*a* Density per 1,000,000 females aged from 50-69 old.

**Medical equipment management unit**

Unit present: Yes  
Professionally trained biomedical/clinical engineers: Yes  
Unit/Department: Health Procurement Committee  
Unit website: [https://www.moh.gov.gr/articles/epitroph-promhtheiwn-ygeias](https://www.moh.gov.gr/articles/epitroph-promhtheiwn-ygeias)

Contact name: —  
Contact email: —
Website with publically available technical specifications: [https://www.moh.gov.gr/articles/epitroph-promhtheiwn-ygeias/diaboyleyseis-technikwn-prodiagrafwn](https://www.moh.gov.gr/articles/epitroph-promhtheiwn-ygeias/diaboyleyseis-technikwn-prodiagrafwn)
Number of regional/state offices/units: —

**Inventories and medical equipment management software**

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)  
Website: —

Use of management software: Yes  
Software name: Various such as Praxis.

**Medical devices workforce**

Density of medical doctors (per 10,000 population): 62.26  
Number of biomedical/clinical engineers professionals in the country: 300

**Contacts**

MOH focal point
Name: Mr. Tarsi Giannouli  
Department: National Evaluation center of quality and technology in health - EKAPTY -  
Email: tgiannouli@ekapty.gr

Other country focal point
Name: —  
Email: —

WHO health products focal point:
Name: —  
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Jaana Marianna Trias  
Email: TriasJ@who.int

**General comments (...Annex 1):**

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**Nomenclature comments (...Annex 1):**

A specific technical committee is responsible for the correlation of Nomenclature, Classification and Codification of Medical Devices. The final deliverable is expected in 2014.

**Medical device incorporation comments (...Annex 1):**

The EU Directive for public procurement and national specific legislation for health procurement (law 3580/2007). A part of procurement of medical devices is carried out at a national level, by the Health Procurement Committee.

**Software comments (...Annex 1):**

“Praxis”, was developed by the Institute of Biomedical Technology (INBIT), and it is a specific one. Also, it is used the Asset Management Software.
## Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank): *</th>
<th>113 (179)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Life expectancy at birth (years):</th>
<th>72</th>
</tr>
</thead>
</table>

### National policy on health technology

- **Health technology (medical device) national policy:** Yes
- **Policy is part of the National Health Program/Plan:** No
- **Language(s):** English
- **MOH responsible for health technology policy implementation:** Administration and Biomedical Engineering Department.

### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: Yes
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —
- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - Lists available: No
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —
- **National list for specific clinical interventions/emergencies:**
  - Lists available: No
  - Website: —

### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):** —
- **National unit/department that includes HTA for medical devices:** No
- **Website(s):** —
- **Contact:** Email: —
- **Committee includes a biomedical or clinical engineer:** —

### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** No
- **Name of regulatory agency:** —
- **Website(s):** —
- **Contact:** Email: —
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** —
- **Other agency’s website:** —

## Approved devices lists comments

(Appendix 1): The list can be requested from the management of the Hospital services. However, there is no web to guideline because it was never used as a policy of the MoH.

## Health care facilities lists comments

(Appendix 1): —

## Specific lists comments

(Appendix 1): No lists available.

## HTA unit comments

(Appendix 1): —

## National regulatory comments

(Appendix 1): —
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: For procurement purposes
Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: —
Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:</td>
<td>1</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:</td>
<td>2</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:</td>
<td>0</td>
</tr>
<tr>
<td>Mammograph:</td>
<td>1</td>
</tr>
<tr>
<td>Radiotherapy:</td>
<td>0</td>
</tr>
</tbody>
</table>

Healthcare facility
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>36</td>
</tr>
<tr>
<td>Health centres:</td>
<td>5</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>1</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>0</td>
</tr>
</tbody>
</table>

Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 1

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes  Software name: Medical device Management System Software.

Medical devices workforce
Density of medical doctors (per 10,000 population):\(^\text{a}\) 14.36
Number of biomedical/clinical engineers professionals in the country: <10

Contacts
MOH focal point
Name: Mr. Stephen Prince
Department: —
Email: princealista@hotmail.com
Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: Ms. Tessa Stroud
Email: stroudet@cpc.paho.org
WHO Representative/WHO Liaison Officer:
Name: Dr. Yitades Gebre
Email: gebrey@paho.org

General comments (...Annex 1): —

\(\text{a}\) Latest (2015-2021), WHO HTA/HBP survey or WHO HTA 2015 survey or WHO 2021 survey
\(\beta\) Latest (2013-21), WHO GHO/2021 survey or IAEA (2017-2021)
\(\gamma\) Latest (2014-21), WHO GHO 2021 survey
\(\epsilon\) WHO GHO 2010
\(\eta\) UN POP/WPP 2019 (2020 POP)
\(\iota\) WB FY21 2019
\(\kappa\) UN POP/WPP 1990-2020 MOR
\(\lambda\) UNDP 2019
\(\mu\) ITU 2017
\(\nu\) WHO GHO 2017
\(\xi\) WHO GHO 2010-2018
\(\gamma\) WHO GHO 2020
\(\delta\) WHO and WB 2017-2019
\(\eta\) Latest (2015-2021), WHO HTA/HBP survey or WHO HTA 2015 survey or WHO 2021 survey
\(\iota\) Latest (2013-21), WHO GHO/2021 survey or IAEA (2017-2021)
\(\kappa\) Latest (2014-21), WHO GHO 2021 survey
\(\lambda\) WHO GHO 2010
\(\mu\) n/a not applicable/not available
Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>17,916 (65)</th>
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</thead>
<tbody>
<tr>
<td>World Bank income group: Upper-Middle</td>
<td></td>
</tr>
</tbody>
</table>

Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Probability of dying aged 30-70 yrs of NCDs (%)</th>
<th>14.90%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank</td>
<td>0.66 (0.48); medium</td>
</tr>
<tr>
<td>National list for different types of healthcare facilities (hospitals, laboratories, etc)</td>
<td>Lists available: No</td>
</tr>
</tbody>
</table>

Website: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: https://www.mspas.gob.gt/

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —


Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: https://www.mspas.gob.gt/

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes

National unit/department that includes HTA for medical devices: No

Website(s): https://sicoin.minfin.gob.gt; https://siges.minfin.gob.gt

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Departamento de Regulación y Control de Productos Farmacéuticos y Afines.

Website(s): https://medicamentos.mspas.gob.gt/

Contact: Ms. Elizabeth Recinos de Posadas Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Ministerio de Energía y Minas.

Other agency’s website: https://mem.gob.gt/?s=equipo+m%C3%A9dico&submit=Go

Approved devices lists comments (...Annex 1):

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):

HTA unit comments (...Annex 1):

National regulatory comments (...Annex 1):

Population 000s (rank):

Under-five mortality (per 1000 live births):

Probability of dying aged 30-70 yrs of NCDs (%):

Human Development Index (inequality adjusted HDI):

Global innovation index (rank):

ICT Development Index (rank):

High-technology exports (% of manufacture exports):

Under-five mortality (per 1000 live births):

Probability of dying aged 30-70 yrs of NCDs (%):

Human Development Index (inequality adjusted HDI):

Global innovation index (rank):

ICT Development Index (rank):

High-technology exports (% of manufacture exports):

Under-five mortality (per 1000 live births):

Probability of dying aged 30-70 yrs of NCDs (%):

Human Development Index (inequality adjusted HDI):

Global innovation index (rank):

ICT Development Index (rank):

High-technology exports (% of manufacture exports):
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: Not specified
Website: https://www.mspas.gob.gt/; https://medicamentos.mspas.gob.gt/

Medical device incorporation
Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: https://www.guatecompras.gob.gt/

Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):
The procurement is done, at general level, by the Sistema de Adquisiciones del Estado de Guatemala.

Medical equipment management unit
Unit present: —  Professionally trained biomedical/clinical engineers: No
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: None
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population):* 3.55
Number of biomedical/clinical engineers professionals in the country:* <10

Contacts
MOH focal point
Name: Ms. Elizabeth Recinos de Posadas
Department: Departamento de Regulacion y Control de Productos Farmaceuticos y Afines
Email: drcpfa.jefatura@gmail.com
Other country focal point
Name: Ms. Silvana Figueroa
Email: silufima@hotmail.com

WHO health products focal point:
Name: Mrs. Juana R. Mejia de Rodriguez
Email: jmrod@paho.org
WHO Representative/WHO Liaison Officer:
Name: Dra. Lilian Ninett Reneau-Vernon
Email: lreneau@paho.org

General comments (...Annex 1): —
### Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population O00s (rank):</td>
<td>13,133 (74)</td>
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<tr>
<td>World Bank income group:</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>63.0</td>
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<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>98.8</td>
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<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>22.40%</td>
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<tr>
<td>Human Development Index (inequality adjusted HDI): rank:</td>
<td>0.48 (0.31): low</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>1.8 (166)</td>
</tr>
</tbody>
</table>

### National policy on health technology

- **Health technology (medical device) national policy:** No
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - **Lists available:** No
  - **Unit:** —
  - **Website:** —
  - **Nomenclature systems used for devices and tests:** —

- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - **Lists available:** Yes
  - **Website - hospitals:** —
  - **Website - IVD:** —
  - **Nomenclature systems used for devices and tests:** —

- **National list for specific clinical interventions/emergencies:**
  - **Lists available:** —
  - **Website:** —

### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):**
  - **National unit/department that includes HTA for medical devices:** No
  - **Website(s):** —
  - **Contact:** — Email: —
  - **Committee includes a biomedical or clinical engineer:** —

### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** Yes
- **Name of regulatory agency:** Division Equipement et Maintenance de la DNEHS.
- **Website(s):** [https://sante.gov.gn/](https://sante.gov.gn/)
- **Contact:** Mr. Amadou Timbi Bah Email: amadoutimbibah@yahoo.fr
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** —
- **Other agency’s website:** —
Medical device nomenclature system

Official nomenclature system for medical devices: No
Type: None
Use: Not specified
Website: —

Medical device incorporation

Procurement
Policy or guideline: No
Website: —
National level procurement: Yes
Website: —

Donations
Policy or guideline: Yes
Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th></th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>0</td>
<td>0</td>
<td>Health posts:</td>
<td>733</td>
<td>6.24</td>
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<tr>
<td>Computerized Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>Health centres:</td>
<td>414</td>
<td>3.52</td>
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<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>31</td>
<td>0.26</td>
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<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
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<td>0.03</td>
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<tr>
<td>Mammograph:*</td>
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<td>0</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
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<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>0</td>
<td>0</td>
<td>—</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes
Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Section Equipement (SE). Unit website: —
Contact name: Mr. Mamadouba Camara Engagé
Contact email: mamadoubaengage@yahoo.fr
Website with publically available technical specifications: —
Number of regional/state offices/units: 4

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: —
Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): 0.83
Number of biomedical/clinical engineers professionals in the country: <10

Contacts

MOH focal point
Name: Mr. Amadou Timbi Bah
Department: Ministère de la Santé et de l’Hygiène Publique
Email: amadoutimbibah@yahoo.fr

Other country focal point
Name: Mr. Mamadouba Camara Engagé
Email: mamadoubaengage@yahoo.fr

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Georges Alfred Ki-Zerbo
Email: kizerbog@who.int

General comments (…Annex 1):
—

WHO African Region

Medical device incorporation comments (…Annex 1):
For procurement or donations: nous procédons par appel d’offres national ou international.

WHO Representative/WHO Liaison Officer:
Name: Dr. Georges Alfred Ki-Zerbo
Email: kizerbog@who.int

General comments (…Annex 1):
—
### Guinea-Bissau

#### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):a</th>
<th>1,968 (146)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:b</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years):c</td>
<td>61.7</td>
</tr>
</tbody>
</table>

### National policy on health technology

- **Health technology (medical device) national policy:** No
- **Policy is part of the National Health Program/Plan:** No
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - **Lists available:** No
  - **Unit:** —
  - **Website:** —
  - **Nomenclature systems used for devices and tests:** —

- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - **Lists available:** Yes
  - **Website - hospitals:** —
  - **Website - IVD:** —
  - **Nomenclature systems used for devices and tests:** —

- **National list for specific clinical interventions/emergencies:**
  - **Lists available:** No
  - **Website:** —

### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):**
  - **Name of regulatory agency:** —
  - **Website(s):** —
  - **Contact:** — Email: —
  - **Committee includes a biomedical or clinical engineer:** —

### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** No
  - **Name of regulatory agency:** —
  - **Website(s):** —
  - **Contact:** — Email: —
  - **Name(s) of other regulatory agency eg. for radiation equipment etc.:** —
  - **Other agency’s website:** —

### Additional Information

- **Under-five mortality (per 1000 live births):d | 78.5 |
- **UHC - Service coverage index (1-100):e | 40 |
- **Probability of dying aged 30-70 yrs of NCDs (%):f | 20.00% |
- **UHC - Population with household spending >10% (>25%) of corresponding income (%):g | — (—) |
- **Human Development Index (inequality adjusted HDI): rank:h | 0.48 (0.3): low |
- **Global innovation index (rank):i | — (—) |
- **ICT Development Index (rank):j | 1.5 (173) |
- **High-technology exports (% of manufacture exports):k | — |

- **Approved devices lists comments (...Annex 1): —
- **Health care facilities lists comments (...Annex 1): —
- **Specific lists comments (...Annex 1): —
- **HTA unit comments (...Annex 1): —
- **National regulatory comments (...Annex 1): —
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: No  Website: —
National level procurement: No  Website: —
Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —  Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging: a</td>
<td>0</td>
</tr>
<tr>
<td>Computerized Tomography Scanner: a</td>
<td>0</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner: a</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine: a</td>
<td>0</td>
</tr>
<tr>
<td>Mammograph: a</td>
<td>0</td>
</tr>
<tr>
<td>Radiotherapy: a</td>
<td>0</td>
</tr>
</tbody>
</table>

Healthcare facility
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>96</td>
</tr>
<tr>
<td>Health centres:</td>
<td>562</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>437</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>525</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —  Website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 1

Inventories and medical equipment management software
Type of inventories available: —
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 1.27
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: Mr. Fodé Carambá Sanhá
Department: Serviço Manutenção Técnica de Equipamentos Médicos
Email: focasa60@gmail.com
Other country focal point
Name: Mr. Hamilton Ferreira
Email: hamiltonpnds@yahoo.es

WHO health products focal point:
Name: Mr. Inácio Alvarenga
Email: alvarengai@who.int
WHO Representative/WHO Liaison Officer:
Name: Dr. Georges Alfred Ki-Zerbo
Email: kizerbog@who.int

General comments (...Annex 1): —
Guyana

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):a</th>
<th>787 (159)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:h</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):c</td>
<td>73.9</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):δ Yes
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

Population 000s (rank):a: 787 (159)
World Bank income group:h: Upper-Middle

<table>
<thead>
<tr>
<th>Probability of dying aged 30-70 yrs of NCDs (%)c:</th>
<th>30.50%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank c:</td>
<td>0.68 (0.56): medium</td>
</tr>
<tr>
<td>ICT Development Index (rank)c:</td>
<td>3.4 (124)</td>
</tr>
</tbody>
</table>

UHC - Service coverage index (1-100):b: 72
UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)
Global innovation index (rank):j: — (—)
High-technology exports (% of manufacture exports):a: 0.10%

Under-five mortality (per 1000 live births):e: 29.3
Life expectancy at birth (years):c: 73.9
Probability of dying aged 30-70 yrs of NCDs (%)c: 30.50%
Human Development Index (inequality adjusted HDI): rank c: 0.68 (0.56): medium
ICT Development Index (rank)c: 3.4 (124)

UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)
Global innovation index (rank):j: — (—)
High-technology exports (% of manufacture exports):a: 0.10%

Population 000s (rank):a: 787 (159)
World Bank income group:h: Upper-Middle

<table>
<thead>
<tr>
<th>Life expectancy at birth (years):c</th>
<th>73.9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%)c:</td>
<td>30.50%</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank c:</td>
<td>0.68 (0.56): medium</td>
</tr>
<tr>
<td>ICT Development Index (rank)c:</td>
<td>3.4 (124)</td>
</tr>
</tbody>
</table>

UHC - Service coverage index (1-100):b: 72
UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)
Global innovation index (rank):j: — (—)
High-technology exports (% of manufacture exports):a: 0.10%

Population 000s (rank):a: 787 (159)
World Bank income group:h: Upper-Middle

<table>
<thead>
<tr>
<th>Life expectancy at birth (years):c</th>
<th>73.9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%)c:</td>
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</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank c:</td>
<td>0.68 (0.56): medium</td>
</tr>
<tr>
<td>ICT Development Index (rank)c:</td>
<td>3.4 (124)</td>
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</tbody>
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UHC - Service coverage index (1-100):b: 72
UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)
Global innovation index (rank):j: — (—)
High-technology exports (% of manufacture exports):a: 0.10%

Population 000s (rank):a: 787 (159)
World Bank income group:h: Upper-Middle

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UHC - Service coverage index (1-100):b: 72
UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)
Global innovation index (rank):j: — (—)
High-technology exports (% of manufacture exports):a: 0.10%
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: https://gafdd.gy/inspectorate/

Medical device incorporation
Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>1</td>
<td>1.25</td>
<td>Health posts:</td>
<td>205</td>
<td>25.64</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>3</td>
<td>3.75</td>
<td>Health centres:</td>
<td>118</td>
<td>14.76</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>16</td>
<td>2</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>1</td>
<td>0.13</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>3</td>
<td>69.98</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>2</td>
<td>2.54</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Regional Radiology. Unit website: —
Contact name: Ms. Donna Bowman  Contact email: dasbowman@yahoo.co.uk
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 18.19
Number of biomedical/clinical engineers professionals in the country: <10

Contacts
MOH focal point
Name: Ms. Donna Bowman
Department: Regional Radiology Services
Email: dasbowman@yahoo.co.uk

Other country focal point
Name: Ms. Donna Bowman
Email: dasbowman@yahoo.co.uk

WHO health products focal point:
Name: Dr. Julian Amsterdam
Email: leamsterdam@yahoo.com

WHO Representative/WHO Liason Officer:
Name: Dr. Luis Felipe Codina
Email: codinalu2@paho.org

General comments (...Annex 1): —

A1B2
C3D4

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Draft
### Haïti

**Country indicators**

<table>
<thead>
<tr>
<th>Population 000s (rank):*</th>
<th>11,403 (81)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:*</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years):*</td>
<td>62.8</td>
</tr>
</tbody>
</table>

| Under-five mortality (per 1000 live births):* | 62.8 |
| Probability of dying aged 30-70 yrs of NCDs (%):* | 26.50% |
| Human Development Index (inequality adjusted HDI): rank:| 0.51 (0.3): low |
| ICT Development Index (rank):* | 1.7 (168) |

**National policy on health technology**

- Health technology (medical device) national policy: No
- Policy is part of the National Health Program/Plan: No
- Website: —
- Language(s): —
- MOH responsible for health technology policy implementation: —

**National lists of medical devices**

- National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
  - Lists available: No
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —

- National list for different types of healthcare facilities (hospitals, laboratories, etc)
  - Lists available: No
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

- National list for specific clinical interventions/emergencies:
  - Lists available: No
  - Website: —

**National health technology assessment unit**

- Designated unit/department for health technology assessment (HTA):
  - National unit/department that includes HTA for medical devices: No
  - Website(s): —
  - Contact: — Email: —
  - Committee includes a biomedical or clinical engineer: —

**National regulatory authority**

- Presence of national authority responsible for regulating medical devices: No
- Name of regulatory agency: —
- Website(s): —
- Contact: — Email: —
- Name(s) of other regulatory agency eg. for radiation equipment etc.: —
- Other agency’s website: —

**Population 000s (rank):** 11,403 (81)

**World Bank income group:*** Low

**Life expectancy at birth (years):** 62.8

**Under-five mortality (per 1000 live births):** 62.8

**Probability of dying aged 30-70 yrs of NCDs (%):** 26.50%

**Human Development Index (inequality adjusted HDI): rank:** 0.51 (0.3): low

**ICT Development Index (rank):** 1.7 (168)

**UHC - Service coverage index (1-100):** 49

**UHC - Population with household spending >10% (≥25%) of corresponding income (%):** 11.5% (4.0%)

**Global innovation index (rank):** — (—)

**High-technology exports (% of manufacture exports):** —

**Population 000s (rank):** 11,403 (81)

**World Bank income group:*** Low

**Life expectancy at birth (years):** 62.8

**Under-five mortality (per 1000 live births):** 62.8

**Probability of dying aged 30-70 yrs of NCDs (%):** 26.50%

**Human Development Index (inequality adjusted HDI): rank:** 0.51 (0.3): low

**ICT Development Index (rank):** 1.7 (168)

**UHC - Service coverage index (1-100):** 49

**UHC - Population with household spending >10% (≥25%) of corresponding income (%):** 11.5% (4.0%)

**Global innovation index (rank):** — (—)

**High-technology exports (% of manufacture exports):** —

**Population 000s (rank):** 11,403 (81)

**World Bank income group:*** Low

**Life expectancy at birth (years):** 62.8

**Under-five mortality (per 1000 live births):** 62.8

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**UHC - Service coverage index (1-100):** 49

**UHC - Population with household spending >10% (≥25%) of corresponding income (%):** 11.5% (4.0%)

**Global innovation index (rank):** — (—)

**High-technology exports (% of manufacture exports):** —

**Population 000s (rank):** 11,403 (81)

**World Bank income group:*** Low

**Life expectancy at birth (years):** 62.8

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**Human Development Index (inequality adjusted HDI): rank:** 0.51 (0.3): low

**ICT Development Index (rank):** 1.7 (168)

**UHC - Service coverage index (1-100):** 49

**UHC - Population with household spending >10% (≥25%) of corresponding income (%):** 11.5% (4.0%)

**Global innovation index (rank):** — (—)

**High-technology exports (% of manufacture exports):** —
### Medical device nomenclature system

Official nomenclature system for medical devices: **No**  
Type: **None**  
Use: **Not specified**  
Website: —

### Medical device incorporation

#### Procurement

Policy or guideline: **No**  
Website: —

National level procurement: **No**  
Website: —

#### Donations

Policy or guideline: **Yes**  
Website: —

### Technical specifications

Technical specifications to support procurement or donations: **Yes**  
Publically available: **No**  
Website: —

#### Software comments (...Annex 1):

Il n’existe pas encore une liste d’inventaire technique national pour les équipements médicaux.

### Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>3</td>
<td>0.29</td>
<td>Health centres:</td>
<td>30</td>
<td>0.29</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>17</td>
<td>0.16</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/ regional/ national hospitals:</td>
<td>4</td>
<td>0.04</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>11</td>
<td>19.47</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>n/a</td>
<td>n/a</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

### Medical equipment management unit

Unit present: **Yes**  
Professionally trained biomedical/clinical engineers: **Yes**  
Unit/Department: —  
Unit website: —

Contact name: —  
Contact email: —

Website with publically available technical specifications: —  
Number of regional/state offices/units: —

### Inventories and medical equipment management software

Type of inventories available: —  
Website: —

Use of management software: **Yes**  
Software name: GMAO.

### Medical devices workforce

Density of medical doctors (per 10 000 population): * 2.34

Number of biomedical/clinical engineers professionals in the country:* 50

### Contacts

**MOH focal point**

Name: Mr. Roland Palme  
Department: Service de Genie et D’entretien Biomedical  
Email: palmeroland@hotmail.com

**Other country focal point**

Name: Dr. Duperval Mona  
Email: Mssp_doss@yahoo.fr

WHO health products focal point:

Name: —  
Email: —

WHO Representative/WHO Liaison Officer:

Name: Dr. Maureen Birmingham  
Email: birminghamm@paho.org

General comments (...Annex 1): Concerning the Infrastructure section: les centres de santé sont dotés de 10 lits.
**Country indicators**

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>9,905 (91)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Lower-Middle</td>
</tr>
</tbody>
</table>

| Life expectancy at birth (years): | 79.1 |

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births):</th>
<th>16.8</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>65</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Probability of dying aged 30-70 yrs of NCDs (%):</th>
<th>14.00%</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>— (—)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Human Development Index (inequality adjusted HDI):</th>
<th>0.63 (0.47): medium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global innovation index (rank):</td>
<td>23 (103)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICT Development Index (rank):</th>
<th>3.3 (129)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>2.00%</td>
</tr>
</tbody>
</table>

**National policy on health technology**

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: [http://www.salud.gob.hn/](http://www.salud.gob.hn/)
Language(s): Español

MOH responsible for health technology policy implementation: Agencia Regulatoria Sanitaria de Honduras.

**National lists of medical devices**

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

**National list for different types of healthcare facilities (hospitals, laboratories, etc):**
Lists available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

**National list for specific clinical interventions/emergencies:**
Lists available: No
Website: —

**National health technology assessment unit**

Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

**HTA unit comments (...Annex 1):**
HTA activities have been identified, but there is not a specific national unit.

**National regulatory authority**

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Agencia Regulatoria Sanitaria de Honduras (ARSA).
Contact: Dr. Francis Contreras Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: Secretaría de Recursos Naturales y Ambiente (MIAmbiente+)

**National regulatory comments (...Annex 1):**

**Approved devices lists comments (...Annex 1):**

**Health care facilities lists comments (...Annex 1):**

**Specific lists comments (...Annex 1):**
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: For various purposes above-mentioned
Website: http://www.salud.gob.hn/site/

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: http://www.honducompras.gob.hn
National level procurement: Yes  Website: https://www.honducompras.gob.hn/

Donations
Policy or guideline: Yes  Website: https://www.arsa.gob.hn/

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>9</td>
<td>0.91</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>17</td>
<td>1.72</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>1</td>
<td>0.1</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>20</td>
<td>34.41</td>
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<td>Radiotherapy:*</td>
<td>9</td>
<td>0.91</td>
</tr>
</tbody>
</table>

Healthcare facility

<table>
<thead>
<tr>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>1684</td>
<td>17</td>
</tr>
<tr>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>17</td>
<td>0.17</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>7</td>
<td>0.09</td>
</tr>
<tr>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes  Software name: SIAFI.

Software comments (...Annex 1):
El inventario es por Objeto de Gasto. Existe el SIAFI que es un sistema informático para fines de presupuesto, el cual actualmente se encuentra en proceso de ampliación ya que permitirá la gestión del equipamiento en todas sus fases.

Medical devices workforce
Density of medical doctors (per 10 000 population):* 3.09
Number of biomedical/clinical engineers professionals in the country: <10

Contacts
MOH focal point
Name: Dr. Francis Contreras
Department: —
Email: franciscontreras@arsa.gob.hn

Other country focal point
Name: Ms. Ritza Lizardo
Email: —

WHO health products focal point:
Name: Dr. Isábel Seaman
Email: seamani@hon.ops-oms.org

WHO Representative/WHO Liaison Officer:
Name: Eng. Ana Solís-Ortega Treasure
Email: treasurea@paho.org

WHO Region of the Americas
World Health Organization

Honduras

General comments (...Annex 1): —

Nomenclature comments (...Annex 1):
El Reglamento para el Control Sanitario de Productos, Servicios y Establecimientos de Interés Sanitario, establece una nomenclatura con fines de Registro.

Medical device incorporation comments (...Annex 1):
Ley de Contratación del Estado y Reglamento de Ley de Contratación del Estado (more information under https://www.arsa.gob.hn/). Cada uno de los Programas de Salud dependientes de la Dirección antes mencionada o entes cooperantes realizan compras de dispositivos médicos para proveer a nivel nacional, como pueden ser pruebas de laboratorio y anticonceptivos. El Programa de Equipamiento se elabora por demanda y por complejidad.

Medical equipment Total

<table>
<thead>
<tr>
<th>Healthcare facility</th>
<th>Total</th>
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<td>n/a</td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.
## Hungary

### Country indicators

- Population 000s (rank): 9,660 (93)
- World Bank income group: High
- Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Year</th>
<th>Hungary</th>
<th>World</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>69.5</td>
<td>76.4</td>
</tr>
<tr>
<td>2020</td>
<td>72.3</td>
<td>76.4</td>
</tr>
</tbody>
</table>

### National policy on health technology

| Health technology (medical device) national policy: | Yes |
| Policy is part of the National Health Program/Plan: | Yes |
| Website: | [https://ogyei.gov.hu/laws_and_regulations](https://ogyei.gov.hu/laws_and_regulations) |
| Language(s): | Hungarian |
| MOH responsible for health technology policy implementation: | — |

### National lists of medical devices

#### National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

- Lists available: Yes
- Unit: National Health Insurance Fund / Central Services Directorate General of the Prime Minister’s Office, respectively.
- Website: —
- Nomenclature systems used for devices and tests: —

#### National list for different types of healthcare facilities (hospitals, laboratories, etc)

- Lists available: Yes
- Nomenclature systems used for devices and tests: —

#### National list for specific clinical interventions/emergencies:

- Lists available: Yes

### National health technology assessment unit

| Designated unit/department for health technology assessment (HTA): | Yes |
| National unit/department that includes HTA for medical devices: | Yes, National Institute for Strategic Health Research - Office of Health Technology Assessment. |
| Contact: Dr. Marta Pekli Email: pekli.marta@eski.hu |
| Committee includes a biomedical or clinical engineer: | — |

### National regulatory authority

| Presence of national authority responsible for regulating medical devices: | Yes |
| Name of regulatory agency: | Office of Health Authorisation and Administrative Procedures - Authority for Medical Devices. |
| Website(s): | — |
| Contact: Mr. György Ferenc Balazs Email: balazs.gyorgy@eekh.hu |
| Name(s) of other regulatory agency eg. for radiation equipment etc.: | Department for Medical Devices, National Institute of Pharmacy. |
| Other agency’s website: | [http://ogyei.gov.hu/presidency2011/about_department_for_medical_deviceesekh](http://ogyei.gov.hu/presidency2011/about_department_for_medical_deviceesekh) |

### Approved devices lists comments

(...Annex 1): —

### Health care facilities lists comments

(...Annex 1): —

### Specific lists comments

(...Annex 1):

The uploaded Ministerial Decree lays down the minimum requirements for the provision of healthcare services. The criteria are equally specified for healthcare facilities (1.2.1) and specific procedures. The document has been uploaded only once. The decree is only available in Hungarian. The assigned URLs contain protocols for pandemic situation according to the National Influenza Pandemic Preparedness Plan (second link). Also, see the Decree 60_2003 on minimum requirements of healthcare services.

| HTA unit comments: |
| There are HTA activities for health products, rarely for medical devices. |

### National regulatory comments

(...Annex 1): —

### Under-five mortality (per 1000 live births): 3.7

### Probability of dying aged 30-70 yrs of NCDs (%): 23.00%

### Human Development Index (inequality adjusted HDI): 0.85 (0.79): very high

### ICT Development Index (rank): 6.9 (48)

### UHC - Service coverage index (1-100): 74

### UHC - Population with household spending >10% (>25%) of corresponding income (%): 7.4% (0.3%)

### Global innovation index (rank): 41.5 (35)

### High-technology exports (% of manufacture exports): 17.50%
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: Not specified
Website: —

Medical device incorporation

Procurement

Policy or guideline: Yes  Website: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99300009.NM
National level procurement: Yes  Website: http://www.oep.hu

Donations

Policy or guideline: No  Website: —

Technical specifications

Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility¹</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>48</td>
<td>4.97</td>
<td>Health posts: 577</td>
<td>5.8</td>
<td></td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>92</td>
<td>9.52</td>
<td>Health centres: 11</td>
<td>0.11</td>
<td></td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>9</td>
<td>0.93</td>
<td>General/district hospitals: 74</td>
<td>0.74</td>
<td></td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>114</td>
<td>11.8</td>
<td>Specialized/regional/national hospitals: 11</td>
<td>0.11</td>
<td></td>
</tr>
<tr>
<td>Mammmograph:*</td>
<td>150</td>
<td>111.13</td>
<td>Estimation % of health facilities with none or very limited oxygen supply: n/a</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>59</td>
<td>6.11</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: —  Professionally trained biomedical/clinical engineers: No
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: https://ogyei.gov.hu/main_page/
Use of management software: Yes  Software name: CT-EcoSTAT.

Medical devices workforce

Density of medical doctors (per 10,000 population):* 34.08
Number of biomedical/clinical engineers professionals in the country: 400

Contacts

MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: pusztai@who.int

WHO Representative/WHO Liaison Officer:
Name: Dr. Ledia Lazeri
Email: lazeri@who.int

General comments (...Annex 1): Concerning the HT policies: “Safety and Partnership Program” - the health program adopted by the Hungarian government on July 9th, 2008 - the acceptance of medical devices and health technologies into the social insurance scheme was defined in the context of improvement of insurance tasks until 2010. Concerning the HT units section: it has been listed units that are subordinated bodies but not within the Ministry of Health. Therefore, we found it appropriate to mention them. Concerning the procurement of certain medical devices: it is performed centrally by the Central Services Directorate General of the Prime Minister’s Office. In the remaining cases, hospitals procure medical devices subject to itemized accounting individually and the National Health Insurance fund reimburses a certain level of the costs (see the list in the corresponding website, but with exception of pacemakers, heart valves, cochlear implants).

WHO European Region

www.who.int/healthsystems
Iceland

Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>341 (171)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>82.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>2</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>84</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>9.10%</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>— (—)</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank:</td>
<td>0.95 (0.89); very high</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>49.2 (21)</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>9 (1)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>38.10%</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

Specific lists comments (...Annex 1):

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Directorate of Health.
Website(s): http://www.landlaeknir.is/
Contact: Ms. Anna Björg Aradóttir Email: annabara@landlaeknir.is
Name(s) of other regulatory agency eg. for radiation equipment etc.: The Directorate of Health is the Competent Authority for Medical Devices.
Other agency’s website: https://www.ima.is/medical_devices

National regulatory comments (...Annex 1):
According to Directives 93/42, 90/385 and 98/79.

Approved devices lists comments (...Annex 1):
Only CE marked medical devices are approved.

Health care facilities lists comments (...Annex 1): —

Specific lists comments (...Annex 1): —

Committee includes a biomedical or clinical engineer: —

UHC - Service coverage index (1-100): 84
UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)
Global innovation index (rank): 49.2 (21)
ICT Development Index (rank): 9 (1)
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified  
Website: https://www.ima.is/medical_devices/about_medical_devices/

Medical device incorporation

Procurement
Policy or guideline: No  Website: — 
National level procurement: No  Website: — 
Donations
Policy or guideline: No  Website: — 

Technical specifications
Technical specifications to support procurement or donations: No  
Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>7</td>
<td>20.53</td>
<td>Health posts</td>
<td>57</td>
<td>17.3</td>
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<tr>
<td>Computerized Tomography Scanner</td>
<td>17</td>
<td>49.85</td>
<td>Health centres</td>
<td>6</td>
<td>1.82</td>
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<tr>
<td>Positron Emission Tomography Scanner</td>
<td>1</td>
<td>2.93</td>
<td>General/district hospitals</td>
<td>7</td>
<td>2.12</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>3</td>
<td>8.8</td>
<td>Specialized/regional/national hospitals</td>
<td>2</td>
<td>0.61</td>
</tr>
<tr>
<td>Mammograph,乳房扫描</td>
<td>6</td>
<td>149.7</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>3</td>
<td>8.8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes  
Unit/Department: —  Unit website: — 
Contact name: —  Contact email: — 
Website with publically available technical specifications: —  
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None  
Website: — 
Use of management software: Yes  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population):* 41.42  
Number of biomedical/clinical engineers professionals in the country: 56

Contacts

MOH focal point
Name: Mrs. Áslaug Einarsdóttir  
Department: Directorate of Legal Affairs, Ministry of Health  
Email: aslaug.einarsdottir@hbr.stjr.is  
Other country focal point
Name: —  Email: —

WHO health products focal point:
Name: —  Email: — 
WHO Representative/WHO Liaison Officer:
Name: —  Email: —

General comments (...Annex 1): —
India

Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Description</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Population 000s</td>
<td>1,380,004 (2)</td>
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</tr>
<tr>
<td>World Bank income group</td>
<td>Lower-Middle</td>
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</tr>
<tr>
<td>Life expectancy at birth (years)</td>
<td>F</td>
<td></td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%)</td>
<td>23.30%</td>
<td></td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank</td>
<td>0.65 (0.48): medium</td>
<td></td>
</tr>
<tr>
<td>ICT Development Index (rank)</td>
<td>3 (134)</td>
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</tr>
<tr>
<td>Under-five mortality (per 1000 live births)</td>
<td>34.3</td>
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</tr>
<tr>
<td>UHC - Service coverage index (1-100)</td>
<td>55</td>
<td></td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%)</td>
<td>17.3% (3.9%)</td>
<td></td>
</tr>
<tr>
<td>Global innovation index (rank)</td>
<td>35.6 (48)</td>
<td></td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports)</td>
<td>10.30%</td>
<td></td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: —

Policy is part of the National Health Program/Plan: —

Website: —

Language(s): —

MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: —

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: —

Website - hospitals: —

Website - IVD: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: —

Website: —

Approved devices lists comments (...Annex 1):

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes

Website(s): https://htain.icmr.org.in/; https://nhsrcindia.org/hc-technology

Contact: — Email: htain-dhr@nic.in

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

HTAIN performs the evaluation and appropriateness and the cost-effectiveness of the available and new health technologies. It includes interventions, drugs, and medical equipment. It has 12 research regional hubs and several technical partners around the country.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Central Drugs Standard Control Organization.

Website(s): https://cdsco.gov.in/opencms/opencms/en/Home/

Contact: Dr. V. G. Somani Email: dci@nb.nic.in

Name(s) of other regulatory agency eg. for radiation equipment etc.: Atomic Energy Regulatory Board (AERB)

Other agency’s website: https://www.aerb.gov.in/english/

National regulatory comments (...Annex 1):

Notified medical devices are regulated under the Drugs and Cosmetics Act and Rules under the 14 rule of medical devices as notified under the corresponding Act.
Medical device nomenclature system
Official nomenclature system for medical devices: No
Type: None
Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: —
Website: —
National level procurement: —
Website: —

Donations
Policy or guideline: —
Website: —

Technical specifications
Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility^</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
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<tr>
<td>Radiotherapy:*</td>
<td>979</td>
<td>0.71</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

^ Density per 1,000,000 females aged from 50-69 old.

Medical device incorporation comments (...Annex 1):

Medical device management unit
Unit present: —
Professionally trained biomedical/clinical engineers: —
Unit/Department: —
Unit website: —
Contact name: —
Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —
Website: —
Use of management software: —
Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population): 9.28
Number of biomedical/clinical engineers professionals in the country: 30000

Contacts
MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Roderico Ofrin
Email: ofrinr@who.int

General comments (...Annex 1): —

WHO South-East Asia Region

WHO health products focal point: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Roderico Ofrin
Email: ofrinr@who.int

General comments (...Annex 1): —
Indonesia

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>273,524 (4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>71.1</td>
</tr>
</tbody>
</table>

Health care facilities lists comments

We do not have lists for different diseases/situations, but we use WHO recommendations.

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: —
Language(s): Indonesian
MOH responsible for health technology policy implementation: a) Directorate of Production and Distribution of Medical Devices (DG of Pharma. and Med.Dev., MoH); b) Directorate of Basic Medical Services (DG of Medical Services, MoH).

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, Directorate of Basic Medical Services (DG of Medical Services, MoH).
Website(s): https://www.bpjsketenagakerjaan.go.id/; https://ppjk.kemkes.go.id/hta/profil-hta/
Contact: Dr. Anwarul Amin Email: hta_indonesia@yahoo.com
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
It has been started the development of HTA systems by establishing nodal agencies and conducting ad-hoc activities. Social Security Management Agency for the Health Sector (BPJS) is focus on HTA for health products. Komite Penilaian Teknologi Kesehatan (Komite PTK) performs economic HTA (not for medical equipment). HTA for medical equipment is rarely performed.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Ministry of health.
Website(s): https://www.kemkes.go.id/index.php?g=LN02
Contact: Ir Rosadi Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: National Nuclear Energy Agency of Indonesia.
Other agency’s website: http://www.batan.go.id/index.php/en/

National regulatory comments (...Annex 1):
—

Population 000s (rank): 273,524 (4)
Under-five mortality (per 1000 live births): 23.9
UHC - Service coverage index (1-100): 57
Probability of dying aged 30-70 yrs of NCDs (%): 26.40%
UHC - Population with household spending >10% (>25%) of corresponding income (%): 2.7% (0.5%)
Human Development Index (inequality adjusted HDI): 0.72 (0.59); high
Global innovation index (rank): 26.5 (85)
ICT Development Index (rank): 4.3 (111)
High-technology exports (% of manufacture exports): 7.60%

Approved devices lists comments (...Annex 1):
—

Health care facilities lists comments (...Annex 1):
—

Specific lists comments (...Annex 1):
—

Global innovation index (rank): 26.5 (85)
ICT Development Index (rank): 4.3 (111)
High-technology exports (% of manufacture exports): 7.60%
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Many co-existence of nomenclatures  Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: https://www.kemkes.go.id/index.php?id=LN02

Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts: 23163</td>
<td>9.27</td>
<td></td>
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<tr>
<td>Computerized Tomography Scanner</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres: 8548</td>
<td>3.42</td>
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<tr>
<td>Positron Emission Tomography Scanner</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals: 1079</td>
<td>0.43</td>
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<tr>
<td>Gamma camera or nuclear medicine</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals: n/a</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Mammograph</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply: n/a</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>81</td>
<td>0.3</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Inventories and medical equipment management software
Type of inventories available: None
Website: —
Use of management software: —  Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population):* 4.65
Number of biomedical/clinical engineers professionals in the country: 55

Contacts
MOH focal point
Name: Dr. T. Bahdar Johan Hamid
Department: DG of Pharmaceutical and Medical Devices, MoH
Email: bahdar2007@yahoo.com
Other country focal point
Name: —
Email: —

General comments (...Annex 1): —

Medical device nomenclature comments (...Annex 1): It is used a Harmonization System code (HS) at the moment. After harmonization GMDN will be used.

Medical device incorporation comments (...Annex 1): We follow the Presidential Decree No. 80 for general procurement. Both, yes and no. Yes, for vertical public hospitals, procurement conducted at national level. No, since re-centralization, procurement of medical devices at province/district’s hospital conducted at local level (province and district level); see yannah on the website.

Medical device incorporation comments (...Annex 1): We follow the Presidential Decree No. 80 for general procurement. Both, yes and no. Yes, for vertical public hospitals, procurement conducted at national level. No, since re-centralization, procurement of medical devices at province/district’s hospital conducted at local level (province and district level); see yannah on the website.

Software comments (...Annex 1): Inventories are still ongoing.

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Navaratnasamy Paranietharan
Email: paranietharann@who.int

General comments (...Annex 1): —

Indonesia
Iran (Islamic Republic of)

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>83,993 (18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
</tbody>
</table>

Life expectancy at birth (years): 83.7

Under-five mortality (per 1000 live births): 13.9

Probability of dying aged 30-70 yrs of NCDs (%): 14.80%

Human Development Index (inequality adjusted HDI): 0.78 (0.69): high

ICT Development Index (rank): 5.6 (81)

UHC - Service coverage index (1-100): 72

UHC - Population with household spending >10% (>25%) of corresponding income (%): 15.8% (3.8%)

Global innovation index (rank): 30.9 (67)

High-technology exports (% of manufacture exports): 0.80%

National policy on health technology

Health technology (medical device) national policy: —
Policy is part of the National Health Program/Plan: —
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: —
Unit: —
Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - IVD: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

Approved devices lists comments (...Annex 1): —

Health care facilities lists comments (...Annex 1): —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes

National unit/department that includes HTA for medical devices: Yes, HTA Office under supervision of Health Technology Assessment, Standardization and Tariffs Office (MOHME’s HTA Office).

Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (...Annex 1): The HTA office under the umbrella of the Ministry of Health and Education (MOHME) was established in 2008, it produces HTA over health products and medical equipment.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Food and Drug Administration of Iran.
Website(s): http://www.fda.gov.ir/
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: Atomic Energy Organization of Iran (AEOI).
Other agency's website: www.aeoi.org.ir; http://dotic.ir/

National regulatory comments (...Annex 1): —

Population 000s (rank): 83,993 (18)
World Bank income group: Upper-Middle

Life expectancy at birth (years): 83.7

Under-five mortality (per 1000 live births): 13.9
Probability of dying aged 30-70 yrs of NCDs (%): 14.80%
Human Development Index (inequality adjusted HDI): 0.78 (0.69): high
ICT Development Index (rank): 5.6 (81)
UHC - Service coverage index (1-100): 72
UHC - Population with household spending >10% (>25%) of corresponding income (%): 15.8% (3.8%)
Global innovation index (rank): 30.9 (67)
High-technology exports (% of manufacture exports): 0.80%
Medical device nomenclature system
Official nomenclature system for medical devices: — Type: — Use: —
Website: —

Medical device incorporation
Procurement
Policy or guideline: — Website: —
National level procurement: — Website: —
Donations
Policy or guideline: — Website: —

Technical specifications
Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>137</td>
<td>1.63</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —
Website: —
Use of management software: — Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population): ε 15.84
Number of biomedical/clinical engineers professionals in the country: γ <10

Contacts
MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Syed Jaffar Hussain
Email: hussains@who.int

General comments (...Annex 1): —
**Iraq**

### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>40,223 (36)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>71.1</td>
</tr>
</tbody>
</table>

### National policy on health technology

**Health technology (medical device) national policy:** No

**Policy is part of the National Health Program/Plan:** No

**Website:** —

**Language(s):** —

**MOH responsible for health technology policy implementation:** Department of Medical Equipment within the Directorate of Technical Affairs (MoH).

### National lists of medical devices

#### National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

- **Lists available:** Yes, but it is only a recommendation
- **Unit:** Technical Affairs (Department of Medical Equipment Management and Needs Assessment).
- **Website:** —

#### National list for different types of healthcare facilities (hospitals, laboratories, etc)

- **Lists available:** Yes
- **Website:** [https://2016.export.gov/industry/health/healthcareresourceguide/eg_main_116238.asp](https://2016.export.gov/industry/health/healthcareresourceguide/eg_main_116238.asp)
- **Website - IVD:** —

#### National list for specific clinical interventions/emergencies:

- **List available:** No
- **Website:** —

### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** Yes

**National unit/department that includes HTA for medical devices:** No

**Website(s):** [https://www.who.int/medicines/areas/coordination/Iraq_PSCPNarrativeQuestionnaire_O1022012.pdf](https://www.who.int/medicines/areas/coordination/Iraq_PSCPNarrativeQuestionnaire_O1022012.pdf)

**Contact:** Dr. Iman M. Hussein  
**Email:** consultivedep@yahoo.com

**Committee includes a biomedical or clinical engineer:** —

### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes

**Name of regulatory agency:** The State Company for Provision of Medicines and Medical Appliances (KIMADIA).

**Website(s):** [https://kimadia.iq/en](https://kimadia.iq/en)

**Contact:** —  
**Email:** —

**Name(s) of other regulatory agency eg. for radiation equipment etc.:** This Company (KIMADIA).

**Other agency’s website:** [https://rpc.gov.iq/](https://rpc.gov.iq/)

### Approved devices lists comments

(...Annex 1):

The lists of medical equipments have been announced on annual basis.

### Health care facilities lists comments

(...Annex 1):

—

### Specific lists comments

(...Annex 1):

—

### HTA unit comments

(...Annex 1):

It has been adopted the EMA (European Medicines Agency) and the ICH (International Council for Harmonisation for Pharmaceuticals) guidelines. Inspector General Office performs health economics HTA. Within the MoH, HTA is focused on pharmaceutics not in medical devices.

### National regulatory comments

(...Annex 1):

The company KIMADIA is responsible for the bulk purchase of medicines, drugs, medical supplies and equipment for whole Iraq on behalf of the MoH. The regulations are pertaining to the procurement aspects.

### Under-five mortality (per 1000 live births):

- **25.9**

### UHC - Service coverage index (1-100):

- **61**

### Probability of dying aged 30-70 yrs of NCDs (%):

- **21.30%**

### UHC - Population with household spending >10% (+25%) of corresponding income (%):

- **3.3% (0.4%)**

### Human Development Index (inequality adjusted HDI):

- **0.67 (0.54): medium**

### Global innovation index (rank):

- **— (—)**

### ICT Development Index (rank):

- **— (—)**

### High-technology exports (% of manufacture exports):

- **—**

### Under-five mortality (per 1000 live births):

- **25.9**

### UHC - Service coverage index (1-100):

- **61**

### Probability of dying aged 30-70 yrs of NCDs (%):

- **21.30%**

### UHC - Population with household spending >10% (+25%) of corresponding income (%):

- **3.3% (0.4%)**

### Human Development Index (inequality adjusted HDI):

- **0.67 (0.54): medium**

### Global innovation index (rank):

- **— (—)**

### ICT Development Index (rank):

- **— (—)**

### High-technology exports (% of manufacture exports):

- **—**

### Under-five mortality (per 1000 live births):

- **25.9**

### UHC - Service coverage index (1-100):

- **61**

### Probability of dying aged 30-70 yrs of NCDs (%):

- **21.30%**

### UHC - Population with household spending >10% (+25%) of corresponding income (%):

- **3.3% (0.4%)**

### Human Development Index (inequality adjusted HDI):

- **0.67 (0.54): medium**

### Global innovation index (rank):

- **— (—)**

### ICT Development Index (rank):

- **— (—)**

### High-technology exports (% of manufacture exports):

- **—**
Medical device nomenclature system

- Official nomenclature system for medical devices: No
- Type: None
- Use: Not specified

Website: https://kimadia.iq/en

Nomenclature comments (...Annex 1):
The MoH is working on adapting a national nomenclature system and linking it to the UMDNS.

Medical device incorporation

- Procurement
  - Policy or guideline: Yes
  - Website: —
  - National level procurement: Yes
  - Website: https://kimadia.iq/en

- Donations
  - Policy or guideline: No
  - Website: —

- Technical specifications
  - Technical specifications to support procurement or donations: Yes
  - Publically available: No
  - Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:α</td>
<td>55</td>
<td>1.63</td>
<td>Health posts:</td>
<td>2331</td>
<td>6.9</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:α</td>
<td>75</td>
<td>2.22</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:α</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:α</td>
<td>5</td>
<td>0.15</td>
<td>Specialized/regional/national hospitals:</td>
<td>61</td>
<td>0.18</td>
</tr>
<tr>
<td>Mammograph:α,β</td>
<td>49</td>
<td>35.43</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:β</td>
<td>19</td>
<td>0.47</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

- Unit present: Yes
- Professionally trained biomedical/clinical engineers: Yes

Unit/Department: State Company for Provision of Medicines and Medical Appliances (KIMADIA).
Website: —
Contact name: Eng. Kadhim D. Sharz
Contact email: kimadia_engineering@yahoo.com
Website with publically available technical specifications: —
Number of regional/state offices/units: 19

Software comments (...Annex 1):
The Ministry of Health at a central level keeps updated records on monthly basis for the functional status of the high-cost technologies. 2- World Health Organization is supporting the procurement of 3 CMMS (from GE - Asset Plus) for three Central Maintenance Repair shops in Baghdad, Erbil and AL-Muthanna Provinces. 3- The Inventories for 6 provinces out of 18 are completed and 6 provinces will be supported to carry out a functional inventory for their medical equipment during the current biennium 2010/11. Finally, MS Excel is been used at the hospitals where inventory was carried out.

Inventories and medical equipment management software

- Type of inventories available: National inventory for medical equipment
- Website: —
- Use of management software: Yes
- Software name: MS Excel

Medical devices workforce

- Density of medical doctors (per 10 000 population):* 7.08
- Number of biomedical/clinical engineers professionals in the country: —

Contacts

- MOH focal point
  - Name: —
  - Department: —
  - Email: —

- Other country focal point
  - Name: Eng. Kadhim D. Sharz
  - Email: kimadia_engineering@yahoo.com

WHO health products focal point:
- Name: Dr. Ezechiel Bisalinkumi
- Email: bisalinkumie@irq.emro.who.int

WHO Representative/WHO Liaison Officer:
- Name: Dr. Ahmed Zouiten
- Email: zouiten@who.int

General comments (...Annex 1): Data were obtained from the annual report from 2010, issued by the Department of Planning and Human Resource Development at the MoH Iraq.
## Ireland

### Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>4,938 (121)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>82.3</td>
</tr>
</tbody>
</table>

### National policy on health technology

**Health technology (medical device) national policy:** Yes

Policy is part of the National Health Program/Plan: No

Website: [https://www.hse.ie/eng/services/publications/corporate/medicaldevicesequipment.pdf](https://www.hse.ie/eng/services/publications/corporate/medicaldevicesequipment.pdf)

Language(s): —

MOH responsible for health technology policy implementation: This is a policy of the Health Service Executive (HSE).

### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**

Lists available: Yes

Unit: —

Website: [www.pcrs.ie](http://www.pcrs.ie)

Nomenclature systems used for devices and tests: —

**National list for different types of healthcare facilities (hospitals, laboratories, etc)**

Lists available: Yes

Website - hospitals: n/a

Website - IVD: n/a

Nomenclature systems used for devices and tests: GMDN.

**National list for specific clinical interventions/emergencies:**

Lists available: No

Website: —

Approved devices lists comments (...Annex 1):

There are also several National Framework Agreement contracts for the supply of medical devices and equipment. List of reimbursable devices from Primary Care Reimbursement Service (PCRS). List of reimbursable devices from PCRS is available at pcrs website under -> online services -> list of reimbursable items.

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):

### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** Yes

National unit/department that includes HTA for medical devices: Yes, the National Patient Safety Office, Department of Health.

Website(s): [https://www.hipa.ie/areas-we-work/health-technology-assessment](https://www.hipa.ie/areas-we-work/health-technology-assessment); [http://www.ncpe.ie](http://www.ncpe.ie)

Contact: Dr. Laura Dooley  Email: laura_dooley@health.gov.ie

Committee includes a biomedical or clinical engineer: No

HTA unit comments (...Annex 1):

Additional HTA contact: deirdre_o_halloran@health.gov.ie

### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes

Name of regulatory agency: Health Products Regulatory Authority (HPRA).

Website(s): [https://www.hpra.ie/](https://www.hpra.ie/); [http://www.imb.ie](http://www.imb.ie)

Contact: —  Email: devices@hpra.ie

Name(s) of other regulatory agency eg. for radiation equipment etc.: Ireland’s Health Services (HSE.ie) (Radiation Protection); Environmental Protection Agency (Radiation).


National regulatory comments (...Annex 1):

—
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Based on GMDN  Use: Not specified
Website: http://www.hpra.ie/homepage/medical-devices/medical-devices-information

Medical device incorporation

Procurement
Policy or guideline: Yes  Website: https://www.hse.ie/eng/about/who/healthbusinessservices/procurement/; http://www.hse.ie/eng/
National level procurement: Yes  Website: Health Service Executive (HSE) https://www.hse.ie/eng/about/who/healthbusinessservices/procurement/; https://www.hse.ie/eng/

Donations
Policy or guideline: Yes  Website: http://www.hse.ie

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>78</td>
<td>15.8</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>105</td>
<td>21.26</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>9</td>
<td>1.82</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>23</td>
<td>4.66</td>
</tr>
<tr>
<td>Mammograph</td>
<td>82</td>
<td>149.96</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>55</td>
<td>11.14</td>
</tr>
</tbody>
</table>

Healthcare facility

<table>
<thead>
<tr>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Health centres</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>General/district hospitals</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Estimation % of health facilities with none or very limited oxygen supply</td>
<td>n/a</td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Health Service Executive (HSE); Corporate Estates  Unit website: —
Contact name: Mr. Ger Flynn  Contact email: gerflynn@hse.ie
Website with publically available technical specifications: n/a
Number of regional/state offices/units: 7

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: Yes  Software name: No common software but a variety of systems including: HEX, SAP, MS Access....

Medical devices workforce

Density of medical doctors (per 10,000 population): 33.52
Number of biomedical/clinical engineers professionals in the country: 330

Contacts

MOH focal point
Name: Dr. Karen McNamara
Department: —
Email: Legislation.Units@health.gov.ie

Other country focal point
Name: Mr. Ger Flynn - National Clinical Head of Medical Devices, HSE
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liason Officer:
Name: —
Email: —

General comments: Concerning the Infrastructure section: the breakdown of infrastructures does not match to our public sector. We have 7 Hospital Groups.

Medical device incorporation comments (...Annex 1):

Portfolio & Category Management approach involves the development of medical devices/equipment procurement strategies at a national level and the facilitation of regional and local decision making consistent with these strategies and accompanying procedures. Go to the website and search for: services/Publications/corporate/procurementpolicy.pdf. Health Service Executive (HSE).

Medical equipment comments (...Annex 1):

There are no national inventories available to date. Inventories of medical equipment (including functional inventories) are maintained at a local level. Often there are separate asset management and medical equipment management inventories. There is an initiative to compile this data into regional/national inventories in the near future. There is no common software but a variety of systems are employed including HEX, SAP, MS Access....
Israel

Country indicators

Population 000s (rank): 8,656 (99)
World Bank income group: High

Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Year</th>
<th>Life expectancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990</td>
<td>75.3</td>
</tr>
<tr>
<td>2000</td>
<td>78.1</td>
</tr>
<tr>
<td>2010</td>
<td>82.7</td>
</tr>
<tr>
<td>2020</td>
<td>82.3</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 3.7
UHC - Service coverage index (1-100): 82

Probability of dying aged 30-70 yrs of NCDs (%): 9.60%
UHC - Population with household spending >10% (>25%) of corresponding income (%): 6.7% (1.0%)

Human Development Index (inequality adjusted HDI): 0.92 (0.81); very high
Global innovation index (rank): 53.5 (13)

ICT Development Index (rank): 7.9 (23)
High-technology exports (% of manufacture exports): 23.10%

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: —
Language(s): Hebrew
MOH responsible for health technology policy implementation: Medical Device Department within the Medical Technology Administration.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes
Unit: Medical Technology Administration.
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: Yes
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, Medical Devices Department and Medical Technology Division.
Website(s): https://www.health.gov.il/English/MinistryUnits/HealthDivision/MedicalTechnologies/MTPD/Pages/default.aspx;
http://www.gertnerinst.org.il/e/health_policy_e/technology
Contact: Dr. Nadav Sheffer Email: nadav.sheffer@moh.health.gov.il
Committee includes a biomedical or clinical engineer: —

HTA unit comments (Annex 1):
The HTA within the MoH, as well as research centers such as the Israeli Center for Technology Assessment in Health Care (ICTAHC).

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Medical Device Department.
Website(s): https://www.health.gov.il/English/MinistryUnits/HealthDivision/MedicalTechnologies/MLD/Pages/default.aspx
Contact: Mr. Nadav Sheffer Email: Nadav.sheffer@moh.health.gov.il
Name(s) of other regulatory agency eg. for radiation equipment etc.: Soreq Nuclear Research Center (SNRC).
Other agency’s website: http://soreq.gov.il/mmg/eng/Pages/Radiation-Safety.aspx

Approved devices lists comments (Annex 1):
List for procurement/reimbursement It is part of the National Insurance Law.

Health care facilities lists comments (Annex 1): —

Specific lists comments (Annex 1):
It is in the Israeli legislation.

National regulatory comments (Annex 1):
The HTA within the MoH, as well as research centers such as the Israeli Center for Technology Assessment in Health Care (ICTAHC).

Contact person: Avi Kravel within the Medical Devices department.

Under-five mortality (per 1000 live births): 3.7
UHC - Service coverage index (1-100): 82

Probability of dying aged 30-70 yrs of NCDs (%): 9.60%
UHC - Population with household spending >10% (>25%) of corresponding income (%): 6.7% (1.0%)

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Global innovation index (rank): 53.5 (13)

ICT Development Index (rank): 7.9 (23)
High-technology exports (% of manufacture exports): 23.10%
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Based on UMDNS  Use: Not specified
Website: https://www.health.gov.il/English/MinistryUnits/HealthDivision/MedicalTechnologies/MLD/Pages/Default.aspx

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: No  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical devices workforce
Density of medical doctors (per 10,000 population): a 54.67
Number of biomedical/clinical engineers professionals in the country: 2000

Contacts

MOH focal point
Name: Dr. Nadav Sheffer
Department: Medical Device Department (MoH)
Email: Nadav.Sheffer@moh.health.gov.il

Other country focal point
Name: Mr. Liron Zohar
Email: liron.zohar@moh.health.gov.il

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: —
Email: —

General comments (...Annex 1): All the divisions and departments mentioned in this survey are part of the Medical Technology Administration of the Ministry of Health in Israel. The Administration is in charge of the regulation, licencing and policy making regarding all medical technologies in Israel (including medical devices).
Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):*</th>
<th>60,462 (23)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>83.1</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 3.1 |
Probability of dying aged 30-70 yrs of NCDs (%): 9.50%
Human Development Index (inequality adjusted HDI): 0.89 (0.78); very high
ICT Development Index (rank): 7 (47)

UHC - Service coverage index (1-100): 82
UHC - Population with household spending >10% (>25%) of corresponding income (%): 9.3% (11%)
Global innovation index (rank): 45.7 (28)
High-technology exports (% of manufacture exports): 8.10%

National policy on health technology
Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: http://www.salute.gov.it/portale/home.html
Language(s): Italian and English
MOH responsible for health technology policy implementation: Directorate General of Medicines and Medical Devices, Department of Innovation, Ministry of Health.

National lists of medical devices
National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes
Unit: Direttore Generale di Programmazione
Nomenclature systems used for devices and tests:
National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - IVD: http://www.dati.salute.gov.it/dati/dettaglioDataset.jsp?menu=dati&idPag=1
Nomenclature systems used for devices and tests: —
National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Approved devices lists comments (...Annex 1):
Documents are available at the websites. Documents are often updated, and many of them under revision.

Health care facilities lists comments (...Annex 1): —
Specific lists comments (...Annex 1): —

National health technology assessment unit
Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, Directorate General for Medical Devices.
Contact: Dr. Giuseppe Ruocco Email: g.ruocco@sanita.it
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
Agenzia Nazionale per i Servizi Sanitari Regionali (AGENAS) performs HTA for medical devices, and Italian medicines agency (AIFA) mainly in pharmaceutics and related. HTA is also performed in research institutes such as PoliclinicoGemelli (last link).

National regulatory authority
Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Directorate General for Medical Devices, Pharmaceutical Services and Safety in Healthcare, Department of Planning and Organization of the National Health Service, Ministry of Health.
Website(s): http://www.salute.gov.it/portale/home.html
Contact: Ms. Marcella Marletta Email: m.marletta@sanita.it
Name(s) of other regulatory agency eg. for radiation equipment etc.: Italian National Agency for New Technologies, Energy and Sustainable Economic Development (IMRI); National Inspectorate for Nuclear Safety and Radiation Protection (ISIN).
Other agency’s website: https://www.inmri.enea.it/; https://www.isinucleare.it/en/about-us

Global innovation index (rank): 45.7 (28)
ICT Development Index (rank): 7 (47)
High-technology exports (% of manufacture exports): 8.10%
Medical device nomenclature system

Official nomenclature system for medical devices: Yes
Type: Based on EMDN
Use: For various purposes above-mentioned
Website: [http://www.salute.gov.it/ims/C_17_pagineAree_328_listaFile_itemName_15_file.pdf](http://www.salute.gov.it/ims/C_17_pagineAree_328_listaFile_itemName_15_file.pdf); [http://www.salute.gov.it/portale/temi/p2_3_dispositivi.html](http://www.salute.gov.it/portale/temi/p2_3_dispositivi.html)

Medical device incorporation

Procurement
Policy or guideline: Yes
Website: [http://www.salute.gov.it/portale/home.html](http://www.salute.gov.it/portale/home.html)
National level procurement: No
Website: [http://www.salute.gov.it/](http://www.salute.gov.it/)

Donations
Policy or guideline: No
Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: Yes

Medical equipment

Total | Density per 1,000,000 population | Healthcare facility | Total | Density per 100,000 population
--- | --- | --- | --- | ---
Magnetic Resonance Imaging\(^a\) | 1736 | 28.71 | Health posts: | n/a | n/a
Computerized Tomography Scanner\(^a\) | 2122 | 35.1 | Health centres: | n/a | n/a
Positron Emission Tomography Scanner\(^a\) | 210 | 3.47 | General/district hospitals: | 67 | 0.11
Gamma camera or nuclear medicine\(^a\) | 465 | 7.69 | Specialized/regional/national hospitals: | 84 | 0.14
Mammography\(^a\) | 2044 | 232.96 | Estimation % of health facilities with none or very limited oxygen supply: | n/a | —
Radiotherapy\(^b\) | 500 | 8.27 | — | — | —

\(^a\) Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes
Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Directorate General for Medical Devices,
Unit website: [http://www.salute.gov.it/portale/home.html](http://www.salute.gov.it/portale/home.html)
Contact name: Mr. Giuseppe Ruocco
Contact email: g.ruocco@sanita.it
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes
Software name: More than one.

Medical devices workforce

Density of medical doctors (per 10 000 population): 80.13
Number of biomedical/clinical engineers professionals in the country: 8477

Contacts

MOH focal point
Name: Dr. Giuseppe Ruocco
Department: Directorate General for Medical Devices, Pharmaceutical Services and Safety in Healthcare, Department of Planning and Organization of the National Health Service, Ministry of Health
Email: g.ruocco@sanita.it

Other country focal point
Name: —
Email: —

General comments (...Annex 1): —

—

WHO European Region

World Health Organization

A1B2 C3D4

Medical device nomenclature system

Official nomenclature system for medical devices: Yes
Type: Based on EMDN
Use: For various purposes above-mentioned
Website: [http://www.salute.gov.it/ims/C_17_pagineAree_328_listaFile_itemName_15_file.pdf](http://www.salute.gov.it/ims/C_17_pagineAree_328_listaFile_itemName_15_file.pdf); [http://www.salute.gov.it/portale/temi/p2_3_dispositivi.html](http://www.salute.gov.it/portale/temi/p2_3_dispositivi.html)

Medical device incorporation

Procurement
Policy or guideline: Yes
Website: [http://www.salute.gov.it/portale/home.html](http://www.salute.gov.it/portale/home.html)
National level procurement: No
Website: [http://www.salute.gov.it/](http://www.salute.gov.it/)

Donations
Policy or guideline: No
Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: Yes

Medical equipment

Total | Density per 1,000,000 population | Healthcare facility | Total | Density per 100,000 population
--- | --- | --- | --- | ---
Magnetic Resonance Imaging\(^a\) | 1736 | 28.71 | Health posts: | n/a | n/a
Computerized Tomography Scanner\(^a\) | 2122 | 35.1 | Health centres: | n/a | n/a
Positron Emission Tomography Scanner\(^a\) | 210 | 3.47 | General/district hospitals: | 67 | 0.11
Gamma camera or nuclear medicine\(^a\) | 465 | 7.69 | Specialized/regional/national hospitals: | 84 | 0.14
Mammography\(^a\) | 2044 | 232.96 | Estimation % of health facilities with none or very limited oxygen supply: | n/a | —
Radiotherapy\(^b\) | 500 | 8.27 | — | — | —

\(^a\) Density per 1,000,000 females aged from 50-69 old.

WHO European Region

World Health Organization

A1B2 C3D4
Jamaica

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):*</th>
<th>2,961 (135)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group</td>
<td>h Upper-Middle</td>
</tr>
</tbody>
</table>

Life expectancy at birth (years):*

- Jamaica: 74.3
- World: 73.0

Under-five mortality (per 1000 live births):* 13.9

Probability of dying aged 30-70 yrs of NCDs (%):* 14.70%

Human Development Index (inequality adjusted HDI): rank: 0.73 (0.61): high

ICT Development Index (rank): 4.8 (98)

Under-five mortality (per 1000 live births):* 13.9

Probability of dying aged 30-70 yrs of NCDs (%):* 14.70%

Human Development Index (inequality adjusted HDI): rank: 0.73 (0.61): high

ICT Development Index (rank): 4.8 (98)

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

MOH responsible for health technology policy implementation: —

Approved devices lists comments (...Annex 1):

- National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - IVD: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

Health care facilities lists comments (...Annex 1):

- Specific lists comments (...Annex 1):

Not available at present.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):* Yes

National unit/department that includes HTA for medical devices: No

Website(s): https://www.moh.gov.jm/

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

It exists the National Surveillance Unit within the MoH which performs HTA for medical products, but not specifically for medical equipment.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Hazardous Substances Regulatory Authority (HSRA), Caribbean Community, International Atomic Energy Agency.

Other agency’s website: https://www.miic.gov.jm/content/hazardous-substances-regulatory-authority-hsra

National regulatory comments (...Annex 1):

-
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified

Medical device incorporation
Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: —
Donations
Policy or guideline: No  Website: —
Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:</td>
<td>4 1.44</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:</td>
<td>4 1.44</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:</td>
<td>0 0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:</td>
<td>n/a n/a</td>
</tr>
<tr>
<td>Mammograph:</td>
<td>11 51.27</td>
</tr>
<tr>
<td>Radiotherapy:</td>
<td>7 2.36</td>
</tr>
</tbody>
</table>

Healthcare facility
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>n/a</td>
</tr>
<tr>
<td>Health centres:</td>
<td>n/a</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>11 0.4</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>2 0.07</td>
</tr>
<tr>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: —
Use of management software: —  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 4.55
Number of biomedical/clinical engineers professionals in the country: <10

Contacts
MOH focal point
Name: Mr. Garfield Prescod
Department: Health Facilities Maintenance Unit
Email: gmprescod@yahoo.com

Other country focal point
Name: Mr. Marlon Jones
Email: marloncurtis@hotmail.com

WHO health products focal point:
Name: —
Email: —

General comments (...Annex 1): Concerning the HT national policy is stated in the document Ritza 04.
Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>126,476 (11)</th>
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<tbody>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>93.5</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: —
Language(s): Japanese
MOH responsible for health technology policy implementation: Economic Affairs Division, Health Policy Bureau.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes
Unit: Medical Economics Division, Health Insurance Bureau.
Website: —
Nomenclature systems used for devices and tests: —
National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —
National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Approved devices lists comments (...Annex 1):
New medical devices which begin to be reimbursed have been published by the Central Social Insurance Medical Council.

Health care facilities lists comments (...Annex 1):
—

Specific lists comments (...Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, Office of Medical Device Evaluation, PFSB, MHLW.
Contact: Mr. Kentaro Azuma Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
There are a medical technology evaluation team, an expert committee for insurance care materials, an expert committee on drug prices (within the MoH: first link). Also, the National Institute of Public Health performs economic health evaluation (second link).

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau.
Website(s): https://www.mhlw.go.jp/index.html
Contact: Mr. Hirotada Nagai Email: nagai-hirotada@mhlw.go.jp
Name(s) of other regulatory agency eg. for radiation equipment etc.: Nuclear Regulation Authority (NRA JAPAN); Ministry of Economy, Trade and Industry (METI).

National regulatory comments (...Annex 1):
—
### Medical device nomenclature system

Official nomenclature system for medical devices: Yes  
Type: Based on GMDN  
Use: For regulatory purposes  
Website: [https://www.pmda.go.jp/english/index.html](https://www.pmda.go.jp/english/index.html)

Japanese Medical Device Nomenclature was developed from the GMDN 2003 version.

### Medical device incorporation

#### Procurement

Policy or guideline: No  
Website: —

National level procurement: No  
Website: —

#### Donations

Policy or guideline: No  
Website: —

#### Technical specifications

Technical specifications to support procurement or donations: No  
Publicly available: —  
Website: —

### Medical equipment

<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Health posts:</td>
<td></td>
<td>n/a n/a</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Health centres:</td>
<td></td>
<td>n/a n/a</td>
</tr>
<tr>
<td></td>
<td></td>
<td>General/district hospitals:</td>
<td>n/a n/a</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a n/a</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
</tbody>
</table>

Magnetic Resonance Imaging: 6996 55.31

Computerized Tomography Scanner: 14126 111.69

Positron Emission Tomography Scanner: 586 4.63

Gamma camera or nuclear medicine: 1455 11.5

Mammograph: 4348 267.44

Radiotherapy: 1278 10.1

* Density per 1,000,000 females aged from 50-69 old.

### Medical equipment management unit

Unit present: —  
Professionally trained biomedical/clinical engineers: No  
Unit/Department: —  
Website: —  
Contact name: —  
Contact email: —  
Website with publically available technical specifications: —  
Number of regional/state offices/units: 0

### Inventories and medical equipment management software

Type of inventories available: None  
Website: —  
Use of management software: No  
Software name: —

### Medical devices workforce

Density of medical doctors (per 10,000 population): 24.8

Number of biomedical/clinical engineers professionals in the country: 41000

### Contacts

**MOH focal point**

Name: —  
Department: —  
Email: —

**Other country focal point**

Name: —  
Email: —

WHO health products focal point:

Name: —  
Email: —

WHO Representative/WHO Liaison Officer:

Name: —  
Email: —

### General comments (...Annex 1):

—

### Medical device incorporation comments (...Annex 1):

—

### Software comments (...Annex 1):

—

### General comments (...Annex 1):

—

---

* Density per 1,000,000 females aged from 50-69 old.

---

Medical equipment T otal

Density per 1,000,000 population

Healthcare facility\(\alpha\)  
Total  
Density per 100,000 population

Magnetic Resonance Imaging: 6996 55.31

Computerized Tomography Scanner: 14126 111.69

Positron Emission Tomography Scanner: 586 4.63

Gamma camera or nuclear medicine: 1455 11.5

Mammograph: 4348 267.44

Radiotherapy: 1278 10.1

### Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>6996</td>
<td>55.31</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>14126</td>
<td>111.69</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>586</td>
<td>4.63</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>1455</td>
<td>11.5</td>
</tr>
<tr>
<td>Mammograph</td>
<td>4348</td>
<td>267.44</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>1278</td>
<td>10.1</td>
</tr>
</tbody>
</table>

### Medical equipment management unit

Unit present: —  
Professionally trained biomedical/clinical engineers: No  
Unit/Department: —  
Website: —  
Contact name: —  
Contact email: —  
Website with publically available technical specifications: —  
Number of regional/state offices/units: 0

### Inventories and medical equipment management software

Type of inventories available: None  
Website: —  
Use of management software: No  
Software name: —

### Medical devices workforce

Density of medical doctors (per 10,000 population): 24.8

Number of biomedical/clinical engineers professionals in the country: 41000

### Contacts

**MOH focal point**

Name: —  
Department: —  
Email: —

**Other country focal point**

Name: —  
Email: —

WHO health products focal point:

Name: —  
Email: —

WHO Representative/WHO Liaison Officer:

Name: —  
Email: —

### General comments (...Annex 1):

—

### Medical device incorporation comments (...Annex 1):

—

### Software comments (...Annex 1):

—

### General comments (...Annex 1):

—

---

* Density per 1,000,000 females aged from 50-69 old.
### Jordan

#### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>10,203 (87)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>69.2</td>
</tr>
</tbody>
</table>

| Under-five mortality (per 1000 live births): | 15.6 |
| Probability of dying aged 30-70 yrs of NCDs (%): | 19.20% |
| Human Development Index (inequality adjusted HDI): (rank): | 0.73 (0.62): high |
| ICT Development Index (rank): | 6 (70) |

| UHC - Service coverage index (1-100): | 76 |
| UHC - Population with household spending >10% (>25%) of corresponding income (%): | — (—) |
| Global innovation index (rank): | 27.8 (81) |
| High-technology exports (% of manufacture exports): | 1.40% |

#### Health technology (medical device) national policy

**Policy is part of the National Health Program/Plan:** Yes


**Language(s):** Arabic and English

**MOH responsible for health technology policy implementation:** Directorate of Biomedical Engineering.

#### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**

- **Lists available:** Yes
- **Unit:** Directorate of Biomedical Engineering / Department of Studies & Projects.
- **Website:** [http://dbe.gov.jo/](http://dbe.gov.jo/)
- **Nomenclature systems used for devices and tests:** UMDNS.

**National list for different types of healthcare facilities (hospitals, laboratories, etc):**

- **Lists available:** Yes
- **Website - hospitals:** —
- **Website - IVD:** —
- **Nomenclature systems used for devices and tests:** UMDNS.

**National list for specific clinical interventions/emergencies:**

- **Lists available:** Yes
- **Website:** —

#### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** Yes

**National unit/department that includes HTA for medical devices:** Yes, Directorate of Biomedical Engineering and the Study & Projects Department.


**Contact:** Eng. Mais Bny Sakher  Email: mais.banysakher@yahoo.com

**Committee includes a biomedical or clinical engineer:** Yes

#### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes

**Name of regulatory agency:** Jordan Food & Drug Administration.

**Website(s):** [http://www.jfda.jo/](http://www.jfda.jo/)

**Contact:** Dr. Mai Masadeh  Email: mai.masadeh@jfda.jo

**Name(s) of other regulatory agency eg. for radiation equipment etc.:** Jordan Atomic Energy Commission

**Other agency’s website:** [https://www.emrc.gov.jo/](https://www.emrc.gov.jo/)

#### Approved devices lists comments

(...Annex 1):

The list is not published. It is within the updated document of the study department.

#### Health care facilities lists comments

(...Annex 1): —

#### Specific lists comments

(...Annex 1):

We have a list but for a specific departments, it is not published. It is only updated and kept in the Study & Project Department. In the near future it will be published the Essential list at our website.

#### HTA unit comments

(...Annex 1):

Structured HTA capacity building is being developed and implemented in the Department of the Pharmacy Center for Drug Policy and Technology Assessment (CDPTA), King Hussein Cancer Center (third link). Jordan started a hospital-level HTA at King Hussein Cancer Center (KHCC). The CDPTA at KHCC is responsible for conducting HTAs, their assessments are appraised by the Pharmacy and Therapeutic (P&T) Committee and HTA results are currently utilized to support formulary listing decisions.

#### National regulatory comments

(...Annex 1):

It also exists the Energy & Minerals Regulatory Commission.
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Many co-existence of nomenclatures  Use: For various purposes above-mentioned
Website: http://www.jfda.jo/Default.aspx

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: http://dbe.gov.jo; http://gsd.gov.jo
National level procurement: Yes  Website: http://gsd.gov.jo
Donations
Policy or guideline: No  Website: —
Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No  Website: http://dbe.gov.jo

Medical equipment
<table>
<thead>
<tr>
<th>Total</th>
<th>Magnetic Resonance Imaging</th>
<th>Health posts:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>40</td>
<td>1500</td>
</tr>
<tr>
<td>Density per</td>
<td>3.92</td>
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<tr>
<td>1,000,000 population</td>
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<td>Total</td>
<td>Computerized Tomography Scanner</td>
<td>Health centres:</td>
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<tr>
<td></td>
<td>80</td>
<td>560</td>
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<tr>
<td>Density per</td>
<td>7.84</td>
<td>5.49</td>
</tr>
<tr>
<td>1,000,000 population</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>Positron Emission Tomography Scanner</td>
<td>General/district hospitals:</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>125</td>
</tr>
<tr>
<td>Density per</td>
<td>0.39</td>
<td>1.23</td>
</tr>
<tr>
<td>1,000,000 population</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>Gamma camera or nuclear medicine</td>
<td>Specialized/regional/national hospitals:</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td>Density per</td>
<td>1.18</td>
<td>0.11</td>
</tr>
<tr>
<td>1,000,000 population</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>Mammograph</td>
<td>Estimated % of health facilities with none or very limited oxygen supply:</td>
</tr>
<tr>
<td></td>
<td>85</td>
<td>129.07</td>
</tr>
<tr>
<td>Density per</td>
<td>129.07</td>
<td>5%</td>
</tr>
<tr>
<td>1,000,000 females aged from 50-69 old.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>Radiotherapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Density per</td>
<td>1.37</td>
<td></td>
</tr>
<tr>
<td>1,000,000 population</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Directorate Of Biomedical Engineering  Unit website: http://dbe.gov.jo
Contact name: Dr. Eng. Firas Abu Dalou  Contact email: dfiras70@yahoo.com
Website with publically available technical specifications: http://dbe.gov.jo/Pages/viewpage?pageID=61
Number of regional/state offices/units: 30

Inventories and medical equipment management software
Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: Yes  Software name: CMMS.

Medical devices workforce
Density of biomedical doctors (per 10 000 population): 23.24
Number of biomedical/clinical engineers professionals in the country: 3000

Contacts
MOH focal point
Name: Dr. Firas Abu Dalou
Department: Directorate Of Biomedical Engineering / MOH
Email: dfiras70@yahoo.com
Other country focal point
Name: —  Email: —

WHO health products focal point:
Name: Dr. Adi Nuseirat
Email: nuseirata@who.int

WHO Representative/WHO Liaison Officer:
Name: Dr. Jamela Saleh Mohamed Al-Raiby
Email: alraibyj@who.int

General comments (Annex 1): Concerning medical equipment management section: we have around 700 type medical equipment tech., spec., updated only in tenders are published; and we have 30 medical equipment, workshops MOH Hospitals.

Nomenclature comments (Annex 1):
We support the WHO to adopt a standard nomenclature for medical devices. We used a nomenclature based on UMDNS for management in the CMMS system, and the government procurement department uses UNSPSC nomenclature for procurement purposes.

Medical device incorporation comments (Annex 1):
The procurement is done at a national level by Ministry of Health. Some manufacturers have guidelines and technical specifications such as: ECRI, AAMI, HTM (See: http://dbe.gov.jo). Although the list is not published neither available online, it is within the updated document of the study department.

Software comments (Annex 1):
—

General comments (Annex 1): Concerning medical equipment management section: we have around 700 type medical equipment tech., spec., updated only in tenders are published; and we have 30 medical equipment, workshops MOH Hospitals.

Medical equipment incorporation comments (Annex 1):
The procurement is done at a national level by Ministry of Health. Some manufacturers have guidelines and technical specifications such as: ECRI, AAMI, HTM (See: http://dbe.gov.jo). Although the list is not published neither available online, it is within the updated document of the study department.

Software comments (Annex 1):
—

General comments (Annex 1): Concerning medical equipment management section: we have around 700 type medical equipment tech., spec., updated only in tenders are published; and we have 30 medical equipment, workshops MOH Hospitals.
Kazakhstan

Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population (000s) (rank):</td>
<td>18,777 (63)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.1</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: [https://www.gov.kz/memleket/entities/dsm?lang=en; http://adilet.zan.kz/eng/docs/K2000000360; https://www.ndda.kz/upload/736_%D0%9F%D1%80%D0%BD%D0%BA%D0%B0%D0%B7.docx](https://www.gov.kz/memleket/entities/dsm?lang=en; http://adilet.zan.kz/eng/docs/K2000000360; https://www.ndda.kz/upload/736_%D0%9F%D1%80%D0%BD%D0%BA%D0%B0%D0%B7.docx)
Language(s): Russian
MOH responsible for health technology policy implementation: Department of Medical and Pharmaceutical Activity Monitoring (MoH).

National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
Lists available: Yes, but it is only a recommendation
Unit: National Expertise Center of pharmaceuticals, medical devices and equipment (REM) within Republican state enterprise (RES).
Website: —
Nomenclature systems used for devices and tests: —

**National list for different types of healthcare facilities (hospitals, laboratories, etc)**
Lists available: —
Website - hospitals: [http://adilet.zan.kz/eng](http://adilet.zan.kz/eng)
Website - IVD: —
Nomenclature systems used for devices and tests: —

**National list for specific clinical interventions/emergencies:**
Lists available: Yes

National health technology assessment unit
Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, Republican Center for Health Development of the MoH: HTA department.
Contact: Ms. Tulegalieva A. G. Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority
Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Department of Medical and Pharmaceutical Activity Monitoring.
Contact: Mr. Baiserkin B.S. Email: b.baiserkin@mz.gov.kz
Name(s) of other regulatory agency eg. for radiation equipment etc.: Committee of atomic and energy supervision and control of the Ministry of Energy of the Republic of Kazakhstan.

Approved devices lists comments (Annex 1): For list of approved medical devices for procurement we have the Medical State Register of Lekarstvennyh.

Health care facilities lists comments (Annex 1): —

Specific lists comments (Annex 1): —

HTA unit comments (Annex 1): Additional HTA contact: Zaid Zholdassov: zholdassov_z@rcrz.kz. The HTA is focused on pharmaceutics, sometimes performed for medical devices.

Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: Not specified
Website: https://www.ndda.kz/category/nomenklatura_men_izd

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: https://www.ndda.kz/category/gos_zakup
Donations
Policy or guideline: No  Website: https://egov.kz/cms/en
Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: Yes
Website: https://www.gov.kz/memleket/entities/dsm?lang=en

Medical device incorporation comments (Annex I): The procurement is done at a national level with the register of procurement of medical equipment. We have the National Register of medical devices.

Medical equipment
<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>18</td>
<td>1.09</td>
<td>Health posts</td>
<td>3684</td>
<td>22.41</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>24</td>
<td>1.46</td>
<td>Health centres</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>1</td>
<td>0.06</td>
<td>General/district hospitals</td>
<td>327</td>
<td>1.99</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>1</td>
<td>0.06</td>
<td>Specialized/regional/national hospitals</td>
<td>27</td>
<td>0.16</td>
</tr>
<tr>
<td>Mammograph</td>
<td>34</td>
<td>22.1</td>
<td>Estimation % of health facilities with none or very limited oxygen supply</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>83</td>
<td>4.42</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

n/a not applicable/not available

Medical device incorporation comments (Annex I): The procurement is done at a national level with the register of procurement of medical equipment. We have the National Register of medical devices.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Contact name: Mr. Horoshash A. N.  Contact email: —
Website with publically available technical specifications: http://kmtlc.kz/ru/postavshchikam/trebovaniya-k-medicinskoy-tehnike1/
Number of regional/state offices/units: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 39.8
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: Mr. Horoshash A. N.
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Caroline Francoise Clarinval
Email: clarinvalc@who.int

Medical devices workforce comments (Annex I): Concerning the Infrastructure section: the division for 20 beds on health centres is not applicable for the Kazakhstan centres network.

General comments (Annex I): Concerning the Infrastructure section: the division for 20 beds on health centres is not applicable for the Kazakhstan centres network.

Kenya

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank)</th>
<th>53,771 (27)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years)</td>
<td>66.2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births)</th>
<th>43.2</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Service coverage index (1-100)</td>
<td>55</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%)</td>
<td>13.40%</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%)</td>
<td>5.4% (1.5%)</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank</td>
<td>0.6 (0.44): medium</td>
</tr>
<tr>
<td>Global innovation index (rank)</td>
<td>26.1 (86)</td>
</tr>
<tr>
<td>ICT Development Index (rank)</td>
<td>2.9 (138)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports)</td>
<td>4.60%</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: — Language(s): — MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes, but it is only a recommendation
Unit: Biomedical Engineering Department.
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: — Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: Yes
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: No
Website(s): — Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
The development of HTA framework for health products is in progress.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: —
Website(s): Kenya Pharmacy and Poisons Board
Contact: Dr. Fred Siyoi Email: fmsiyoi@gmail.com
Name(s) of other regulatory agency eg. for radiation equipment etc.: The Radiation Protection Board (RPB)

Approved devices lists comments (...Annex 1):
Lists are developed locally and available in hard copy only. Lists for procedures only cover surgical procedures.

Health care facilities lists comments (...Annex 1):
—

Specific lists comments (...Annex 1):
It only covers surgical procedures which are locally developed. No available.

National regulatory comments (...Annex 1):
Kenya has demonstrated its commitment to improve the national legal and regulatory framework for radiation safety. Currently, The Radiation Protection Board (RPB) regulates such activities in Kenya, including those with sealed and unsealed radioactive sources as well as X-ray and other radiation-emitting devices.
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Based on GMDN  Use: For regulatory purposes
Website: https://www.gmdnagency.org

Nomenclature comments (...Annex 1): The GMDN is used for regulatory purposes.

Medical device incorporation

Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: http://www.kemsa.co.ke/

Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>7</td>
<td>0.16</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>11</td>
<td>0.25</td>
</tr>
<tr>
<td>Postron Emission Tomography Scanner</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>2</td>
<td>0.05</td>
</tr>
<tr>
<td>Mammograph</td>
<td>12</td>
<td>6.82</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>17</td>
<td>0.32</td>
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</table>

Healthcare facility

<table>
<thead>
<tr>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts</td>
<td>3350</td>
<td>7.55</td>
</tr>
<tr>
<td>Health centres</td>
<td>2655</td>
<td>5.99</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>627</td>
<td>1.41</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>7</td>
<td>0.02</td>
</tr>
<tr>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Biomedical Engineering Division.  Unit website: —
Contact name: Mr. Martin Owino  Contact email: Martin.owino@yahoo.com
Website with publically available technical specifications: —
Number of regional/state offices/units: 8

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): 1.57
Number of biomedical/clinical engineers professionals in the country: 50

Contacts

MOH focal point
Name: Mr. Martin Owino
Department: Head Biomedical Engineering and Maintenance Services Department (Ministry of Medical Services)
Email: martin.owino@yahoo.com

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: Dr. Regina Mbinydo
Email: mbindyor@who.int

WHO Representative/WHO Liaison Officer:
Name: Dr. Rudi Eggers
Email: eggersr@who.int

General comments (...Annex 1): The corresponding technical specifications, as well as donation guidelines are available upon request in soft copy (not pdf versions).
Kiribati

**Country indicators**

<table>
<thead>
<tr>
<th>Population 000s (rank):a</th>
<th>119 (177)</th>
<th>World Bank income group:b</th>
<th>Lower-Middle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Life expectancy at birth (years):c</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births):c</td>
<td>50.9</td>
<td>UHC - Service coverage index (1-100):c</td>
<td>41</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):c</td>
<td>28.40%</td>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):c</td>
<td>— (—)</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank:d</td>
<td>0.63 (0.52); medium</td>
<td>Global innovation index (rank):c</td>
<td>— (—)</td>
</tr>
<tr>
<td>ICT Development Index (rank):c</td>
<td>2.2 (154)</td>
<td>High-technology exports (% of manufacture exports):c</td>
<td>—</td>
</tr>
</tbody>
</table>

**National policy on health technology**

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

**National lists of medical devices**

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
- Lists available: Yes
- Unit: Tungaru Central Hospital, Medical and Pharmacy Stores
- Website: —
- Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
- Lists available: No
- Website - hospitals: —
- Website - IVD: —
- Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
- Lists available: Yes
- Website: —

**National health technology assessment unit**

Designated unit/department for health technology assessment (HTA):d No
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

**National regulatory authority**

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

Approved devices lists comments (...Annex 1):
We do not have a standard list in place but we do overseas and local procurement for specific medical devices needed for MoH; e.g., in 2009 overseas procurement for medical devices was made through medical healthcare prioritization according to doctors and head nurses. The selection and orders of medical devices were made to medical suppliers (such as South Austral and Braun) taking into account quality, affordability and critical need to meet quality health care services and patient’s safety and satisfaction.

Health care facilities lists comments (...Annex 1):
—

Specific lists comments (...Annex 1):
We do not have a standard list in place but we do overseas and local procurement for specific medical devices needed for MoH; e.g., in 2009 overseas procurement for medical devices was made through medical healthcare prioritization according to doctors and head nurses. The selection and orders of medical devices were made to medical suppliers (such as South Austral and Braun) taking into account quality, affordability and critical need to meet quality health care services and patient’s safety and satisfaction. In 2010 (8/3/2010) we received some medical devices.

Kiribati outbreak manual for public health nurses and curative: national pandemic guidelines, national disaster guideline.

HTA unit comments (...Annex 1):
—

National regulatory comments (...Annex 1):
—
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:</td>
<td>0</td>
<td>0</td>
<td>Health posts:</td>
<td>85</td>
<td>83.05</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:</td>
<td>0</td>
<td>0</td>
<td>Health centres:</td>
<td>144</td>
<td>140.69</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mammograph:</td>
<td>0</td>
<td>0</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

α Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population): 2.04
Number of biomedical/clinical engineers professionals in the country: <10

Contacts
MOH focal point
Name: Ms. Akineti Bauro
Department: Tungaru Central Hospital
Email: bauroakineti@yahoo.com

Other country focal point
Name: Dr. Teatao Tiira
Email: —

WHO health products focal point:
Name: —
Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Wendy Dawn Snowdon
Email: snowdonw@who.int

General comments (Annex 1): Medical devices components such as tools, knowledge, skills, repair and maintenance are very crucial and essential therefore Kiribati is very fortunate to be part of this surveillance thus is the only way to maintain our QA/QI (quality assurance and quality improvement) to achieve MoH objectives (utilization of quality medical/nursing care to all Kiribati individual patient/client to provide patient’s safety, quality health care services and patient’ satisfaction). We would appreciate being advised in ongoing training especially for nurses.
Kuwait

Country indicators

Population 000s (rank): 4,271 (126)
World Bank income group: High

Life expectancy at birth (years): 75.1

Under-five mortality (per 1000 live births): 7.9
UHC - Service coverage index (1-100): 76

Probability of dying aged 30-70 yrs of NCDs (%): 17.40%
UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)

Human Development Index (rank): 0.81 (—); very high
Global innovation index (rank): 28.4 (78)

ICT Development Index (rank): 6 (71)
High-technology exports (% of manufacture exports): 0.90%

National policy on health technology

Health technology (medical device) national policy: —
Policy is part of the National Health Program/Plan: —
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: —
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (Annex 1):
It has been started the institutionalizing of HTA within the MoH, with activities such as the building capacity.

National regulatory authority

Presence of national authority responsible for regulating medical devices: —
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: https://www.iaea.org/newscenter/news/iaea-assists-efforts-to-strengthen-kuwait’s-legal-framework

Approved devices lists comments (Annex 1):

Health care facilities lists comments (Annex 1):

Specific lists comments (Annex 1):

Native regulatory comments (Annex 1):
Medical device nomenclature system
Official nomenclature system for medical devices: — Type: — Use: — Website: —

Medical device incorporation
Procurement
Policy or guideline: — Website: —
National level procurement: — Website: —
Donations
Policy or guideline: — Website: —

Technical specifications
Technical specifications to support procurement or donations: — Publically available: — Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>6</td>
<td>1.4</td>
<td>—</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —
Website: —
Use of management software: — Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): * 26.46
Number of biomedical/clinical engineers professionals in the country: γ <10

Contacts
MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Assad Hafeez
Email: hafeeza@who.int

General comments (...Annex 1): —
# Kyrgyzstan

## Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>6,524 (109)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.1</td>
</tr>
</tbody>
</table>

## Health technology policy

**Policy**
- National policy: Yes
- Policy is part of the National Health Program/Plan: Yes

**Website**
- [http://www.pharm.kg/ru/live_important/](http://www.pharm.kg/ru/live_important/)
- [http://www.pharm.kg/upload/LAW%20on%20Health%20Protection%20in%20KG.doc](http://www.pharm.kg/upload/LAW%20on%20Health%20Protection%20in%20KG.doc)

**Language(s):** Russian

**MOH responsible for health technology policy implementation:** Department of Medicines and Medical Devices under Ministry of Health of the Kyrgyz Republic.

## National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
- Lists available: Yes
- Unit: Ministry of Health.
- Website: [www.med.kg](http://www.med.kg); [http://www.pharm.kg/](http://www.pharm.kg/)
- Nomenclature systems used for devices and tests: GMDN.

**National list for different types of healthcare facilities (hospitals, laboratories, etc):**
- Lists available: Yes
- Website - hospitals: [http://www.pharm.kg/ru/medicalequipment/](http://www.pharm.kg/ru/medicalequipment/)
- Website - IVD: [http://212.112.103.101/reestr](http://212.112.103.101/reestr)

**Nomenclature systems used for devices and tests:** —

**National list for specific clinical interventions/emergencies:**
- Lists available: Yes
- Website: [http://www.pharm.kg/ru/live_important/](http://www.pharm.kg/ru/live_important/)

## National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** Yes

**National unit/department that includes HTA for medical devices:** Yes, Department of Medicines and Medical Devices under Ministry of Health of the Kyrgyz Republic.

**Website(s):** [http://www.pharm.kg/ru/live_important/](http://www.pharm.kg/ru/live_important/)

**Contact:** Ms. Ainura Abalieva  Email: abalieva-a@yandex.ru

**Committee includes a biomedical or clinical engineer:** —

## National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes

**Name of regulatory agency:** Department of Medicines and Medical Devices under Ministry of Health of the Kyrgyz Republic.


**Contact:** Ms. Ainura Abalieva  Email: abalieva-a@yandex.ru

**Name(s) of other regulatory agency eg. for radiation equipment etc.:** National Institute of Standardization and Metrology.

**Other agency’s website:** [http://www.nism.gov.kg/](http://www.nism.gov.kg/)

## Approved devices lists comments

(...Annex 1):
- Standards: The law on the Health Care institutions. We have lists for communicable diseases, and public health emergency situations, as well as clinical protocols. The register of registered medical equipment is made at the website of the Department of Drug Provision and Medical Equipment MoH of the Kyrgyz Republic.

## Health care facilities lists comments

(...Annex 1):
- Equipment timesheets are available, but without the use of nomenclature.

## Specific lists comments

(...Annex 1):
- Clinical protocols.

## HTA unit comments

(...Annex 1):
- —

## National regulatory comments

(...Annex 1):
- —

## Under-five mortality (per 1000 live births): 18.3

## UHC - Service coverage index (1-100): 70

## Probability of dying aged 30-70 yrs of NCDs (%): 24.90%

## UHC - Population with household spending >10% (>25%) of corresponding income (%): 3.5% (0.7%)

## Human Development Index (inequality adjusted HDI): rank: 0.7 (0.63): medium

## Global innovation index (rank): 24.5 (94)

## ICT Development Index (rank): 4.4 (109)

## High-technology exports (% of manufacture exports): 6.80%

## Population 000s (rank):

<table>
<thead>
<tr>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>109</td>
</tr>
</tbody>
</table>

## World Bank income group:

<table>
<thead>
<tr>
<th>Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower-Middle</td>
</tr>
</tbody>
</table>

## Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020</td>
</tr>
<tr>
<td>2030</td>
</tr>
<tr>
<td>2040</td>
</tr>
<tr>
<td>2050</td>
</tr>
</tbody>
</table>

## UHC - Service coverage index (1-100):

<table>
<thead>
<tr>
<th>Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>70</td>
</tr>
</tbody>
</table>

## Probability of dying aged 30-70 yrs of NCDs (%):

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<thead>
<tr>
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## Human Development Index (inequality adjusted HDI): rank:

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<th>Rank</th>
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<td>0.7 (0.63): medium</td>
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## Global innovation index (rank):

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## High-technology exports (% of manufacture exports):

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## Population 000s (rank):

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## World Bank income group:

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## Global innovation index (rank):

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## ICT Development Index (rank):

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</table>

## High-technology exports (% of manufacture exports):

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<tr>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.80%</td>
</tr>
</tbody>
</table>
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Based on GMDN  Use: For various purposes above-mentioned

Nomenclature comments (...Annex 1):
The nomenclature is used for various purposes: regulation, procurement, in-vitro diagnostics lists and inventory.

Medical device incorporation comments (...Annex 1):
Kyrghyz Republic National Health Care Reform Program "Manas taalimi". Procurements are carry out through the National (budget) or donor projects.

Medical device incorporation
National level procurement: Yes  Website: http://zakupka.med.kg/ru/; http://www.med.kg/
Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: No
Website: No

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>5</td>
<td>0.77</td>
<td>Health posts:</td>
<td>1648</td>
<td>25.26</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>13</td>
<td>1.99</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>99</td>
<td>1.52</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>4</td>
<td>0.61</td>
<td>Specialized/regional/national hospitals:</td>
<td>39</td>
<td>0.6</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>6</td>
<td>11.72</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>n/a</td>
<td>0.46</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical device incorporation comments (...Annex 1):
Kyrghyz Republic National Health Care Reform Program "Manas taalimi". Procurements are carry out through the National (budget) or donor projects.

Medical equipment management unit
Unit present: No  Professionally trained biomedical/clinical engineers: No
Contact name: Ms. Dinara Sagynbaeva  Contact email: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: http://www.pharm.kg
Use of management software: Yes  Software name: Nationally developed database for material and technical facilities/medical facilities of public health institutions.

Medical devices workforce
Density of medical doctors (per 10,000 population): * 22.13
Number of biomedical/clinical engineers professionals in the country:* <10

Contacts
MOH focal point
Name: Ms. Ainura Abalieva
Department: Department of Medicines and Medical Devices under Ministry of Health of the Kyrgyz Republic
Email: abalieva-a@yandex.ru
Other country focal point
Name: Ms. Larisa Kachybekova
Email: —

WHO health products focal point:
Name: Ms. Saltanat Moldoisaeva
Email: moldoisaevas@who.int
WHO Representative/WHO Liaison Officer:
Name: Dr. Nazira Poolatovna Artykova.
Email: artykovan@who.int

General comments (...Annex 1): —

Software comments (...Annex 1):
The National Register for Medical Equipment and the National Functional Register for Medical Equipment. The National Functional Register for the Medical Equipment is a database for medical facilities of the public health institutions; meanwhile, the National Register of the Medical Equipment is a national list of pharmaceuticals and medical equipment authorized and registered for utilization in the Kyrgyz Republic. A database is employed for material and technical facilities and medical facilities of public health institutions.

Medical devices workforce
Density of medical doctors (per 10,000 population): * 22.13
Number of biomedical/clinical engineers professionals in the country:* <10

Contacts
MOH focal point
Name: Ms. Ainura Abalieva
Department: Department of Medicines and Medical Devices under Ministry of Health of the Kyrgyz Republic
Email: abalieva-a@yandex.ru
Other country focal point
Name: Ms. Larisa Kachybekova
Email: —

WHO health products focal point:
Name: Ms. Saltanat Moldoisaeva
Email: moldoisaevas@who.int
WHO Representative/WHO Liaison Officer:
Name: Dr. Nazira Poolatovna Artykova.
Email: artykovan@who.int

General comments (...Annex 1): —
### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank): 7,276 (103)</th>
<th>Under-five mortality (per 1000 live births): 45.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group: Lower-Middle</td>
<td>UHC - Service coverage index (1-100): 51</td>
</tr>
<tr>
<td>Life expectancy at birth (years): 62.1</td>
<td>Probability of dying aged 30-70 yrs of NCDs (%): 27.00%</td>
</tr>
<tr>
<td></td>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%): — (—)</td>
</tr>
<tr>
<td></td>
<td>Human Development Index (inequality adjusted HDI): 0.61 (0.46): medium</td>
</tr>
<tr>
<td></td>
<td>Global innovation index (rank): 20.6 (113)</td>
</tr>
<tr>
<td></td>
<td>ICT Development Index (rank): 2.9 (139)</td>
</tr>
<tr>
<td></td>
<td>High-technology exports (% of manufacture exports): 20.60%</td>
</tr>
</tbody>
</table>

### National policy on health technology

- **Health technology (medical device) national policy:** Yes
- **Policy is part of the National Health Program/Plan:** Yes
- **Website:** —
- **Language(s):** Lao and English
- **MOH responsible for health technology policy implementation:** Medical Products Supply Center.

### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: No
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —

- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - Lists available: Yes
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

- **National list for specific clinical interventions/emergencies:**
  - Lists available: No
  - Website: —

### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):** No
- **National unit/department that includes HTA for medical devices:** No
- **Website(s):** —
- **Contact:** Email: —
- **Committee includes a biomedical or clinical engineer:** —

### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** Yes
- **Name of regulatory agency:** Food and Drug Department
- **Website(s):** [https://moh.gov.la/](https://moh.gov.la/)
- **Contact:** Dr. Somthavy Changvisommit Email: csomthavy_fdd@yahoo.com
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** Health Care Department.

---

**Approved devices lists comments (...Annex 1):** —

**Health care facilities lists comments (...Annex 1):** —

**Specific lists comments (...Annex 1):** —

**HTA unit comments (...Annex 1):** It has been started the development of HTA systems by establishing nodal agencies and conducting ad-hoc activities. There are identified HTA activities but not national unit. The creation of a national health insurance authority towards the UHC goal is in progress.

**National regulatory comments (...Annex 1):** There is the political will to strengthen the Nuclear and radiation safety and security, as well as the corresponding legal framework (as seen in the 2020-2025 plan).
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Based on UMDNS
Use: Not specified
Website: http://www.fdd.gov.la/index_en.php

Medical device incorporation

Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>0</td>
<td>0</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>5</td>
<td>0.74</td>
<td>Health centres:</td>
<td>877</td>
<td>12.95</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>129</td>
<td>1.91</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>7</td>
<td>0.1</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>0</td>
<td>0</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>2</td>
<td>0.27</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Health Care Department.  Unit website: —
Contact name: Dr. Chanhphomma Vongsamphanh  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes  Software name: PLAMAHS.

Medical devices workforce

Density of medical doctors (per 10 000 population):* 3.73
Number of biomedical/clinical engineers professionals in the country:* <10

Contacts

<table>
<thead>
<tr>
<th>MOH focal point</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: Mr. Thanom Insal</td>
<td>Department: Medical Products Supply Center, MoH</td>
<td>Email: <a href="mailto:mpsc@laotel.com">mpsc@laotel.com</a></td>
</tr>
<tr>
<td>Other country focal point</td>
<td>Name: Dr. Chanhphomma Vongsamphanh</td>
<td>Email: —</td>
</tr>
</tbody>
</table>

General comments (…Annex 1): —
### Country indicators

<table>
<thead>
<tr>
<th></th>
<th>Latvia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population ≥800s (rank)</td>
<td>1,886 (147)</td>
</tr>
<tr>
<td>World Bank income group</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years)</td>
<td>75.1</td>
</tr>
<tr>
<td></td>
<td>72.3</td>
</tr>
</tbody>
</table>

### National policy on health technology

- **Health technology (medical device) national policy:** Yes
- **Website:** [https://likumi.lv/](https://likumi.lv/)
- **Language(s):** Latvian
- **MOH responsible for health technology policy implementation:** Regulation of Cabinet of Ministers No. 581 (adopted 02.08.2005).

### National lists of medical devices

#### National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
- **Lists available:** No
- **Website:** —
- **Nomenclature systems used for devices and tests:** —

#### National list for different types of healthcare facilities (hospitals, laboratories, etc)
- **Lists available:** Yes
- **Website - hospitals:** [http://www.pharm.kg/ru/live_important/](http://www.pharm.kg/ru/live_important/)
- **Nomenclature systems used for devices and tests:** —

#### National list for specific clinical interventions/emergencies:
- **Lists available:** Yes

### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):** Yes
- **Contact:** Ms. Daiga Behmane  Email: daiga.lagzdina@zva.gov.lv
- **Committee includes a biomedical or clinical engineer:** —

### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** Yes
- **Name of regulatory agency:** State Agency of Medicines.
- **Website(s):** [http://www.zva.gov.lv](http://www.zva.gov.lv)
- **Contact:** Ms. Daiga Lagzdina  Email: daiga.lagzdina@zva.gov.lv
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** —
- **Other agency’s website:** [https://www.vvd.gov.lv/lv/pakalpojumi/darbibas-ar-jonizējošā-starojuma-avotiem](https://www.vvd.gov.lv/lv/pakalpojumi/darbibas-ar-jonizējošā-starojuma-avotiem)
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Based on GMDN  Use: Not specified
Website: http://www.zva.gov.lv; https://www.gmdnagency.org/

Medical device incorporation
Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: https://www.zva.gov.lv/
Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>26</td>
<td>13.79</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>74</td>
<td>39.24</td>
<td>Health centres:</td>
<td>31</td>
<td>1.51</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>2</td>
<td>1.06</td>
<td>General/district hospitals:</td>
<td>10</td>
<td>0.49</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>7</td>
<td>3.71</td>
<td>Specialized/regional/national hospitals:</td>
<td>15</td>
<td>0.73</td>
</tr>
<tr>
<td>Mammograph</td>
<td>51</td>
<td>177.83</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>12</td>
<td>6.36</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Centre of Health Economics  Unit website: https://www.wvmvd.gov.lv/en
Contact name: Ms. Iveta Gavare  Contact email: iveta.gavare@vec.gov.lv
Website with publically available technical specifications: https://likumi.lv/ta/id/295401-medicinisko-iericu-registracijas-atbilstibas-novertesanas-izplatīšanas-ekspļūšanas-un-techniskas-uzraudzības-kartiba
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: None
Website: —
Use of management software: —  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population):* 33.02
Number of biomedical/clinical engineers professionals in the country: 220

Contacts
MOH focal point
Name: —
Department: —
Email: —
Other country focal point
Name: Ms. Iveta Gavare
Email: iveta.gavare@vec.gov.lv

WHO health products focal point:
Name: —
Email: —
WHO Representative/WHO Liason Officer:
Name: Dr. Ulidis Mitenbergs
Email: umitenbergs@who.int

General comments (...Annex 1): —

a  UN POP/WPP 2019 (2020 POP)
b  WB FY21 2019
c  UN POP/WPP 2019 (1990-2020 MOR)
d  WHO GHO 2019
e  WHO GHO 2016
f  UNDP 2019
g  ITU 2017
h  WHO GHO 2017
i  WHO GHO 2010-2018
j  WIPO 2020
k  UN and WB 2017-2019
m  Latest (2013-2021): WHO GHO/2021 survey

* Density per 1,000,000 females aged from 50-69 old.
Lebanon

Country indicators

<table>
<thead>
<tr>
<th>Population (000s, rank)</th>
<th>6,825 (107)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years)</td>
<td>78.8</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births) | 7.2 |
Probability of dying aged 30-70 yrs of NCDs (%) | 17.90% |
Human Development Index (inequality adjusted HDI): rank | 0.74 (—): high |
ICT Development Index (rank) | 6.3 (64) |

UHC - Service coverage index (1-100) | 73 |
UHC - Population with household spending >10% (>25%) of corresponding income (%) | — (—) |
Global innovation index (rank) | 26 (87) |
High-technology exports (% of manufacture exports) | 2.40% |

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: No, Projects and Health Programs.
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

The HTA is at initial stages to inform health policy and products. National strategy will incorporate several actors: MoH, National Social Security Funds, General Security, etc.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Ministry of Public Health.
Website(s): http://www.moph.gov.lb/
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: National Council for Atomic Energy.

National regulatory comments (...Annex 1):

It controls the importation of all radiological devices (x-ray devices, tracers for nuclear medicine, etc.).
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified


Nomenclature comments (...Annex 1):

The Ministry of Health is planning to acquire the Global Medical Devices Nomenclature system to adopt it and use it for regulatory and procurement purposes.

Medical device incorporation

Procurement

Policy or guideline: No  Website: —
National level procurement: No  Website: —

Donations

Policy or guideline: No  Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes
Publically available: No  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Equipment Type</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>40</td>
<td>8.3</td>
<td>Health posts:</td>
<td>118</td>
<td>2.45</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>121</td>
<td>25.09</td>
<td>Health centres:</td>
<td>3</td>
<td>0.06</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner*:</td>
<td>6</td>
<td>1.24</td>
<td>General/district hospitals:</td>
<td>37</td>
<td>0.77</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>1</td>
<td>0.21</td>
<td>Specialized/regional/national hospitals:</td>
<td>32</td>
<td>0.66</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>131</td>
<td>370.23</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>24</td>
<td>3.52</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*a Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Projects & Health Programs  Unit website: —
Contact name: Ms. Sizar Akoum  Contact email: sizarak@hotmail.com

Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners).

Website: —
Use of management software: —  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): 21.04
Number of biomedical/clinical engineers professionals in the country: 750

Contacts

MOH focal point
Name: Ms. Sizar Akoum  Contact email: sizarak@hotmail.com

WHO health products focal point:
Name: Dr. Alissar Rady  Email: radya@who.int

WHO Representative/WHO Liaison Officer:
Name: Dr. Iman Shankiti  Email: shankitii@who.int

General comments (...Annex 1): —

WHO Eastern Mediterranean Region

World Health Organization
Lesotho

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>2,142 (143)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>63.9</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births):</th>
<th>86.4</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>48</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Probability of dying aged 30-70 yrs of NCDs (%):</th>
<th>26.60%</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>4.5%</td>
</tr>
<tr>
<td>(1.4%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Human Development Index (inequality adjusted HDI): rank:</th>
<th>0.53 (0.38): low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global innovation index (rank):</td>
<td>— (—)</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>3 (133)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>0.20%</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: —
Policy is part of the National Health Program/Plan: —
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

Approved devices lists comments (...Annex 1): —

Health care facilities lists comments (...Annex 1): —
Specific lists comments (...Annex 1): —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: —
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

National regulatory comments (...Annex 1): —
Medical device nomenclature system
Official nomenclature system for medical devices: —
Type: —
Use: —
Website: —

Medical device incorporation
Procurement
Policy or guideline: —
Website: —
National level procurement: —
Website: —
Donations
Policy or guideline: —
Website: —
Technical specifications
Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: —
Professionally trained biomedical/clinical engineers: —
Unit/Department: —
Website: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —
Website: —
Use of management software: —
Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population): 0.69
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: —
Department: —
Email: —
Other country focal point
Name: —
Email: —

WHO health products focal point
Name: —
Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Richard Banda
Email: bandar@who.int

General comments (...Annex 1): —
Liberia

Country indicators

- Population 000s (rank): 5,058 (120)
- World Bank income group: Low
- Life expectancy at birth (years):
  - IFR: 63.7
  - World: 72.1

National policy on health technology

- Health technology (medical device) national policy: No
- Policy is part of the National Health Program/Plan: No
- Website: —
- Language(s): —
- MOH responsible for health technology policy implementation: —

National lists of medical devices

- National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
  - Lists available: No
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —

- National list for different types of healthcare facilities (hospitals, laboratories, etc)
  - Lists available: —
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

- National list for specific clinical interventions/emergencies:
  - Lists available: No
  - Website: —

National health technology assessment unit

- Designated unit/department for health technology assessment (HTA): Yes
- National unit/department that includes HTA for medical devices: No
- Website(s): —
- Contact: — Email: —
- Committee includes a biomedical or clinical engineer: —

National regulatory authority

- Presence of national authority responsible for regulating medical devices: No
- Name of regulatory agency: Liberia Medicines & Health Products Regulatory Authority (LMHRA)
- Website(s): https://www.lmhra.org/
- Contact: — Email: —
- Name(s) of other regulatory agency eg. for radiation equipment etc.: —
- Other agency’s website: —

Population 000s (rank): 5,058 (120)
Life expectancy at birth (years): 63.7
World Bank income group: Low
World: 72.1

UHC - Service coverage index (1-100): 39
Probability of dying aged 30-70 yrs of NCDs (%): 17.60%
Human Development Index (rank): 0.48 (0.33): low
ICT Development Index (rank): — (—)

Approved devices lists comments (Annex 1):
Lists of standards and lists are: "Basic Package of Health Services" which contains a list of the equipment at the "annexe". However, the list is subject to revision. The WHO guidelines are being used for donations. The process has been initiated for the adaptation of the guidelines.

Health care facilities lists comments (Annex 1):
The list of equipment can be found in the index of the following document Basic Package of Health Services. However, the list is subject to revision.

HTA unit comments (Annex 1):

National regulatory comments (Annex 1):
Currently, there is a National Drug Regulatory Authority that is in the process of institutionalization.
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified  Website: —

Nomenclature comments (...Annex 1): No comments as the nomenclature does not exist.

Medical device incorporation

Procurement

Policy or guideline: No  Website: —
National level procurement: No  Website: —

Donations

Policy or guideline: Yes  Website: —

Technical specifications

Technical specifications to support procurement or donations: No  Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>400</td>
<td>9.32</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>45</td>
<td>1.05</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>15</td>
<td>0.35</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>1</td>
<td>0.02</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: —  Professionally trained biomedical/clinical engineers: No
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment  Website: —
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population):* 0.38
Number of biomedical/clinical engineers professionals in the country: <10

Contacts

MOH focal point

Name: Mr. Thomas K. Nagbe
Department: Disease Prevention and Control Division, MoH and Social Welfare
Email: tnkne3112@gmail.com

Other country focal point

Name: Dr. Louise Kpoto
Email: —

General comments (...Annex 1): —

WHO health products focal point

Name: Mr. Eric Johnson
Email: johnsoner@who.int

WHO Representative/WHO Liaison Officer

Name: Dr. Lugala Peter Lasuba Clement
Email: clementp@who.int

General comments (...Annex 1): —

Medical device incorporation comments (...Annex 1): The procurements are based on the WHO guidelines and they are mainly organized through partners.
Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):a</th>
<th>6,871 (106)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:b</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):c</td>
<td>67.3 (13)</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births):c 11.5
UHC - Service coverage index (1-100):c 64
Probability of dying aged 30-70 yrs of NCDs (%):d 20.10%
UHC - Population with household spending >10% (>25%) of corresponding income (%):e — (—)
Human Development Index (inequality adjusted HDI): rankf 0.72 (—); high
global innovation index (rank):g — (—)
ICT Development Index (rank):h 4.1 (115)
High-technology exports (% of manufacture exports):i —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):i No
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Pharmacy Management, Equipment, Supplies and Medical Supplies Ministry of Health.
Contact: Dr. Mahdi Al Ekary. Email: pharmacy912@yahoo.com
Name(s) of other regulatory agency eg. for radiation equipment etc.: Medical Supply Organization (MSO).

Approved devices lists comments (...Annex 1):
There are national standards lists but they are not written. There are lists for sundries Hospital consumable- Diagnostics Laboratory 3/3.

Health care facilities lists comments (...Annex 1):
—

Specific lists comments (...Annex 1):
There are national standards lists but they are not written. It exists also lists for interventions, and emergencies. See the following file: [General_terms_and_conditions_for_medicines_and_medical_consumables_and_equipment.pdf](https://gnsn.iaea.org/main/ANNuR/Activity%20Documents%20%20Public/Regional%20Workshop%20and%20Seminar%20on%20Capacity%20Building%20Education%20and%20Training%20Review%20Service%20(ETRES)/National%20Presentation-%20Libya.pdf)

HTA unit comments (...Annex 1):
—

National regulatory comments (...Annex 1):
The Medical Supply Organization (MSO) is responsible for the procurement of medical appliances for the public sector.

Libya

Country indicators

<table>
<thead>
<tr>
<th>National policy on health technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health technology (medical device) national policy: Yes</td>
</tr>
<tr>
<td>Policy is part of the National Health Program/Plan: Yes</td>
</tr>
<tr>
<td>Language(s): Arabic</td>
</tr>
<tr>
<td>MOH responsible for health technology policy implementation: Pharmacy and Medical Devices Department.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>National lists of medical devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:</td>
</tr>
<tr>
<td>Lists available: Yes, but it is only a recommendation</td>
</tr>
<tr>
<td>Unit: —</td>
</tr>
<tr>
<td>Website: —</td>
</tr>
<tr>
<td>Nomenclature systems used for devices and tests: —</td>
</tr>
<tr>
<td>National list for different types of healthcare facilities (hospitals, laboratories, etc)</td>
</tr>
<tr>
<td>Lists available: Yes</td>
</tr>
<tr>
<td>Website - hospitals: —</td>
</tr>
<tr>
<td>Website - IVD: —</td>
</tr>
<tr>
<td>Nomenclature systems used for devices and tests: —</td>
</tr>
<tr>
<td>National list for specific clinical interventions/emergencies:</td>
</tr>
<tr>
<td>Lists available: Yes</td>
</tr>
<tr>
<td>Website: —</td>
</tr>
</tbody>
</table>

Approved devices lists comments (...Annex 1):
There are national standards lists but they are not written. There are lists for Sundries Hospital consumable- Diagnostics Laboratory 3/3.

Health care facilities lists comments (...Annex 1):
—

Specific lists comments (...Annex 1):
There are national standards lists but they are not written. It exists also lists for interventions, and emergencies. See the following file: [General_terms_and_conditions_for_medicines_and_medical_consumables_and_equipment.pdf](https://gnsn.iaea.org/main/ANNuR/Activity%20Documents%20%20Public/Regional%20Workshop%20and%20Seminar%20on%20Capacity%20Building%20Education%20and%20Training%20Review%20Service%20(ETRES)/National%20Presentation-%20Libya.pdf)

HTA unit comments (...Annex 1):
—

National regulatory comments (...Annex 1):
The Medical Supply Organization (MSO) is responsible for the procurement of medical appliances for the public sector.
Medical device nomenclature system

Medical device incorporation
Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No  Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility*</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging*</td>
<td>32</td>
<td>5.16</td>
<td>Health posts:</td>
<td>1814</td>
<td>29.25</td>
</tr>
<tr>
<td>Computerized Tomography Scanner*</td>
<td>60</td>
<td>9.68</td>
<td>Health centres:</td>
<td>104</td>
<td>1.68</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner*</td>
<td>1</td>
<td>0.16</td>
<td>General/district hospitals:</td>
<td>99</td>
<td>1.6</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine*</td>
<td>2</td>
<td>0.32</td>
<td>Specialized/regional/national hospitals:</td>
<td>31</td>
<td>0.5</td>
</tr>
<tr>
<td>Mammograph*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Radiotherapy*</td>
<td>8</td>
<td>1.16</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical device incorporation comments (...Annex 1):
In regards to the technical specifications of medical devices, we depend mainly on the technical committees which consist of experts in medicine, pharmacy and biomedical engineer. These committees set up decrees issued by the Secretariat of Health.

Medical equipment management unit
Unit present: —  Professionally trained biomedical/clinical engineers: —
Contact name: Dr. Nasereddin Emhemed Alriyani, Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 23

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment  Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population):* 20.91
Number of biomedical/clinical engineers professionals in the country:** 40

Contacts
MOH focal point
Name: Mr. Ezzedin S. Z. Durar
Department: Pharmacy and Medical Equipment Administration, Secretariat of Health, Ministry of Health of Libya
Email: edurar2004@yahoo.com
Other country focal point
Name: Dr. Nasereddin Emhemed Alriyani
Email: —

WHO health products focal point:
Name: Ms. Najwa El-Emam
Email: elemamn@who.int
WHO Representative/WHO Liaison Officer:
Name: Dr. Elizabeth Hoff
Email: hoffe@who.int

General comments (...Annex 1): This is the first time for us to participate in this survey. Our standards and policies are under development and/or being updated. Many issues in this survey are available but still not documented.
Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>2,722 (138)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.1</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: [https://e-seimas.lt/portal/legalAct/lt/TAD/35834810004f11e4b0ef967b19d90c08/asr](https://e-seimas.lt/portal/legalAct/lt/TAD/35834810004f11e4b0ef967b19d90c08/asr)
Language(s): Lithuanian
MOH responsible for health technology policy implementation: Ministry of Health.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes
Unit: Public Procurement Office operating under the Ministry of Economy.
Nomenclature systems used for devices and tests:

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Nomenclature systems used for devices and tests:

National list for specific clinical interventions/emergencies:
Lists available: Yes

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, Health Technology Division of State Health Care Accreditation Agency under the Ministry of Health.
Contact: Ms. Neringa Puidokiene Email: neringa.puidokiene@vaspvt.gov.lt
Committee includes a biomedical or clinical engineer:

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: State Health Care Accreditation Agency under the Ministry of Health of the Republic of Lithuania.
Website(s): [www.vaspvt.gov.lt](http://www.vaspvt.gov.lt)
Contact: Ms. Jolanata Karavackaite Email: jolanata.karavackaite@vaspvt.gov.lt
Name(s) of other regulatory agency eg. for radiation equipment etc.: State Nuclear Power Safety Inspectorate (VATESI); Radiation Protection Centre (Ministry of Health).

Approved devices lists comments (...Annex 1):
Licensing regulations for health care facilities.
General and specific requirements for institutional health care services. There is a list of medical devices that are mandatory for specialized and surgical health care services.
Public Procurement Office operating under the Ministry of Economy, compiles the list of drugs and medical supplies, annually. The list is approved by the Minister of Health. The items included in this list are procured in a centralized way. The procurement expenses are disbursed from the National Health Insurance Fund Budget. The National Health Insurance Fund under the Ministry of Health is responsible for public procurement of the items of the list, mentioned above.

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):
These are lists of indications and reimbursement regulations for expensive health technology examination techniques (e.g. CT, MRI) and diagnostic procedures (e.g. diagnostic interventional procedures). Only available in Lithuanian language. General and specific requirements for institutional health care services. There is a list of medical devices that are mandatory for specialized and surgical health care services. There are no separate lists of communicable or non-communicable diseases.

HTA unit comments (...Annex 1):

National regulatory comments (...Annex 1):
Medical device nomenclature system
Official nomenclature system for medical devices: No Type: None Use: Not specified
Website: http://www.vaspvt.gov.lt/en

Medical device incorporation
Procurement
Policy or guideline: Yes Website: http://www3.lrs.lt/pls/inter3/dokpaeiksk.ShowDoc_I?P_ID=448409&Query=%26P TR2=2

Donations
Policy or guideline: Yes Website: http://www3.lrs.lt/pls/inter3/dokpaeiksk.ShowDoc_I?P_ID=228695&Query=%26P TR2=2
Publicly available: Yes Website: https://www.lrs.lt/

Medical equipment
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:</td>
<td>40</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:</td>
<td>73</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:</td>
<td>2</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:</td>
<td>7</td>
</tr>
<tr>
<td>Mammograph:</td>
<td>35</td>
</tr>
<tr>
<td>Radiotherapy:</td>
<td>24</td>
</tr>
</tbody>
</table>

Healthcare facility
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>634</td>
</tr>
<tr>
<td>Health centres:</td>
<td>629</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>58</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>15</td>
</tr>
</tbody>
</table>

Inventories and medical equipment management software
Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: —
Use of management software: No Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 50.4
Number of biomedical/clinical engineers professionals in the country: 250

Contacts
MOH focal point
Name: Ms. Nora Ribokien
Department: State Health Care Accreditation Agency under the Ministry of Health of the Republic of Lithuania
Email: vaspvt@vaspvt.gov.lt
Other country focal point
Name: —
Email: —

WHO health products focal point
Name: Mr. Robertas Petkevicius
Email: per@euro.who.int
WHO Representative/WHO Liaison Officer
Name: Ms. Ingrida Zurlyte
Email: zurlytei@who.int

General comments...

Lithuania
WHO European Region
World Health Organization

A1B2 C3D4

Nomenclature comments (...Annex 1):

Medical device incorporation comments (...Annex 1):
Guidelines for procurement of expensive health technologies (i.e. MRI, CT etc.). Guidelines are in the Lithuanian language only. There are basic requirements for technical specification of medical devices that are procured in a public centralized way.

Software comments (...Annex 1):
The State Health Care Accreditation Agency, under the Ministry of Health, is responsible for the management of national data regarding expensive health technologies (i.e. MRI, CT, etc.).

Medical equipment Total |
| Healthcare facility |
| Density per 1,000,000 population |
| Health posts: | 634 | 21.01 |
| Health centres: | 629 | 23.11 |
| General/district hospitals: | 58 | 2.13 |
| Specialized/regional/national hospitals: | 15 | 0.5 |

Inventories and medical equipment management software
Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: —
Use of management software: No Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 50.4
Number of biomedical/clinical engineers professionals in the country: 250

Contacts
MOH focal point
Name: Ms. Nora Ribokien
Department: State Health Care Accreditation Agency under the Ministry of Health of the Republic of Lithuania
Email: vaspvt@vaspvt.gov.lt
Other country focal point
Name: —
Email: —

General comments...

a UN POP/WPP 2019 (2020 POP)
b WB FYI 2019
c UN POP/WPP 2019 (1990-2020 MOR)
d WHO GHO 2019
e WHO GHO 2016
f UNDP 2019
h UN 2017
i WHO GHO 2017
k WHO GHO 2017
l WHO GHO 2010-2016
m WIPO 2020
n UN and WB 2017-2019
e WHO GHO 2010-2018
f N/A not applicable/not available
Luxembourg

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):a</th>
<th>626 (163)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:b</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):c</td>
<td></td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births):d | 2.8 |

Probability of dying aged 30-70 yrs of NCDs (%):e | 10.00% |

Human Development Index (inequality adjusted HDI): rank:f | 0.92 (0.83); very high |

ICT Development Index (rank):g | 8.5 (9) |

UHC - Service coverage index (1-100):h | 83 |

UHC - Population with household spending >10% (>25%) of corresponding income (%):i | 3.4% (0.2%) |

Global innovation index (rank):j | 50.8 (18) |

High-technology exports (% of manufacture exports):k | 6.60% |

National policy on health technology

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No


Language(s): —

MOH responsible for health technology policy implementation: Direction de la Santé.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc):

Lists available: No

Website - hospitals: http://legilux.public.lu/eli/etat/leg/iol/2001/06/20/n2/jo


Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: Yes


National health technology assessment unit

Designated unit/department for health technology assessment (HTA):a Yes

National unit/department that includes HTA for medical devices: Yes, Cellule d’expertise Médicale (CEM).


Contact: Dr. Isabelle Rolland Email: isabelle.rolland@igss.etat.lu

Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (…Annex 1):

—

Specific lists comments (…Annex 1):

Contenues notamment dans le plan pandémie grippale qui n’est pas sur l’internet public.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Ministère de la Santé.


Contact: Dr. Anna Chioti Email: meddevices@ms.etat.lu

Name(s) of other regulatory agency eg. for radiation equipment etc.: Division de la Médecine Curative et de la Qualité en santé; Ministère-Direction de la Santé.


Approved devices lists comments (…Annex 1):

—

Health care facilities lists comments (…Annex 1):

—

Global innovation index (rank): 50.8 (18)

Human Development Index (inequality adjusted HDI): 0.92 (0.83); very high

ICT Development Index (rank): 8.5 (9)

UHC - Service coverage index (1-100): 83

UHC - Population with household spending >10% (>25%) of corresponding income (%): 3.4% (0.2%)

Global innovation index (rank): 50.8 (18)

High-technology exports (% of manufacture exports): 6.60%
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: https://cns.public.lu/fr/professionnels-sante/medicaments/dispositifs-medicaux.html

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: No  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>9</td>
<td>14.38</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>14</td>
<td>22.36</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>1</td>
<td>1.6</td>
<td>General/district hospitals:</td>
<td>1</td>
<td>0.16</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>7</td>
<td>11.18</td>
<td>Specialized/regional/national hospitals:</td>
<td>4</td>
<td>0.64</td>
</tr>
<tr>
<td>Mammograph</td>
<td>7</td>
<td>94.39</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>6</td>
<td>9.58</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Direction de la Santé.  Unit website: —
Contact name: None  Contact email: None
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: https://cns.public.lu/fr/professionnels-sante/medicaments/dispositifs-medicaux.html; https://sante.public.lu/
Use of management software: Yes  Software name: Le Software est choisi par chaque hôpital individuellement.

Medical devices workforce

Density of medical doctors (per 10 000 population): 30.07
Number of biomedical/clinical engineers professionals in the country: —

Contacts

MOH focal point
Name: Dr. Françoise Berthet
Department: Direction de la santé
Email: francoise.berthet@ms.etat.lu

Other country focal point
Name: Mr. Carlo Back
Email: carlo.back@ms.etat.lu

WHO health products focal point:
Name: —
Email: —

General comments (...Annex 1): —
## Madagascar

### Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>27,691 (51)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.1</td>
</tr>
</tbody>
</table>

### National policy on health technology

- Health technology (medical device) national policy: **Yes**
- Policy is part of the National Health Program/Plan: **Yes**
- Language(s): **Français**
- MOH responsible for health technology policy implementation: **Service des Equipements et de la Maintenance**

### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: No
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —

- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - Lists available: Yes
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

- **National list for specific clinical interventions/emergencies:**
  - Lists available: No
  - Website: —

### National health technology assessment unit

- Designated unit/department for health technology assessment (HTA): **No**
- National unit/department that includes HTA for medical devices: **No**
- Website(s): —
- Contact: — Email: —
- Committee includes a biomedical or clinical engineer: —

### National regulatory authority

- Presence of national authority responsible for regulating medical devices: **No**
- Name of regulatory agency: —
- Website(s): —
- Contact: — Email: —
- Name(s) of other regulatory agency eg. for radiation equipment etc.: —
- Other agency’s website: —

### Approved devices lists comments (...Annex 1):

### Health care facilities lists comments (...Annex 1):

### Specific lists comments (...Annex 1):

### HTA unit comments (...Annex 1):

### National regulatory comments (...Annex 1):
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: Not specified
Website: http://www.agmed.mg/

Medical device incorporation

Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>3</td>
<td>0.13</td>
</tr>
<tr>
<td>Postion Emission Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>6</td>
<td>6.23</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>2</td>
<td>0.07</td>
</tr>
</tbody>
</table>

α Density per 1,000,000 females aged from 50-69 old.

Medical device incorporation comments (...Annex 1):
Specifications techniques pour: Matériels et équipements pour les Centres de Santé de base; matériels et équipements de laboratoire pour les Centres Hospitaliers de Districts de niveau 2; matériels et équipements biomédicaux et hospitaliers pour les Centres Hospitaliers de Districts de niveau 2.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Service d’Appui aux Hôpitaux de Référence Nationaux et Régionaux (SAHRNR).  Unit website: —
Contact name: —  Contact email: siem@sante.gov.mg
Website with publically available technical specifications: —
Number of regional/state offices/units: 5

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Software comments (...Annex 1):
Inventaire effectué en 2007 avec le projet CRESAN 2 (55 Centre Hospitalier de District de niveau 1 (CHD1), 29 Centres Hospitaliers de Districts de niveau 2 (CHD2), 10 Centres Hospitalier de Référence Régionale (CHR), 10 Centre Hospitalier Universitaire (CHU) et Etablissements Sanitaires. Mise à jour en cours.

Medical devices workforce

Density of medical doctors (per 10 000 population):* 1.81
Number of biomedical/clinical engineers professionals in the country: —

Contacts

MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: Chef de Service
Email: siem@sante.gov.mg

WHO health products focal point:
Name: —
Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Marcellin Nimpa Mengouo
Email: nimparmengouo@who.int


Times (%) of health facilities with none or very limited oxygen supply:

### Magnetic Resonance Imaging:
- Health posts: 2972 (12.96)
- Health centres: 63 (0.27)
- General/district hospitals: 76 (0.33)
- Specialized/regional/national hospitals: 6 (0.03)
- Estimation % of health facilities with none or very limited oxygen supply: n/a

### Medical devices workforce

- Density of medical doctors (per 10 000 population): 1.81
- Number of biomedical/clinical engineers professionals in the country: —

### Contacts

- **MOH focal point**
  - Name: —
  - Department: —
  - Email: —

- **Other country focal point**
  - Name: Chef de Service
  - Email: siem@sante.gov.mg

- **WHO health products focal point**
  - Name: —
  - Email: —

- **WHO Representative/WHO Liaison Officer**
  - Name: Dr. Marcellin Nimpa Mengouo
  - Email: nimparmengouo@who.int

### General comments (...Annex 1):
Formation en maintenance biomédicale à Madagascar: Depuis 1980, la multiplication des établissements hospitaliers et l’avènement des nouvelles technologies au service de santé ont induit une arrivée massive et diversifiée d’appareillages biomédicaux et ont fait apparaître le problème crucial de leur maintenance. La dernière action de recyclage (formation continue) des techniciens date de 2001.
Malawi

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>19,130 (61)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>-</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 41.6
UHC - Service coverage index (1-100): 46

Probability of dying aged 30-70 yrs of NCDs (%): 16.40%
UHC - Population with household spending >10% (>25%) of corresponding income (%): 4.2% (0.9%)

Human Development Index (inequality adjusted HDI): 0.48 (0.35): low
Global innovation index (rank): 21.4 (111)
ICT Development Index (rank): 1.7 (167)
High-technology exports (% of manufacture exports): 7.30%

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: https://m.facebook.com/malawimoh/
Language(s): -
MOH responsible for health technology policy implementation: Physical Assets Management Division.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes
Unit: Physical Assets Management.
Website: -
Nomenclature systems used for devices and tests: -

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: -
Website - IVD: -
Nomenclature systems used for devices and tests: -

National list for specific clinical interventions/emergencies:
Lists available: No
Website: -

Approved devices lists comments (...Annex 1):
The standard list provided is for health centres, community hospitals and district hospitals. The standard list for central hospitals is being developed and will be published very soon (file names: “jica” and “customer”, respectively).

Health care facilities lists comments (...Annex 1):
- Specific lists comments (...Annex 1):
- HTA unit comments (...Annex 1):
- National regulatory comments (...Annex 1):

Radiation protection and nuclear safety is done via AERA and it is in process of institutionalization.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No
Website(s): -
Contact: - Email: -
Committee includes a biomedical or clinical engineer: -

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: -
Website(s): https://m.facebook.com/malawimoh/
Contact: Mr. Godfrey Kadewere Email: gkadds@gmail.com
Name(s) of other regulatory agency eg. for radiation equipment etc.: Atomic Energy Regulatory Authority
Other agency’s website: https://www.iaea.org/sites/default/files/19/10/malawi_overview_2019.pdf
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device Incorporation</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>1</td>
<td>0.06</td>
<td>Health posts:</td>
<td>73</td>
<td>0.45</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>5</td>
<td>0.31</td>
<td>Health centres:</td>
<td>377</td>
<td>2.3</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>37</td>
<td>0.23</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>0</td>
<td>0</td>
<td>Specialized/ regional/national hospitals:</td>
<td>5</td>
<td>0.03</td>
</tr>
<tr>
<td>Mammograph</td>
<td>0</td>
<td>0</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Physical Assets Management  Unit website: —
Contact name: Dr. Lovemore Mkukuma  Contact email: mkukuma@yahoo.co.uk
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes  Software name: Planning and Management of Assets in Health Sector (PLAMAHS).

Medical devices workforce
Density of medical doctors (per 10,000 population): 0.36
Number of biomedical/clinical engineers professionals in the country: <10

Contacts
MOH focal point
Name: —
Department: —
Email: —
Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: Mr. Wilfred Dodoli
Email: dodoliw@who.int

WHO Representative/WHO Liaison Officer:
Name: Dr. Nonhlanhla Dlamini
Email: dlaminin@who.int

General comments (...Annex 1): —
### Malaysia

#### Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>32,366 (45)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>8.6</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>17.20%</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI):</td>
<td>0.81 (very high)</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>6.4 (63)</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>73</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>2.0% (0.2%)</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>42.4 (33)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>51.80%</td>
</tr>
</tbody>
</table>

#### National policy on health technology

| National policy on health technology (medical device) national policy: | No |
| Policy is part of the National Health Program/Plan:                  | No |
| Language(s):                                                         | —  |
| MOH responsible for health technology policy implementation:         | —  |

#### National lists of medical devices

| National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement: |
| Lists available: | No |
| Unit:           | —  |
| Website:        | —  |

| Nomenclature systems used for devices and tests: |
| — |

| National list for different types of healthcare facilities (hospitals, laboratories, etc): |
| Lists available: | No |
| Website - hospitals: | — |
| Website - IVD: | — |

| Nomenclature systems used for devices and tests: |
| — |

| National list for specific clinical interventions/emergencies: |
| Lists available: | No |
| Website:        | —  |

#### National health technology assessment unit

| Designated unit/department for health technology assessment (HTA): | Yes |
| National unit/department that includes HTA for medical devices: | Yes, Health Technology Assessment Unit, Medical Development Division. |
| Contact: | Dr. Izzuna Mudla Ghazali Email: izzuna@gmail.com |

Committee includes a biomedical or clinical engineer: —

#### National regulatory authority

| Presence of national authority responsible for regulating medical devices: | No |
| Name of regulatory agency: | Medical Device Authority, Ministry of Health Malaysia. |
| Website(s): | https://portal.mda.gov.my/ |
| Contact: | Mr. Zamane Bin Abdul Rahman Email: zamane@mdb.gov.my |
| Name(s) of other regulatory agency eg. for radiation equipment etc.: | Atomic Energy Licensing Board, Ministry of Science, Technology and Innovation. |
| Other agency’s website: | https://www.aelb.gov.my/malay/dokumen/perundangan/RADIATION%20PROTECTION%20LICENSE%20REGULATIONS%201986.pdf |

#### Approved devices lists comments

The corresponding lists are only prepared based on the needs.

#### Health care facilities lists comments

There is no standardized list. It is based on needs.

#### Specific lists comments

There is no standardized list. It is based on needs.

#### HTA unit comments

Malaysian Health Technology Assessment Section (MaHTAS) of the MoH performs HTA for health products including medical devices.

#### National regulatory comments

The Medical Device Act 2012 (Act 737) has come into force on June 30th 2013, while the effective date for its subsidiary legislations, the Medical Device Regulations (MDR) 2012 was on July 1th 2013. Act 737 provides two and one years, respectively, of a transition period for the industry to submit applications for medical device registration and establishment licensing before the law is fully enforced.

Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Based on GMDN  Use: Not specified


Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: No  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging a</td>
<td>86</td>
<td>2.89</td>
<td>Health posts</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner a</td>
<td>191</td>
<td>6.43</td>
<td>Health centres</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner a</td>
<td>11</td>
<td>0.37</td>
<td>General/district hospitals</td>
<td>95</td>
<td>0.32</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine a</td>
<td>21</td>
<td>0.71</td>
<td>Specialized/regional/national hospitals</td>
<td>23</td>
<td>0.08</td>
</tr>
<tr>
<td>Mammograph a</td>
<td>194</td>
<td>86.7</td>
<td>Estimation % of health facilities with none or very limited oxygen supply</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>73</td>
<td>2.26</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*a Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Training Management Division  Unit website: https://mda.gov.my/
Contact name: —  Contact email: —
Website with publically available technical specifications: https://mmdr.mda.gov.my/
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: https://mdar.mda.gov.my/frontend/web/index.php?r=carian
Use of management software: Yes  Software name: Central Management Information System.

Medical devices workforce

Density of medical doctors (per 10,000 population): 15.36
Number of biomedical/clinical engineers professionals in the country: 800

Contacts

MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: Dr. Asmah Samat
Email: asmah_samat@moh.gov.my

WHO health products focal point:
Name: —
Email: —
WHO Representative/WHO Liaison Officer:
Name: —
Email: wpmyswr@who.int

General comments (...Annex 1): —

Medical device incorporation comments (...Annex 1):
Depending on the types of Medical Devices. Some are procured at a national level, some at the state level and some at the hospital level.

Software comments (...Annex 1): —

Medical device incorporation comments (...Annex 1): —

General comments (...Annex 1): —
## Maldives

### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>541 (166)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
</tbody>
</table>

| Life expectancy at birth (years): | 70.5 |

| Under-five mortality (per 1000 live births): | 7.6 |
| UHC - Service coverage index (1-100): | 62 |

| Probability of dying aged 30-70 yrs of NCDs (%): | 13.40% |
| UHC - Population with household spending >10% (>25%) of corresponding income (%): | 10.3% (4.1%) |

| Human Development Index (inequality adjusted HDI): | 0.74 (0.58): high |
| Global innovation index (rank): | — (—) |

| ICT Development Index (rank): | 5.3 (85) |
| High-technology exports (% of manufacture exports): | 0.10% |

### National policy on health technology

- **Health technology (medical device) national policy:** No
- **Policy is part of the National Health Program/Plan:** No
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: No
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —

- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - Lists available: No
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

- **National list for specific clinical interventions/emergencies:**
  - Lists available: No
  - Website: —

### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):** No
- **National unit/department that includes HTA for medical devices:** No
- **Website(s):** —
- **Contact:** —  Email: —
- **Committee includes a biomedical or clinical engineer:** —

### National regulatory authority

- **Name of regulatory agency:** Medicine and Therapeutic Goods / Maldives Food and Drug Authority.
- **Contact:** Ms. Shareefa Adam Manik  Email: shareefa@health.gov.mv
- **Other agency’s website:** http://www.mdb.gov.my/mdb/
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: http://health.gov.mv/

Medical device incorporation
Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: http://health.gov.mv

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No  Website: —

Medical equipment
| Total | Density per 1,000,000 population | Healthcare facility
| Total | Density per 100,000 population |
|-------------------|-------------------------------|---------------------|
| Magnetic Resonance Imaging:* | 1 | 2.9 | Health posts: |
| Computerized Tomography Scanner:* | 2 | 5.8 | Health centres: |
| Positron Emission Tomography Scanner:* | 0 | 0 | General/district hospitals: |
| Gamma camera or nuclear medicine:* | 0 | 0 | Specialized/regional/national hospitals: |
| Mammograph:* | 1 | 57.09 | Estimation % of health facilities with none or very limited oxygen supply: |
| Radiotherapy:* | 0 | 0 | |

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: None
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population): 17.08
Number of biomedical/clinical engineers professionals in the country: <10

Contacts
MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: Ms. Aishath Mohamed
Email: anthu9696@hotmail.com

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Nazneen Anwar
Email: anwarna@who.int

General comments (Annex 1): —
Mali

Country indicators

Population 000s (rank): 20,251 (59)
World Bank income group: Low
Life expectancy at birth (years): 72.1

Under-five mortality (per 1000 live births): 94
UHC - Service coverage index (1-100): 38
Probability of dying aged 30-70 yrs of NCDs (%): 24.60%
UHC - Population with household spending >10% (>25%) of corresponding income (%): 6.5% (11%)
Human Development Index (inequality adjusted HDI): 0.43 (0.29): low
Global innovation index (rank): 19.2 (123)
ICT Development Index (rank): 2.2 (155)
High-technology exports (% of manufacture exports): 1.20%

National policy on health technology
Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: Direction établissements sanitaires et réglementation - Direction nationale de la Santé

National lists of medical devices
National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes
Unit: —
Website: —
Nomenclature systems used for devices and tests: —
National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —
National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit
Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

Health care facilities lists comments (...Annex 1):
Specific lists comments (...Annex 1):
Approved devices lists comments (...Annex 1):

National regulatory authority
Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Division établissements sanitaires et réglementation - Direction nationale de la Santé
Website(s): http://cnom.sante.gov.ml/
Contact: Dr. Yattara Moussa Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

Health care facilities lists comments (...Annex 1):
Specific lists comments (...Annex 1):
Approved devices lists comments (...Annex 1):

National regulatory comments (...Annex 1):

Population 000s (rank): 20,251 (59)
World Bank income group: Low
Life expectancy at birth (years): 72.1
Medical equipment management unit
Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: DNS/DFM/SEPAUMAT et Departement des Affaires financières (DAF). Unit website: —
Contact name: Mr. Alamir Touré Contact email: alamirtoure@yahoo.fr
Website with publically available technical specifications: —
Number of regional/state offices/units: 4

Inventories and medical equipment management software
Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: No Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population): 1.29
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: —
Department: —
Email: —
Other country focal point
Name: Mr. Alamir Touré
Email: alamirtoure@yahoo.fr

WHO health products focal point:
Name: Mr. Alioune Ibyn Abytalib Diouf
Email: adiouf@who.int
WHO Representative/WHO Liaison Officer:
Name: Dr. Jean-Pierre Baptiste
Email: baptistej@who.int

Medical device nomenclature system
Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: Not specified
Website: —

Nomenclature comments (...Annex 1):
Il existe dans le document de la comptabilité matiere une rubrique nomenclature sommaire ou les differents produits sont classés par categories, mais c'est un domaine tres important qui mérite une action.

Medical device incorporation comments (...Annex 1):
Guidelines for procurement: existe un document de projet de politique nationale en matière d'équipements et d'infrastructures sanitaires qui traite ces cas, mais il reste à être validé. Jusqu'à l'adoption de la loi hospitalière, la DFM était le seul organisme d'achat de dispositifs médicaux. Vue que cette loi accorde un statut particulier à certaines structures sanitaires notamment l'autonomie de gestion, mais aussi dans le cadre de la décentralisation il y a le transfert de compétences entre le Ministère de la Santé et les collectivités territoriales, de sorte que ces structures peuvent acheter indépendamment

Medical equipment
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility*</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:</td>
<td>0</td>
<td>0</td>
<td>Health posts:</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:</td>
<td>3</td>
<td>0.2</td>
<td>Health centres:</td>
<td>873</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>59</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:</td>
<td>1</td>
<td>0.07</td>
<td>Specialized/regional/national hospitals:</td>
<td>4</td>
</tr>
<tr>
<td>Mammograph:</td>
<td>3</td>
<td>5.42</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:</td>
<td>1</td>
<td>0.05</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged 50-69 old.

General comments (...Annex 1): Concerning the Infrastructure section: nous n'avons pas encore une politique nationale pour les équipements mais nous y travaillons, nous avons tenu deux ateliers: l'un pour l'élaboration des éléments de la politique et l'autre pour la rédaction du document de politique. Le document attend sa validation lors d'un atelier national pour les établissements sanitaires qui traite ces cas , mais il reste à être validé. Jusqu'à l'adoption de la loi hospitalière, la DFM était le seul organisme d'achat de dispositifs médicaux. Vue que cette loi accorde un statut particulier à certaines structures sanitaires notamment l'autonomie de gestion, mais aussi dans le cadre de la décentralisation il y a le transfert de compétences entre le Ministère de la Santé et les collectivités territoriales, de sorte que ces structures peuvent acheter indépendamment.

WHO African Region

213
### Malta

#### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>442 (167)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>75.8 81.3</td>
</tr>
</tbody>
</table>

#### National policy on health technology

**Health technology (medical device) national policy:** No  
**Policy is part of the National Health Program/Plan:** No  
**Website:** —  
**Language(s):** —  
**MOH responsible for health technology policy implementation:** —

#### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**  
Lists available: No  
**Unit:** —  
**Website:** —  
**Nomenclature systems used for devices and tests:** —

**National list for different types of healthcare facilities (hospitals, laboratories, etc)**  
Lists available: No  
**Nomenclature systems used for devices and tests:** —

**National list for specific clinical interventions/emergencies:**  
Lists available: No  
**Website:** —

#### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** Yes  
**National unit/department that includes HTA for medical devices:** No  
**Contact: — Email: —**  
**Committee includes a biomedical or clinical engineer:** —

#### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes  
**Name of regulatory agency:** Malta Standards Authority.  
**Website(s):** [https://deputyprimeminister.gov.mt/en/cpsu/Pages/Reports/Stock-Reports.aspx](https://deputyprimeminister.gov.mt/en/cpsu/Pages/Reports/Stock-Reports.aspx)  
**Contact: Mr. David Pulis Email: david.pulis@msa.org.mt**  
**Name(s) of other regulatory agency eg. for radiation equipment etc.:** Ministry of Health (Medical Physics).  
**Other agency’s website:** [https://deputyprimeminister.gov.mt/en/ahcs/Pages/medicalphysics.aspx](https://deputyprimeminister.gov.mt/en/ahcs/Pages/medicalphysics.aspx)
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: https://deputyprimeminister.gov.mt/en/Pages/health.aspx

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>4     9.32</td>
<td>Health posts:</td>
<td>9     2.1</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>4     9.32</td>
<td>Health centres:</td>
<td>8     1.86</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>1     2.33</td>
<td>General/district hospitals:</td>
<td>2     0.47</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>3     6.99</td>
<td>Specialized/regional/national hospitals:</td>
<td>1     0.23</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>6     99.69</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>4     9.05</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical device incorporation comments (...Annex 1):
Procurement at national level: there is a strong collaboration between the two. For capital expenditure for new technologies it is usually the department, for others it is usually coordinated by the hospital itself.

Medical device incorporation

Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes  Software name: Clingo.

Medical devices workforce

Density of medical doctors (per 10 000 population): 28.6
Number of biomedical/clinical engineers professionals in the country: —

Contacts

MOH focal point
Name: Dr. Renzo Pace Asciak
Department: Strategy & Sustainability Division
Email: renzo.pace-asciak@gov.mt

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: —
Email: —

Software comments (...Annex 1):
The name of the Software is Clingo from the company Carestream Health Italia SRL.

General comments (...Annex 1): The Ministry of Health has started to provide emphasis on new health technology and its assessment. Over the last 2 years, it has been developed a short form and guidelines for the completion of all the requests for the implementation of new health technologies and services. Together, the Director Generals for Strategy & Sustainability, and Healthcare Services have met three times a year to evaluate the proposals received. It is envisaged that a health technology evaluation unit will be developed in the short term.
# Marshall Islands

## Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>59 (186)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.1</td>
</tr>
</tbody>
</table>

## National policy on health technology

- **Health technology (medical device) national policy:** No
- **Policy is part of the National Health Program/Plan:** No
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

## National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: No
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —

- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - Lists available: No
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

- **National list for specific clinical interventions/emergencies:**
  - Lists available: No
  - Website: —

## National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):**
  - National unit/department that includes HTA for medical devices: No
  - Website(s): —
  - Contact: — Email: —
  - Committee includes a biomedical or clinical engineer: —

## National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** No
- **Name of regulatory agency:** Ministry of Health Board.
- **Website(s):** —
- **Contact:** — Email: —
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** —
- **Other agency’s website:** —

### Approved devices lists comments
(...Annex 1):
—

### Health care facilities lists comments
(...Annex 1):
—

### Specific lists comments
(...Annex 1):
—

### HTA unit comments
(...Annex 1):
—

### National regulatory comments
(...Annex 1):
—
Medical device nomenclature system

Official nomenclature system for medical devices: No
Type: None
Use: Not specified
Website: —

Medical device incorporation

Procurement
Policy or guideline: No
Website: —
National level procurement: No
Website: —

Donations
Policy or guideline: No
Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>0</td>
<td>0</td>
<td>Health posts:</td>
<td>1</td>
<td>1.9</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>1</td>
<td>19</td>
<td>Health centres:</td>
<td>52</td>
<td>98.8</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mammograph</td>
<td>1</td>
<td>142.73</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged 50-69 old.

Medical equipment management unit

Unit present: —
Professionally trained biomedical/clinical engineers: —
Unit/Department: —
Unit website: —
Contact name: —
Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: —
Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): 4.23
Number of biomedical/clinical engineers professionals in the country: —

Contacts

MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: Ms. Mary Hicking
Email: mhicking@gmail.com

WHO health products focal point:
Name: Dr. Palvin Boris
Email: pavlinb@wpro.who.int

WHO Representative/WHO Liaison Officer:
Name: Dr. Mark Andrew Jacobs
Email: jacobsma@who.int

General comments (…Annex 1): —
Mauritania

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>4,650 (124)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td></td>
</tr>
</tbody>
</table>

Global policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: https://www.sante.gov.mr/?page_id=516
Language(s): Français
MOH responsible for health technology policy implementation: Des Infrastructures, du Materiel et de la Maintenance (DIMM).

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: No
Website(s): https://www.sante.gov.mr/?page_id=34
Contact: Dr. Moustapha Ould Abdallahi Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: —
Name of regulatory agency: Direction de la Medecine Hospitaliere (DMH).
Website(s): https://www.sante.gov.mr/?page_id=34
Contact: Dr. Moustapha Ould Abdallahi Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: National authority for radiation protection, safety and nuclear security (ARSN)

Approved devices lists comments (Annex 1):
—

Health care facilities lists comments (Annex 1):
—

Specific lists comments (Annex 1):
Il existent des paquets d'activités par niveau des soins de la pyramide sanitaire.

HTA unit comments (Annex 1):
—

National regulatory comments (Annex 1):
Direction de la Medecine Hospitaliere qui a l'attribution de élaborer et suit la réglementation et les normes hospitalières, et prépare l'autorisation d'ouverture à titre privé des cliniques et des cabinets de soins infirmiers. Inspection Générale de la Santé (IGS) a l'attribution de vérifier la gestion des activités de l'ensembles des services du département et des organes sous tutelles, et leurs conformité aux lois et règlement en vigueur cf. voir organigramme du ministère de la santé qui se trouve dans le site web du ministère.
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: https://www.sante.gov.mr/?wpfb_dl=205
National level procurement: Yes  Website: https://www.sante.gov.mr/?wpfb_dl=205
Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>3</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>6</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph</td>
<td>4</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>3</td>
</tr>
</tbody>
</table>

Healthcare facility
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>453</td>
</tr>
<tr>
<td>Health centres:</td>
<td>148</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>27</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>7</td>
</tr>
</tbody>
</table>

Mammograph Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Direction des Infrastructures, du Materiel et de la Maintenance.  Unit website: https://www.sante.gov.mr/?page_id=34
Contact name: Mr. Roughaya Habott  Contact email: throughaya@yahoo.fr
Website with publically available technical specifications: https://www.sante.gov.mr/?p=2094
Number of regional/state offices/units: 5

Inventories and medical equipment management software
Type of inventories available: None
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 1.87
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: Mr. Roughaya Habott
Department: Direction des Infrastructures, du Materiel et de la Maintenance (DIMM)/Ministre de la Santé
Email: throughaya@yahoo.fr
Other country focal point
Name: —
Email: —

General comments: Le suivi de la maintenance des équipements est une mission confiée à la Direction des Infrastructures, du Matériel et de la Maintenance (DIMM) et mis en œuvre par le service de la Maintenance. Le service de la maintenance comprend deux divisions :- Division de la maintenance des infrastructures;- Division de la maintenance des équipements et des matériels. Le service de la maintenance dispose d'un plateau technique composé, au niveau central de 7. techniciens biomédicaux, de 2 ingénieurs biomédicaux et d'un ingénieur électrotechnicien, au niveau périphérique de : 5 unités régionales, qui assurent une maintenance de proximité. La qualité du service est insuffisante dans la quasi-totalité des structures de maintenance lié à la perception même de la composante maintenance, qui n'est généralement pas prise en compte lors de l'élaboration des projets et de certaines défaillances au niveau du développement des compétences
Mauritius indicators

<table>
<thead>
<tr>
<th>Population 000s (rank): a</th>
<th>1,272 (153)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group: b</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years): c</td>
<td>69.2</td>
</tr>
</tbody>
</table>

**Country indicators**

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births): d</th>
<th>16</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Service coverage index (1-100): e</td>
<td>63</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%): f</td>
<td>22.60%</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%): g</td>
<td>8.9% (1.8%)</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): h</td>
<td>0.8 (0.69): very high</td>
</tr>
<tr>
<td>Global innovation index (rank): i</td>
<td>34.4 (52)</td>
</tr>
<tr>
<td>ICT Development Index (rank): j</td>
<td>5.9 (72)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports): k</td>
<td>2.10%</td>
</tr>
</tbody>
</table>

**National policy on health technology**

**Health technology (medical device) national policy:** No

**Website:** —

**Language(s):** —

**MOH responsible for health technology policy implementation:** Equipment Committee under chairmanship of Director of the Health Services.

**National lists of medical devices**

**National list of approved priority/essential medical devices (including IVDs), for procurement or reimbursement:**

- **Lists available:** No
- **Unit:** —
- **Website:** —
- **Nomenclature systems used for devices and tests:** —

**National list for different types of healthcare facilities (hospitals, laboratories, etc):**

- **Lists available:** No
- **Website - hospitals:** —
- **Website - IVD:** —
- **Nomenclature systems used for devices and tests:** —

**National list for specific clinical interventions/emergencies:**

- **Lists available:** No
- **Website:** —

**National health technology assessment unit**

**Designated unit/department for health technology assessment (HTA):** Yes

**Website(s):** —

**Contact:** —  **Email:** —

**Committee includes a biomedical or clinical engineer:** —

**National regulatory authority**

**Presence of national authority responsible for regulating medical devices:** No

**Name of regulatory agency:** —

**Website(s):** [http://www.camec.mr/](http://www.camec.mr/)

**Contact:** —  **Email:** —

**Name(s) of other regulatory agency eg. for radiation equipment etc.:** Radiation Safety and Nuclear Security Authority (under the aegis of the Ministry of Energy and Public Utilities).

**Other agency’s website:** [https://rsnsa.govmu.org/Pages/default.aspx](https://rsnsa.govmu.org/Pages/default.aspx)

**Approved devices lists comments (Annex 1):**

Some lists are available for certain specific conditions e.g. pandemic, fogging, sprayers, etc. (an specific Plan is in preparation), there are no specific lists for non-comunicable nor communicable diseases. It must be pointed out that the Ministry

**Health care facilities lists comments (Annex 1):**

—

**Specific lists comments (Annex 1):**

Some lists are available for certain specific conditions e.g. Pandemic, fogging, sprayers, etc. There is no specific list for Communicable Diseases but a PLAN is in preparation.

**HTA unit comments (Annex 1):**

—

**National regulatory comments (Annex 1):**

Radiation Protection Authority for Radiation.
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation

Procurement
Policy or guideline: No  Website: http://www.camecmr/index.php/appels-d-offre
National level procurement: No  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>6</td>
<td>4.82</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>8</td>
<td>6.43</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>3</td>
<td>2.41</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>7</td>
<td>49.68</td>
</tr>
<tr>
<td>Radiotherapy:§</td>
<td>4</td>
<td>3.14</td>
</tr>
</tbody>
</table>

Healthcare facility

<table>
<thead>
<tr>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>110</td>
<td>8.84</td>
</tr>
<tr>
<td>Health centres:</td>
<td>2</td>
<td>0.16</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>2</td>
<td>0.16</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>5</td>
<td>0.4</td>
</tr>
<tr>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: SSR National Hospital.  Unit website: —
Contact name: Dr. Bissoondoyal  Contact email: kbissoondoyal@mail.gov.mu
Website with publically available technical specifications: —
Number of regional/state offices/units: 5

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes  Software name: Locally developed.

Medical devices workforce

Density of medical doctors (per 10 000 population): § 25.33
Number of biomedical/clinical engineers professionals in the country: —

Contacts

MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: Dr. Bissoondoyal
Email: kbissoondoyal@mail.gov.mu

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Laurent Musango
Email: musangol@who.int

General comments (…Annex 1): Concerning the HT national police it is stated in following document: politique santé.
**Country indicators**

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>128,933 (10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Life expectancy at birth (years):</th>
<th>75.9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>15.70%</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI):</td>
<td>0.78 (0.61): high</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>5.2 (87)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births):</th>
<th>14.2</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>76</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>1.6% (0.2%)</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>33.6 (55)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>20.40%</td>
</tr>
</tbody>
</table>

**National policy on health technology**

Health technology (medical device) national policy: Yes

- Policy is part of the National Health Program/Plan: Yes

Language(s): Español

MOH responsible for health technology policy implementation: Centro Nacional de Excelencia Tecnológica en Salud.

**National lists of medical devices**

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: Yes
  - Unit: Consejo de Salubridad General.

- **Nomenclature systems used for devices and tests:** National.

- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - Lists available: Yes

- **Nomenclature systems used for devices and tests:** Nationally developed.

- **National list for specific clinical interventions/emergencies:**
  - Lists available: Yes
  - Website: [https://www.gob.mx/salud](https://www.gob.mx/salud); [https://www.gob.mx/salud/acciones-y-programas/areas-de-la-subsecretaria-de-prevencion-de-la-salud](https://www.gob.mx/salud/acciones-y-programas/areas-de-la-subsecretaria-de-prevencion-de-la-salud); [http://sinaiscap.salud.gob.mx:8080/DGIS/](http://sinaiscap.salud.gob.mx:8080/DGIS/); [https://www.gob.mx/insabi/documentos/66-intervenciones?idiom=e](https://www.gob.mx/insabi/documentos/66-intervenciones?idiom=e)

**National health technology assessment unit**

- Designated unit/department for health technology assessment (HTA): Yes
  - HTA unit comments (...Annex 1):

**National regulatory authority**

- Presence of national authority responsible for regulating medical devices: Yes
  - National regulatory comments (...Annex 1): —

**Population 000s (rank): 128,933 (10)**

**World Bank income group:** Upper-Middle

**Life expectancy at birth (years):** 75.9

**Probability of dying aged 30-70 yrs of NCDs (%):** 15.70%

**Human Development Index (inequality adjusted HDI):** 0.78 (0.61): high

**ICT Development Index (rank):** 5.2 (87)

**Under-five mortality (per 1000 live births):** 14.2

**UHC - Service coverage index (1-100):** 76

**UHC - Population with household spending >10% (>25%) of corresponding income (%):** 1.6% (0.2%)

**Global innovation index (rank):** 33.6 (55)

**High-technology exports (% of manufacture exports):** 20.40%

**Mexico**

**Country indicators**

- Population 000s (rank): 128,933 (10)
- World Bank income group: Upper-Middle

**Life expectancy at birth (years):** 75.9

**Probability of dying aged 30-70 yrs of NCDs (%):** 15.70%

**Human Development Index (inequality adjusted HDI):** 0.78 (0.61): high

**ICT Development Index (rank):** 5.2 (87)

**Under-five mortality (per 1000 live births):** 14.2

**UHC - Service coverage index (1-100):** 76

**UHC - Population with household spending >10% (>25%) of corresponding income (%):** 1.6% (0.2%)

**Global innovation index (rank):** 33.6 (55)

**High-technology exports (% of manufacture exports):** 20.40%
**Medical device nomenclature system**

Official nomenclature system for medical devices: Yes  
Type: Nationally developed

Use: For various purposes above-mentioned

Website: [https://www.gob.mx; https://www.dof.gob.mx](https://www.gob.mx; https://www.dof.gob.mx)

**Medical device incorporation**

**Procurement**

Policy or guideline: Yes  

National level procurement: Yes  
Website: [https://www.gob.mx/salud/cenetec/acciones-y-programas/certificado-de-necesidad-de-equipamiento-medicinal](https://www.gob.mx/salud/cenetec/acciones-y-programas/certificado-de-necesidad-de-equipamiento-medicinal)

Donations

Policy or guideline: Yes  

Technical specifications

Technical specifications to support procurement or donations: Yes  
Publically available: Yes  
Website: [https://www.gob.mx/salud/cenetec/acciones-y-programas/cedulas-de-especificaciones-tecnicas-para-equipamiento-medicino](https://www.gob.mx/salud/cenetec/acciones-y-programas/cedulas-de-especificaciones-tecnicas-para-equipamiento-medicino)

**Medical equipment**

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>316</td>
<td>2.45</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>793</td>
<td>6.15</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>31</td>
<td>0.24</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>115</td>
<td>0.89</td>
</tr>
<tr>
<td>Mammograh:*</td>
<td>1449</td>
<td>129.17</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>240</td>
<td>1.86</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

**Medical equipment management unit**

Unit present: Yes  
Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Dirección de Ingeniería Biomédica.  

Contact name: Dr. Oscar René Marrufio Meléndez  
Contact email: oscar.marrufio@salud.gob.mx


Number of regional/state offices/units: 0

**Inventories and medical equipment management software**

Type of inventories available: Other

Website: [http://sinaiscap.salud.gob.mx:8080/DGIS](http://sinaiscap.salud.gob.mx:8080/DGIS)

Use of management software: Yes  
Software name: There are not only one, in general these are made in each one of the units for their particular needs.

**Medical devices workforce**

Density of medical doctors (per 10,000 population):* 48.5

Number of biomedical/clinical engineers professionals in the country:* 3000

**Contacts**

**MOH focal point**

Name: Mtra. Dafne Ruiz Vargas

Department: Dirección General de Relaciones Internacionales

Email: dafne.ruiz@salud.gob.mx

**WHO health products focal point**

Name: —  
Email: —  
WHO Representative/WHO Liaison Officer: Name: Mr. Cristian Roberto Morales Fuhrimann  
Email: moralesc@paho.org

General comments (...Annex 1): —
Micronesia (Federated States of)

**Country indicators**

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>115 (178)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>—</td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>29.4</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>47</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>26.10%</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>— (—)</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank:</td>
<td>0.62 (—): medium</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>— (—)</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>— (—)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>—</td>
</tr>
</tbody>
</table>

**National policy on health technology**

- **Health technology (medical device) national policy:** No
- **Policy is part of the National Health Program/Plan:** No
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

**National lists of medical devices**

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:** Lists available: No
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —

- **National list for different types of healthcare facilities (hospitals, laboratories, etc):** Lists available: No
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

- **National list for specific clinical interventions/emergencies:** Lists available: No
  - Website: —

**National health technology assessment unit**

- **Designated unit/department for health technology assessment (HTA):** Yes
- **National unit/department that includes HTA for medical devices:** No
- **Website(s):** —
- **Contact:** Email: —
- **Committee includes a biomedical or clinical engineer:** —

**National regulatory authority**

- **Presence of national authority responsible for regulating medical devices:** No
- **Name of regulatory agency:** —
- **Website(s):** —
- **Contact:** Email: —
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** —
- **Other agency’s website:** —

**Population 000s (rank):** 115 (178)
**Life expectancy at birth (years):** —
**Under-five mortality (per 1000 live births):** 29.4
**UHC - Service coverage index (1-100):** 47
**Probability of dying aged 30-70 yrs of NCDs (%):** 26.10%
**UHC - Population with household spending >10% (>25%) of corresponding income (%):** — (—)
**Human Development Index (inequality adjusted HDI): rank:** 0.62 (—): medium
**Global innovation index (rank):** — (—)
**ICT Development Index (rank):** — (—)
**High-technology exports (% of manufacture exports):** —

**HTA unit comments (…Annex 1):**
The unit of Budget and Planning with the department of finance and administration (DOFA) performs economic analysis, however, there is no HTA for medical products.

**National regulatory comments (…Annex 1):** —
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Nomenclature comments (...Annex 1):

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: No  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

| Magnetic Resonance Imaging: a | 0 | 0 |
| Computerized Tomography Scanner: a | 1 | 8.7 |
| Positron Emission Tomography Scanner: a | 0 | 0 |
| Gamma camera or nuclear medicine: a | 0 | 0 |
| Mammograph: a, b | 0 | 0 |
| Radiotherapy: b | 0 | 0 |

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: No  Professionally trained biomedical/clinical engineers: No
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): ε 1.94
Number of biomedical/clinical engineers professionals in the country: γ <10

Contacts

MOH focal point
Name: Ms. Lisa Barrow Kohler
Department: Epidemiology and Laboratory Capacity
Email: lbarrow@fsmhealth.fm
Other country focal point
Name: Mr. Andy Wilson
Email: awilson@fsmhealth.fm

WHO health products focal point:
Name: —
Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Momoe Takeuchi
Email: takeuchim@who.int

General comments (...Annex 1): There is limited expertise in the country. There are no qualified radiographers nor pathologists. Only 3 over 30 laboratory technicians have a bachelors degree in medical laboratory science.
## Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>39 (188)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.3</td>
</tr>
</tbody>
</table>

### National policy on health technology

**Health technology (medical device) national policy:** No

- Policy is part of the National Health Program/Plan: No
- Website: —
- Language(s): —
- MOH responsible for health technology policy implementation: —

### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**

- Lists available: No
- Unit: —
- Website: —
- Nomenclature systems used for devices and tests: —

**National list for different types of healthcare facilities (hospitals, laboratories, etc)**

- Lists available: Yes
- Website - hospitals: —
- Website - IVD: —
- Nomenclature systems used for devices and tests: —

**National list for specific clinical interventions/emergencies:**

- Lists available: No
- Website: —

### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** No

- National unit/department that includes HTA for medical devices: No
- Website(s): [https://www.gouv.mc/Gouvernement-et-Institutions/Le-Gouvernement/Departement-des-Affaires-Sociales-et-de-la-Sante/Direction-de-l-Action-Sanitaire](https://www.gouv.mc/Gouvernement-et-Institutions/Le-Gouvernement/Departement-des-Affaires-Sociales-et-de-la-Sante/Direction-de-l-Action-Sanitaire)
- Contact: — Email: —
- Committee includes a biomedical or clinical engineer: —

### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes

- Name of regulatory agency: Direction de l’Action Sanitaire et Sociale.
- Website(s): [https://www.gouv.mc/Gouvernement-et-Institutions/Le-Gouvernement/Departement-des-Affaires-Sociales-et-de-la-Sante/Direction-de-l-Action-Sanitaire](https://www.gouv.mc/Gouvernement-et-Institutions/Le-Gouvernement/Departement-des-Affaires-Sociales-et-de-la-Sante/Direction-de-l-Action-Sanitaire)
- Contact: Ms. Anne Negre Email: dass@gouv.mc
- Name(s) of other regulatory agency eg. for radiation equipment etc.: —
- Other agency’s website: —

### Approved devices lists comments

(...Annex 1):

- —

### Health care facilities lists comments

(...Annex 1):

- —

### Specific lists comments

(...Annex 1):

- There are “Plans d’urgence”.

### HTA unit comments

(...Annex 1):

- La Direction de l’Action Sanitaire pourrait commander évaluations des technologies de Santé.

### National regulatory comments

(...Annex 1):

- —

---

**Global Development Index (inequality adjusted HDI):**

- Rank: — (—)

**Human Development Index (rank):**

- 8.1 (19)

**ICT Development Index (rank):**

- 8.1 (19)

**Under-five mortality (per 1000 live births):**

- 3.1

**Probability of dying aged 30-70 yrs of NCDs (%):**

- —

**Probability of dying amongst women aged 30-70 yrs of NCDs (%):**

- —

**Under-five mortality (per 1000 live births):**

- 3.1

**Probability of dying amongst women aged 30-70 yrs of NCDs (%):**

- —

**UHC - Service coverage index (1-100):**

- —

**UHC - Population with household spending >10% (>25%) of corresponding income (%):**

- — (—)

**Global innovation index (rank):**

- — (—)

**Probabilité of dying aged 30-70 yrs of NCDs (%):**

- —

**Under-five mortality (per 1000 live births):**

- 3.1

**Probability of dying amongst women aged 30-70 yrs of NCDs (%):**

- —

**UHC - Service coverage index (1-100):**

- —

**UHC - Population with household spending >10% (>25%) of corresponding income (%):**

- — (—)

**Global innovation index (rank):**

- — (—)

---

**Population 000s (rank):**

- 39 (188)

**World Bank income group:**

- High

---

**Probability of dying amongst women aged 30-70 yrs of NCDs (%):**

- —

**Probability of dying amongst women aged 30-70 yrs of NCDs (%):**

- —

**UHC - Service coverage index (1-100):**

- —

**UHC - Population with household spending >10% (>25%) of corresponding income (%):**

- — (—)

---

**National lists of medical devices**

- National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
  - Lists available: No
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —

- National list for different types of healthcare facilities (hospitals, laboratories, etc)
  - Lists available: Yes
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

- National list for specific clinical interventions/emergencies:
  - Lists available: No
  - Website: —

---

**National health technology assessment unit**

- Designated unit/department for health technology assessment (HTA): No
  - National unit/department that includes HTA for medical devices: No
  - Website(s): [https://www.gouv.mc/Gouvernement-et-Institutions/Le-Gouvernement/Departement-des-Affaires-Sociales-et-de-la-Sante/Direction-de-l-Action-Sanitaire](https://www.gouv.mc/Gouvernement-et-Institutions/Le-Gouvernement/Departement-des-Affaires-Sociales-et-de-la-Sante/Direction-de-l-Action-Sanitaire)
  - Contact: — Email: —
  - Committee includes a biomedical or clinical engineer: —

---

**National regulatory authority**

- Presence of national authority responsible for regulating medical devices: Yes
  - Name of regulatory agency: Direction de l’Action Sanitaire et Sociale.
  - Website(s): [https://www.gouv.mc/Gouvernement-et-Institutions/Le-Gouvernement/Departement-des-Affaires-Sociales-et-de-la-Sante/Direction-de-l-Action-Sanitaire](https://www.gouv.mc/Gouvernement-et-Institutions/Le-Gouvernement/Departement-des-Affaires-Sociales-et-de-la-Sante/Direction-de-l-Action-Sanitaire)
  - Contact: Ms. Anne Negre Email: dass@gouv.mc
  - Name(s) of other regulatory agency eg. for radiation equipment etc.: —
  - Other agency’s website: —
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: For regulatory purposes
Website: https://www.gouv.mc/Gouvernement-et-Institutions/Le-Gouvernement/Departement-des-Affaires-Sociales-et-de-la-Sante/DIRECTION-de-l-Action-et-de-l-Aide-Sociales

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: —
National level procurement: No  Website: —
Donations
Policy or guideline: Yes  Website: —
Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical equipment
Total  Density per 1,000,000 population

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>5</td>
<td>132.17</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>5</td>
<td>132.17</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>1</td>
<td>26.43</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>1</td>
<td>26.43</td>
</tr>
<tr>
<td>Mammograph</td>
<td>2</td>
<td>599.3</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>2</td>
<td>51.28</td>
</tr>
</tbody>
</table>

Healthcare facility
Total  Density per 100,000 population

<table>
<thead>
<tr>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Health centres</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>General/district hospitals</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Estimation % of health facilities with none or very limited oxygen supply</td>
<td>n/a</td>
<td>—</td>
</tr>
</tbody>
</table>

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Département des Affaires Sociales et de la Santé  Unit website: —
Contact name: Ms. Anne Eastwood  Contact email: aeastwood@gouv.mc
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: None
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population): 75.07
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: Ms. Anne Negre
Department: Département des Affaires Sociales et de la Santé
Email: dass@gouv.mc
Other country focal point
Name: Ms. Anne Eastwood
Email: aeastwood@gouv.mc

General comments (...Annex 1): —

A1B2 C3D4

Directives 93/42/EEC.
## Country indicators

<table>
<thead>
<tr>
<th>National policy on health technology</th>
<th>Country indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td><strong>3,278 (133)</strong></td>
</tr>
<tr>
<td>World Bank income group:</td>
<td><strong>Lower-Middle</strong></td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>69.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health care indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank:</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
</tr>
</tbody>
</table>

## National policy on health technology

**Health technology (medical device) national policy:** Yes

**Policy is part of the National Health Program/Plan:** No

**Language(s):** Mongolian

**MOH responsible for health technology policy implementation:** Department of Strategic Policy and Planning.

## National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**

- Lists available: No
- Unit: —
- Website: —

**Nomenclature systems used for devices and tests:**

- National list for different types of healthcare facilities (hospitals, laboratories, etc)
  - Lists available: Yes
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

**National list for specific clinical interventions/emergencies:**

- Lists available: No
- Website: —

## National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** Yes

**National unit/department that includes HTA for medical devices:** No

**Website(s):** —

**Contact:** — Email: —

**Committee includes a biomedical or clinical engineer:** —

## National regulatory authority

**Presence of national authority responsible for regulating medical devices:** No

**Name of regulatory agency:** —

**Website(s):** —

**Contact:** — Email: —

**Name(s) of other regulatory agency eg. for radiation equipment etc.:** —

**Other agency’s website:** —

---

**Population 000s (rank):** 3,278 (133)

**World Bank income group:** Lower-Middle

**Life expectancy at birth (years):** 69.3

**Under-five mortality (per 1000 live births):** 15.6

**UHC - Service coverage index (1-100):** 62

**Probability of dying aged 30-70 yrs of NCDs (%):** 30.20%

**UHC - Population with household spending >10% (>25%) of corresponding income (%):** 2.4% (0.5%)

**Human Development Index (inequality adjusted HDI): rank:** 0.74 (0.63): high

**Global innovation index (rank):** 33.4 (58)

**ICT Development Index (rank):** 5 (91)

**High-technology exports (% of manufacture exports):** 18.90%
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified  Website: —

Medical device incorporation
Procurement
Policy or guideline: No  Website: —  National level procurement: —  Website: —
Donations
Policy or guideline: No  Website: —
Technical specifications
Technical specifications to support procurement or donations: No  Publically available: —  Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Description</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Description</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>4</td>
<td>1.41</td>
<td>Health posts:</td>
<td>1165</td>
<td>41.03</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>23</td>
<td>8.1</td>
<td>Health centres:</td>
<td>464</td>
<td>16.34</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>35</td>
<td>1.23</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>2</td>
<td>0.7</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>6</td>
<td>33.26</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>6</td>
<td>1.83</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

α Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes  Unit/Department: —  Unit website: —  Contact name: —  Contact email: —  Website with publically available technical specifications: —  Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment  Website: —  Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population):* 38.52  Number of biomedical/clinical engineers professionals in the country: 240

Contacts
MOH focal point
Name: Ms. Bulgansuren  Department: Department of Strategic Policy and Planning  Email: bulgan_21@yahoo.com  Other country focal point
Name: —  Email: —

WHO health products focal point:
Name: —  Email: — WHO Representative/WHO Liaison Officer:
Name: Dr. Sergey Diorditsa  Email: diorditsas@who.int

General comments (...Annex 1): —
### Montenegro

#### Country indicators

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>628 (162)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td></td>
</tr>
</tbody>
</table>

#### National policy on health technology

**Health technology (medical device) national policy:** Yes

Policy is part of the National Health Program/Plan: Yes


**Language(s):** Montenegrin

**MOH responsible for health technology policy implementation:** Unit for Management in Health Care.

#### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**

Lists available: Yes

Unit: Health Insurance Fond.

Website: [http://www.mup.gov.me/biblioteka/strategije](http://www.mup.gov.me/biblioteka/strategije)

Nomenclature systems used for devices and tests: —

**National list for different types of healthcare facilities (hospitals, laboratories, etc)**

Lists available: Yes

Website - hospitals: [https://mzdravlja.gov.me/ministarstvo](https://mzdravlja.gov.me/ministarstvo)

Website - IVD: [https://www.cinmed.me/Portal/faces/pretragaS?_adf.ctrl-state=feep92qs_4&_afrLoop=7290369444662547](https://www.cinmed.me/Portal/faces/pretragaS?_adf.ctrl-state=feep92qs_4&_afrLoop=7290369444662547)

Nomenclature systems used for devices and tests: —

**National list for specific clinical interventions/emergencies:**

Lists available: No

Website: [http://www.mup.gov.me/biblioteka/strategije](http://www.mup.gov.me/biblioteka/strategije)

#### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** No

National unit/department that includes HTA for medical devices: No

Website(s): [https://www.cinmed.me/Portal/faces/dinamickeStrane?_adf.ctrl-state=1720yojvsi_112; http://calims.me/Portal/faces/glavna.jspx?_afrWindowMode=0&_afrLoop=18093784927814901&_adf.ctrl-state=17pyrlqel8_92](https://www.cinmed.me/Portal/faces/dinamickeStrane?_adf.ctrl-state=1720yojvsi_112; http://calims.me/Portal/faces/glavna.jspx?_afrWindowMode=0&_afrLoop=18093784927814901&_adf.ctrl-state=17pyrlqel8_92)

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

#### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes

Name of regulatory agency: Agency for Medicines and Medical Devices of Montenegro, Department for medical devices.

Website(s): [https://www.cinmed.me/Portal/faces/dinamickeStrane?_adf.ctrl-state=1720yojvsi_112; http://calims.me/Portal/faces/glavna.jspx?_afrWindowMode=0&_afrLoop=18093784927814901&_adf.ctrl-state=17pyrlqel8_92](https://www.cinmed.me/Portal/faces/dinamickeStrane?_adf.ctrl-state=1720yojvsi_112; http://calims.me/Portal/faces/glavna.jspx?_afrWindowMode=0&_afrLoop=18093784927814901&_adf.ctrl-state=17pyrlqel8_92)

Contact: Ms. Erna Sehovic Email: erna.sehovic@calims.me

Name(s) of other regulatory agency eg. for radiation equipment etc.: Environmental Protection Agency of Montenegro.

Other agency's website: —

### Approved devices lists comments

(...Annex 1): There is a list of medical devices (based on the opinion of a team of doctors) that are provided or reimbursed to the patient by the Health Insurance Fond. The list is created as a result of different indications mostly for treatment.

### Health care facilities lists comments

(...Annex 1): —

### Specific lists comments

(...Annex 1): There are no national standards for medical devices, but Competent Authority, in accordance with the law on medical devices recognize appropriate international standards (EC, ISO). There is the Law on Protection of Population against Communicable Diseases. Also, we have National strategy for emergency situation.

### HTA unit comments

(...Annex 1): There is no HTA framework yet, but positive political will.

### National regulatory comments

(...Annex 1): There is no HTA framework yet, but positive political will.
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use:  For regulatory purposes
Website: https://www.calims.me/Portal/faces/dinamicneStrane?

Medical device incorporation
Policy or guideline: Yes  Website: https://www.calims.me/Portal/ faces/ servlet1?id=4615648966646692&; https://www.calims.me/Fees_medical+ devices_CALIMS_2009.pdf; https://www.calims.me/Portal/Zakon+o+medicinskim+sredstvima.pdf

Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: Yes
Website: https://www.calims.me/Guidelines

Medical equipment
Total Density per 1,000,000 population Healthcare facility Y Total Density per 100,000 population
Magnetic Resonance Imaging a 2 3.22 Health posts: 99 15.93
Computerized Tomography Scanner a 10 16.09 Health centres: 18 2.9
Positron Emission Tomography Scanner a 0 0 General/district hospitals: 9 1.45
Gamma camera or nuclear medicine a 1 1.61 Specialized/regional/national hospitals: 1 0.16
Mammograph a 15 196.48 Estimation % of health facilities with none or very limited oxygen supply: n/a
Radiotherapy a 4 6.37

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: —  Professionally trained biomedical/clinical engineers: No
Unit/Department: Health Insurance Fond.  Unit website: https://fzocg.me/page.php?type=novost&id=320
Contact name: —  Contact email: —
Website with publically available technical specifications: https://fzocg.me/Administracija/Documents/1589285931Politika%20 sistema%20upravljanja%20kvalitetom%20i%20sigurnost%20informacije.pdf
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: National inventory only for high cost technologies (such as MRI, CT, or PET scanners)
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population):* 27.56
Number of biomedical/clinical engineers professionals in the country: 15

Contacts
MOH focal point
Name: Ms. Erna Sehovic
Department: Agency for Medicines and Medical Devices
Email: erne.sehovic@calims.me

Other country focal point
Name: Ms. Majda Sahman
Email: majda.sahman@calims.me
WHO Representative/WHO Liaison Officer:
Name: Ms. Mina Brajovic
Email: brajovicm@who.int

General comments (...Annex 1): Concerning the Infrastructure section: We would like to inform you that we have specialized hospitals for only one speciality as psychiatric, orthopaedic and lungs diseases. We have 3 institutions like this.

Other relevant references:
a UN POP/WPP 2019 (2020 POP)
b WB FYI 2019
c UN POP/WPP 2019 (1990-2020 MOR)
d WHO GHO 2019
e WHO GHO 2016
f UNDP 2019
g ITU 2017
h WHO GHO 2017
i WHO GHO 2010-2018
j WIPO 2020
k UN and WB 2017-2019

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Morocco

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank): 36,911 (40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group: Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
</tr>
</tbody>
</table>

| Under-five mortality (per 1000 live births): 21.4 |
| UHC - Service coverage index (1-100): 70 |

| Probability of dying aged 30-70 yrs of NCDs (%): 12.40% |
| UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—) |

| Human Development Index (inequality adjusted HDI): 0.69 (—): medium |
| Global innovation index (rank): 29 (75) |

| ICT Development Index (rank): 4.8 (100) |
| High-technology exports (% of manufacture exports): 4.90% |

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): Français

MOH responsible for health technology policy implementation: Department of Equipe Medicale (DEM) within MoH.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
List available: Yes, but it is only a recommendation
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
List available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
List available: —
Website: —

Approved devices lists comments
(...Annex 1):
Des listes standardisées de dispositifs médicaux pour différents établissements de soins sont établies au niveau de la DEM.

Health care facilities lists comments
(...Annex 1):
—

Specific lists comments (...Annex 1):
Concernant les points “b” et “c” des listes sont établies au niveau de la DEM. La DELM prend en charge les points “a” et “b” aussi (see comments of other lists).

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
Adopted EMA (European Medicines Agency) and ICH (International Council for Harmonisation for Pharmaceuticals) guidelines. Inspector General Office performs health economics HTA. Within the MoH, HTA is focused on pharmaceutics but not in medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: Ministère de la Santé.
Website(s): https://www.sante.gov.ma/
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: Radiation Safety and Nuclear Security Authority (Ministry of Energy and Public Utilities) and Moroccan Agency for Nuclear and Radiological Safety and Security (AMSSNuR).

National regulatory comments
(...Annex 1): —
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Based on UMDNS  Use: Not specified
Website: http://dmp.sante.gov.ma/classification?rlc=587d5c&tirt=Dispositifs%20m%C3%A9dicaux&id=8

Medical device incorporation
Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: —
Donations
Policy or guideline: No  Website: —
Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:a</td>
<td>12</td>
<td>0.36</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:a</td>
<td>40</td>
<td>1.21</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:a</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:a</td>
<td>44</td>
<td>18.46</td>
</tr>
<tr>
<td>Radiotherapy:a</td>
<td>52</td>
<td>1.41</td>
</tr>
</tbody>
</table>

Healthcare facility
<table>
<thead>
<tr>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Estimation % of health facilities with none or very limited oxygen supply: n/a

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Contact name: —  Website: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 16

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes  Software name: Up Manager Praxis.

Medical devices workforce
Density of medical doctors (per 10,000 population): 7.31
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: Ms. Nadia Gaagouch
Department: Direction des Equipements et de la Maintenance
Email: nadia.gaagouch@gmail.com
Other country focal point
Name: —  Email: —

WHO health products focal point:
Name: —  Email: —
WHO Representative/WHO Liaison Officer:
Name: Ms. Maryam Bigdeli
Email: BigdeliM@who.int

General comments (...Annex 1): —

WHO Eastern Mediterranean Region
World Health Organization

Morocco
### Mozambique

#### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>31,255 (46)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.1</td>
</tr>
</tbody>
</table>

#### National policy on health technology

- **Health technology (medical device) national policy:** Yes
- **Policy is part of the National Health Program/Plan:** Yes
- **Website:** —
- **Language(s):** Portuguese
- **MOH responsible for health technology policy implementation:** Direcção Nacional Assistência Médica.

#### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: No
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —
- **National list for different types of healthcare facilities (hospitals, laboratories, etc)**
  - Lists available: Yes
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —
- **National list for specific clinical interventions/emergencies:**
  - Lists available: Yes
  - Website: —

#### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):** Yes
- **National unit/department that includes HTA for medical devices:** No
- **Website(s):** —
- **Contact:** — Email: —
- **Committee includes a biomedical or clinical engineer:** —

#### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** No
- **Name of regulatory agency:** Direction des Equipements et de la Maintenance, Ministère de la Santé
- **Website(s):** —
- **Contact:** — Email: —
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** National Atomic Energy Agency of Mozambique and the International Atomic Energy Agency (IAEA).
- **Other agency’s website:** https://www.iaea.org/newscenter/news/iaea-advises-mozambique-on-strengthening-regulatory-infrastructure

#### Approved devices lists comments

(...Annex 1):

- —

#### Health care facilities lists comments

(...Annex 1):

- —

#### Specific lists comments

(...Annex 1):

- —

#### HTA unit comments

(...Annex 1):

- The Department of Health Information (DIS), Ministry of Health (MISAU), performs HTA for technologies related to prevention and control of diseases, but no specifically for medical devices.

#### National regulatory comments

(...Annex 1):

- —

#### Other indicators

- **Under-five mortality (per 1000 live births):** 74.3
- **UHC - Service coverage index (1-100):** 46
- **Probability of dying aged 30–70 yrs of NCDs (%):** 18.40%
- **UHC - Population with household spending >10% (>25%) of corresponding income (%):** 1.6% (0.4%)
- **Human Development Index (inequality adjusted HDI): rank:** 0.46 (0.32): low
- **Global innovation index (rank):** 18.7 (124)
- **ICT Development Index (rank):** 2.3 (150)
- **High-technology exports (% of manufacture exports):** 5.60%
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: —
Donations
Policy or guideline: Yes  Website: —
Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>1</td>
<td>0.03</td>
</tr>
</tbody>
</table>

Medical equipment management unit
Unit present: —  Professionally trained biomedical/clinical engineers: No
Unit/Department: Centro de Abastecimiento  Unit website: —
Contact name: Dr. Ernesto Mazivilla  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: —
Use of management software: Yes  Software name: Simorganizer.

Medical devices workforce
Density of medical doctors (per 10,000 population):* 0.85
Number of biomedical/clinical engineers professionals in the country:* <10

Contacts
MOH focal point
Name: Mr. Amisse Momade
Department: —
Email: amisse.momade@gmail.com

Other country focal point
Name: Dr. Ernesto Mazivilla
Email: alessandro.campione@gmail.com

WHO health products focal point:
Name: Dr. Ana Fernandes
Email: fernandes@who.int

WHO Representative/WHO Liaison Officer:
Name: Dr. Severin Ritter Von Xylander
Email: xylanders@who.int

General comments (...Annex 1): —
Myanmar

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>54,410 (26)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td></td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>44.7</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>61</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>24.20%</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>14.4% (2.8%)</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank:</td>
<td>0.58 (—): medium</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>17.7 (129)</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>3 (135)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>2.80%</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: www.mohs.gov.mm
Language(s): Myanmar and English
MOH responsible for health technology policy implementation: Department of Food and Drug Administration, Department of Medical Services.

National lists of medical devices

Approved devices lists comments (...Annex 1):

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
- Lists available: No
- Unit: —
- Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
- Lists available: Yes
- Website - hospitals: —
- Website - IVD: —
- Nomenclature systems used for devices and tests: —

Specific lists comments (...Annex 1):

National list for specific clinical interventions/emergencies:
- Lists available: Yes
- Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, Department of Food and Drug Administration, Department of Medical services.
Website(s): www.mohs.gov.mm
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
- It has started the development of HTA systems by establishing nodal agencies and conducting ad-hoc activities.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Department of Food and Drug Administration.
Contact: Dr. NweOo Email: drnweoo1980@gmail.com
Name(s) of other regulatory agency eg. for radiation equipment etc.: Food and Drug Administration, Myanmar (Medical devices); Association of Southeast Asian Nations (ASEAN).
Other agency’s website: https://www.fda.gov.mm/?s=medical+devices; https://asean.org/
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified  Website: —

Medical device incorporation

Procurement

Policy or guideline: Yes  Website: www.mohs.gov.mm
National level procurement: Yes  Website: —

Donations

Policy or guideline: Yes  Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes  Publically available: No  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:α</td>
<td>13</td>
<td>0.24</td>
<td>Health posts:</td>
<td>2018</td>
<td>3.71</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:α</td>
<td>44</td>
<td>0.81</td>
<td>Health centres:</td>
<td>508</td>
<td>0.93</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:α</td>
<td>2</td>
<td>0.04</td>
<td>General/district hospitals:</td>
<td>273</td>
<td>0.5</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:α</td>
<td>7</td>
<td>0.13</td>
<td>Specialized/regional/national hospitals:</td>
<td>27</td>
<td>0.05</td>
</tr>
<tr>
<td>Mammograph:α</td>
<td>11</td>
<td>2.16</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:α</td>
<td>29</td>
<td>0.53</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

α Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Department of Medical Services  Unit website: www.mohs.gov.mm
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): 7.37
Number of biomedical/clinical engineers professionals in the country: <10

Contacts

MOH focal point
Name: Dr. NweOo
Department: Medical Device and Cosmetic Control Division, FDA
Email: dnrweoo1980@gmail.com
Other country focal point
Name: Dr. Soe Aung
Email: dnrweoo1980@gmail.com

WHO health products focal point:
Name: Dr. Maung Maung Lin
Email: linm@who.int
WHO Representative/WHO Liason Officer:
Name: Dr. Stephan Paul Jost
Email: josts@who.int

General comments (...Annex 1): —

Medical device incorporation comments (...Annex 1): The Procurement and Distribution Division, Department of Medical Services is in charge of procurement at a national level.
## Namibia

### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):a</th>
<th>2,541 (139)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:b</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):c</td>
<td>68.5</td>
</tr>
</tbody>
</table>

### National policy on health technology

**Health technology (medical device) national policy:** Yes  
Policy is part of the National Health Program/Plan: Yes  
Language(s): English  
MOH responsible for health technology policy implementation: Directorate of Tertiary Health Care & Clinical Support Services (THC & CSS).

### National lists of medical devices

**National list of approved priority/essential medical devices (including IVDs), for procurement or reimbursement:**  
Lists available: No  
Unit: —  
Website: —  
Nomenclature systems used for devices and tests: —

**National list for different types of healthcare facilities (hospitals, laboratories, etc)**  
Lists available: —  
Website - hospitals: —  
Website - IVD: —  
Nomenclature systems used for devices and tests: —

**National list for specific clinical interventions/emergencies:**  
Lists available: —  
Website: —

### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** Yes  
National unit/department that includes HTA for medical devices: No  
Website(s): [https://mhss.gov.na/](https://mhss.gov.na/)  
Contact: — Email: —  
Committee includes a biomedical or clinical engineer: —

### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes  
Name of regulatory agency: Namibia Medicines Regulatory Council.  
Website(s): [https://nmrc.gov.na/](https://nmrc.gov.na/)  
Contact: Mr. Axel Tibinyane Email: atibinyane@mhss.gov.na  
Name(s) of other regulatory agency eg. for radiation equipment etc.: Directorate of Atomic Energy & Radiation Protection Authority.  
Other agency’s website: [https://mhss.gov.na/home](https://mhss.gov.na/home)

## National indicators

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births):d</th>
<th>42.4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):e</td>
<td>21.30%</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): (rank):f</td>
<td>0.65 (0.42); medium</td>
</tr>
<tr>
<td>ICT Development Index (rank):g</td>
<td>3.9 (118)</td>
</tr>
</tbody>
</table>

**UHC - Service coverage index (1-100):**  
62

**UHC - Population with household spending >10% (>25%) of corresponding income (%):** — (—)

**Global innovation index (rank):**  
22.5 (104)

**High-technology exports (% of manufacture exports):**  
0.20%
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: https://mhss.gov.na/procurement-act
National level procurement: Yes  Website: —

Donations
Policy or guideline: Yes  Website: https://mhss.gov.na/

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

| Medical device | Total | Density per 1,000,000 population | Healthcare facility | Total | Density per 100,000 population |
|----------------|-------|----------------------------------|____________________|-------|--------------------------------|
| Magnetic Resonance Imaging | 2 | 0.87 | Health posts: 294 | 12.76 |
| Computerized Tomography Scanner | 11 | 4.78 | Health centres: 53 | 2.3 |
| Positron Emission Tomography Scanner | 0 | 0 | General/district hospitals: 30 | 1.3 |
| Gamma camera or nuclear medicine | 2 | 0.87 | Specialized/regional/national hospitals: 10 | 0.43 |
| Mammograph | 5 | 42.3 | Estimation % of health facilities with none or very limited oxygen supply: n/a |
| Radiotherapy | 3 | 1.18 |

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Atomic Energy & Radiation Protection.  Unit website: —
Contact name: Mr. A. Tibinyane  Contact email: atibinyane@mhss.gov.na
Website with publically available technical specifications: —
Number of regional/state offices/units: 4

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes  Software name: Medical Equipment Management System Software (MEMS).

Medical devices workforce
Density of medical doctors (per 10,000 population): 5.91
Number of biomedical/clinical engineers professionals in the country: <10

Contacts
MOH focal point
Name: Ms. Belinda Woelbling  Department: Medical Equipment Management (MEM)  Email: bwolbling@mhss.gov.na

Other country focal point
Name: Mr. A. Tibinyane  Email: atibinyane@mhss.gov.na

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Charles Sagoe-Moses
Email: sagoemosesc@who.int

General comments (Annex 1): —

a  UN POP/WPP 2019 (2020 POP)
b  WB PY21 2019
c  UN POP/WPP 1990-2020 MOR
d  WHO GHO 2020
e  WHO GHO 2019
f  UNDP 2019
g  ITU 2017
h  WHO GHO 2017
i  WHO GHO 2010-2018
j  WIPO 2020
k  UN and WB 2017-2019


Medical device incorporation comments (Annex 1):
There are guidelines for implementation of the National Health Care Technology Policy & Medical Equipment Management. Since finances have been decentralised, each of the 13 political regions is responsible for budgeting and procuring medical equipment for the health facilities in that region. Advise on budgeting and tender specifications can be obtained from MEM at a National Level.

### Nauru

#### Population indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>11 (193)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>77.1</td>
</tr>
</tbody>
</table>

#### Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>30.9</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>—</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%)</td>
<td>—</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%)</td>
<td>— (—)</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI):</td>
<td>— (—)</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>— (—)</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>— (—)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>—</td>
</tr>
</tbody>
</table>

#### National policy on health technology

**Health technology (medical device) national policy:** No  
Policy is part of the National Health Program/Plan: No  
Website: —  
Language(s): —  
MOH responsible for health technology policy implementation: —

#### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**  
Lists available: No  
Unit: —  
Website: —  
Nomenclature systems used for devices and tests: —

**National list for different types of healthcare facilities (hospitals, laboratories, etc):**  
Lists available: —  
Website - hospitals: —  
Website - IVD: —  
Nomenclature systems used for devices and tests: —

**National list for specific clinical interventions/emergencies:**  
Lists available: No  
Website: —

#### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** No  
National unit/department that includes HTA for medical devices: No  
Website(s): —  
Contact: —  
Email: —  
Committee includes a biomedical or clinical engineer: —

#### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** No  
Name of regulatory agency: —  
Website(s): —  
Contact: —  
Email: —  
Name(s) of other regulatory agency eg. for radiation equipment etc.: —

#### Approved devices lists comments

(...Annex 1):

—

#### Health care facilities lists comments

(...Annex 1):

—

#### Specific lists comments

(...Annex 1):

SPC assist us with our supplies for the Pandemic preparedness but we do not have a list as most of these are consumables.

#### HTA unit comments

(...Annex 1):

—

#### National regulatory comments

(...Annex 1):

—
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: No  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device Incorporation</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

α Density per 1,000,000 females aged from 50-69 old.

Medical device incorporation comments (...Annex 1):
The procurement for the medical devices is based on the Hospital's Senior Management Team decision and the availability of the fund.

Medical equipment management unit

Unit present: —  Professionally trained biomedical/clinical engineers: No
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/offices: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): 13.46
Number of biomedical/clinical engineers professionals in the country: —

Contacts

MOH focal point
Name: Dr. Alani Tangitau
Department: Health
Email: alani.tangitau@nauru.gov.nr

Other country focal point
Name: Mr. Jiosese Mailulu
Email: jiosese.mailulu@nauru.gov.nr

WHO health products focal point:
Name: Dr. Subhash Yadav
Email: syadav@who.int

WHO Representative/WHO Liaison Officer:
Name: Dr. Mark Andrew Jacobs
Email: jacobsma@who.int

General comments (...Annex 1): —
Nepal

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):*</th>
<th>29,137 (49)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:*</td>
<td>Lower-Middle</td>
</tr>
</tbody>
</table>

| Life expectancy at birth (years):* | 69.7 |

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births):*</th>
<th>30.8</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Service coverage index (1-100):*</td>
<td>48</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Probability of dying aged 30-70 yrs of NCDs (%):*</th>
<th>21.80%</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):*</td>
<td>10.7% (2.4%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Human Development Index (inequality adjusted HDI): rank:</th>
<th>0.6 (0.45): medium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global innovation index (rank):</td>
<td>24.4 (95)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICT Development Index (rank):</th>
<th>2.9 (140)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-technology exports (% of manufacture exports):*</td>
<td>1.20%</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Language(s): English
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: [http://182.93.95.152/tsb/](http://182.93.95.152/tsb/)
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Approved devices lists comments (...Annex 1):
—

Health care facilities lists comments (...Annex 1):
—

Specific lists comments (...Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):* Yes
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
There are identified HTA activities but not national unit per se. However, there is research in the health unit within the MOH. The HTA under the government umbrella is in progress and a requirement to reach the Universal Health Care country goal.

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: Department of Health Services and Logistics Management Division.
Contact: Dr. Mingmar G. Sherpa Email: doctor_mingma@hotmail.com
Name(s) of other regulatory agency eg. for radiation equipment etc.: Ministry of Health and Population (MoHP).
Other agency’s website: [https://mohp.govnp/en](https://mohp.govnp/en)

National regulatory comments (...Annex 1):
—

Population 000s (rank):* 29,137 (49)
World Bank income group:* Lower-Middle

[Image of Nepal flag]

[Image of bar chart showing demographic data]

[Image of graph showing health indicators]

[Image of table summarizing health technology policies and lists]

[Image of health technology assessment unit]

[Image of national regulatory authority]

242
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: Many co-existence of nomenclatures  Use: For various purposes above-mentioned
Website: —

Medical device incorporation

Procurement

Policy or guideline: No  Website: —
National level procurement: Yes  Website: http://www.dohslmd.gov.np/

Donations

Policy or guideline: No  Website: —

Technical specifications

Technical specifications to support procurement or donations: No  Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device Incorporation</th>
<th>Total</th>
<th>Medical equipment Management Unit</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>n/a</td>
<td>Health posts: 699</td>
<td>2.51</td>
</tr>
<tr>
<td>Computerized Tomography</td>
<td>n/a</td>
<td>Health centres: 201</td>
<td>0.72</td>
</tr>
<tr>
<td>Positron Emission Tomography</td>
<td>n/a</td>
<td>General/district hospitals: 65</td>
<td>0.23</td>
</tr>
<tr>
<td>Gamma camera or nuclear</td>
<td>n/a</td>
<td>Specialized/regional/national</td>
<td>0.04</td>
</tr>
<tr>
<td>Mammograph</td>
<td>n/a</td>
<td>hospitals: 12</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>11</td>
<td>Estimation % of health facilities</td>
<td>n/a</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: —  Professionally trained biomedical/clinical engineers: No
Contact name: Dr. Mingmar G. Sherpa  Contact email: doctor_mingma@hotmail.com
Website with publically available technical specifications: http://182.93.95.152/tsb/
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Use of management software: Yes  Software name: Web-based LMIS web based equipment/instrument, Inventory Management System.

Medical devices workforce

Density of medical doctors (per 10,000 population): 8.09
Number of biomedical/clinical engineers professionals in the country: <10

Contacts

MOH focal point
Name: Dr. Mingmar G. Sherpa
Department: Health Services Division
Email: doctor_mingma@hotmail.com

WHO health products focal point:
Name: —  Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Rajesh Pandav  Email: pandavr@who.int

General comments (...Annex 1): —

WHO South-East Asia Region
Netherlands

**Country indicators**

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>17,135 (68)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>82.1</td>
</tr>
</tbody>
</table>

**Under-five mortality (per 1000 live births):** 4

**Probability of dying aged 30-70 yrs of NCDs (%):** 11.20%

**Human Development Index (inequality adjusted HDI):** 0.94 (0.88); very high

**ICT Development Index (rank):** 8.5 (7)

**UHC - Service coverage index (1-100):** 86

**UHC - Population with household spending >10% (>25%) of corresponding income (%):** — (—)

**Global innovation index (rank):** 58.8 (5)

**High-technology exports (% of manufacture exports):** 23.10%

**Health technology (medical device) national policy:** Yes

**Policy is part of the National Health Program/Plan:** Yes


**Language(s):** Dutch

**MOH responsible for health technology policy implementation:** Department Pharmaceutical Affairs and Medical Technology.

**National lists of medical devices**

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**

- Lists available: No
- Unit: Department of Pharmaceutical Affairs and Medical Technology
- Website: [https://english.igj.nl/medical-technology/market-authorisation/registration-and-deregistration](https://english.igj.nl/medical-technology/market-authorisation/registration-and-deregistration)

**Nomenclature systems used for devices and tests:** —

**National list for different types of healthcare facilities (hospitals, laboratories, etc):**

- Lists available: No

**Nomenclature systems used for devices and tests:** —

**National list for specific clinical interventions/emergencies:**

- Lists available: No
- Website: —

**National health technology assessment unit**

**Designated unit/department for health technology assessment (HTA):** Yes

**National unit/department that includes HTA for medical devices:** Zorginstituut.

**Website(s):** [http://www.zorginstituutnederland.nl/](http://www.zorginstituutnederland.nl/)

**Contact:** — Email: —

**Committee includes a biomedical or clinical engineer:** Yes

**Approved devices lists comments (...Annex 1):**

The health insurance scheme takes care of the reimbursement of extramural medical devices in the Netherlands. The reimbursement of medical devices is function orientated.

**Health care facilities lists comments (...Annex 1):** —

**Specific lists comments (...Annex 1):**

In the Netherlands, the professional has to decide, recommend or indicate a medical device. The cupola of the professionals can publish a guideline for specific procedures. There is no national policy on diseases or situations.

**HTA unit comments (...Annex 1):** —

**National regulatory authority**

**Presence of national authority responsible for regulating medical devices:** Yes

**Name of regulatory agency:** Ministry of Health, Welfare and Sport, Department of Pharmaceutical Affairs and Medical Technology.

**Website(s):** [https://www.rijksoverheid.nl/onderwerpen/medische-hulpmiddelen](https://www.rijksoverheid.nl/onderwerpen/medische-hulpmiddelen)

**Contact:** Mr. Jan van Ginneken Email: i.v.ginneken@minvws.nl

**Name(s) of other regulatory agency eg. for radiation equipment etc.:** Dutch Healthcare Inspectorate; Authority for Nuclear Safety and Radiation Protection (ANVS).

**Other agency’s website:** [https://english.igj.nl/; www.anvs.nl](https://english.igj.nl/; www.anvs.nl)

**National regulatory comments (...Annex 1):**

For vigilance and post market surveillance (more info in the medische-hulpmiddelen corresponding link).
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Based on GMDN  Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: No   Website: —
National level procurement: No   Website: —
Donations
Policy or guideline: No   Website: —
Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: Yes

Medical equipment
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>203</td>
<td>11.85</td>
<td>Health posts:</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>205</td>
<td>11.96</td>
<td>Health centres:</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>40</td>
<td>2.33</td>
<td>General/district hospitals:</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>179</td>
<td>10.45</td>
<td>Specialized/regional/national hospitals:</td>
<td>128</td>
</tr>
<tr>
<td>Mammograph</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>172</td>
<td>10.04</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

α Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: No   Professionally trained biomedical/clinical engineers: No
Unit/Department: Health Care Insurance Board (CVZ)   Unit website: http://www.gipdatabase.nl/; http://www.cvz.nl/
Contact name: Mr. J. A. C. van Ginneken   Contact email: j.v.ginneken@minvws.nl
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: None
Website: —
Use of management software: —   Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 37.07
Number of biomedical/clinical engineers professionals in the country: 500

Contacts
MOH focal point
Name: Mr. Jan van Ginneken
Department: Department of Pharmaceutical Affairs and Medical Technology
Email: j.v.ginneken@minvws.nl
Other country focal point
Name: Mr. J. A. C. van Ginneken
Email: j.v.ginneken@minvws.nl

General comments (...Annex 1): —

WHO health products focal point:
Name: —
Email: —
WHO Representative/WHO Liason Officer:
Name: —
Email: —

WHO European Region

Medical device incorporation comments (...Annex 1):
There is the Commission decision of 7 May 2002 on common technical specifications for in vitro-diagnostic medical devices.

Netherlands

Medical equipment management unit comments (...Annex 1):
The Netherlands has no national inventory for medical devices.

Software comments (...Annex 1):
The Netherlands has no national inventory for medical devices.

General comments (...Annex 1): —
New Zealand

Country indicators

Population 000s (rank): 4,822 (123)
World Bank income group: High
Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births): 4.7</th>
<th>UHC - Service coverage index (1-100): 87</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%): 10.10%</td>
<td></td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): 0.93 (0.86); very high</td>
<td></td>
</tr>
<tr>
<td>ICT Development Index (rank): 8.3 (13)</td>
<td></td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports): 9.90%</td>
<td></td>
</tr>
</tbody>
</table>

National policy on health technology
Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices
National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —
National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —
National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Approved devices lists comments (...Annex 1):
Under New Zealand law there is no approval system for medical devices and hence no pre-market scrutiny of their safety and performance. There is a legal requirement for the sponsor (importer/exporter/supplier) of a medical device (with some exceptions) to notify the device to a database maintained by Medsafe within 30 working days of becoming the sponsor for the device.

Health care facilities lists comments (...Annex 1):
—

Specific lists comments (...Annex 1):
—

National health technology assessment unit
Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
National Health Committee performs HTA in several areas, but not for medical devices.

National regulatory authority
Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: The Medicines and Medical Devices Safety Authority (Medsafe), a business unit of the Ministry of Health.
Website(s): https://www.medsafe.govt.nz/regulatory/DevicesNew/3-2Explanation.asp
Contact: Ms. Susan Martindale Email: susan_martindale@moh.govt.nz
Name(s) of other regulatory agency eg. for radiation equipment etc.: Medicines and Medical Device Safety Authority (MedSafe).
Other agency’s website: http://www.medsafe.govt.nz/

National regulatory comments (...Annex 1):
—
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Based on GMDN  Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: —
National level procurement: No  Website: —
Donations
Policy or guideline: No  Website: —
Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>76</td>
<td>15.76</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>76</td>
<td>15.76</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>5</td>
<td>1.04</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>18</td>
<td>3.73</td>
</tr>
<tr>
<td>Mammograph</td>
<td>97</td>
<td>162.36</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>36</td>
<td>7.47</td>
</tr>
</tbody>
</table>

Healthcare facility

<table>
<thead>
<tr>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Health centres</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>General/district hospitals</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Estimation % of health facilities with none or very limited oxygen supply: n/a

Medical device incorporation comments (...Annex 1):
National requirements apply only to procurement of electro-medical devices through a set of AS/NZ standards such as AS/NZ3551:2004 which are mandated under a national law. Government publishes standards that are applicable to some devices.

Medical device incorporation comments (...Annex 1):
National requirements apply only to procurement of electro-medical devices through a set of AS/NZ standards such as AS/NZ3551:2004 which are mandated under a national law. Government publishes standards that are applicable to some devices.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: None
Website: —
Use of management software: Yes  Software name: Hardcat, Tektrak and Beims.

Medical devices workforce
Density of medical doctors (per 10 000 population): 34.21
Number of biomedical/clinical engineers professionals in the country: 26

Contacts
MOH focal point
Name: —  Department: —  Email: —

Other country focal point
Name: —  Email: —

WHO health products focal point:
Name: —  Email: —

WHO Representative/WHO Liason Officer:
Name: Dr. Corinne Reisinger Capuano  Email: CapuanoC@who.int

General comments (...Annex 1): The definition of medical device used in NZ law (the Medicines Act 1981) is not currently aligned with the GHTF approach. Consequently, some products that are regarded as devices in other countries are currently regulated as medicines in NZ. Examples include pregnancy tests, condoms with spermicide, IUCDs with copper and nasal irrigation solutions.

* Density per 1,000,000 females aged from 50-69 old.

New Zealand
### Nicaragua

#### Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank)</td>
<td>6,625 (108)</td>
</tr>
<tr>
<td>World Bank income group</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years)</td>
<td>74.2</td>
</tr>
</tbody>
</table>

#### National policy on health technology

<table>
<thead>
<tr>
<th>Policy/Website/Website(s)</th>
<th>Language(s)</th>
<th>MOH responsible for health technology policy implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health technology (medical device) national policy</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Policy is part of the National Health Program/Plan</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Website</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Language(s)</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>MOH responsible for health technology policy implementation</td>
<td>—</td>
<td></td>
</tr>
</tbody>
</table>

#### National lists of medical devices

<table>
<thead>
<tr>
<th>Lists available</th>
<th>Website(s)</th>
<th>Nomenclature systems used for devices and tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved devices lists comments</td>
<td>(...Annex 1)</td>
<td></td>
</tr>
<tr>
<td>Health care facilities lists comments</td>
<td>(...Annex 1)</td>
<td></td>
</tr>
<tr>
<td>National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Website</td>
<td><a href="http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Dispositivos-M%C3%A9dicos/repository">http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Dispositivos-M%C3%A9dicos/repository</a></td>
<td></td>
</tr>
<tr>
<td>National list for different types of healthcare facilities (hospitals, laboratories, etc)</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Website - hospitals</td>
<td><a href="http://www.minsa.gob.ni/">http://www.minsa.gob.ni/</a></td>
<td></td>
</tr>
<tr>
<td>Website - IVD</td>
<td><a href="http://www.minsa.gob.ni/index.php/repository/func-download/399/chk_be041b94ed602d617d517851511ca3b7/no_html/">http://www.minsa.gob.ni/index.php/repository/func-download/399/chk_be041b94ed602d617d517851511ca3b7/no_html/</a>; <a href="http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Divisi%C3%B3n-General-de-Consumos-M%C3%A9dicos/Lista-B%2C%3Alos-de-Consumos/Lista-B%C3%A1sica-de-Consumos-de-Laboratorios/">http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Divisi%C3%B3n-General-de-Consumos-M%C3%A9dicos/Lista-B%2C%3Alos-de-Consumos/Lista-B%C3%A1sica-de-Consumos-de-Laboratorios/</a></td>
<td></td>
</tr>
<tr>
<td>Specific lists comments</td>
<td>(...Annex 1): The Ministry of Health does not have lists recommending health technology for different diseases or situations.</td>
<td></td>
</tr>
<tr>
<td>National list for specific clinical interventions/emergencies</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Website</td>
<td><a href="http://www.minsa.gob.ni/index.php/repository/func-download/359/chk_850a55c3bca951031a3dc35ab94264a6/no_html/">http://www.minsa.gob.ni/index.php/repository/func-download/359/chk_850a55c3bca951031a3dc35ab94264a6/no_html/</a></td>
<td></td>
</tr>
</tbody>
</table>

#### National health technology assessment unit

| Designated unit/department for health technology assessment (HTA) | No |
| Website(s) | — |
| Contact | — |
| Email | — |
| Committee includes a biomedical or clinical engineer | — |

#### National regulatory authority

| Presence of national authority responsible for regulating medical devices | Yes |
| Name of regulatory agency | Dirección General de Regulación Sanitaria. |
| Website(s) | http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Dispositivos-M%C3%A9dicos/repository |
| Contact | Lic. Luz María Torrez |
| Email | dgrs@minsa.gob.ni |
| Name(s) of other regulatory agency eg. for radiation equipment etc. | — |
| Other agency’s website | — |

#### Approved devices lists comments

- (...Annex 1):

#### Health care facilities lists comments

- (...Annex 1):

#### National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement

- No

#### Website

- http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Dispositivos-M%C3%A9dicos/repository

#### Nomenclature systems used for devices and tests

- No

#### National list for different types of healthcare facilities (hospitals, laboratories, etc)

- Yes

#### Website - hospitals

- http://www.minsa.gob.ni/

#### Website - IVD

- http://www.minsa.gob.ni/index.php/repository/func-download/399/chk_be041b94ed602d617d517851511ca3b7/no_html/; http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Divisi%C3%B3n-General-de-Consumos-M%C3%A9dicos/Lista-B%2C%3Alos-de-Consumos/Lista-B%C3%A1sica-de-Consumos-de-Laboratorios/

#### Nomenclature systems used for devices and tests

- No

#### National list for specific clinical interventions/emergencies

- Yes

#### Website

Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Based on GMDN  Use: For regulatory purposes
Website: —

Nomenclature comments (...Annex 1): Although we do have an official nomenclature system for medical devices, it is not use for various reasons.

Medical device incorporation

Procurement

Policy or guideline: No  Website: —
National level procurement: Yes  Website: http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Divisi%C3%B3n-de-Adquisiciones/Normativas-y-Funciones/repository

Donations

Policy or guideline: Yes  Website: http://www.minsa.gob.ni

Technical specifications

Technical specifications to support procurement or donations: No  Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging*</td>
<td>1</td>
<td>0.16</td>
<td>Health posts:</td>
<td>890</td>
<td>14.64</td>
</tr>
<tr>
<td>Computerized Tomography Scanner*</td>
<td>3</td>
<td>0.49</td>
<td>Health centres:</td>
<td>158</td>
<td>2.6</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner*</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>26</td>
<td>0.43</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine*</td>
<td>1</td>
<td>0.16</td>
<td>Specialized/regional/national hospitals:</td>
<td>6</td>
<td>0.1</td>
</tr>
<tr>
<td>Mammograph*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy*</td>
<td>6</td>
<td>0.91</td>
<td>—</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Dirección General de Regulación Sanitaria.  Unit website: http://www.minsa.gob.ni
Contact name: Lic. Luz Maria Torrez.  Contact email: dgrs@minsa.gob.ni
Website with publically available technical specifications: http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Dispositivos-M%C3%A9dicos/Normativa-064%E2%80%9CNorma-para-el-registro-de-dispositivos-m%C3%A9dicos/E2%80%9D/
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): 16.65
Number of biomedical/clinical engineers professionals in the country: —

Contacts

MOH focal point
Name: Ms. Tatiana Valdez García
Department: Dirección de Infraestructura y Desarrollo Tecnológico
Email: didti01@minsa.gob.ni
Other country focal point
Name: Lic. Luz Maria Torrez
Email: dgrs@minsa.gob.ni

WHO health products focal point:
Name: —
Email: —
WHO Representative/WHO Liaison Officer:
Name: Ing. Ana Solis-Ortega Treasure
Email: treasurea@paho.org

General comments (...Annex 1): Our Ministry of Health is doing big efforts to normalize and regulate the procurement of medical devices, but we do require training for our personnel to perform a better job. We also have limitations in providing maintenance to the acquired equipment.
Country indicators

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>24,207 (56)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>71.7</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

Approved devices lists comments (...Annex 1):

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): —
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —
### Medical device nomenclature system
- **Official nomenclature system for medical devices:** No
- **Type:** Many co-existence of nomenclatures
- **Use:** Not specified
- **Website:** —

### Medical device incorporation
**Procurement**
- **Policy or guideline:** No
- **National level procurement:** Yes
- **Website:** —

**Donations**
- **Policy or guideline:** No
- **Website:** —

### Technical specifications
- **Technical specifications to support procurement or donations:** Yes
- **Publically available:** No
- **Website:** —

### Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility*</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0</td>
<td>0</td>
<td>Health posts:</td>
<td>2493</td>
<td>13.98</td>
</tr>
<tr>
<td>Computerized Tomography Scanner&lt;sup&gt;a&lt;/sup&gt;</td>
<td>3</td>
<td>0.17</td>
<td>Health centres:</td>
<td>886</td>
<td>4.97</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>77</td>
<td>0.43</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>10</td>
<td>0.06</td>
</tr>
<tr>
<td>Mammograph&lt;sup&gt;a&lt;/sup&gt;&lt;sup&gt;*&lt;/sup&gt;</td>
<td>7</td>
<td>10.94</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>—</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0</td>
<td>0</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

<sup>a</sup> Density per 1,000,000 females aged 50-69 old.

### Medical equipment management unit
- **Unit present:** Yes
- **Professionally trained biomedical/clinical engineers:** Yes
- **Unit/Department:** Direction des Infrastructures et Equipements Sanitaires.
- **Unit website:** —
- **Contact name:** Mr. Moumouni Alhassane
- **Contact email:** kouubii@yahoo.fr
- **Website with publically available technical specifications:** —
- **Number of regional/state offices/units:** 8

### Inventories and medical equipment management software
- **Type of inventories available:** National inventory for medical equipment
- **Website:** —
- **Use of management software:** No
- **Software name:** —

### Medical devices workforce
- **Density of medical doctors (per 10 000 population):** 0.43
- **Number of biomedical/clinical engineers professionals in the country:** —

### Contacts
- **MOH focal point**
  - **Name:** Ms. Maman Kiassa Adamou
  - **Department:** Direction des Infrastructures et Équipements Sanitaires
  - **Email:** kiasas@yahoo.fr
  - **Other country focal point**
    - **Name:** Mr. Moumouni Alhassane
    - **Email:** kouubii@yahoo.fr

- **WHO health products focal point:**
  - **Name:** —
  - **Email:** —

- **WHO Representative/WHO Liaison Officer**
  - **Name:** Dr. Blanche-Philomene Melanga Anya
  - **Email:** anyab@who.int

### General comments (...Annex 1):
Le Niger dispose d'une stratégie nationale de maintenance adoptée depuis avril 2008.
Nigeria

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>206,140 (7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>77.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births):</th>
<th>117.2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>22.50%</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank:</td>
<td>0.54 (0.35): low</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>2.6 (143)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>UHC - Service coverage index (1-100):</th>
<th>42</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>15.1% (4.1%)</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>20.1 (117)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>1.50%</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: Food and Drug Services.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —
National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —
National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Approved devices lists comments (...Annex 1):
—
Health care facilities lists comments (...Annex 1):
—
Specific lists comments (...Annex 1):
—

HTA unit comments (...Annex 1):
Three organisms perform HTA at a national level: The Agency for Food and Drugs Administration and Control (NAFDAC), Nigeria Institute for Pharmaceutical Research and Development (NIPRD) and the National Health Insurance Scheme. (NHIS). The action plan 2018-2021 of the MoH states the progress to a National Quality Review & Health Technology Assessment Systems to determine which health interventions are cost effective including medical devices (see fourth link). HTA is a pliar for UHC’s goal.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, Nigeria Institute for Pharmaceutical Research and Development (NIPRD).
Contact: — Email: information.niprd@niprd.gov.ng
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: National Agency for Food and Drug Administration and Control.
Website(s): http://www.nafdac.gov.ng/
Contact: Dr. Chinyere Ilonze Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: National Agency for Food and Drug Administration and Control (NAFDAC).
Other agency’s website: http://www.nafdac.gov.ng/products/medicalsmenu

National regulatory comments (...Annex 1):
—
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified  Website: —

Medical device incorporation

Procurement

Policy or guideline: No  Website: —
National level procurement: No  Website: —

Donations

Policy or guideline: No  Website: —

Technical specifications

Technical specifications to support procurement or donations: No  Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/ regional/ national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>9</td>
<td>0.04</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Medical Devices Management and Standardization Unit.  Unit website: —
Contact name: Mr. Esan Bukola Emmanuel. Contact email: bukolaesan2000@yahoo.com
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: None  Website: —
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): * 3.81
Number of biomedical/clinical engineers professionals in the country:* 280

Contacts

MOH focal point
Name: Mr. Esan Bukola Emmanuel  Department: Hospital Services  Email: bukolaesan2000@yahoo.com
Other country focal point
Name: —  Email: —

WHO health products focal point:
Name: —  Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Walter Kazadi Mulombo  Email: kazadimulombow@who.int

General comments (...Annex 1): —
### Niue

#### Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>2 (194)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>—</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.3</td>
</tr>
</tbody>
</table>

#### National policy on health technology

**Health technology (medical device) national policy:**
- Policy is part of the National Health Program/Plan: —
- Website: —
- Language(s): —
- MOH responsible for health technology policy implementation: —

#### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
- Lists available: —
- Unit: —
- Website: —

**National list for different types of healthcare facilities (hospitals, laboratories, etc):**
- Lists available: —
- Website - hospitals: —
- Website - IVD: —

**National list for specific clinical interventions/emergencies:**
- Lists available: —

#### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):**
- National unit/department that includes HTA for medical devices: —
- Website(s): —
- Contact: — Email: —
- Committee includes a biomedical or clinical engineer: —

#### National regulatory authority

**Presence of national authority responsible for regulating medical devices:**
- Name of regulatory agency: —
- Website(s): —
- Contact: — Email: —
- Name(s) of other regulatory agency eg. for radiation equipment etc.: —

---

Global atlas of medical devices 2022

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Medical device nomenclature system

Official nomenclature system for medical devices: — Type: — Use: —
Website: —

Medical device incorporation

Procurement
Policy or guideline: — Website: —
National level procurement: — Website: —

Donations
Policy or guideline: — Website: —

Technical specifications
Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:α</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:α</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:α</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:α</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:α,β</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:γ</td>
<td>n/a</td>
<td>n/a</td>
<td>—</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: — Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): 18.75
Number of biomedical/clinical engineers professionals in the country: —

Contacts

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Mark Andrew Jacobs
Email: jacobsma@who.int

General comments (...Annex 1): —
### North Macedonia

<table>
<thead>
<tr>
<th>Country indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
</tr>
<tr>
<td>World Bank income group:</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank:</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
</tr>
</tbody>
</table>

### National policy on health technology

- Health technology (medical device) national policy: —
- Website: —
- Language(s): —
- MOH responsible for health technology policy implementation: —

#### National lists of medical devices

#### National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

- Lists available: No
- Unit: —
- Website: www.fzo.org.mk
- Nomenclature systems used for devices and tests: —

#### National list for different types of healthcare facilities (hospitals, laboratories, etc)

- Lists available: —
- Website - hospitals: —
- Website - IVD: —
- Nomenclature systems used for devices and tests: —

#### National list for specific clinical interventions/emergencies:

- Lists available: No
- Website: —

### National health technology assessment unit

- Designated unit/department for health technology assessment (HTA): Yes
- National unit/department that includes HTA for medical devices: No
- Website(s): —
- Contact: — Email: —
- Committee includes a biomedical or clinical engineer: —

### National regulatory authority

- Presence of national authority responsible for regulating medical devices: Yes
- Name of regulatory agency: Bureau of Drugs, Ministry of health is responsible for implementing the regulations for medical devices.
- Website(s): www.zdravstvo.gov.mk
- Contact: Ms. Katerina Aleksoska  Email: katerina.aleksoska@zdravstvo.gov.mk
- Name(s) of other regulatory agency eg. for radiation equipment etc.: Radiation Safety Directorate.
- Other agency’s website: https://www.iaea.org/sites/default/files/fyrm_nr-7th-rm.pdf

Approved devices lists comments

(...Annex 1):
- The reimbursement is performed by the National Health Insurance Fund, the list of medical devices that are reimbursed are posted on the “fzo website”. In public health facilities the procurement is currently going through a public competition with those medical devices that have entered the register of medical devices.

Health care facilities lists comments

(...Annex 1):
- —

Specific lists comments (...Annex 1):
- —

HTA unit comments (...Annex 1):
- There is not an HTA national unit yet per se but it has been acknowledged at a political level by the MoH. There are HTA activities for the selection of specific medicines. It exists a Centralized System for external price referencing and decentralized procurement prices of non-prescription medicines and devices.

National regulatory comments

(...Annex 1):
- —
Medical device nomenclature system
Official nomenclature system for medical devices: No
Type: None
Use: Not specified
Website: —

Nomenclature comments (...Annex 1): No, but we are recognising GMDN code.

Medical device incorporation
Procurement
Policy or guideline: No
Website: —
National level procurement: Yes
Website: —

Donations
Policy or guideline: No
Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>7</td>
<td>3.32</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>13</td>
<td>6.17</td>
<td>Health centres:</td>
<td>36</td>
<td>1.71</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>16</td>
<td>0.76</td>
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<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>2</td>
<td>0.95</td>
<td>Specialized/regional/national hospitals:</td>
<td>35</td>
<td>1.66</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>20</td>
<td>79.81</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>—</td>
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<tr>
<td>Radiotherapy:*</td>
<td>5</td>
<td>2.4</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50–69 old.

Medical equipment management unit
Unit present: —
Professionally trained biomedical/clinical engineers: No
Unit/Department: —
Unit website: —
Contact name: —
Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —
Website: —
Use of management software: —
Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population): 28.74
Number of biomedical/clinical engineers professionals in the country: <10

Contacts
WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: —
Email: —

General comments (...Annex 1): —
Norway

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>5,421 (117)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>82.2</td>
</tr>
</tbody>
</table>

Global advantage of medical devices 2022

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: https://www.regjeringen.no/no/dokumenter/meld-st-10-20122013/id709025/
Language(s): —
MOH responsible for health technology policy implementation: The Department of Specialized Health Care Services.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes
Unit: —
Website: —
Nomenclature systems used for devices and tests: —
National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —
National list for specific clinical interventions/emergencies:
Lists available: Yes
Website: https://www.helsedirektoratet.no/tema/beredskap-og-krisehandtering

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, Norwegian Knowledge Centre for the Health Services within Norwegian Institute of Public Health (NIH).
Website(s): https://www.hfi.no/en/gk/HTA/; https://helsedirektoratet.no/english
Contact: — Email: Folkehelseinstituttet@fhi.no
Committee includes a biomedical or clinical engineer: —

Approved devices lists comments (...Annex 1):
A few devices - those being reimbursed via the blue prescription system i- are listed. Lists are made by The Norwegian Labour and Welfare Administration, refer to the procurement of medical devices at national level section.

Health care facilities lists comments (...Annex 1):
—

Specific lists comments (...Annex 1):
—

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Norwegian Directorate of Health, Department of Medical Devices and Medicinal Products.
Website(s): http://www.helsedir.no; https://lovdata.no/dokument/SF/forskrift/2005-12-15-1690/*#&x2a;
Contact: Ms. Marit Endresen Email: meddev-no@helsedir.no
Name(s) of other regulatory agency eg. for radiation equipment etc.: Directorate of Health: Department of Medical Devices and Medicinal Products.
Other agency’s website: https://lovdata.no/dokument/SF/forskrift/2005-12-15-1690/*#&x2a

HTA unit comments (...Annex 1):
The system has two levels; a national level where decisions based on HTAs are made by the four regional health authorities in concert, and a local/hospital-level where decisions are made based on the mini-HTAs performed locally in each hospital. Pharmaceuticals have to pass always by the national level. The Norwegian Knowledge Centre for the Health Services (member of the NIPH since 2016) do HTAs on selected procedures and devices upon request.

National regulatory comments (...Annex 1):
The Directorate of Health, Department of medical devices and medicinal products is the Competent Authority for medical devices in Norway, it has the tasks of the competent authority as they are given in the European directives for medical devices. These tasks, however, are not identical with those listed under the corresponding ones of this survey.

Population 000s (rank): 5,421 (117)
World Bank income group: High
Life expectancy at birth (years): 82.2

Under-five mortality (per 1000 live births): 2.4
Probability of dying aged 30-70 yrs of NCDs (%): 9.20%
Human Development Index (inequality adjusted HDI): 0.96 (0.9); very high
ICT Development Index (rank): 8.5 (8)
UHC - Service coverage index (1-100): 87
UHC - Population with household spending >10% (>25%) of corresponding income (%): — —
Global innovation index (rank): 49.3 (20)
High-technology exports (% of manufacture exports): 22.60%
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  
Type: Based on GMDN  
Use: For regulatory purposes  
Website: https://www.gmdnagency.org/

Nomenclature comments (...Annex 1): The use of GMDN is not imposed by law.

Medical device incorporation

Procurement

Policy or guideline: Yes  
Website: —

National level procurement: Yes  
Website: https://www.helfo.no/prod-og-prislister/prod-og-prislister?malgruppe=leverandor

Donations

Policy or guideline: No  
Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes  
Publically available: No  
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Service</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>55</td>
<td>10.15</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

α Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: —  
Professionally trained biomedical/clinical engineers: —

Unit/Department: Norwegian Knowledgecenter for the Health Care Services, Department for Evidence-based Health Care.

Unit website: —

Contact name: Ms. Gro Jamtvedt and Ms. Inger Norderhaug  
Contact email: grj@nock.no

Website with publically available technical specifications: —

Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —

Website: —

Use of management software: Yes  
Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): 48.85

Number of biomedical/clinical engineers professionals in the country: <10

Contacts

MOH focal point

Name: —

Department: —

Email: —

Other country focal point

Name: Ms. Gro Jamtvedt and Ms. Inger Norderhaug

Email: grj@nock.no

WHO health products focal point:

Name: —

Email: —

WHO Representative/WHO Liaison Officer:

Name: —

Email: —

General comments (...Annex 1): Concerning the HT national policy, it was provided the following document: plan van aanpak patientveiligheid medische technologie.pdf. Concerning the infrastructure section: As of 01.01.2009: 11,885 beds in specialised healthcare. 117 of these are in the private sector.

Medical equipment incorporation comments (...Annex 1): Only procurement of devices being reimbursed via the blue prescription system is carried out at a national level, by The Norwegian Labour and Welfare Administration.
### Oman

#### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):&lt;sup&gt;a&lt;/sup&gt;</th>
<th>5,107 (118)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:&lt;sup&gt;b&lt;/sup&gt;</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):&lt;sup&gt;c&lt;/sup&gt;</td>
<td>72.5</td>
</tr>
</tbody>
</table>

#### National policy on health technology

- **Health technology (medical device) national policy:** Yes
- **Policy is part of the National Health Program/Plan:** No
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

#### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: Yes, but it is only a recommendation
  - Unit: Directorate of Medical Technologies.
  - Website: —
  - Nomenclature systems used for devices and tests: —

- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - Lists available: Yes
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

- **National list for specific clinical interventions/emergencies:**
  - Lists available: Yes
  - Website: —

#### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):**<sup>d</sup> Yes
- **National unit/department that includes HTA for medical devices:** No
- **Website(s):** [https://www.moh.gov.om/en/](https://www.moh.gov.om/en/)
- **Contact:** — Email: —
- **Committee includes a biomedical or clinical engineer:** —

#### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** Yes
- **Name of regulatory agency:** Directorate General of Medical Supply, Ministry of Health.
- **Website(s):** [https://www.moh.gov.om/web/directorate-general-of-medical-supplies](https://www.moh.gov.om/web/directorate-general-of-medical-supplies)
- **Contact:** Engr. Rashid bin Hamdan Al Hajri, DMT. Email: ralhajri@omantel.net.om
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** —
- **Other agency’s website:** —

#### Approved devices lists comments

(...Annex 1):

—

#### Health care facilities lists comments

(...Annex 1):

—

#### Specific lists comments (...Annex 1):

Medical devices for specific procedures, whenever required, are prepared or modified based on the requirement from end users. Available at Directorate of Medical Technologies.

#### HTA unit comments (...Annex 1):

Drug control, bulk procurement and distribution of drugs are managed by MoH. There are identified HTA activities but there is no national unit per se.

#### National regulatory comments

(...Annex 1):

—

#### Under-five mortality (per 1000 live births):<sup>e</sup> 11.4

#### UHC - Service coverage index (1-100):<sup>f</sup> 69

#### Probability of dying aged 30-70 yrs of NCDs (%):<sup>g</sup> 17.80%

#### UHC - Population with household spending >10% (>25%) of corresponding income (%):<sup>h</sup> — (—)

#### Human Development Index (inequality adjusted HDI): rank<sup>i</sup> 0.81 (0.71); very high

#### Global innovation index (rank):<sup>j</sup> 26.5 (84)

#### ICT Development Index (rank):<sup>k</sup> 6.4 (62)

#### High-technology exports (% of manufacture exports):<sup>l</sup> 1.30%

#### Under-five mortality (per 1000 live births):<sup>e</sup> 11.4

#### UHC - Service coverage index (1-100):<sup>f</sup> 69

#### Probability of dying aged 30-70 yrs of NCDs (%):<sup>g</sup> 17.80%

#### UHC - Population with household spending >10% (>25%) of corresponding income (%):<sup>h</sup> — (—)

#### Human Development Index (inequality adjusted HDI): rank<sup>i</sup> 0.81 (0.71); very high

#### Global innovation index (rank):<sup>j</sup> 26.5 (84)

#### ICT Development Index (rank):<sup>k</sup> 6.4 (62)

#### High-technology exports (% of manufacture exports):<sup>l</sup> 1.30%

#### Under-five mortality (per 1000 live births):<sup>e</sup> 11.4

#### UHC - Service coverage index (1-100):<sup>f</sup> 69

#### Probability of dying aged 30-70 yrs of NCDs (%):<sup>g</sup> 17.80%

#### UHC - Population with household spending >10% (>25%) of corresponding income (%):<sup>h</sup> — (—)

#### Human Development Index (inequality adjusted HDI): rank<sup>i</sup> 0.81 (0.71); very high

#### Global innovation index (rank):<sup>j</sup> 26.5 (84)

#### ICT Development Index (rank):<sup>k</sup> 6.4 (62)

#### High-technology exports (% of manufacture exports):<sup>l</sup> 1.30%
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: —
Donations
Policy or guideline: Yes  Website: —
Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging&quot;a</td>
<td>16</td>
<td>4.4</td>
</tr>
<tr>
<td>Computerized Tomography Scanner&quot;a</td>
<td>25</td>
<td>6.88</td>
</tr>
<tr>
<td>Positron Emission Tomography Scannera</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine&quot;a</td>
<td>4</td>
<td>1.1</td>
</tr>
<tr>
<td>Mammograph&quot;a&quot;</td>
<td>15</td>
<td>149.75</td>
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<tr>
<td>Radiotherapy&quot;a&quot;</td>
<td>3</td>
<td>0.59</td>
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</table>

Healthcare facility
<table>
<thead>
<tr>
<th>Facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
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</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>101</td>
<td>2.78</td>
</tr>
<tr>
<td>Health centres:</td>
<td>74</td>
<td>2.04</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>35</td>
<td>0.96</td>
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<tr>
<td>Specialized/regional/national hospitals:</td>
<td>4</td>
<td>0.11</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Directorate of Medical Technologies.  Unit website: —
Contact name: Engr. Rashid bin Hamdan Al Hajri  Contact email: ralhajri@omantel.net.om
Website with publically available technical specifications: —
Number of regional/state offices/units: 11

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes  Software name: Al Shifa.

Medical devices workforce
Density of medical doctors (per 10,000 population): 193
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: Mr. Rashid Bin Hamdan Al Hajri
Department: Directorate of Medical Technologies
Email: ralhajri@omantel.net.om
Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: Mrs. Reem Bou-Kamel
Email: boukamelr@oma.emro.who.int
WHO Representative/WHO Liaison Officer:
Name: Mr. Jean Yaacoub Jabbour
Email: jabbourj@who.int

General comments (...Annex 1): —
Pakistan

Country indicators

Population 000s (rank): 220,892 (5)
World Bank income group: Lower-Middle

Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Year</th>
<th>RA</th>
<th>World</th>
</tr>
</thead>
<tbody>
<tr>
<td>1950</td>
<td>62.3</td>
<td>47.3</td>
</tr>
<tr>
<td>2000</td>
<td>67.0</td>
<td>65.2</td>
</tr>
<tr>
<td>2050</td>
<td>72.1</td>
<td>71.8</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 67.2
UHC - Service coverage index (1-100): 45

Probability of dying aged 30-70 yrs of NCDs (%): 24.70%
UHC - Population with household spending >10% (>25%) of corresponding income (%): 4.5% (0.5%)

Human Development Index (inequality adjusted HDI): 0.56 (0.38); medium
Global innovation index (rank): 22.3 (107)

ICT Development Index (rank): 2.4 (148)
High-technology exports (% of manufacture exports): 2.30%

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: https://www.dra.gov.pk/Home/MDMC#gsc.tab=0
Language(s): English

MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes, but it is only a recommendation
Unit: —
Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - IVD: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: www.ppra.org.pk; https://www.dra.gov.pk/Home/MDMC#gsc.tab=0

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

Approved devices lists comments (...Annex 1):

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):
The provinces develop their lists of equipment based on their health facilities, the available funds, and according to the Priced Vocabulary of Medical Stores (PVMS) (Available). World Health Organization Pakistan share such lists with the Ministry of Health at time of emergency.

HTA unit comments (...Annex 1):

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Medical Devices and Medicated Cosmetics Division within the Drug Regulatory Authority.
Website(s): https://www.dra.gov.pk/Home/MDMC#gsc.tab=0
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: Pakistan Nuclear Regulatory Authority (PNRA does a partially regulation for some medical devices) other wise, there is no authority.
Other agency’s website: http://www.pnra.org/

National regulatory comments (...Annex 1):
The WHO country team helped the Ministry of Health in drafting rules for regulations of medical devices, but they are not applicable after the 18th amendment.
## Medical device nomenclature system

**Official nomenclature system for medical devices:** No  
**Type:** None  
**Use:** Not specified

Website: [https://www.dra.gov.pk/Home/](https://www.dra.gov.pk/Home/)
[Download?ImageName=ChecklistforGDPMDverificati.docx](https://www.dra.gov.pk/Home/)

[https://www.dra.gov.pk/Home/](https://www.dra.gov.pk/Home/)
[Download?ImageName=FFSCHEDULEACLASSIFICATIONOFMEDICALDEVICES.pdf](https://www.dra.gov.pk/Home/)

Nomenclature comments (...Annex 1):

---

## Medical device incorporation

### Procurement

**Policy or guideline:** Yes  
**Website:** [https://www.dra.gov.pk/Home/MDMC#gsc.tab=0](https://www.dra.gov.pk/Home/MDMC#gsc.tab=0)

**National level procurement:** Yes  
**Website:** —

### Donations

**Policy or guideline:** No  
**Website:** [https://www.dra.gov.pk/Home/](https://www.dra.gov.pk/Home/)

**Technical specifications**

**Technical specifications to support procurement or donations:** Yes  
**Publically available:** Yes  

### Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>40</td>
<td>0.22</td>
<td>Health posts:</td>
<td>5430</td>
<td>2.98</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>61</td>
<td>0.33</td>
<td>Health centres:</td>
<td>1508</td>
<td>0.83</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>5</td>
<td>0.03</td>
<td>General/district hospitals:</td>
<td>636</td>
<td>0.35</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>7</td>
<td>0.04</td>
<td>Specialized/regional/national hospitals:</td>
<td>180</td>
<td>0.1</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>15</td>
<td>1.61</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>77</td>
<td>0.35</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

### Medical equipment management unit

**Unit present:** Yes  
**Professionally trained biomedical/clinical engineers:** Yes

**Unit/Department:** —  
**Website:** —

**Contact name:** —  
**Contact email:** —

**Website with publically available technical specifications:** —

**Number of regional/state offices/units:** 6

### Inventories and medical equipment management software

**Type of inventories available:** —

**Website:** —

**Use of management software:** No  
**Software name:** —

### Medical devices workforce

**Density of medical doctors (per 10,000 population):** 11.18

**Number of biomedical/clinical engineers professionals in the country:** 1200

### Contacts

**MOH focal point**

**Name:** Mr. Ayaz Ali khan  
**Department:** Health system strengthening and policy unit  
**HSA MoH Pakistan**  
**Email:** ayazalikhan1@gmail.com

**Other country focal point**

**Name:** —  
**Email:** —

**WHO health products focal point:**

**Name:** —  
**Email:** —

**WHO Representative/WHO Liaison Officer:**

**Name:** Dr. Palitha Gunarathna Mahipala  
**Email:** mahipalap@who.int

**General comments (...Annex 1):** After the 18th amendment and devolution of the MoH, no person nor authority can provide information, the WHO as convening body of health systems in Pakistan collected the information separately from all regions/provinces then the information was compiled by the WHO focal person of health technologies.
Palau

Country indicators

Population 000s (rank): 18 (190)
World Bank income group: High
Life expectancy at birth (years): n/a

Under-five mortality (per 1000 live births): 17.3
Probability of dying aged 30-70 yrs of NCDs (%): —
Human Development Index (inequality adjusted HDI): 0.83 (—)
ICT Development Index (rank): — (—)

UHC - Service coverage index (1-100): —
UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)
Global innovation index (rank): — (—)
High-technology exports (% of manufacture exports): 51.70%

National policy on health technology

Health technology (medical device) national policy: —
Policy is part of the National Health Program/Plan: —
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: —
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): —
National unit/department that includes HTA for medical devices: —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: —
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

National regulatory comments (...Annex 1): —
Medical device nomenclature system

Official nomenclature system for medical devices: —  Type: —  Use: —
Website: —

Medical device incorporation
Procurement
Policy or guideline: —  Website: —
National level procurement: —  Website: —

Donations
Policy or guideline: —  Website: —

Technical specifications
Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical device incorporation comments (...Annex 1):

Medical equipment management unit

Unit present: —  Professionally trained biomedical/clinical engineers: —
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: —  Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): ε 14.21
Number of biomedical/clinical engineers professionals in the country: γ —

Contacts

MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Mark Andrew Jacobs
Email: jacobsma@who.int

General comments (...Annex 1): —
### Panama

#### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>4,315 (125)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.2</td>
</tr>
</tbody>
</table>

#### National policy on health technology

- **Health technology (medical device) national policy:** Yes
- **Policy is part of the National Health Program/Plan:** Yes
- **Website:** [http://www.minsa.gob.pa/normatividad/leyes](http://www.minsa.gob.pa/normatividad/leyes)
- **Language(s):** Español

**MOH responsible for health technology policy implementation:** Comisión Nacional de Registro Nacional de Ofereñtes - Departamento de investigación - Desarrollo Tecnológico en Salud y Comité Técnico Nacional Interinstitucional - Dirección Nacional de Farmacias y Drogras - Laboratorio Central de Referencia.

#### National lists of medical devices

#### Approved devices lists comments

Available at the specified website.

#### Health care facilities lists comments

#### Specific lists comments

#### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):** No

**Contact:** Email: —

Committee includes a biomedical or clinical engineer: —

#### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** Yes
- **Name of regulatory agency:** La Dirección Nacional de Farmacia y Drogas del Ministerio de Salud de Panamá.
- **Website(s):** [http://www.minsa.gob.pa/direccion/direccion-nacional-de-dispositivos-medicos](http://www.minsa.gob.pa/direccion/direccion-nacional-de-dispositivos-medicos)

**Contact:** Dr. Humberto Olarte. Email: —

**Name(s) of other regulatory agency eg. for radiation equipment etc.:** International Atomic Energy Agency (IAEA).

**Other agency's website:** [https://www.iaea.org/es/el-oiea/lista-de-estados-miembros](https://www.iaea.org/es/el-oiea/lista-de-estados-miembros)

### Key indicators

- **Under-five mortality (per 1000 live births):** 14.9
- **Probability of dying aged 30-70 yrs of NCDs (%):** 13.00%
- **Human Development Index (inequality adjusted HDI):** 0.82 (0.64): very high
- **ICT Development Index (rank):** 4.9 (94)
- **Global innovation index (rank):** 29 (73)
- **High-technology exports (% of manufacture exports):** 13.70%

#### Under-five mortality (per 1000 live births): 14.9

#### Probability of dying aged 30-70 yrs of NCDs (%): 13.00%

#### Human Development Index (inequality adjusted HDI): 0.82 (0.64): very high

#### ICT Development Index (rank): 4.9 (94)

#### Global innovation index (rank): 29 (73)

#### High-technology exports (% of manufacture exports): 13.70%
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: Not specified

Medical device incorporation

Procurement

Donations
Policy or guideline: Yes  Website: -

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: —
Website: -

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:α</td>
<td>11</td>
<td>2.85</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:β</td>
<td>37</td>
<td>9.58</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:γ</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:γ</td>
<td>8</td>
<td>2.07</td>
</tr>
<tr>
<td>Mammograph:α</td>
<td>79</td>
<td>278.54</td>
</tr>
<tr>
<td>Radiotherapy:γ</td>
<td>10</td>
<td>2.32</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>480</td>
<td>12.42</td>
</tr>
<tr>
<td>Health centres:</td>
<td>388</td>
<td>10.04</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>15</td>
<td>0.39</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>7</td>
<td>0.18</td>
</tr>
</tbody>
</table>

Estimation % of health facilities with none or very limited oxygen supply: n/a

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Contact name: Dr. Alejandro Martinez  Contact email: amartinez@minsa.gob.pa
Website with publically available technical specifications: http://appwebs.minsa.gob.pa/woferentes/ConsultaCatalogos.aspx
Number of regional/state offices/units: 7

Inventories and medical equipment management software

Type of inventories available: None
Website: http://appwebs.minsa.gob.pa/woferentes/ConsultaCatalogos.aspx
Use of management software: Yes  Software name: ECRI.

Medical devices workforce

Density of medical doctors (per 10 000 population): 16.32
Number of biomedical/clinical engineers professionals in the country: 325

Contacts

MOH focal point
Name: Lic. Sousa
Department: —
Email: lsousa@minsa.gob.pa

Other country focal point
Name: Dr. Alejandro Martinez
Email: amartinez@minsa.gob.pa

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Gerardo Alfaro Cantón
Email: alfaroge@paho.org

General comments (...Annex 1):
—
### Papua New Guinea

#### Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank)</td>
<td>8,947 (97)</td>
</tr>
<tr>
<td>World Bank income group</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years)</td>
<td>72.1</td>
</tr>
<tr>
<td>Hotline adequacy</td>
<td>0.56</td>
</tr>
<tr>
<td>ICT Development Index (rank)</td>
<td>0.56</td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births)</td>
<td>44.8</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%)</td>
<td>30.00%</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank</td>
<td>0.56 (0.39): medium</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100)</td>
<td>40</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%)</td>
<td>— (—)</td>
</tr>
<tr>
<td>ICT Development Index (rank)</td>
<td>— (—)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports)</td>
<td>—</td>
</tr>
</tbody>
</table>

#### National policy on health technology

- **Health technology (medical device) national policy:** Yes
- **Policy is part of the National Health Program/Plan:** Yes
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

#### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:** No
- **Unit:** —
- **Website:** —
- **Nomenclature systems used for devices and tests:** —
- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - **Lists available:** Yes
  - **Website - hospitals:** —
  - **Website - IVD:** —
  - **Nomenclature systems used for devices and tests:** —
- **National list for specific clinical interventions/emergencies:**
  - **Lists available:** —
  - **Website:** —

#### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):** Yes
- **National unit/department that includes HTA for medical devices:** No
- **Website(s):** —
- **Contact:** —
  - **Email:** —
- **Committee includes a biomedical or clinical engineer:** —
- **HTA unit comments (Annex 1):**
  - The 2011 initiative undertaken to establish a national e-health strategic framework and committee, as first steps. There are identified HTA activities but not national unit. The Universal Health Care country goal is in progress.

#### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** —
- **Name of regulatory agency:** —
- **Website(s):** —
- **Contact:** Ms. Jonila Kepas.
  - **Email:** jjonilak248@gmail.com
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** —
- **Other agency’s website:** —

#### Population 000s (rank)

- **Rank:** 97

#### World Bank income group

- **Income group:** Lower-Middle

#### Under-five mortality (per 1000 live births)

- **Value:** 44.8

#### Probability of dying aged 30-70 yrs of NCDs (%)

- **Value:** 30.00%

#### Human Development Index (inequality adjusted HDI): rank

- **Value:** 0.56 (0.39): medium

#### UHC - Service coverage index (1-100)

- **Value:** 40

#### UHC - Population with household spending >10% (>25%) of corresponding income (%)

- **Value:** — (—)

#### Global innovation index (rank)

- **Value:** — (—)

#### High-technology exports (% of manufacture exports)

- **Value:** —
Medical device nomenclature system

Official nomenclature system for medical devices: — Type: — Use: — Website: —

Medical device incorporation

Procurement
Policy or guideline: — Website: —
National level procurement: Yes Website: —

Donations
Policy or guideline: Yes Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No Website: —

Medical equipment

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:</td>
<td>0</td>
<td>0</td>
<td>Health posts:</td>
<td>2600</td>
<td>35.51</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:</td>
<td>3</td>
<td>0.41</td>
<td>Health centres:</td>
<td>677</td>
<td>9.25</td>
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<tr>
<td>Positron Emission Tomography Scanner:</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>89</td>
<td>1.22</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:</td>
<td>0</td>
<td>0</td>
<td>Specialized/ regional/ national hospitals:</td>
<td>7</td>
<td>0.1</td>
</tr>
<tr>
<td>Mammograph:</td>
<td>3</td>
<td>8.51</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:</td>
<td>1</td>
<td>0.14</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/ clinical engineers: Yes
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/ state offices/ units: —

Inventories and medical equipment management software

Type of inventories available: National Inventory for medical equipment
Website: —
Use of management software: Yes Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): 0.66
Number of biomedical/ clinical engineers professionals in the country: —

Contacts

MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Ms. Anna Alexandra S. Maalsen
Email: maalsena@who.int

General comments (...Annex 1): —
### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>7,133 (104)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
</tbody>
</table>

| Life expectancy at birth (years): | 73.1 |

### National policy on health technology

- **Health technology (medical device) national policy:** No
- **Policy is part of the National Health Program/Plan:** No
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: No
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —

- **National list for different types of healthcare facilities (hospitals, laboratories, etc)**
  - Lists available: No
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

- **National list for specific clinical interventions/emergencies:**
  - Lists available: No
  - Website: —

### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):** No
- **National unit/department that includes HTA for medical devices:** No
- **Website(s):** —
  - **Contact:** Mr. Adolfo Maldonado  Email: ninomaldonado@hotmail.com
  - Committee includes a biomedical or clinical engineer: —

### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** No
- **Name of regulatory agency:** Dirección General de Control de Profesionales, Establecimientos y Tecnología de la Salud, Ministerio de Salud Pública y Bienestar Social.
- **Website(s):** [https://www.mspbs.gov.py/drcps](https://www.mspbs.gov.py/drcps)
- **Contact:** —  Email: —
  - **Name(s) of other regulatory agency eg. for radiation equipment etc.:** Autoridad Reguladora Radiológica y Nuclear.
  - **Other agency’s website:** [http://www.arrn.gov.py/](http://www.arrn.gov.py/)

### Approved devices lists comments

(...Annex 1):

—

### Health care facilities lists comments

(...Annex 1):

—

### Specific lists comments (...Annex 1):

—

### HTA unit comments (...Annex 1):

HTA activities identified, but not proven at national or subnational level.

### National regulatory comments

(...Annex 1):

—

### Under-five mortality (per 1000 live births):

19.4

### UHC - Service coverage index (1-100):

69

### Probability of dying aged 30-70 yrs of NCDs (%):  

17.50%

### UHC - Population with household spending >10% (≥25%) of corresponding income (%):

7.1% (1.9%)

### Human Development Index (inequality adjusted HDI):  

0.73 (0.56): high

### Global innovation index (rank):  

24.1 (97)

### ICT Development Index (rank):  

4.2 (113)

### High-technology exports (% of manufacture exports):  

7.20%
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Equipment Type</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare Facility</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
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<tbody>
<tr>
<td>Magnetic Resonance Imaging:</td>
<td>2</td>
<td>0.29</td>
<td>Health posts:</td>
<td>657</td>
<td>9.66</td>
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<td>Computerized Tomography Scanner:</td>
<td>7</td>
<td>1.03</td>
<td>Health centres:</td>
<td>118</td>
<td>1.73</td>
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<tr>
<td>Positron Emission Tomography Scanner:</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>140</td>
<td>2.06</td>
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<tr>
<td>Gamma camera or nuclear medicine:</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>17</td>
<td>0.25</td>
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<tr>
<td>Mammograph:</td>
<td>3</td>
<td>7.33</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Radiotherapy:</td>
<td>11</td>
<td>1.54</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Dirección de Desarrollo de Servicios de Salud. Unit website: —
Contact name: Ms. Ana Bordon  Contact email: acbo@hotmail.com
Website with publically available technical specifications: —
Number of regional/state offices/units: 10

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population): 13.54
Number of biomedical/clinical engineers professionals in the country: 60

Contacts

MOH focal point
Name: Dr. Julio Borba
Department: —
Email: julioborba29@hotmail.com

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Luis Roberto Escoto
Email: escotoro@paho.org

General comments (...Annex I): Concerning the HT national policy, it was provided the following document: DECRETO EJECUTIVO 468.pdf
Peru

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>32,972 (43)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
</tbody>
</table>

Life expectancy at birth (years): 72.3

Under-five mortality (per 1000 live births): 13.2

Probability of dying aged 30-70 yrs of NCDs (%): 12.60%

Human Development Index (inequality adjusted HDI): 0.78 (0.63): high

ICT Development Index (rank): 4.9 (96)

UHC - Service coverage index (1-100): 77

UHC - Population with household spending >10% (>25%) of corresponding income (%): 9.2% (1.3%)

Global innovation index (rank): 28.8 (76)

High-technology exports (% of manufacture exports): 4.10%

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: [http://www.digemid.minsa.gob.pe/Main.asp?Seccion=474](http://www.digemid.minsa.gob.pe/Main.asp?Seccion=474)
Language(s): Español
MOH responsible for health technology policy implementation: National Authority for Pharmaceutical Products, Medical Devices ans Sanitary Products (DIGEMID) from the Ministry of Health.

Approved devices lists comments (...Annex 1):

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):

There are National Standards or list of recommended medical devices for specific procedures but it is managed by protocols of care at the Hospital, Health Center or Specialty Hospital. For a), b) and c) there are protocols of care at level of hospitals. d) No. There aren’t. There are contingency plans at levels of hospitals. Public health emergency situations (pandemic, acts of terrorism, natural disasters, contamination, etc.).

HTA unit comments (...Annex 1):

Three institutions perform HTA: Ministry of Health-DIGEMID; National Institute of Health (INS) and the Institute of Health Technology Assessment and Research (IETSI-ESSALUD).

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes
Unit: Agencia de Cooperación Internacional.
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: Yes
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, DIGEMID/INS/IETSI-ESSALUD.
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Dirección General de Medicamentos, Insumos y Drogas (DIGEMED).
Website(s): [http://www.digemid.minsa.gob.pe/Main.asp?Seccion=453](http://www.digemid.minsa.gob.pe/Main.asp?Seccion=453)
Contact: Ms. Silvia Perez Valdez Email: sperez@digemid.minsa.gob.pe
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

Population 000s (rank): 32,972 (43)
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: Not specified

Medical device incorporation

Procurement
Policy or guideline: Yes  Website: http://www.digemid.minsa.gob.pe/UpLoad/Uploaded/PDF/Ley29459.pdf
National level procurement: Yes  Website: https://www.gob.pe/minsa

Donations
Policy or guideline: Yes  Website: http://www.digemid.minsa.gob.pe/UpLoad/Uploaded/PDF/Ley29459.pdf

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device INCORPORATION</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:</td>
<td>73</td>
<td>2.21</td>
</tr>
</tbody>
</table>

Healthcare facility

<table>
<thead>
<tr>
<th>Health facility INCORPORATION</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Medical equipment management unit

Unit present: —  Professionally trained biomedical/clinical engineers: No
Unit/Department: Unit of Medical Devices  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): 8.2
Number of biomedical/clinical engineers professionals in the country: 360

Contacts

MOH focal point
Name: —
Department: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Carlos Garzon Becerra
Email: garzonc@paho.org

General comments

—

WHO Region of the Americas
Philippines

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>109,581 (13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>71.3</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 27.3

| Probability of dying aged 30-70 yrs of NCDs (%): | 26.80% |
| UHC - Service coverage index (1-100): | 61 |
| UHC - Population with household spending >10% (>25%) of corresponding income (%): | 6.3% (1.4%) |
| Human Development Index (inequality adjusted HDI): rank: | 0.72 (0.59): high |
| Global innovation index (rank): | 35.2 (50) |
| ICT Development Index (rank): | 4.7 (101) |

High-technology exports (% of manufacturing exports): 62.20%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes

Unit: Bureau of Health Devices and Technology (BHDT)- Department of Health (to be renamed as Center for Device Regulation, Radiation Health and Research-Food and Drug Authority).

Website: https://www.fda.gov.ph/

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes


Website - IVD: https://www.fda.gov.ph/

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: Yes


National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes

National unit/department that includes HTA for medical devices: Yes, HTA Department of Health.

Website(s): https://hta.doh.gov.ph/

Contact: Dr. Anna Melissa S. Guerrero  Email: asguerrero@doh.gov.ph; hta@doh.gov.ph

Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (Annex 1):

HTAC has one biomedical engineer and one medical physicist.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Bureau of Health Devices and Technology- Department of Health (to be renamed as Center for Device Regulation, Radiation Health and Research-Food and Drug Authority).

Website(s): https://www.fda.gov.ph/

Contact: Dir. Maria Cecilia P. Matienzo  Email: cdrrhr@fda.gov.ph; cdrrhr.lrd@fda.gov.ph

Name(s) of other regulatory agency eg. for radiation equipment etc.: Food and Drug Administration; Philippine Nuclear Research Institute.

Other agency’s website: https://www.fda.gov.ph/; https://www.pnridost.gov.ph/

Approved devices lists comments (Annex 1):

The lists are limited to diagnostics, no interventional equipment noted (ie, ECMO, DaVinci, etc.)

Health care facilities lists comments (Annex 1):

—

Specific lists comments (Annex 1):

This is part of the requirements for the licensing of health facilities. The given URL is for general surgery. The indicated website can be browsed for other recommended medical devices for other procedures.

National regulatory comments (Annex 1):

—

Global innovation index (rank): 35.2 (50)

ICT Development Index (rank): 4.7 (101)

High-technology exports (% of manufacturing exports): 62.20%
Medical device nomenclature system
Official nomenclature system for medical devices: No Type: None Use: Not specified Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes Website: https://www.gppb.gov.ph/gppb-admin/monitoring/app/APP20-DOH.CO.pdf
National level procurement: No Website: https://doh.gov.ph/node/1468

Donations
Policy or guideline: Yes Website: https://doh.gov.ph/node/1468

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: Yes
Website: https://home.doh.gov.ph/auth

Medical equipment
Total Density per 1,000,000 Total Density per 100,000 population population

| Medical device                        | Type | Use                  | Website | National level procurement | Regional level procurement | Local level procurement | Donations | Technical specifications | Publically available
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td></td>
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<td></td>
<td>Yes</td>
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<tr>
<td>Computerized Tomography Scanner</td>
<td></td>
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<td></td>
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<td></td>
<td>Yes</td>
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<tr>
<td>Positron Emission Tomography Scanner</td>
<td></td>
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<td></td>
<td>Yes</td>
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<td>Gamma camera or nuclear medicine</td>
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<td></td>
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<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: —
Use of management software: No Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population): 6
Number of biomedical/clinical engineers professionals in the country: 50

Contacts
MOH focal point
Name: — Department: — Email: —
Other country focal point
Name: Ms. Gladys Cabrera Email: —

WHO health products focal point:
Name: — Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Rabindra Romuald Abeyasinghe Email: abeyasingher@who.int

General comments (...)Annex 1: —

Nomenclature comments (...)Annex 1:
The Philippines will be using the Nomenclature that will be decided by the member states of the ASEAN who are working on the harmonization of medical device regulation in the region, where medical device nomenclature is one of the concerns.

Medical device incorporation comments (...)Annex 1:
The procurement for a medical device is part of the National Procurements system of the Philippine Government (see website). Procurement of medical devices can be done at a national level, at a regional level and local government units.

Medical equipment Total Density per 1,000,000 Total Density per 100,000 population population

| Medical device                        | Type | Use                  | Website | National level procurement | Regional level procurement | Local level procurement | Donations | Technical specifications | Publically available
<table>
<thead>
<tr>
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<td></td>
<td></td>
<td></td>
<td>Yes</td>
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<tr>
<td>Computerized Tomography Scanner</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td></td>
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<td></td>
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<td></td>
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<tr>
<td>Gamma camera or nuclear medicine</td>
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<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.
## Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):a</th>
<th>37,847 (38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:b</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):c</td>
<td>78.5</td>
</tr>
</tbody>
</table>

### National policy on health technology

- **Health technology (medical device) national policy:** No
- **Policy is part of the National Health Program/Plan:** No
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: No
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —

### National list for different types of healthcare facilities (hospitals, laboratories, etc)

- **Lists available:** —
- **Website - hospitals:** —
- **Website - IVD:** —
- **Nomenclature systems used for devices and tests:** —

### National list for specific clinical interventions/emergencies:

- **Lists available:** No
- **Website:** —

### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):d** Yes
- **National unit/department that includes HTA for medical devices:** Yes, the Agency for Health Technology Assessment and Tariff System (AOTMiT).
- **Website(s):** [https://www.aotm.gov.pl/](https://www.aotm.gov.pl/) / [https://www2.aotm.gov.pl/hta/](https://www2.aotm.gov.pl/hta/)
- **Contact:** Email: sekretariat@aotm.gov.pl
- **Committee includes a biomedical or clinical engineer:** No

### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** Yes
- **Name of regulatory agency:** The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
- **Contact:** Email: wm@urpl.gov.pl
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** —
- **Other agency’s website:** —

### Approved devices lists comments (...Annex 1):

The polish competent authority for medical devices is the Office for Registration of Medicinal products, Medical devices and Biocidal products, which keeps the register of medical devices in a database; it is only used for market surveillance and vigilance purposes. On polish market can be placed all CE-marked medical devices according to current EU regulatory framework and directives (90/385/EEC; 93/42/EC; 98/79/EC).

### Health care facilities lists comments (...Annex 1):

There are no lists, but basic (minimal) requirements regarding the necessary medical devices that are a part of the health benefit package regulations and are created concerning the type of facility (including specialisation) and with clear-cut requirements on specialised health care services.

### Specific lists comments (...Annex 1):

There are no lists, but basic (minimal) requirements regarding the necessary medical devices that are a part of the health benefit package regulations and are created concerning the type of facility (including specialisation) and with clear-cut requirements on specialised health care services.

### HTA unit comments (...Annex 1):

AOTMiT evaluates pharmaceutical and non-pharmaceutical technologies including medical devices assessment. The Agency for Health Technology Assessment and Tariff System evaluates pharmaceutical and non-pharmaceutical technologies including medical devices assessment.

### National regulatory comments (...Annex 1):

The Ministry of Health is the national regulatory authority in the area of the health system and The Office for registration of Medicinal Products, Medical Devices and Biocidal Products is the polish competent authority responsible for cooperation with European Commission in the medical device regulatory area. Another regulatory agency is the Market Surveillance, Vigilance system, Clinical trial registration and Inspection, Cooperation with the European Commission and other Competent Authorities.
Medical device nomenclature system

Official nomenclature system for medical devices: Yes
Type: Based on GMDN
Use: For regulatory purposes

Medical device incorporation

Policy or guideline: No
National level procurement: No
Donations
Policy or guideline: No
Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>350</td>
<td>9.25</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>33</td>
<td>0.87</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>140</td>
<td>3.7</td>
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<tr>
<td>Mammograph*</td>
<td>379</td>
<td>73.97</td>
</tr>
<tr>
<td>Radiotherapy*</td>
<td>175</td>
<td>4.62</td>
</tr>
</tbody>
</table>

Healthcare facility

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>70</td>
<td>0.18</td>
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<tr>
<td>Specialized/regional/national hospitals:</td>
<td>57</td>
<td>0.15</td>
</tr>
<tr>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: —
Professionally trained biomedical/clinical engineers: —
Unit/Department: —
Website: —
Contact name: —
Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: —
Use of management software: No
Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): 23.79
Number of biomedical/clinical engineers professionals in the country: 163

Contacts

MOH focal point
Name: Ms. Anna Rychert
Department: Healthcare Services Division, Agency for Health Technology Assessment and Tariff System
Email: a.rychert@aotm.gov.pl
Other country focal point
Name: Mr. Wojciech Marciszko
Email: —

WHO health products focal point:
Name: —
Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Paloma Cuchi
Email: cuchip@who.int

General comments

Nomenclature comments:
The GMDN code is mentioned as a basic medical device nomenclature system in Polish legislation: Act of 20 May 2010 on Medical Devices; however, the use of other nomenclatures is allowed. Poland is part of the EU medical device regulatory framework so a new obligation from the European Commission in the area of medical device nomenclature and Eudamed will be implemented, e.g. adopting the European Medical Device Nomenclature (EMDN) when available. Nevertheless, according to the EC statement, this nomenclature will still share some features with the GMDN code.

Medical device incorporation comments:
—

Software comments:
—

General comments: —
### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>10,197 (88)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>—</td>
</tr>
</tbody>
</table>

| Under-five mortality (per 1000 live births): | 3.7 |
| Probability of dying aged 30-70 yrs of NCDs (%): | 11.10% |
| Human Development Index (inequality adjusted HDI): (rank): | 0.86 (0.76): very high |
| ICT Development Index (rank): | 71 (44) |

| UHC - Service coverage index (1-100): | 82 |
| UHC - Population with household spending >10% (>25%) of corresponding income (%): | 18.4% (3.3%) |
| Global innovation index (rank): | 43.5 (31) |
| High-technology exports (% of manufacture exports): | 6.90% |

### National policy on health technology

**Health technology (medical device) national policy:** Yes  
**Policy is part of the National Health Program/Plan:** Yes  
**Language(s):** Anglais et Portugais  
**MOH responsible for health technology policy implementation:** Administração Central do Sistema de Saúde (ACSS, IP).

### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**  
Lists available: No  
Unit: —  
Website: —  
Nomenclature systems used for devices and tests: —

**National list for different types of healthcare facilities (hospitals, laboratories, etc)**  
Lists available: No  
Website - hospitals: —  
Nomenclature systems used for devices and tests: —

**National list for specific clinical interventions/emergencies:**  
Lists available: —  
Website: —

### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** Yes  
**National unit/department that includes HTA for medical devices:** Yes, National Authority of Medicines and Health Products (INFARMED).  
**Website(s):** [http://www.infarmed.pt/](http://www.infarmed.pt/); [https://www.infarmed.pt/web/infarmed/entidades/dispositivos-medicos/avaliacao-de-tecnologias-de-saude/comparticipacao-de-dispositivos-medicos](https://www.infarmed.pt/web/infarmed/entidades/dispositivos-medicos/avaliacao-de-tecnologias-de-saude/comparticipacao-de-dispositivos-medicos)  
**Contact:** Helena Monteiro  
Email: dats@infarmed.pt; avalia.dispositivos@infarmed.pt  
Committee includes a biomedical or clinical engineer: —

### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes  
**Name of regulatory agency:** National Authority of Medicines and Health Products (INFARMED, I.P).  
**Website(s):** [https://www.infarmed.pt/web/infarmed;](https://www.infarmed.pt/web/infarmed)  
**Contact:** Dr. António Faria Vaz  
Email: daps@infarmed.pt  
**Name(s) of other regulatory agency eg. for radiation equipment etc.:** National Authority of Medicines and Health Products (INFARMED, I.P).

### National health technology assessment unit comments

Functions of Infarmed: Research, assessment, registration, monitoring and supervision of health products. Clinical research evaluation, assessment and registration of CE marked medical devices, notification of health care products and market supervision activities.

### National regulatory comments

...
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Based on EMDN  Use: For regulatory purposes
Website: https://www.infarmed.pt/web/infarmed/pesquisa-dispositivos

Medical device incorporation
Procurement
Policy or guideline: No  Website: —
Donations
Policy or guideline: No  Website: —
Technical specifications
Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>105</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>291</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanners*</td>
<td>7</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine*</td>
<td>54</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>375</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>73</td>
</tr>
</tbody>
</table>

Healthcare facility
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>327</td>
</tr>
<tr>
<td>Health centres:</td>
<td>19</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>n/a</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
</tr>
<tr>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: —  Professionally trained biomedical/clinical engineers: No
Unit/Department: —  Unit website: https://extranet.infarmed.pt/SIDM-fo/
Contact name: —  Contact email: —
Website with publically available technical specifications: https://extranet.infarmed.pt/SIDM-fo/
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: https://www.infarmed.pt/web/infarmed/pesquisa-dispositivos; https://www.infarmed.pt/web/infarmed/pesquisa-dispositivos#
Use of management software: —  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population):* 53.12
Number of biomedical/clinical engineers professionals in the country:* 2060

Contacts
MOH focal point
Name: Ms. Luisa Taveira
Department: UOIIIE - Unidade Operacional de Investimentos em Instalações e Equipamentos
Email: ltaveira@acss.min-saude.pt
Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —
WHO Representative/WHO Liaison Officer:
Name: —
Email: —

General comments (...Annex 1): —
### Qatar

#### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):*</th>
<th>2,881 (136)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:*</td>
<td>High</td>
</tr>
</tbody>
</table>

**Life expectancy at birth (years):**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>74.7</td>
<td>75.2</td>
<td>76.0</td>
<td>76.7</td>
<td>77.4</td>
<td>78.0</td>
<td>79.0</td>
<td>80.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births):*</th>
<th>6.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Service coverage index (1-100):*</td>
<td>68</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Probability of dying aged 30-70 yrs of NCDs (%):*</th>
<th>15.30%</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>— (—)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Human Development Index (inequality adjusted HDI): rank*</th>
<th>0.85 (&lt;-): very high</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global innovation index (rank):</td>
<td>30.8 (70)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICT Development Index (rank):*</th>
<th>7.2 (39)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-technology exports (% of manufacture exports):*</td>
<td>0.00%</td>
</tr>
</tbody>
</table>

#### National policy on health technology

**Health technology (medical device) national policy:** Yes

**Policy is part of the National Health Program/Plan:** No

**Website:** [https://www.hamad.qa/EN/Pages/default.aspx](https://www.hamad.qa/EN/Pages/default.aspx)

**Language(s):** English

**MOH responsible for health technology policy implementation:** Bio-Medical Engineering Department.

#### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**

- **Lists available:** Yes, but it is only a recommendation
- **Unit:** Bio-Medical Engineering Department
- **Website:** [—]
- **Nomenclature systems used for devices and tests:** [—]

**National list for different types of healthcare facilities (hospitals, laboratories, etc):**

- **Lists available:** Yes
- **Website - hospitals:** [—]
- **Website - IVD:** [—]
- **Nomenclature systems used for devices and tests:** [—]

**National list for specific clinical interventions/emergencies:**

- **Lists available:** Yes
- **Website:** [—]

#### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** No

**National unit/department that includes HTA for medical devices:** No

**Website(s):** [https://www.moph.gov.qa/english/Pages/default.aspx](https://www.moph.gov.qa/english/Pages/default.aspx)

**Contact:** Email: [—]

**Committee includes a biomedical or clinical engineer:** Yes

#### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes

**Name of regulatory agency:** Medical Licensing Department


**Contact:** Dr. Jamal Rashid S. Khanji  Email: [—]

**Name(s) of other regulatory agency eg. for radiation equipment etc.:** [—]

**Other agency’s website:** [—]

#### Approved devices lists comments

(...Annex 1):

There are functional inventory of medical devices for procurement and/ or reimbursement in HMC hospitals. HMC disciplines occupies functional inventory of medical devices for prompt delivery of patient care services. Emergency preparedness policy reference.

#### Health care facilities lists comments

(...Annex 1):

Specific lists comments (...Annex 1):

- HMC disciplines occupies functional inventory of medical devices for prompt delivery of patient care services. It exists the emergency preparedness policy reference (including lists) too.

#### HTA unit comments

(...Annex 1):

There are identified HTA activities. HTA consultancy is required for building high-level infrastructure and there is the formation of an HTA workforce but there is not a national unit. Drugs pricing falls on External Reference Pricing stated in the national objectives towards Universal Health Care (UHC) implementation goal.

#### National regulatory comments

(...Annex 1):

If ever a private agency, hospital or clinic needs a specific product they should approach the Medical Licensing which in turn seeks technical evaluation (such as specification, safety, compliance, etc.) from the Bio-Medical Engineering to import the product to the country. Bio-Eng does verify FDA, CE and/ or equivalent compliance on medical device/ equipment for safety, especially for Hamad Medical Corporation (HMC) hospitals.
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  
Type: Based on UMDNS  
Use: Not specified  
Website: https://www.ecri.org/solutions/umdns/

Medical device incorporation
Procurement
Policy or guideline: Yes  
Website: —  
National level procurement: Yes  
Website: https://www.hamad.qa/EN/Pages/default.aspx

Donations
Policy or guideline: Yes  
Website: —  
Technical specifications
Technical specifications to support procurement or donations: Yes  
Publically available: No  
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:</td>
<td>20</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:</td>
<td>18</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:</td>
<td>1</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:</td>
<td>4</td>
</tr>
<tr>
<td>Mammograph:</td>
<td>9</td>
</tr>
<tr>
<td>Radiotherapy:</td>
<td>4</td>
</tr>
</tbody>
</table>

Healthcare facility
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>n/a</td>
</tr>
<tr>
<td>Health centres:</td>
<td>n/a</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>n/a</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Nomenclature comments (Annex 1): This is used for planning of medical equipment for new/upcoming projects.

Medical device incorporation comments (Annex 1): The specification compliance on safety and clinical requisites is regularly updated.  
The Hamad Medical Corporation (HMC) Materials Management and Tender committee take over the procurement activities of Medical and Non-Medical Equipment/items for HMC hospitals, and the ministry upon request, as deemed necessary. Specification of equipment formulated in cooperation with end-user prepared by Bio-eng.

Medical device incorporation comments (Annex 1): The specification compliance on safety and clinical requisites is regularly updated. The Hamad Medical Corporation (HMC) Materials Management and Tender committee take over the procurement activities of Medical and Non-Medical Equipment/items for HMC hospitals, and the ministry upon request, as deemed necessary. Specification of equipment formulated in cooperation with end-user prepared by Bio-eng.

Medical equipment management unit
Unit present: Yes  
Professionally trained biomedical/clinical engineers: Yes  
Unit/Department: Biomedical Engineering Department  
Unit website: https://www.hamad.qa/EN/Pages/default.aspx  
Contact name: Mr. Rashid al Mansoori  
Contact email: ralmansoori@hmc.org.qa  
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: National functional inventory for medical equipment  
Website: —  
Use of management software: Yes  
Software name: AssetPlus (by GE).

Medical devices workforce
Density of medical doctors (per 10,000 population): 24.85  
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: —  
Department: —  
Email: —  
Other country focal point
Name: —  
Email: —  

WHO health products focal point
Name: —  
Email: —  
WHO Representative/WHO Liaison Officer
Name: Dr. Rayana Ahmad Bou Haka  
Email: emqatdesk@who.int

General comments (Annex 1): List of accredited HMC hospitals: Hamad General Hospital, Women’s Hospital, Rumailah Hospital, Al Amal Hospital, and Al Khor Hospital. Emergency Medical Services (EMS), Pediatric Emergency, Trauma Centers, Orthopedic Center, Dental and School Health, Home Healthcare, Primary Health Centers, Skilled Nursing Facility.  
Upcoming projects: Qatar Heart Center, New Children’s Hospital, Al-Wakra Hospital. Please visit the Hamad Medical Corporation website (www.hamad.qa) and the Qatar Supreme Council of Health website (https://www.moph.gov.qa/) for more details.
# Republic of Korea

## Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):a</th>
<th>51,269 (28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:b</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):c</td>
<td>72.1 (World: 72.8)</td>
</tr>
</tbody>
</table>

## Health technology on health technology

<table>
<thead>
<tr>
<th>National policy on health technology</th>
<th>Republic of Korea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health technology (medical device) national policy:</td>
<td>Yes</td>
</tr>
<tr>
<td>Policy is part of the National Health Program/Plan:</td>
<td>Yes</td>
</tr>
<tr>
<td>Website:</td>
<td><a href="https://law.go.kr/">https://law.go.kr/</a></td>
</tr>
<tr>
<td>Language(s):</td>
<td>Korean</td>
</tr>
<tr>
<td>MOH responsible for health technology policy implementation:</td>
<td>Division of Pharmaceutical Policy</td>
</tr>
</tbody>
</table>

## National lists of medical devices

<table>
<thead>
<tr>
<th>National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:</th>
<th>Approved devices lists comments (Annex 1):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lists available:</td>
<td>The Health Insurance and Review Assessment (HIRA) is responsible for listing treatment materials for public insurance.</td>
</tr>
<tr>
<td>Unit: Health Insurance Review &amp; Assessment Service (HIRA).</td>
<td></td>
</tr>
<tr>
<td>Website:</td>
<td></td>
</tr>
<tr>
<td>Nomenclature systems used for devices and tests:</td>
<td>Health care facilities lists comments (Annex 1):</td>
</tr>
<tr>
<td>National list for different types of healthcare facilities (hospitals, laboratories, etc)</td>
<td></td>
</tr>
<tr>
<td>Lists available:</td>
<td></td>
</tr>
<tr>
<td>Website - hospitals:</td>
<td></td>
</tr>
<tr>
<td>Website - IVD:</td>
<td>[<a href="https://www.mfds.go.kr/eng/brd/m_40/view.do?seq=72625&amp;srchFr=&amp;srchTo=&amp;srchWord=&amp;srchTp=&amp;itm_seq_1=0&amp;itm_seq_2=0&amp;multi">https://www.mfds.go.kr/eng/brd/m_40/view.do?seq=72625&amp;srchFr=&amp;srchTo=&amp;srchWord=&amp;srchTp=&amp;itm_seq_1=0&amp;itm_seq_2=0&amp;multi</a> Italics=0&amp;company_cd=&amp;company_nm=&amp;page=1](<a href="https://www.mfds.go.kr/eng/brd/m_40/view.do?seq=72625&amp;srchFr=&amp;srchTo=&amp;srchWord=&amp;srchTp=&amp;itm_seq_1=0&amp;itm_seq_2=0&amp;multi">https://www.mfds.go.kr/eng/brd/m_40/view.do?seq=72625&amp;srchFr=&amp;srchTo=&amp;srchWord=&amp;srchTp=&amp;itm_seq_1=0&amp;itm_seq_2=0&amp;multi</a> Italics=0&amp;company_cd=&amp;company_nm=&amp;page=1)</td>
</tr>
<tr>
<td>Nomenclature systems used for devices and tests:</td>
<td>Specific lists comments (Annex 1):</td>
</tr>
<tr>
<td>National list for specific clinical interventions/emergencies:</td>
<td></td>
</tr>
<tr>
<td>Lists available:</td>
<td></td>
</tr>
<tr>
<td>Website:</td>
<td></td>
</tr>
</tbody>
</table>

## National health technology assessment unit

<table>
<thead>
<tr>
<th>National health technology assessment unit</th>
<th>National regulatory comments (Annex 1):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designated unit/department for health technology assessment (HTA):d</td>
<td>HTA is performed in a variety of health areas including medical technologies, devices, interventions, etc.</td>
</tr>
<tr>
<td>National unit/department that includes HTA for medical devices:</td>
<td>Yes, National Evidence-based healthcare Collaborating Agency (NECA).</td>
</tr>
<tr>
<td>Website(s):</td>
<td><a href="https://www.neca.re.kr/eng/index.do">https://www.neca.re.kr/eng/index.do</a></td>
</tr>
<tr>
<td>Contact:</td>
<td>Email:</td>
</tr>
<tr>
<td>Committee includes a biomedical or clinical engineer:</td>
<td></td>
</tr>
</tbody>
</table>

## National regulatory authority

<table>
<thead>
<tr>
<th>National regulatory authority</th>
<th>National regulatory comments (Annex 1):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presence of national authority responsible for regulating medical devices:</td>
<td>Yes</td>
</tr>
<tr>
<td>Name of regulatory agency: Korea Food &amp; Drug Administration.</td>
<td></td>
</tr>
<tr>
<td>Contact: Lim, Jai-gui</td>
<td>Email:</td>
</tr>
<tr>
<td>Name(s) of other regulatory agency eg. for radiation equipment etc.: Korea Institute of Nuclear Safety (KINS); Nuclear Safety and Security Commission.</td>
<td></td>
</tr>
<tr>
<td>Other agency’s website:</td>
<td><a href="https://www.kins.re.kr/eng">https://www.kins.re.kr/eng</a></td>
</tr>
</tbody>
</table>
Medical device nomenclature system
Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: Not specified
Website: https://www.mfds.go.kr/eng/wpge/m_39/denofile.do

Medical device incorporation
Procurement
Policy or guideline: Yes Website: http://www.pps.go.kr
National level procurement: Yes Website: http://www.pps.go.kr
Donations
Policy or guideline: Yes Website: https://www.kofih.org/projects/healthcare-resources-support/

Technical specifications
Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:</td>
<td>1553</td>
<td>30.29</td>
<td>Health posts:</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:</td>
<td>1991</td>
<td>38.83</td>
<td>Health centres:</td>
<td>27818</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:</td>
<td>195</td>
<td>3.8</td>
<td>General/district hospitals:</td>
<td>1366</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:</td>
<td>306</td>
<td>5.97</td>
<td>Specialized/regional/national hospitals:</td>
<td>44</td>
</tr>
<tr>
<td>Mammograph:</td>
<td>3179</td>
<td>421.87</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:</td>
<td>218</td>
<td>4.25</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: — Unit website: https://www.mfds.go.kr/eng/wpge/m_55/de011038l001.do;https://emed.mfds.go.kr/#!CEAA4B02F22D
Contact name: — Contact email: —
Website with publically available technical specifications: https://www.mfds.go.kr/eng/brd/m_40/view.do?seq=7809&srchFr=0&srchTo=0&srchWord=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=0&company_nm=&page=1; https://www.mfds.go.kr/eng/brd/m_41/down.do?brd_id=eng0011&seq=71809&data_tp=A&file_seq=2
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —
Website: https://www.mfds.go.kr/eng/brd/m_40/view.do?seq=7809&srchFr=0&srchTo=0&srchWord=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=0&company_nm=&page=1; https://www.mfds.go.kr/eng/brd/m_41/down.do?brd_id=eng0012&seq=70934&data_tp=A&file_seq=1
Use of management software: — Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 24.08
Number of biomedical/clinical engineers professionals in the country: <10

Contacts
MOH focal point
Name: Mr. Jae Lee Kwang
Department: Division of Pharmaceutical Policy
Email: surreal@korea.kr

Other country focal point
Name: Mr. Lim Jae-Gui
Email: guitar92@korea.kr

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: —
Email: —

General comments (...Annex 1): Concerning the Infrastructure section: Korea Health Center is down to 29 beds.
Republic of Moldova

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank)</th>
<th>4,034 (128)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years)</td>
<td>71.7</td>
</tr>
</tbody>
</table>

Health technology policy

Policy is part of the National Health Program/Plan: Yes
Language(s): Romanian and Russian
MOH responsible for health technology policy implementation: Department of Medicines and Medical Devices.

National lists of medical devices

Approved devices lists comments
(...Annex 1):
A special group of Agency of Medicines and Medical Devices organise the procurement of medical equipment from the state budget.

Health care facilities lists comments
(...Annex 1):
—

Specific lists comments
(...Annex 1):
Medical standards on diagnostic and treatment for pathological conditions in surgery, therapeutic profile for adults and children, have been developed. Also, development of guidelines is based on international recommendations for family physicians and blood transfusion agencies.

HTA unit comments
(...Annex 1):
There are identified HTA activities but not a national unit per se.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Agency of Medicines and Medical Devices.
Contact: Mr. Aleksandr Coman Email: office@amed.md
Name(s) of other regulatory agency eg. for radiation equipment etc.: The National Center of Public Health; National Agency for Regulation of Nuclear and Radiological Activities (Ministry of Ecology and Natural Resources).
Other agency’s website: http://www.vertic.org/media/National%20Legislation/Moldova/MD_Statute_ANRANR_eng1.pdf

Population 000s (rank): 4,034 (128)
World Bank income group: Lower-Middle
Life expectancy at birth (years): 71.7

Under-five mortality (per 1000 live births): 14.4
UHC - Service coverage index (1-100): 69

Probability of dying aged 30-70 yrs of NCDs (%): 24.90%
UHC - Population with household spending >10% (>25%) of corresponding income (%): 18.7% (3.6%)

Human Development Index (inequality adjusted HDI): 0.75 (0.67): high
Global innovation index (rank): 33 (59)

ICT Development Index (rank): 6.5 (59)
High-technology exports (% of manufacture exports): 3.00%

Under-five mortality (per 1000 live births): 14.4
UHC - Service coverage index (1-100): 69
## Medical device nomenclature system

**Official nomenclature system for medical devices:** No  
**Type:** None  
**Use:** Not specified


## Medical device incorporation

### Procurement

**Policy or guideline:** Yes  
**National level procurement:** Yes  
**Website:** [http://capcs.md/](http://capcs.md/)

### Donations

**Policy or guideline:** Yes  
**Website:** [http://capcs.md/](http://capcs.md/)

### Technical specifications

**Technical specifications to support procurement or donations:** Yes

*Website:* [https://msmps.gov.md/](https://msmps.gov.md/)  
[https://amdm.gov.md/ro/](https://amdm.gov.md/ro/)

## Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Magnetic Resonance Imaging</strong></td>
<td>5</td>
<td>1.43</td>
<td>Health posts:</td>
<td>1025</td>
<td>29.39</td>
</tr>
<tr>
<td><strong>Computerized Tomography Scanner</strong></td>
<td>19</td>
<td>5.45</td>
<td>Health centres:</td>
<td>352</td>
<td>10.09</td>
</tr>
<tr>
<td><strong>Positron Emission Tomography Scanner</strong></td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>34</td>
<td>0.97</td>
</tr>
<tr>
<td><strong>Gamma camera or nuclear medicine</strong></td>
<td>4</td>
<td>1.15</td>
<td>Specialized/regional/national hospitals:</td>
<td>17</td>
<td>0.49</td>
</tr>
<tr>
<td><strong>Mammograph</strong></td>
<td>19</td>
<td>40.95</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td><strong>Radiotherapy</strong></td>
<td>4</td>
<td>0.99</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Density per 1,000,000 females aged from 50-69 old.

## Medical equipment management unit

**Unit present:** Yes  
**Professionally trained biomedical/clinical engineers:** Yes

**Unit/Department:** Department of Medical Devices of the Agency of Medicines and Medical Devices.

**Unit website:** [http://lex.justice.md/md/375113/](http://lex.justice.md/md/375113/)  
[https://amdm.gov.md/ro/](https://amdm.gov.md/ro/)

**Contact name:** Mr. Aleksandr Spynu  
**Contact email:** aspinu@gmail.com


**Number of regional/state offices/units:** 0

## Inventories and medical equipment management software

**Type of inventories available:** None

**Website:** [http://nomenclator.amdm.gov.md/](http://nomenclator.amdm.gov.md/)  

**Use of management software:** Yes  
**Software name:** OpenMedis

## Medical devices workforce

**Density of medical doctors (per 10 000 population):** 25.59

**Number of biomedical/clinical engineers professionals in the country:** 90

## Contacts

**MOH focal point**

**Name:** —  
**Department:** —  
**Email:** —

**Other country focal point**

**Name:** Mr. Aleksandr Spynu
**Email:** aspinu@gmail.com

## WHO health products focal point

**Name:** —  
**Email:** —

---

**a** UN POP/WPP 2019 (2020 POP)  
**b** WB FY21 2019  
**c** UN POP/WPP 2019 (1990-2020 MOR)  
**d** WHO GHO 2019  
**e** WHO GHO 2016  
**f** UNDP 2019  
**g** ITU 2017  
**h** WHO GHO 2017  
**i** WHO GHO 2010-2018  
**j** WIPO 2020  
**k** UN and WB 2017-2019  
**δ** Latest (2015-2021): WHO HTA/HBP 2021 survey or WHO HTA 2015 survey or WHO 2021 survey  
**γ** Latest (2014-2021): WHO GHO 2021 survey  

**n/a** not applicable/not available
Romania

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>19,238 (60)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>71.5</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, National Drugs Agency.
Contact: — Email: secretariat@anm.ro
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: National Agency for Medicines and Medical Devices.
Contact: Ms. Ana Maria Tanase Email: atanase@ms.ro
Name(s) of other regulatory agency eg. for radiation equipment etc.: Agentia Nationala a Medicamentului si a Dispozitivelor Medicale din Romania (ANM).
Other agency's website: http://www.cnccan.ro/; https://www.anm.ro

Approved devices lists comments (...Annex 1):

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):

HTA unit comments (...Annex 1):
Several national entities are in charge of performing HTA activities, each one focus in various areas (see corresponding links).

National regulatory comments (...Annex 1):
### Medical device nomenclature system

Official nomenclature system for medical devices: **Yes**  
**Type:** Based on EMDN  
**Use:** Not specified  
**Website:** —

### Medical device incorporation

#### Procurement

**Policy or guideline:** Yes  
**Website:** [https://www.anm.ro/informatii-de-interes-public/progrumul-annual-al-achizitiilor-publice/](https://www.anm.ro/informatii-de-interes-public/progrumul-annual-al-achizitiilor-publice/)

**National level procurement:** Yes  

#### Donations

**Policy or guideline:** No  
**Website:** —

#### Technical specifications

**Technical specifications to support procurement or donations:** Yes  
**Publically available:** Yes  
**Website:** [https://www.anm.ro/dispozitive-medicale/elibere-aviz-de-donatie/](https://www.anm.ro/dispozitive-medicale/elibere-aviz-de-donatie/)

### Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>43</td>
<td>1.98</td>
<td>Health posts</td>
<td>4</td>
<td>0.02</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>118</td>
<td>5.44</td>
<td>Health centres</td>
<td>13</td>
<td>0.06</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>1</td>
<td>0.05</td>
<td>General/district hospitals</td>
<td>92</td>
<td>0.42</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>25</td>
<td>1.15</td>
<td>Specialized/regional/national hospitals</td>
<td>163</td>
<td>0.75</td>
</tr>
<tr>
<td>Mammograph</td>
<td>112</td>
<td>41.84</td>
<td>Estimation % of health facilities with none or very limited oxygen supply</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>69</td>
<td>3.59</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

### Inventories and medical equipment management software

**Type of inventories available:** National inventory only for high cost technologies (such as MRI, CT or PET scanners)  
**Website:** [https://www.anm.ro/dispozitive-medicale/inregistrare-dispozitive-medicale-in-baza-nationala-de-date/](https://www.anm.ro/dispozitive-medicale/inregistrare-dispozitive-medicale-in-baza-nationala-de-date/)

**Use of management software:** No  
**Software name:** —

### Medical devices workforce

**Density of medical doctors (per 10,000 population):** 29.81

**Number of biomedical/clinical engineers professionals in the country:** 1250

### Contacts

**MOH focal point**  
**Name:** —  
**Department:** —  
**Email:** —

**Other country focal point**  
**Name:** Ms. Ioana Pertache  
**Email:** pertache@ccss.ro

**WHO health products focal point**  
**Name:** —  
**Email:** —

**WHO Representative/WHO Liaison Officer**  
**Name:** Dr. Andreea-Cassandra Butu  
**Email:** butua@who.int

### General comments

General comments (...Annex 1): —
**Country indicators**

<table>
<thead>
<tr>
<th>Population 000s (rank):a</th>
<th>145,934 (9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:b</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):c</td>
<td>69.1 (69.3)</td>
</tr>
</tbody>
</table>

**Under-five mortality (per 1000 live births):d | 5.8 |

| Probability of dying aged 30-70 yrs of NCDs (%):e | 25.40% |
| Human Development Index (inequality adjusted HDI): rank:f | 0.82 (0.74); very high |

| ICT Development Index (rank):g | 71 (45) |

| UHC - Service coverage index (1-100):h | 75 |
| UHC - Population with household spending >10% (>25%) of corresponding income (%):i | 4.9% (0.6%) |

| Global innovation index (rank):j | 35.6 (47) |

| High-technology exports (% of manufacture exports):k | 13.00% |

**National policy on health technology**

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: Yes


Language(s): Russian

MOH responsible for health technology policy implementation: —

**National lists of medical devices**

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**

Lists available: Yes, but it is only a recommendation

Unit: Department of Health Care and Health Development.


Nomenclature systems used for devices and tests: —

**National list for different types of healthcare facilities (hospitals, laboratories, etc)**

Lists available: Yes


Website - IVD: [https://roszdravnadzor.gov.ru/medproducts](https://roszdravnadzor.gov.ru/medproducts)

Nomenclature systems used for devices and tests: —

**National list for specific clinical interventions/emergencies:**

Lists available: Yes


**National health technology assessment unit**

Designated unit/department for health technology assessment (HTA): Yes

National unit/department that includes HTA for medical devices: Yes, Department of the Pharmaceutical and Medical Devices Market Development.

Website(s): [https://minzdrav.gov.ru/documents](https://minzdrav.gov.ru/documents)

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

**National regulatory authority**

Presence of national authority responsible for regulating medical devices: Yes


Website(s): [http://roszdravnadzor.ru](http://roszdravnadzor.ru)

Contact: — Email: interdep@rosminzdrav.ru

Name(s) of other regulatory agency eg. for radiation equipment etc.: Federal Environmental, Industrial and Nuclear Supervision Service of Russia; Ministry of Health of the Russian Federation.


**HTA unit comments (...Annex 1):**

The HTA system development is inserted in the Russian Federation healthcare legislation. Currently, the procedure for a comprehensive assessment of drugs has been approved and is constantly being improved. However it is still at their start phase for medical devices and biomedical products.

**National regulatory comments (...Annex 1):**

However, the system is still in its early stages for medical devices and biomedical products.
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: Not specified
Website: https://roszdravnadzor.gov.ru/services/mi_reestr

Medical device incorporation

Procurement
National level procurement: No  Website: https://minzdrav.gov.ru/ministry/tenders

Donations

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: Yes

Medical equipment

| Magnetic Resonance Imaging:a | 711 | 4.87 | Health posts: n/a | n/a |
| Computerized Tomography Scanner:a | 1963 | 13.45 | Health centres: n/a | n/a |
| Positron Emission Tomography Scanner:a | n/a | n/a | General/distinct hospitals: n/a | n/a |
| Gamma camera or nuclear medicine:a | n/a | n/a | Specialized/regional/national hospitals: n/a | n/a |
| Mammograph:a | n/a | n/a | Estimation % of health facilities with none or very limited oxygen supply: n/a |
| Radiotherapy:b | 694 | 4.76 | |

*a Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Department of Health Care and Health Development. Unit website: https://roszdravnadzor.gov.ru/
Contact name: Ms. Olga Krivonos Vladimirovna  Contact email: KrivonosOV@rosminzdrav.ru
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: https://roszdravnadzor.gov.ru/services/mirearch;
Use of management software: —  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): ε 44.4
Number of biomedical/clinical engineers professionals in the country: γ <10

Contacts

MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: Ms. Olga Krivonos Vladimirovna  Email: KrivonosOV@rosminzdrav.ru

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liason Officer:
Name: Dr. Melita Vujnovic  Email: vujnovicm@who.int

General comments (...Annex 1): —
### Rwanda

#### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank): a</th>
<th>12,952 (75)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group: b</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years): c</td>
<td>68.8</td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births): d</td>
<td>34.3</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%): e</td>
<td>18.20%</td>
</tr>
<tr>
<td>Human Development Index (rank): f</td>
<td>0.54 (0.39): low</td>
</tr>
<tr>
<td>ICT Development Index (rank): g</td>
<td>2.2 (153)</td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births): h</td>
<td>34.3</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100): i</td>
<td>57</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%): j</td>
<td>1.2% (0.1%)</td>
</tr>
<tr>
<td>Global innovation index (rank): k</td>
<td>25.1 (91)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports): l</td>
<td>10.60%</td>
</tr>
</tbody>
</table>

#### National policy on health technology

**Health technology (medical device) national policy:** —
- **Policy is part of the National Health Program/Plan:** —
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

#### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
- **Lists available:** —
- **Unit:** —
- **Website:** —
- **Nomenclature systems used for devices and tests:** —

**National list for different types of healthcare facilities (hospitals, laboratories, etc):**
- **Lists available:** —
- **Website - hospitals:** —
- **Website - IVD:** —
- **Nomenclature systems used for devices and tests:** —

**National list for specific clinical interventions/emergencies:**
- **Lists available:** —
- **Website:** —

#### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA): a** No
- **National unit/department that includes HTA for medical devices:** No
- **Website(s):** —
- **Contact:** Email: —
- **Committee includes a biomedical or clinical engineer:** —

#### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** —
- **Name of regulatory agency:** —
- **Website(s):** —
- **Contact:** Email: —
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** —
- **Other agency’s website:** —

---

*Note: Annex 1 contains additional approved devices lists comments, health care facilities lists comments, specific lists comments, HTA unit comments, and national regulatory comments.*
Medical device nomenclature system

Official nomenclature system for medical devices: Yes
Type: Many co-existence of nomenclatures
Use: For various purposes above-mentioned
Website: —

Medical device incorporation

Procurement

Policy or guideline: —
Website: —
National level procurement: —
Website: —

Donations

Policy or guideline: —
Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical device incorporation comments (...Annex 1):

—

Medical equipment

<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging(a)</td>
<td>n/a</td>
<td>Health posts: n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner(a)</td>
<td>n/a</td>
<td>Health centres: n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner(a)</td>
<td>n/a</td>
<td>General/district hospitals: n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine(a)</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals: n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph(a)</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply: n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy(a)</td>
<td>2</td>
<td>0.15</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(a\) Density per 1,000,000 females aged from 50-69 old.

Medical device incorporation comments (...Annex 1):

—

Medical equipment management unit

Unit present: —
Professionally trained biomedical/clinical engineers: —
Unit/Department: —
Website: —
Contact name: —
Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Medical equipment management unit comments (...Annex 1):

—

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: —
Software name: —

Inventories and medical equipment management software comments (...Annex 1):

—

Medical devices workforce

Density of medical doctors (per 10 000 population): \(\alpha\) 1.18
Number of biomedical/clinical engineers professionals in the country: \(\gamma\) 15

Medical devices workforce comments (...Annex 1):

—

Contacts

MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Brian Clever Chirombo
Email: chirombob@who.int

General comments (...Annex 1):

—

WHO African Region

Rwanda has started to use Online Public Procurement, each device should have an unique identification code (mainly based on UMDNS). But it is challenging when dealing with different code nomenclature such as the sterilizer, autoclave or medical gases. Rwanda uses UMDNS for inventory and maintenance of medical equipment.

Medical device incorporation comments (...Annex 1):

—

WHO African Region

Rwanda
## Saint Kitts and Nevis

### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank): a</th>
<th>53 (187)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group: b</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years): c</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births): c</th>
<th>15.4</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Service coverage index (1-100): c</td>
<td>—</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%): c</td>
<td>—</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%): c</td>
<td>— (—)</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank: c</td>
<td>0.78 (—): high</td>
</tr>
<tr>
<td>Global innovation index (rank): c</td>
<td>— (—)</td>
</tr>
<tr>
<td>ICT Development Index (rank): c</td>
<td>7.2 (37)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports): c</td>
<td>34.60%</td>
</tr>
</tbody>
</table>

### National policy on health technology

- Health technology (medical device) national policy: No
- Policy is part of the National Health Program/Plan: No
- Website: —
- Language(s): —
- MOH responsible for health technology policy implementation: —

### National lists of medical devices

- National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
  - Lists available: No
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —

- National list for different types of healthcare facilities (hospitals, laboratories, etc)
  - Lists available: No
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

- National list for specific clinical interventions/emergencies:
  - Lists available: No
  - Website: —

### National health technology assessment unit

- Designated unit/department for health technology assessment (HTA): No
- National unit/department that includes HTA for medical devices: No
- Website(s): —
- Contact: — Email: —
- Committee includes a biomedical or clinical engineer: —

### National regulatory authority

- Presence of national authority responsible for regulating medical devices: No
- Name of regulatory agency: —
- Website(s): —
- Contact: — Email: —
- Name(s) of other regulatory agency eg. for radiation equipment etc.: —
- Other agency’s website: —

---

*Note: The table and content are extracted from the Global Atlas of Medical Devices 2022.*
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: —
Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Device Type</th>
<th>Quantity</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Quantity</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>0</td>
<td>0</td>
<td>Health posts</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>1</td>
<td>18.45</td>
<td>Health centres</td>
<td>17</td>
<td>31.37</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals</td>
<td>2</td>
<td>3.69</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>0</td>
<td>0</td>
<td>Specialized/ regional/ national hospitals</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mammograph*</td>
<td>1</td>
<td>149.44</td>
<td>Estimation % of health facilities with none or very limited oxygen supply</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy*</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: None
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population): 27.67
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: Mr. Patrick Martin
Department: Ministry of Health
Email: skncmo@yahoo.com
Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Yitades Gebre
Email: gebrey@paho.org

General comments (...Annex 1): —
Saint Lucia

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>184 (176)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
</tbody>
</table>

Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births):</th>
<th>22.3</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>68</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>18.80%</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>— (—)</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI):</td>
<td>0.76 (0.63): high</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>— (—)</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>4.6 (104)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>10.50%</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —
National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —
National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

National regulatory comments (...Annex 1):

There is the Bureau of Standards which will do the regulatory activities.

Population 000s (rank): 184 (176)
World Bank income group: Upper-Middle
Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births):</th>
<th>22.3</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>68</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
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</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>— (—)</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI):</td>
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<tr>
<td>Global innovation index (rank):</td>
<td>— (—)</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>4.6 (104)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>10.50%</td>
</tr>
</tbody>
</table>

Approved devices lists comments (...Annex 1):

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):

HTA unit comments (...Annex 1):

National regulatory comments (...Annex 1):

There is the Bureau of Standards which will do the regulatory activities.
Medical device nomenclature system

Official nomenclature system for medical devices: No
Type: None
Use: Not specified
Website: —

Nomenclature comments (...Annex 1):

Medical device incorporation

Procurement
Policy or guideline: No
Website: —
National level procurement: No
Website: —

Donations
Policy or guideline: No
Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:α</td>
<td>2</td>
<td>10.97</td>
<td>Health posts:</td>
<td>34</td>
<td>18.65</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:β</td>
<td>2</td>
<td>10.97</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:β</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:β</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>3</td>
<td>1.65</td>
</tr>
<tr>
<td>Mammograph:α,β</td>
<td>2</td>
<td>131.06</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:β</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Software comments (...Annex 1):
The medical equipment inventories of public hospitals exist. The functional status of such equipment is reflected in these lists. No PET scanners are available on the island. CT and MRI are available only in one private hospital facility.

Medical equipment management unit

Unit present: Yes
 Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —
 Website: —
 Contact name: —
Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No
Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): 6.41
Number of biomedical/clinical engineers professionals in the country: —

Contacts

MOH focal point
Name: Mr. Protus Angus Jean Baptiste
Department: Corporate Planning Unit Ministry of Health
Email: Mellow64@gmail.com

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Yitades Gebre
Email: gebrey@paho.org

General comments (...Annex 1): —
### Saint Vincent and the Grenadines

#### Country indicators

<table>
<thead>
<tr>
<th>Measure</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>111 (180)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.1</td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>14.6</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>23.20%</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank:</td>
<td>high</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>5.5 (82)</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>71</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>— (—)</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>— (—)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>9.90%</td>
</tr>
</tbody>
</table>

#### National policy on health technology

- **Health technology (medical device) national policy:** No
- **Policy is part of the National Health Program/Plan:** No
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

#### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: No
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —

- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - Lists available: No
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

- **National list for specific clinical interventions/emergencies:**
  - Lists available: No
  - Website: —

#### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):** No
- **National unit/department that includes HTA for medical devices:** No
- **Contact:** — Email: —
- **Committee includes a biomedical or clinical engineer:** —

#### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** No
- **Name of regulatory agency:** —
- **Website(s):** —
- **Contact:** — Email: —
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** —
- **Other agency’s website:** —

#### HTA unit comments (...Annex 1):

There are identified HTA activities but not a national unit. The development of one is in progress.

#### National regulatory comments (...Annex 1):

—
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified  Website: —

Medical device incorporation

Policy or guideline: No  Website: —

Procurement

Policy or guideline: No  Website: —

National level procurement: Yes  Website: —

Donations

Policy or guideline: No  Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Equipment Type</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>0</td>
<td>0</td>
<td>Health posts:</td>
<td>39</td>
<td>35.66</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>Health centres:</td>
<td>1</td>
<td>0.91</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mammography:*</td>
<td>2</td>
<td>229.86</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>0</td>
<td>0</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes

Unit/Department: —  Unit website: —

Contact name: —  Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None  Website: —

Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): * 9.41

Number of biomedical/clinical engineers professionals in the country: —

Contacts

MOH focal point

Name: Mr. Fitzroy T. Jones

Department: Milton Cato Memorial Hospital

Email: mcmh@gov.vc

Other country focal point

Name: Mr. Pedro Richards

Email: pedradxray@yahoo.com

WHO health products focal point:

Name: —

Email: —

WHO Representative/WHO Liaison Officer:

Name: Dr. Yitades Gebre

Email: gebrey@paho.org

General comments (...Annex 1): —

WHO Region of the Americas

World Health Organization

St. Vincent and the Grenadines

Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified  Website: —

Medical device incorporation

Policy or guideline: No  Website: —

Procurement

Policy or guideline: No  Website: —

National level procurement: Yes  Website: —

Donations

Policy or guideline: No  Website: —

Technical specifications

Technical specifications to support procurement or donations: No

Publically available: —

Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Equipment Type</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>0</td>
<td>0</td>
<td>Health posts:</td>
<td>39</td>
<td>35.66</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>Health centres:</td>
<td>1</td>
<td>0.91</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mammography:*</td>
<td>2</td>
<td>229.86</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>0</td>
<td>0</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes

Unit/Department: —  Unit website: —

Contact name: —  Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None  Website: —

Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): * 9.41

Number of biomedical/clinical engineers professionals in the country: —

Contacts

MOH focal point

Name: Mr. Fitzroy T. Jones

Department: Milton Cato Memorial Hospital

Email: mcmh@gov.vc

Other country focal point

Name: Mr. Pedro Richards

Email: pedradxray@yahoo.com

WHO health products focal point:

Name: —

Email: —

WHO Representative/WHO Liaison Officer:

Name: Dr. Yitades Gebre

Email: gebrey@paho.org

General comments (...Annex 1): —
### Samoa

**Country indicators**

<table>
<thead>
<tr>
<th>Population 000s (rank): a</th>
<th>198 (175)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group: b</td>
<td>Upper-Middle</td>
</tr>
</tbody>
</table>

**Life expectancy at birth (years): c**

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births): d</th>
<th>15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%): e</td>
<td>20.60%</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank f</td>
<td>0.72 (—); high</td>
</tr>
<tr>
<td>ICT Development Index (rank): g</td>
<td>3.3 (127)</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100): h</td>
<td>58</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%): i</td>
<td>— (—)</td>
</tr>
<tr>
<td>Global innovation index (rank): j</td>
<td>— (—)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports): k</td>
<td>2.30%</td>
</tr>
</tbody>
</table>

### National policy on health technology

**Policy and planning**

- **Health technology (medical device) national policy:** No
- **Policy is part of the National Health Program/Plan:** No
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**

- **Lists available:** Yes, but it is only a recommendation
- **Unit:** Biomedical Engineering Unit.
- **Website:** —
- **Nomenclature systems used for devices and tests:** —

**National list for different types of healthcare facilities (hospitals, laboratories, etc):**

- **Lists available:** Yes
- **Website - hospitals:** —
- **Website - IVD:** —
- **Nomenclature systems used for devices and tests:** —

**National list for specific clinical interventions/emergencies:**

- **Lists available:** Yes
- **Website:** [https://www.samoagovt.ws/tag/ministry-of-health/](https://www.samoagovt.ws/tag/ministry-of-health/)

### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):**

- **Designated unit/department:** No
- **National unit/department that includes HTA for medical devices:** No
- **Website(s):** —
- **Contact:** —
- **Email:** —
- **Committee includes a biomedical or clinical engineer:** —

### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes

**Name of regulatory agency:** Ministry of Health, Medical Equipment Management Committee.

- **Website(s):** [https://www.samoagovt.ws/tag/ministry-of-health/](https://www.samoagovt.ws/tag/ministry-of-health/)
- **Contact:** Ms. Palanitina Toelupe
- **Email:** —

**Name(s) of other regulatory agency eg. for radiation equipment etc.:** National Health Services Motootua Samoa, Government Apia Samoa.

**Other agency’s website:** [https://www.health.gov.ws/](https://www.health.gov.ws/)

**UHC - Service coverage index (1-100):**

- **15**

**UHC - Population with household spending >10% (>25%) of corresponding income (%):**

- **— (—)**

**Global innovation index (rank):**

- **— (—)**

**High-technology exports (% of manufacture exports):**

- **2.30%**

**ICT Development Index (rank):**

- **3.3 (127)**

**Human Development Index (inequality adjusted HDI):**

- **0.72 (—); high**

**Probability of dying aged 30-70 yrs of NCDs (%):**

- **20.60%**

**Under-five mortality (per 1000 live births):**

- **15**

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**

- **Lists available:** Yes, but it is only a recommendation

**National list for different types of healthcare facilities (hospitals, laboratories, etc):**

- **Lists available:** Yes

**National list for specific clinical interventions/emergencies:**

- **Lists available:** Yes

**Website:** [https://www.samoagovt.ws/tag/ministry-of-health/](https://www.samoagovt.ws/tag/ministry-of-health/)

**Committee includes a biomedical or clinical engineer:** —

**National regulatory comments (Annex 1):**

- There are identified HTA activities but not a national unit. MoH together with National Health Services (NHS) intend to develop one, but it is still on progress.
Medical device nomenclature system
Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For procurement purposes
Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes Website: www.mof.gov.ws
National level procurement: Yes Website: —
Donations
Policy or guideline: Yes Website: —
Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical equipment
Total | Density per 1,000,000 population | Healthcare facility
--- | --- | ---
Magnetic Resonance Imaging\(^a\) | 0 | 0 | Health posts: 0 | 0
Computerized Tomography Scanner\(^a\) | 1 | 5.25 | Health centres: 3 | 1.58
Positron Emission Tomography Scanner\(^a\) | 0 | 0 | General/district hospitals: 6 | 3.15
Gamma camera or nuclear medicine\(^a\) | 0 | 0 | Specialized/regional/national hospitals: 1 | 0.53
Mammograph\(^a\)* | 1 | 91.16 | Estimation % of health facilities with none or very limited oxygen supply: n/a
Radiotherapy\(^a\) | 0 | 0 |

\(^a\) Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Tupua Tamasese Meaole (TTM) Hospital Administrator. Unit website: —
Contact name: Ms. Kristy. T. Contact email: KristyT@mof.gov.ws
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: National functional inventory for medical equipment
Use of management software: No Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): \(^a\) 3.45
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: —
Department: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Mark Andrew Jacobs
Email: jacobsma@who.int

Other country focal point
Name: Ms. Kristy. T.
Email: KristyT@mof.gov.ws

General comments (...Annex 1): Concerning the Infrastructure section: there are 18 General Practitioner Clinics in the Private sector.
San Marino

Country indicators

Population 000s (rank): 34 (189)
World Bank income group: High

Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Year</th>
<th>1990</th>
<th>2000</th>
<th>2010</th>
<th>2020</th>
<th>World</th>
</tr>
</thead>
<tbody>
<tr>
<td>Life Expectancy</td>
<td>83.7</td>
<td>84.2</td>
<td>85.3</td>
<td>85.8</td>
<td>72.3</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 1.7

Probability of dying aged 30-70 yrs of NCDs (%): —

Human Development Index (inequality adjusted HDI): rank —

ICT Development Index (rank): —

UHC - Service coverage index (1-100): —

UHC - Population with household spending >10% (>25%) of corresponding income (%): —

Global innovation index (rank): —

High-technology exports (% of manufacture exports): —

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: http://www.sanita.sm/on-line/home/authority-sanitaria.html
Language(s): Italiano
MOH responsible for health technology policy implementation: Health Authority for Authorization, Accreditation and Quality of Health Services.

National lists of medical devices

Approved devices lists comments (...Annex 1):

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

Health care facilities lists comments (...Annex 1):

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

Specific lists comments (...Annex 1):

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No
Website(s): http://www.sanita.sm/on-line/home.html
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
There are identified HTA activities but not a national unit.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Health Authority for Authorization, Accreditation and Quality of Health Services.
Website(s): http://www.sanita.sm/on-line/home/authority-sanitaria.html
Contact: Mr. Andrea Gualtieri. Email: andrea.gualtieri.authority@pa.sm
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

National regulatory comments (...Annex 1):
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified  Website: —

Medical device incorporation

Procurement

Policy or guideline: No  Website: —

National level procurement: No  Website: —

Donations

Policy or guideline: Yes  Website: —

Technical specifications

Technical specifications to support procurement or donations: No  Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th></th>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>2</td>
<td>63.6</td>
<td></td>
<td>Healthcare facility</td>
<td>Total</td>
<td>Density per 100,000 population</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>1</td>
<td>31.8</td>
<td></td>
<td>Health posts</td>
<td>3</td>
<td>9.54</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>0</td>
<td>0</td>
<td></td>
<td>Health centres</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>0</td>
<td>0</td>
<td></td>
<td>General/district hospitals</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mammograph</td>
<td>1</td>
<td>229.11</td>
<td></td>
<td>Specialized/regional/national hospitals</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>0</td>
<td>0</td>
<td></td>
<td>Estimation % of health facilities with none or very limited oxygen supply</td>
<td>n/a</td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Health Authority for Authorization, Accreditation and Quality of Health Services.


Contact name: Mr. Andrea Gualtieri  Contact email: andrea.gualtieri.authority@pa.sm


Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None  Website: —  Use of management software: —  Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): 61.09

Number of biomedical/clinical engineers professionals in the country: —

Contacts

**MOH focal point**

Name: Mr. Andrea Gualtieri  Department: Health Authority for Authorization, Accreditation and Quality of Health Services  Email: andrea.gualtieri.authority@pa.sm

Other country focal point

Name: —  Email: —

WHO health products focal point:

Name: —  Email: —

WHO Representative/WHO Liason Officer:

Name: —  Email: —

General comments (...Annex 1): For specialized care and diagnostics, patients can be treated in Italian hospitals that have agreements with San Marino.

---

### Medical equipment

| Medical equipment | Total | Density per 1,000,000 population | Medical equipment | Total | Density per 100,000 population |
|-------------------|-------|----------------------------------|---|-------------------|-------|----------------------------------|
| Magnetic Resonance Imaging | 2 | 63.6 | | Healthcare facility | Total | Density per 100,000 population |
| Computerized Tomography Scanner | 1 | 31.8 | | Health posts | 3 | 9.54 |
| Positron Emission Tomography Scanner | 0 | 0 | | Health centres | 0 | 0 |
| Gamma camera or nuclear medicine | 0 | 0 | | General/district hospitals | 0 | 0 |
| Mammograph | 1 | 229.11 | | Specialized/regional/national hospitals | 0 | 0 |
| Radiotherapy | 0 | 0 | | Estimation % of health facilities with none or very limited oxygen supply | n/a |

* Density per 1,000,000 females aged from 50-69 old.

### Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes

Unit/Department: Health Authority for Authorization, Accreditation and Quality of Health Services.


Contact name: Mr. Andrea Gualtieri  Contact email: andrea.gualtieri.authority@pa.sm


Number of regional/state offices/units: 0

### Inventories and medical equipment management software

Type of inventories available: None  Website: —  Use of management software: —  Software name: —

### Medical devices workforce

Density of medical doctors (per 10 000 population): 61.09

Number of biomedical/clinical engineers professionals in the country: —

### Contacts

**MOH focal point**

Name: Mr. Andrea Gualtieri  Department: Health Authority for Authorization, Accreditation and Quality of Health Services  Email: andrea.gualtieri.authority@pa.sm

Other country focal point

Name: —  Email: —

WHO health products focal point:

Name: —  Email: —

WHO Representative/WHO Liason Officer:

Name: —  Email: —

General comments (...Annex 1): For specialized care and diagnostics, patients can be treated in Italian hospitals that have agreements with San Marino.
Sao Tome and Principe

Country indicators

<table>
<thead>
<tr>
<th>Populations of medical devices</th>
<th>219 (174)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.3</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 29.8

Probability of dying aged 30-70 yrs of NCDs (%): 18.50%

Human Development Index (inequality adjusted HDI): 0.63 (0.52); rank: medium

ICT Development Index (rank): 3.1 (132)

UHC - Service coverage index (1-100): 55

UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)

Global innovation index (rank): — (—)

UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)

Global innovation index (rank): — (—)

High-technology exports (% of manufacture exports): 17.00%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

MOH responsible for health technology policy implementation: —

Approved devices lists comments (...Annex 1): —

Health care facilities lists comments (...Annex 1): —

Specific lists comments (...Annex 1): Il n'existe pas au niveau national aucune liste recommandant des technologies de santé.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: No

Unit: —

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: No

Website - hospitals: —

Website - IVD: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: No

Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): No

National unit/department that includes HTA for medical devices: No

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No

Name of regulatory agency: —

Website(s): —

Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: —

Other agency’s website: —

National regulatory comments (...Annex 1): —
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: No  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>28</td>
<td>14.51</td>
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<tr>
<td>Computerized Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>4</td>
<td>2.07</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: —  Professionally trained biomedical/clinical engineers: No
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: None
Website: —
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population):* 3.16
Number of biomedical/clinical engineers professionals in the country: —

Contacts

MOH focal point
Name: Mr. Florentino Fernandes Dos Ramos
Department: Service d’Instalation et Equipement de L’Hopital Dr Ayres de Menezes
Email: frigao@hotmail.com
Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: Dr. Claudina Augusto da Cruz
Email: cruzc@who.int
WHO Representative/WHO Liaison Officer:
Name: Dr. Anne Marie F. J. Ancia
Email: anciaa@who.int

General comments (...Annex 1): —

Saudi Arabia

**Country indicators**

<table>
<thead>
<tr>
<th>Population 000s (rank):a</th>
<th>34,814 (41)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:b</td>
<td>High</td>
</tr>
</tbody>
</table>

**National policy on health technology**

| Health technology (medical device) national policy: | Yes |
| Policy is part of the National Health Program/Plan: | No |
| Website: | http://www.sfda.gov.sa |
| Language(s): | English |
| MOH responsible for health technology policy implementation: | General Supplies and Equipment Directorate. |

**National lists of medical devices**

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**

- Lists available: Yes, but it is only a recommendation
- Unit: National Unified Procurement Company for Medical Supplies (NUPCO) & Saudi Food and Drug Administration (SFDA).
- Website: —
- Nomenclature systems used for devices and tests: —

**National list for different types of healthcare facilities (hospitals, laboratories, etc)**

- Lists available: Yes
- Website - hospitals: —
- Website - IVD: —
- Nomenclature systems used for devices and tests: —

**National list for specific clinical interventions/emergencies:**

- Lists available: Yes
- Website: [https://old.sfda.gov.sa/ar/medicaldevices/Authorized/Pages/Authorized-Medical.aspx](https://old.sfda.gov.sa/ar/medicaldevices/Authorized/Pages/Authorized-Medical.aspx)

**National health technology assessment unit**

**Designated unit/department for health technology assessment (HTA):a**

- Yes

**National unit/department that includes HTA for medical devices:**

- Saudi Food and Drug Authority.

**Website(s):** https://beta.sfda.gov.sa/sites/default/files/2020-03/MDS%E2%80%93G28.pdf

**Contact:** Email: webmaster@sfda.gov.sa

**Committee includes a biomedical or clinical engineer:** —

**National regulatory authority**

**Presence of national authority responsible for regulating medical devices:**

- Yes

**Name of regulatory agency:** Directorates of Supplies and Equipment and Maintenance.

**Website(s):** http://www.sfda.gov.sa/ar/Pages/default.aspx

**Contact:** Mr. Mohamed Bani Al-Hathri and Mr. Abdel-Rahman Al-Zamel Email: Bani5442@hotmail.com

**Name(s) of other regulatory agency eg. for radiation equipment etc.:** Saudi Food & Drug Authority.

**Other agency’s website:** [https://old.sfda.gov.sa/ar/medicaldevices/Pages/default.aspx](https://old.sfda.gov.sa/ar/medicaldevices/Pages/default.aspx)

---

**Global atlas of medical devices 2022**

| Under-five mortality (per 1000 live births):c | 6.7 |
| UHC - Service coverage index (1-100):e | 74 |
| Probability of dying aged 30-70 yrs of NCDs (%)c | 16.40% |
| UHC - Population with household spending >10% (>25%) of corresponding income (%):f | — (—) |
| Human Development Index (inequality adjusted HDI): rank:g | 0.85 (—): very high |
| Global innovation index (rank):j | 30.9 (66) |
| ICT Development Index (rank):a | 6.7 (54) |
| High-technology exports (% of manufacture exports):a | 0.60% |

Under-five mortality (per 1000 live births): 6.7

UHC - Service coverage index (1-100): 74

Probability of dying aged 30-70 yrs of NCDs (%): 16.40%

UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)

Human Development Index (inequality adjusted HDI): rank: 0.85 (—): very high

Global innovation index (rank): 30.9 (66)

ICT Development Index (rank): 6.7 (54)

High-technology exports (% of manufacture exports): 0.60%
Medical device nomenclature system
Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For regulatory and procurement purposes
Website: http://www.nupco.com

Medical device incorporation
Procurement
Policy or guideline: Yes Website: http://www.nupco.com
National level procurement: Yes Website: http://www.nupco.com

Donations
Policy or guideline: Yes Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>28</td>
<td>0.97</td>
<td>Health posts: 0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>110</td>
<td>3.82</td>
<td>Health centres: 0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals: 61</td>
<td>0.21</td>
<td></td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>11</td>
<td>0.38</td>
<td>Specialized/regional/national hospitals: 4</td>
<td>0.01</td>
<td></td>
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<tr>
<td>Mammograph</td>
<td>50</td>
<td>40.62</td>
<td>Estimation % of health facilities with none or very limited oxygen supply: n/a</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>43</td>
<td>1.24</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Maintenance Directorate. Unit website: —
Contact name: Mr. Abdel-Rahman Al-Zamel Contact email: Abomohanad@yahoo.com
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes Software name: Bank Maintennace.

Medcdical devices workforce
Density of medical doctors (per 10 000 population): 26.12
Number of biomedical/clinical engineers professionals in the country: 300

Contacts
MOH focal point
Name: Mr. Mohamed Bani Al-Harthi Department: General Supplies and Equipment Directorate Email: Bani5442@hotmail.com
Other country focal point
Name: Mr. Abdel-Rahman Al-Zamel Email: Abomohanad@yahoo.com

WHO health products focal point:
Name: — Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Ibrahim Jawdat El-Ziq Email: elziqi@who.int

General comments (...Annex 1): Concerning the HT national policy it is stated on the Medical Egypt Management Plan (Corporate).

<table>
<thead>
<tr>
<th>Medical devices workforce</th>
<th>Density per 10 000 population</th>
<th>Number of biomedical/clinical engineers professionals in the country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>26.12</td>
<td>300</td>
</tr>
</tbody>
</table>

Software comments (...Annex 1):
For every hospital and health centre there is a maintenance-specialized company contracted to make the inventory and perform necessary maintenance activities for all medical devices within the facility. Also, there is a National inventory for high cost technologies (such as MRI, CT or PET scanners).
Senegal

Country indicators

Population 000s (rank): 16,744 (69)
World Bank income group: Lower-Middle

Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Age</th>
<th>Senegal</th>
<th>World</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>56.0</td>
<td>68.2</td>
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<tr>
<td>10</td>
<td>58.7</td>
<td>72.6</td>
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<td>20</td>
<td>61.3</td>
<td>75.0</td>
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<td>60</td>
<td>69.7</td>
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<tr>
<td>70</td>
<td>71.5</td>
<td>84.5</td>
</tr>
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</table>

Under-five mortality (per 1000 live births): 45.3

Probability of dying aged 30-70 yrs of NCDs (%): 18.10%

Human Development Index (inequality adjusted HDI): 0.51 (0.35): low

ICT Development Index (rank): 2.7 (142)

UHC - Service coverage index (1-100): 45

UHC - Population with household spending >10% (>25%) of corresponding income (%): 3.3% (0.2%)

Global innovation index (rank): 23.7 (102)

High-technology exports (% of manufacture exports): 0.90%

National policy on health technology

Policy is part of the National Health Program/Plan: No
Website: http://www.sante.gouv.sn
Language(s): Français
MOH responsible for health technology policy implementation: Direction des Infrastructures, des Equipements et de la Maintenance.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes, but it is only a recommendation
Unit: Direction des Infrastructures, des Equipements et de la Maintenance (DIEM).
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: Yes
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
Website(s): http://www.sante.gouv.sn; http://www.sante.gouv.sn/les-directions/la-direction-de-%E2%80%99administration-g%C3%A9n%C3%A9rale-et-de-%E2%80%99equipment; http://www.sante.gouv.sn/les-directions/la-direction-de-%E2%80%99administration-g%C3%A9n%C3%A9rale-de-la-sant%C3%A9-publique
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: La Direction des Infrastructures, des Equipements et de la Maintenance (DIEM).
Website(s): http://www.sante.gouv.sn; http://www.sante.gouv.sn/les-directions/la-direction-de-%E2%80%99administration-g%C3%A9n%C3%A9rale-de-la-sant%C3%A9-publique
Contact: Monsieur Amad Diouf Email: amadediouf@yahoo.fr
Name(s) of other regulatory agency eg. for radiation equipment etc.: Autorité de Radioprotection et de Surêté Nucléaire.
Other agency’s website: http://www.sante.gouv.sn/les-services-rattaches/le-laboratoire-national-de-contr%C3%B4le-des-m%C3%A9dicaments

Approved devices lists comments
(...Annex 1): —

Health care facilities lists comments
(...Annex 1): —

Specific lists comments

HTA unit comments
(...Annex 1): —

National regulatory comments
(...Annex 1): —

Under-five mortality (per 1000 live births): 45.3

UHC - Service coverage index (1-100): 45

UHC - Population with household spending >10% (>25%) of corresponding income (%): 3.3% (0.2%)

Global innovation index (rank): 23.7 (102)

High-technology exports (% of manufacture exports): 0.90%
Medical device nomenclature system
Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For procurement purposes
Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes Website: http://www.sante.gouv.sn
National level procurement: — Website: —
Donations
Policy or guideline: Yes Website: —
Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical equipment
| Total | Density per 1,000,000 population | Healthcare facility
| Total | Density per 100,000 population |
|-------|-------------------------------|---------------------|
| Magnetic Resonance Imaging | 4 | 0.24 | Health posts: 1426 | 8.52 |
| Computerized Tomography Scanner | 20 | 1.19 | Health centres: 98 | 0.59 |
| Positron Emission Tomography Scanner | 0 | 0 | General/district hospitals: 40 | 0.24 |
| Gamma camera or nuclear medicine | 2 | 0.12 | Specialized/regional/national hospitals: n/a | n/a |
| Mammograph | 17 | 22.36 | Estimation % of health facilities with none or very limited oxygen supply: | n/a |
| Radiotherapy | 3 | 0.18 |

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Department for Infrastructure, Equipment, and Maintenance (DIEM).
Unit website: http://www.sante.gouv.sn/
Contact name: Monsieur Amad Diouf Contact email: amadediouf@yahoo.fr
Website with publically available technical specifications: http://www.sante.gouv.sn/les-directions/la-direction-de-la-pharmacie-et-du-m%C3%A9dicament
Number of regional/state offices/units: 4

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes Software name: Système de gestion de la maintenance assistée par ordinateur (GMAO).

Medical devices workforce
Density of medical doctors (per 10,000 population)* 0.88
Number of biomedical/clinical engineers professionals in the country: 23

Contacts
MOH focal point
Name: Mr. Amad Diouf
Department: Direction des Infrastructures, des Equipements et de la Maintenance
Email: amadediouf@yahoo.fr
Other country focal point
Name: Mme. Awa Ndiaye Diouf
Email: awandiayediouf@yahoo.fr

General comments (...Annex 1): —


Medical devices workforce
Density of medical doctors (per 10,000 population)* 0.88
Number of biomedical/clinical engineers professionals in the country: 23

Contacts
MOH focal point
Name: Mr. Amad Diouf
Department: Direction des Infrastructures, des Equipements et de la Maintenance
Email: amadediouf@yahoo.fr
Other country focal point
Name: Mme. Awa Ndiaye Diouf
Email: awandiayediouf@yahoo.fr

General comments (...Annex 1): —

Medical device incorporation comments (...Annex 1): On procède à des appels d’offres nationaux et les représentants des fabricants étrangers fournissent les équipements.
Serbia

Country indicators

Population 000s (rank): 8,737 (98)
World Bank income group: Upper-Middle

Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Year</th>
<th>National</th>
<th>World</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020</td>
<td>80.8</td>
<td>70.8</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 5.3
UHC - Service coverage index (1-100): 65

Probability of dying aged 30-70 yrs of NCDs (%):

<table>
<thead>
<tr>
<th>NCDs</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>CVD</td>
<td>19.10%</td>
</tr>
</tbody>
</table>

UHC - Population with household spending >10% (>25%) of corresponding income (%):

<table>
<thead>
<tr>
<th>Income Level</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>8.1% (0.5%)</td>
</tr>
</tbody>
</table>

Global innovation index (rank):

<table>
<thead>
<tr>
<th>Rank</th>
<th>Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>53</td>
<td>34.3</td>
</tr>
</tbody>
</table>

Human Development Index (inequality adjusted HDI):

<table>
<thead>
<tr>
<th>Index</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.81 (0.71)</td>
<td>very high</td>
</tr>
</tbody>
</table>

ICT Development Index (rank):

<table>
<thead>
<tr>
<th>Rank</th>
<th>Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>55</td>
<td>6.6</td>
</tr>
</tbody>
</table>

High-technology exports (% of manufacture exports):

<table>
<thead>
<tr>
<th>Exports</th>
<th>Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: http://www.zdravlje.gov.rs/index.php
Language(s): Serbian and English
MOH responsible for health technology policy implementation: Committee for Health Technology Assessment.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes
Unit: Committee for Health Technology Assessment.
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, Ministry of Health - Committee for health technology assessment.
Contact: Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Medicines and Medical Devices Agency (ALIMS).
Website(s): https://www.alims.gov.rs/eng/
Contact: Ms. Tatjana Sipetic Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

Approved devices lists comments (...Annex 1):
Not available at the moment.

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):
There are no specific national standards nor recommended medical devices for specific procedures. And there are no lists recommending health technology for different diseases/situations.

HTA unit comments (...Annex 1):
It conducts centralized public procurement for health products including devices. HTA is in the law and with a centralized national unit either MoH sector for inspection affairs or Public Health Institute (NIS).

National regulatory comments (...Annex 1): —

Under-five mortality (per 1000 live births): 5.3
UHC - Service coverage index (1-100): 65

Probability of dying aged 30-70 yrs of NCDs (%):

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Population 000s (rank): 8,737 (98)
World Bank income group: Upper-Middle

Probability of dying aged 30-70 yrs of NCDs (%):

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</tr>
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<tbody>
<tr>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>
Medical device nomenclature system
Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: Not specified
Website: http://www.zdravlje.gov.rs

Medical device incorporation
Procurement
Policy or guideline: No Website: —
National level procurement: Yes Website: https://www.zdravlje.gov.rs/

Donations
Policy or guideline: No Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Equipment Type</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>59</td>
<td>6.2</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>130</td>
<td>13.67</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>2</td>
<td>0.21</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>3</td>
<td>0.32</td>
</tr>
<tr>
<td>Mammograph</td>
<td>105</td>
<td>84.56</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>36</td>
<td>4.12</td>
</tr>
</tbody>
</table>

Healthcare facility
<table>
<thead>
<tr>
<th>Facility Type</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>158</td>
<td>1.66</td>
</tr>
<tr>
<td>Health centres:</td>
<td>158</td>
<td>1.66</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>40</td>
<td>0.42</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>23</td>
<td>0.24</td>
</tr>
</tbody>
</table>

Estimation % of health facilities with none or very limited oxygen supply: n/a

Medical device incorporation comments (...Annex 1):
Go to the website and search for the corresponding documents.

Software comments (...Annex 1):
The inventory was made in 2000, according to methodology. In 2003, European Agency for Reconstruction commissioned a project performed by IPH Serbia, but the methodology was not included in the national Law on Health Records and Statistics and has not been adopted, so the inventory continued to be performed on annual basis based on the existing Law on Health Records and classification of medical equipment (1980's). The inventory is not available.

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 31.13
Number of biomedical/clinical engineers professionals in the country: 300

Contacts
MOH focal point
Name: —
Department: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Fabio Scano
Email: scanof@who.int

General comments (...Annex 1):
The Institute of Public Health of Serbia has a department for health technology assessment mainly responsible for updating nomenclature and type of technology.
### Seychelles

#### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):a</th>
<th>98 (182)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:b</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):c</td>
<td></td>
</tr>
</tbody>
</table>

#### National policy on health technology

**Health technology (medical device) national policy:** No  
**Policy is part of the National Health Program/Plan:** No  
**Website:** —  
**Language(s):** —  
**MOH responsible for health technology policy implementation:** —

#### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**  
**Lists available:** Yes, but it is only a recommendation  
**Unit:** —  
**Website:** —  
**Nomenclature systems used for devices and tests:** —  
**National list for different types of healthcare facilities (hospitals, laboratories, etc)**  
**Lists available:** No  
**Website - hospitals:** —  
**Website - IVD:** —  
**Nomenclature systems used for devices and tests:** —  
**National list for specific clinical interventions/emergencies:**  
**Lists available:** No  
**Website:** —

#### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** Yes  
**National unit/department that includes HTA for medical devices:** No  
**Website(s):** —  
**Contact:** —  
**Email:** —  
**Committee includes a biomedical or clinical engineer:** —

#### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** No  
**Name of regulatory agency:** —  
**Website(s):** —  
**Contact:** —  
**Email:** —  
**Name(s) of other regulatory agency eg. for radiation equipment etc.:** —  
**Other agency’s website:** —

#### Key indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under-five mortality (per 1000 live births):d</td>
<td>14.3</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):e</td>
<td>71</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):f</td>
<td>21.20%</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):g</td>
<td>3.5% (1.6%)</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank:h</td>
<td>0.8 (0.67): high</td>
</tr>
<tr>
<td>Global innovation index (rank):i</td>
<td>— (—)</td>
</tr>
<tr>
<td>ICT Development Index (rank):j</td>
<td>5 (90)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):k</td>
<td>2.20%</td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births):d</td>
<td>14.3</td>
</tr>
<tr>
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<td>2.20%</td>
</tr>
</tbody>
</table>

#### Notes

- a: Population 000s (rank)  
- b: World Bank income group  
- c: Life expectancy at birth (years)  
- d: Under-five mortality (per 1000 live births)  
- e: UHC - Service coverage index  
- f: Probability of dying aged 30-70 yrs of NCDs  
- g: UHC - Population with household spending >10% (>25%) of corresponding income  
- h: Human Development Index  
- i: Global innovation index  
- j: ICT Development Index  
- k: High-technology exports (% of manufacture exports)

---

**Approved devices lists comments** (...Annex 1): —  
**Health care facilities lists comments** (...Annex 1): —  
**Specific lists comments** (...Annex 1): —  
**HTA unit comments** (...Annex 1): —  
**National regulatory comments** (...Annex 1): —
Seychelles

Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>1</td>
<td>10.77</td>
<td>Health posts:</td>
<td>19</td>
<td>20.47</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>1</td>
<td>10.77</td>
<td>Health centres:</td>
<td>5</td>
<td>5.39</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/ regional/national hospitals:</td>
<td>1</td>
<td>1.08</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>1</td>
<td>127.73</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>n/a</td>
<td>n/a</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population):* 24.72
Number of biomedical/clinical engineers professionals in the country:* <10

Contacts
MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Teniin Gakuruh
Email: gakuruh@who.int

General comments (...Annex 1): —

Medical device incorporation comments (...Annex 1):
It is a small committee that meets to discuss equipment request by the various units within the Ministry of Health. Please note that Seychelles has a small population and we do not purchase equipment on a big scale.

* Density per 1,000,000 females aged from 50-69 old.

Software comments (...Annex 1): —
Sierra Leone

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>7,977 (102)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td></td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 109.2

Probability of dying aged 30-70 yrs of NCDs (%): 30.50%

Human Development Index (inequality adjusted HDI): 0.45 (0.29): low

ICT Development Index (rank): — (—)

UHC - Service coverage index (1-100): 39

UHC - Population with household spending >10% (>25%) of corresponding income (%): 54.2% (22.2%)

Global innovation index (rank): — (—)

High-technology exports (% of manufacture exports): 0.70%

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: —
Language(s): English
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes
Unit: Procurement Unit.
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Procurement Unit, Ministry of Health and Sanitation.
Website(s): http://www.health.gov.sl/home/; http://www.pharmacyboard.gov.sl/ Contact: Mr. Mohamed Kallon Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

Approved devices lists comments
(Annex 1): Lists for procurements are still being worked on not yet completed. However we do have public health emergency situations lists.

Health care facilities lists comments
(Annex 1): —

Specific lists comments (Annex 1): —

HTA unit comments (Annex 1): —

National regulatory comments
(Annex 1): —

Population 000s (rank): a 7,977 (102)
World Bank income group: b Low
Life expectancy at birth (years): c 54.1
Under-five mortality (per 1000 live births): d 109.2
Probability of dying aged 30-70 yrs of NCDs (%): e 30.50%
Human Development Index (inequality adjusted HDI): f 0.45 (0.29): low
ICT Development Index (rank): g — (—)
UHC - Service coverage index (1-100): h 39
UHC - Population with household spending >10% (>25%) of corresponding income (%): i 54.2% (22.2%)
Global innovation index (rank): j — (—)
High-technology exports (% of manufacture exports): k 0.70%

Population 000s (rank): a 7,977 (102)
World Bank income group: b Low
Life expectancy at birth (years): c 54.1
Under-five mortality (per 1000 live births): d 109.2
Probability of dying aged 30-70 yrs of NCDs (%): e 30.50%
Human Development Index (inequality adjusted HDI): f 0.45 (0.29): low
ICT Development Index (rank): g — (—)
UHC - Service coverage index (1-100): h 39
UHC - Population with household spending >10% (>25%) of corresponding income (%): i 54.2% (22.2%)
Global innovation index (rank): j — (—)
High-technology exports (% of manufacture exports): k 0.70%
Medical device nomenclature system
Official nomenclature system for medical devices: Yes Type: Based on UMDNS Use: For procurement purposes Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes Website: —
National level procurement: Yes Website: —
Donations
Policy or guideline: Yes Website: —
Technical specifications
Technical specifications to support procurement or donations: No Publically available: — Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging(a)</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner(a)</td>
<td>2</td>
<td>0.33</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner(a)</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine(a)</td>
<td>1</td>
<td>0.16</td>
</tr>
<tr>
<td>Mammograph(a,*,)</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy(a)</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Healthcare facility\(a\)
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>n/a n/a</td>
</tr>
<tr>
<td>Health centres:</td>
<td>74</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>n/a n/a</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>n/a n/a</td>
</tr>
</tbody>
</table>
Estimation % of health facilities with none or very limited oxygen supply: n/a

Medical device incorporation comments (Annex 1):
Most of the equipment has been used and found incomplete, and this is the reason why its installation is difficult. Procurement of medical devices is carried out without involving the specialists.

Medical device incorporation
Policy or guideline: Yes Website: —
National level procurement: Yes Website: —
Donations
Policy or guideline: Yes Website: —
Technical specifications
Technical specifications to support procurement or donations: No Publically available: — Website: —

Medical equipment management unit
Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Procurement Unit. Unit website: —
Contact name: Mr. Mohamed Kallon. Contact email: — Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment Website: —
Use of management software: — Software name: —

Software comments (Annex 1):
The last inventory was done twelve years ago. Looking forward to start another one.

Medical devices workforce
Density of medical doctors (per 10,000 population): \(a\) 0.74
Number of biomedical/clinical engineers professionals in the country: \(\beta\) <10

Contacts
MOH focal point
Name: —
Department: —
Email: — Other country focal point
Name: Mr. Mohamed Kallon Email: —

WHO health products focal point:
Name: — Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Evans Majani Liyosi Email: liyosie@who.int

General comments (Annex 1): There is a limited number of technical personnel to meet the service demand. Most of the equipment supplied by donors are obsolete and out of order.

\(a\) Latest (2015-2021); WHO HTA/HBP survey or WHO HTA 2015 survey or WHO 2021 survey
\(\beta\) Latest (2013-2021); WHO GHO/2021 survey or WHO 2021 survey or OECD (2017-2019)
\(\delta\) Latest (2013-2021); WHO GHO/2021 survey or WHO 2021 survey or OECD (2017-2019)
\(\gamma\) n/a not applicable/not available
## Singapore

### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>5,850 (112)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births):</th>
<th>2.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>86</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Probability of dying aged 30-70 yrs of NCDs (%):</th>
<th>9.30%</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>9.0% (1.5%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Human Development Index (inequality adjusted HDI): (rank):</th>
<th>0.94 (0.81); very high</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global innovation index (rank):</td>
<td>56.6 (8)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICT Development Index (rank):</th>
<th>8.1 (18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>52.10%</td>
</tr>
</tbody>
</table>

### National policy on health technology

Health technology (medical device) national policy: Yes  
Policy is part of the National Health Program/Plan: Yes  
Website: [https://www.hsa.gov.sg/](https://www.hsa.gov.sg/)  
Language(s): English  
MOH responsible for health technology policy implementation: —

### National lists of medical devices

#### National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

- Lists available: Yes  
- Unit: Medical Devices Branch / Health Sciences Authority (HSA)  
- Nomenclature systems used for devices and tests: —

#### National list for different types of healthcare facilities (hospitals, laboratories, etc)

- Lists available: No  
- Website - hospitals: —  
- Website - IVD: —  
- Nomenclature systems used for devices and tests: —

#### National list for specific clinical interventions/emergencies:

- Lists available: No  
- Website: —

### National health technology assessment unit

- Designated unit/department for health technology assessment (HTA): Yes  
- National unit/department that includes HTA for medical devices: Yes, Health Technology Assessment Branch, and Agency for care effectiveness (ACE).  
- Website(s): [https://www.ace-hta.gov.sg/](https://www.ace-hta.gov.sg/)  
- Contact: — Email: —  
- Committee includes a biomedical or clinical engineer: —

### National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes  
Name of regulatory agency: Medical Device Branch, Health Sciences Authority.  
Website(s): [https://www.hsa.gov.sg/medical-devices/](https://www.hsa.gov.sg/medical-devices/)  
Contact: Ms. Joanna Koh Email: Joanna_koh@hsa.gov.sg  
Name(s) of other regulatory agency eg. for radiation equipment etc.: —  
Other agency’s website: —

Approved devices lists comments (...Annex 1):  
A list is available in the form of the Singapore Medical Device Register (SMDR). This shows all approved medical devices in Singapore and provides information on them. It is not a list of recommended devices for procurement.

Health care facilities lists comments (...Annex 1): —

Specific lists comments (...Annex 1): —

HTA unit comments (...Annex 1): —

National regulatory comments (...Annex 1): —
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: https://www.hsa.gov.sg/medical-devices/registration/guides

Medical device incorporation
Procurement
Policy or guideline: No  Website: —
National level procurement: No  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:α</td>
<td>42</td>
<td>7.76</td>
<td>Health posts: 3205</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:α</td>
<td>48</td>
<td>8.87</td>
<td>Health centres: n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:α</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals: n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:α</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals: n/a</td>
</tr>
<tr>
<td>Mammograph:α*</td>
<td>85</td>
<td>127.65</td>
<td>Estimation % of health facilities with none or very limited oxygen supply: n/a</td>
</tr>
<tr>
<td>Radiotherapy:β</td>
<td>30</td>
<td>5.13</td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: —  Professionally trained biomedical/clinical engineers: No
Unit/Department: Health Technology Assessment Branch, Ministry of Health.
Unit website: https://www.hsa.gov.sg/medical-devices
Contact name: Dr. Pwee Keng Ho  Contact email: pwee_keng_ho@moh.gov.sg
Website with publically available technical specifications: https://www.hsa.gov.sg/medical-devices
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: None
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): 22.94
Number of biomedical/clinical engineers professionals in the country: 600

Contacts
MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: Dr. Pwee Keng Ho
Email: pwee_keng_ho@moh.gov.sg

General comments (...Annex 1): —
## Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):a</th>
<th>5,460 (116)</th>
<th>Under-five mortality (per 1000 live births):a</th>
<th>5.8</th>
<th>UHC - Service coverage index (1-100):a</th>
<th>77</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>World Bank income group:b</th>
<th>High</th>
<th>Probability of dying aged 30-70 yrs of NCDs (%):a</th>
<th>17.20%</th>
<th>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):a</th>
<th>3.8% (0.4%)</th>
</tr>
</thead>
</table>

| Life expectancy at birth (years):a | 71.3 (2019) | Human Development Index (inequality adjusted HDI): rankc | 0.86 (0.81); very high | Global innovation index (rank):d | 39.7 (39) |

| ICT Development Index (rank):a | 71 (46) | High-technology exports (% of manufacture exports):a | 9.90% |

### National policy on health technology

**Health technology (medical device) national policy:** Yes

**Policy is part of the National Health Program/Plan:** No

**Website:** [http://www.skmed.sk](http://www.skmed.sk)

**Language(s):** Slovak

**MOH responsible for health technology policy implementation:** Department of Categorization Pricing and Drug Policy.

### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**

- **Lists available:** Yes
- **Unit:** Ministry of Health
- **Website:** [https://www.health.gov.sk/Sources/dokumenty/zdravotnicke_pomocky/20100401/Zoznam_201002.xls](https://www.health.gov.sk/Sources/dokumenty/zdravotnicke_pomocky/20100401/Zoznam_201002.xls)

**Nomenclature systems used for devices and tests:**

- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - **Lists available:** No
  - **Website - hospitals:** —
  - **Website - IVD:** —
  - **Nomenclature systems used for devices and tests:** —

**National list for specific clinical interventions/emergencies:**

- **Lists available:** No
- **Website:** —

### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):**
- Yes

**National unit/department that includes HTA for medical devices:** No

**Website(s):** [www.health.gov.sk](http://www.health.gov.sk)

**Contact:** —

**Committee includes a biomedical or clinical engineer:** —

### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes

**Name of regulatory agency:** State Institute for Drug Control


**Contact:** Dr. Marek Slávik

**Email:** slavik@sukl.sk

**Name(s) of other regulatory agency eg. for radiation equipment etc.:** Nuclear Regulatory Authority of the Slovak Republic

**Other agency's website:** [https://www.ujd.gov.sk/ujd/www1.nsf/viewByKeyMenu/En-01](https://www.ujd.gov.sk/ujd/www1.nsf/viewByKeyMenu/En-01)
### Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: Not specified
Website: [http://www.health.gov.sk](http://www.health.gov.sk)

### Medical device incorporation

**Procurement**
- Policy or guideline: No  Website: —
- National level procurement: No  Website: —

**Donations**
- Policy or guideline: No  Website: —

**Technical specifications**
- Technical specifications to support procurement or donations: No
- Publically available: —
- Website: —

### Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>52</td>
<td>9.52</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>100</td>
<td>18.32</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>8</td>
<td>1.47</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>30</td>
<td>5.49</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>100</td>
<td>135.44</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>37</td>
<td>6.78</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Healthcare facility*</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>16</td>
<td>0.29</td>
</tr>
<tr>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>6</td>
<td>0.11</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>52</td>
<td>0.95</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

### Medical equipment management unit

- Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
- Unit/Department: —  Unit website: —
- Contact name: —  Contact email: —
- Website with publically available technical specifications: —
- Number of regional/state offices/units: 0

### Inventories and medical equipment management software

- Type of inventories available: National functional inventory for medical equipment
- Website: —
- Use of management software: Yes  Software name: —

### Medical devices workforce

- Density of medical doctors (per 10,000 population): * 35.17
- Number of biomedical/clinical engineers professionals in the country: * 63

### Contacts

- **Moh focal point**
  - Name: Dr. Branislav Jadud
  - Department: Department of Categorization Pricing and Drug Policy
  - Email: branislav.jadud@health.gov.sk
  - Other country focal point
  - Name: —
  - Email: —

- **WHO health products focal point**
  - Name: —
  - Email: —

- **WHO Representative/WHO Liaison Officer**
  - Name: Dr. Tatul Hakobyan
  - Email: hakobyant@who.int

### General comments (...Annex 1): —

### WHO European Region

Slovakia
Country indicators

Slovenia

<table>
<thead>
<tr>
<th>National policy on health technology</th>
<th>Approved devices lists comments (...Annex 1): –</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health technology (medical device) national policy: Yes</td>
<td>–</td>
</tr>
<tr>
<td>Policy is part of the National Health Program/Plan: Yes</td>
<td>–</td>
</tr>
<tr>
<td>Website: <a href="http://pisrs.si/Pis.web/pregledPredpisa?id=RESO102#">http://pisrs.si/Pis.web/pregledPredpisa?id=RESO102#</a></td>
<td>–</td>
</tr>
<tr>
<td>Language(s): Slovenian</td>
<td>–</td>
</tr>
<tr>
<td>MOH responsible for health technology policy implementation: Directorate for healthcare economics</td>
<td>–</td>
</tr>
</tbody>
</table>

National lists of medical devices

| National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement: | – |
| Lists available: Yes | – |
| Unit: Agency for Medicinal Products and Medical Devices of the Republic of Slovenia | – |
| Nomenclature systems used for devices and tests: – | – |

| National list for different types of healthcare facilities (hospitals, laboratories, etc) | – |
| Lists available: Yes | – |
| Website - hospitals: [https://www.zdrzz.si/O_Zdruzenju/](https://www.zdrzz.si/O_Zdruzenju/) | – |
| Website - IVD: – | – |
| Nomenclature systems used for devices and tests: – | – |

| National list for specific clinical interventions/emergencies: | – |
| Lists available: Yes | – |
| Website: – | – |

National health technology assessment unit

| Designated unit/department for health technology assessment (HTA): No | – |
| National unit/department that includes HTA for medical devices: – | – |
| Website(s): – | – |
| Contact: – Email: – | – |
| Committee includes a biomedical or clinical engineer: – | – |

National regulatory authority

| Presence of national authority responsible for regulating medical devices: Yes | – |
| Name of regulatory agency: Javna Agencija za zdravila in medicinske pripomocke / Agency for Medicinal Products and Medical Devices of the Republic of Slovenia. | – |
| Contact: Momir Radulovič Email: info@jazmp.si | – |
| Name(s) of other regulatory agency eg. for radiation equipment etc.: Slovenian Nuclear Safety Administration; Agency for Medicinal Products and and Medical Devices of the Republic of Slovenia. | – |
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Many co-existence of nomenclatures  Use: For regulatory and procurement purposes

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: http://www.pisrs.si/Pis.web/pregledPredpisa?id=ZAKO7086
National level procurement: Yes  Website: https://www.gov.si/drzavni-organji/ministrstva/; https://www.enarocanje.si/

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging*</td>
<td>26</td>
<td>12.51</td>
<td>Health posts</td>
<td>83</td>
<td>4.01</td>
</tr>
<tr>
<td>Computerized Tomography Scanner*</td>
<td>38</td>
<td>18.28</td>
<td>Health centres</td>
<td>57</td>
<td>2.75</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner*</td>
<td>3</td>
<td>1.44</td>
<td>General district hospitals</td>
<td>14</td>
<td>0.68</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine*</td>
<td>17</td>
<td>8.18</td>
<td>Specialized/regional/national hospitals</td>
<td>2</td>
<td>0.1</td>
</tr>
<tr>
<td>Mammograph*</td>
<td>31</td>
<td>106.03</td>
<td>Estimation % of health facilities with none or very limited oxygen supply: n/a</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>17</td>
<td>8.18</td>
<td>—</td>
<td></td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Donations
Policy or guideline: No  Website: —

Medical equipment management unit
Unit present: —  Professionally trained biomedical/clinical engineers: No
Contact name: Mr. Smiljan Mekicar  Contact email: smiljan.mekicar@gov.si
Website with publically available technical specifications: https://www.enarocanje.si/
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population): 31.72
Number of biomedical/clinical engineers professionals in the country: 174

Contacts
MOH focal point
Name: Mr. Smiljan Mekicar  Department: Division of Investment and Public Procurement, directorate for healthcare economics (MoH)
Email: smiljan.mekicar@gov.si
Other country focal point
Name: Momir Radulović  Email: info@jazmp.si

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Aiga Rurane  Email: ruranea@who.int

General comments (...Annex 1): —

Nomenclature comments (...Annex 1):
When medical devices are being produced by the manufacturers of medical devices with their registered place of business in the Republic of Slovenia, are notified to the national competent authority, GMDN code should be submitted, if available. The CPV establishes a single classification system for public procurement aimed at standardising the references used by contracting authorities and entities to describe the subject of the procurement contracts. Thus, we are using various co-existent types of nomenclature systems, mainly for procurement and regulatory purposes, such as EUDAMED, GMDN, and CPV.

Medical device incorporation comments (...Annex 1):
—

Medical equipment comments (...Annex 1):
—

Software comments (...Annex 1):
The inventories website is still in development and is not yet available to the public.
Solomon Islands

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):*</th>
<th>687 (161)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:**</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.8</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 19.7
UHC - Service coverage index (1-100): 47
Probability of dying aged 30-70 yrs of NCDs (%)*: 23.80%
UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)
Human Development Index (inequality adjusted HDI): 0.57 (—); medium
Global innovation index (rank): — (—)
ICT Development Index (rank): 21 (157)
High-technology exports (% of manufacture exports): 1.40%

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: Equipment Committee.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Approved devices lists comments (...Annex 1):
Health care facilities lists comments (...Annex 1):
Specific lists comments (...Annex 1):
Donation equipment have various brands.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):* Yes
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
There is no formalized HTA available and it relies heavily on other institutions assessment mechanisms, such as the WHO.

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: Ministry of Health & Medical Services, Solomon Islands Government.
Website(s): https://solomons.gov.sb/ministry-of-health-medical-services/#division
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

National regulatory comments (...Annex 1):
The National Referral Hospital (NHR) performs most of the procurement, planning and allocation for the Provincial Hospital. There is a disposable procurement by the Ministry of Finance.
### Medical device nomenclature system

- **Official nomenclature system for medical devices:** No  
- **Type:** None  
- **Use:** Not specified  
- **Website:** —

### Medical device incorporation

#### Procurement

- **Policy or guideline:** Yes  
- **Website:** —

#### Donations

- **Policy or guideline:** No  
- **Website:** —

### Technical specifications

- **Technical specifications to support procurement or donations:** No  
- **Publically available:** —  
- **Website:** —

### Medical equipment

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:</td>
<td>n/a</td>
<td>n/a</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged 50-69 old.

### Medical equipment management unit

- **Unit present:** —  
- **Professionally trained biomedical/clinical engineers:** —  
- **Unit/Department:** —  
- **Contact name:** —  
- **Contact email:** —  
- **Website with publically available technical specifications:** —

### Inventories and medical equipment management software

- **Type of inventories available:** —  
- **Website:** —  
- **Use of management software:** No  
- **Software name:** —

### Medical devices workforce

- **Density of medical doctors (per 10,000 population):** 1.94  
- **Number of biomedical/clinical engineers professionals in the country:** —

### Contacts

#### MOH focal point

- **Name:** Mr. Tenneth Dalipanda  
- **Department:** Public Health  
- **Email:** tdalipanda@moh.gov.sb

#### Other country focal point

- **Name:** —  
- **Email:** —

#### WHO health products focal point

- **Name:** —  
- **Email:** —

#### WHO Representative/WHO Liaison Officer

- **Name:** Dr. Sevil Huseynova  
- **Email:** huseynovas@who.int

### General comments (...Annex 1):

- There is virtually none of this currently in place.

### Medical device incorporation comments (...Annex 1):

- The procurement Unit, Ministry of Health & Medical Service, has mainly to do with the finance but no with the technical aspect of the equipment. The Committee is Ad hoc and meets only to allocate equipment base on Departmental requests.
### National policy on health technology

**Health technology (medical device) national policy:** Yes

**Policy is part of the National Health Program/Plan:** Yes

**Website:** —

**Language(s):** English

**MOH responsible for health technology policy implementation:** National Medicines Regulatory Authority.

### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**

- **Lists available:** No
- **Unit:** —
- **Website:** —

**Nomenclature systems used for devices and tests:** —

**National list for different types of healthcare facilities (hospitals, laboratories, etc)**

- **Lists available:** No
- **Website - hospitals:** —
- **Website - IVD:** —

**Nomenclature systems used for devices and tests:** —

**National list for specific clinical interventions/emergencies:**

- **Lists available:** No
- **Website:** —

### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** Yes

**National unit/department that includes HTA for medical devices:** Yes, National Medicines Regulatory Authority (NMRA): Department Medical Services.

**Website(s):** —

**Contact:** Mr. Saed Nuh Ahmed  
**Email:** saednux@gmail.com

**Committee includes a biomedical or clinical engineer:** No

### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes

**Name of regulatory agency:** National Medicines Regulatory Authority.

**Website(s):**  
- https://moh.nomadilab.org/policy-planing/  
- https://moh.nomadilab.org/1181-2/  
- https://moewr.gov.so/

**Name(s) of other regulatory agency eg. for radiation equipment etc.:** Ministry of Health Somalia, Department of Public Health; Ministry of Energy & Water Resources.

**Other agency’s website:** —

### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank)</th>
<th>15,893 (72)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years)</td>
<td>63.7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births)</th>
<th>117</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%)</td>
<td>21.8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>UHC - Service coverage index (1-100)</th>
<th>25</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%)</td>
<td>— (—)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Human Development Index (inequality adjusted HDI): rank</th>
<th>— (—)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global innovation index (rank)</td>
<td>— (—)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICT Development Index (rank)</th>
<th>— (—)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-technology exports (% of manufacture exports)</td>
<td>—</td>
</tr>
</tbody>
</table>

### HTA unit comments (...Annex 1):

National Medicines Regulatory Authority (NMRA) under Department of Medical Services has an HTA role. However, even if the designated unit is present in the organigram is not yet well established. There are scarce HTA activities, but the plans are to expand, specially in pharmaceutics. The UHC country goal is in progress.

### National regulatory comments (...Annex 1):

National Medicines Regulatory Authority (NMRA) under Department of Medical Services has an HTA role. However, even if the designated unit is present in the organigram is not yet well established. There are scarce HTA activities, but the plans are to expand, specially in pharmaceutics. The UHC country goal is in progress.
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: For regulatory purposes
Website: —

Nomenclature comments (...)Annex 1):
The definition of medical devices is included in the national medicines law which is not yet ratified.

Medical device incorporation

Policy or guideline: No  Website: —
National level procurement: No  Website: —

Donations
Policy or guideline: No  Website: —

Technical specifications
Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging ²</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>148</td>
<td>0.93</td>
</tr>
<tr>
<td>Computerized Tomography Scanner ²</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>182</td>
<td>1.15</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner ²</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>26</td>
<td>0.16</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine ²</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mammograph ²</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>75%</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy ²</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

² Density per 1,000,000 females aged from 50-69 old.

Medical device incorporation comments (...)Annex 1):

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: —
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —
Website: —
Use of management software: —  Software name: —

Medicine devices workforce
Density of medical doctors (per 10 000 population): ² 0.23
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: Mr. Saed Nuh Ahmed
Department: National Medicines Regulatory Authority, under Ministry of Health
Email: saednux@gmail.com
Other country focal point
Name: Mr. Hassan Elmi
Email: elmih@som.emro.who.int

WHO health products focal point:
Name: Dr. Hassan Mohamed Elmi
Email: lmih@who.int

WHO Representative/WHO Liaison Officer:
Name: Dr. Mamunur Md Sk Malik
Email: malikm@who.int

General comments (...)Annex 1):

* Density per 1,000,000 females aged from 50-69 old.

Medical device incorporation comments (...)Annex 1):

A1B2 C3D4

Medical equipment Total

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner ²</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner ²</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine ²</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph ²</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy ²</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Medical device incorporation comments (...)Annex 1):

WHO Eastern Mediterranean Region
World Health Organization

Somalia
South Africa

Country indicators

Population 000s (rank):59,309 (25)
World Bank income group: Upper-Middle

Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Year</th>
<th>Life Expectancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990</td>
<td>52.3</td>
</tr>
<tr>
<td>2000</td>
<td>56.2</td>
</tr>
<tr>
<td>2020</td>
<td>63.5</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births):34.5
Probability of dying aged 30-70 yrs of NCDs (%):26.20%
Human Development Index (inequality adjusted HDI): 0.71 (0.47): high
ICT Development Index (rank): 5 (92)

Under-five mortality (per 1000 live births):

<table>
<thead>
<tr>
<th>Rank</th>
<th>Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>34.5</td>
</tr>
</tbody>
</table>

Probability of dying aged 30-70 yrs of NCDs (%):

<table>
<thead>
<tr>
<th>Rank</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>26.20%</td>
</tr>
</tbody>
</table>

Human Development Index (inequality adjusted HDI):

<table>
<thead>
<tr>
<th>Rank</th>
<th>Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>0.71 (0.47)</td>
</tr>
</tbody>
</table>

ICT Development Index (rank):

<table>
<thead>
<tr>
<th>Rank</th>
<th>Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>5 (92)</td>
</tr>
</tbody>
</table>

Global innovation index (rank): 32.7 (60)

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: https://www.sahpra.org.za/
Language(s): English
MOH responsible for health technology policy implementation: Health Technology Directorate.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes
Unit: Health Technology.
Website: —
Nomenclature systems used for devices and tests: GMDN.

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - IVD: https://www.sahpra.org.za/biological-products/
Nomenclature systems used for devices and tests: GMDN.

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, National Health Technology Committee.
Website(s): http://www.health.gov.za/, https://www.gov.za/about-government/government-programmes/national-health-insurance-0?gclid=Cj0KCQjw4v2EBhC1ARt1ACsn3wMeUvMBkrHmkK5Jw8W_OwOGvAxawbfPsZ6neNv26BCG1iw0Tq3yEaAk2PEALw-wC5#
Contact: Mr. Sam Bakhane  Email: setlhare.bakhane@health.gov.za
Committee includes a biomedical or clinical engineer: Yes

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: South African Health Products Regulatory Authority (SAHPRA).
Website(s): www.sahpra.org.za
Contact: Ms. Andrea Julsing  Email: andrea.julsing@org.za
Name(s) of other regulatory agency eg. for radiation equipment etc.: Directorate of Radiation Control.
**Medical device nomenclature system**

Official nomenclature system for medical devices: Yes  
**Type:** Based on GMDN  
Use: For regulatory purposes  
Website: —

**Nomenclature comments (Annex 1):**  
The regulator has adopted the use of GMDN which will be a nationally accepted nomenclature.

**Medical device incorporation**

**Procurement**

Policy or guideline: Yes  
National level procurement: No  
Website: —

**Donations**

Policy or guideline: Yes  
Website: —

**Technical specifications**

Technical specifications to support procurement or donations: Yes  
Publically available: Yes  
Website: www.treasury.gov.za

**Medical equipment**

<table>
<thead>
<tr>
<th>Magnetic Resonance Imaging a</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>12</td>
<td>0.2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Computerized Tomography Scanner a</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>51</td>
<td>0.86</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Positron Emission Tomography Scanner a</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3</td>
<td>0.05</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gamma camera or nuclear medicine a</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>28</td>
<td>0.47</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mammograph a*</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>32</td>
<td>7.34</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Radiotherapy a</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>135</td>
<td>2.28</td>
</tr>
</tbody>
</table>

**Medical equipment incorporation comments (Annex 1):**  
The Office of the Chief Procurement Officer is in charge of the procurement of medical devices.

**Medical equipment management unit**

Unit present: Yes  
Professionally trained biomedical/clinical engineers: Yes  
Unit/Department: Health Technology Policy  
Unit website: —  
Contact name: Mr. Sam Bakhane  
Contact email: setlhare.bakhane@health.gov.za  
Website with publically available technical specifications: www.treasury.gov.za  
Number of regional/state offices/units: 9

**Inventories and medical equipment management software**

Type of inventories available: None  
Website: —  
Use of management software: Yes  
Software name: —

**Medical devices workforce**

Density of medical doctors (per 10,000 population): 7.92  
Number of biomedical/clinical engineers professionals in the country: 300

**Contacts**

**MOH focal point**

Name: Mr. Sam Setlhare Bakhane  
Department: National Department of Health  
Email: setlhare.bakhane@health.gov.za

**Other country focal point**

Name: Mr. S. du Plessis  
Email: duples@fshealth.gov.za

**WHO health products focal point**

Name: Dr. Habib Somanje  
Email: somanjeha@who.int

**WHO Representative/WHO Liaison Officer**

Name: Dr. Owen Laws Kaluwa  
Email: kaluwao@who.int

**General comments (Annex 1):**

—

---

a  Density per 1,000,000 females aged from 50-69 old.

---

South Africa
South Sudan

Country indicators

| Population 000s (rank): | 11,194 (83) | Population with household spending >10% (>25%) of corresponding income (%):
| Life expectancy at birth (years): | 63.7 | — (—) |

National policy on health technology

Health technology (medical device) national policy:
- Policy is part of the National Health Program/Plan:
- Website:
- Language(s):
- MOH responsible for health technology policy implementation:

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
- Lists available:
- Unit:
- Website:
- Nomenclature systems used for devices and tests:

National list for different types of healthcare facilities (hospitals, laboratories, etc)
- Lists available:
- Website - hospitals:
- Website - IVD:
- Nomenclature systems used for devices and tests:

National list for specific clinical interventions/emergencies:
- Lists available:
- Website:

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):
- Yes
- HTA unit comments (...Annex 1):

National regulatory authority

Presence of national authority responsible for regulating medical devices:
- Name of regulatory agency:
- Website(s):
- Contact: — Email:
- Name(s) of other regulatory agency eg. for radiation equipment etc.: —
- Other agency’s website:

Approved devices lists comments (...Annex 1):

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):

HTA unit comments (...Annex 1):

National regulatory comments (...Annex 1):
Medical device nomenclature system
Official nomenclature system for medical devices: __ Type: __ Use: __
Website: —

Medical device incorporation
Procurement
Policy or guideline: — Website: —
National level procurement: — Website: —
Donations
Policy or guideline: — Website: —

Technical specifications
Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility¹</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging: α</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner: α</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner: α</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine: β</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph: γ</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy: δ</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹ Density per 1,000,000 females aged from 50-69 old.

Inventories and medical equipment management software
Type of inventories available: —
Website: —
Use of management software: — Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population): —
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Olushayo Olu
Email: afwcosswho@who.int

General comments (Annex 1): —
Spain

Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Spain</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>46,755 (30)</td>
<td></td>
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<tr>
<td>World Bank income group:</td>
<td>High</td>
<td></td>
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<tr>
<td>Life expectancy at birth (years):</td>
<td>72.3</td>
<td></td>
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<tr>
<td>Health technology (medical device) national policy:</td>
<td>Yes</td>
<td></td>
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<tr>
<td>National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:</td>
<td>Lists available: Yes</td>
<td>Approved devices lists comments (...Annex 1):</td>
</tr>
<tr>
<td>Unit: Direccion General de Ordenacion Profesional, Cohesion del Sistema Nacional de Salud y Alta Inspeccion.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Website: —</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nomenclature systems used for devices and tests: —</td>
<td></td>
<td></td>
</tr>
<tr>
<td>National list for different types of healthcare facilities (hospitals, laboratories, etc):</td>
<td>Lists available: No</td>
<td>Health care facilities lists comments (...Annex 1):</td>
</tr>
<tr>
<td>Website - hospitals: —</td>
<td></td>
<td></td>
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<tr>
<td>Nomenclature systems used for devices and tests: —</td>
<td></td>
<td></td>
</tr>
<tr>
<td>National list for specific clinical interventions/emergencies:</td>
<td>Lists available: No</td>
<td>Specific lists comments (...Annex 1):</td>
</tr>
<tr>
<td>Website: —</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Designated unit/department for health technology assessment (HTA):</td>
<td>Yes</td>
<td>HTA unit comments (...Annex 1):</td>
</tr>
<tr>
<td>National health technology assessment unit</td>
<td>National unit/department that includes HTA for medical devices: Yes, AETS-IscIII.</td>
<td></td>
</tr>
<tr>
<td>Website(s): <a href="https://www.aemps.gob.es/productos-sanitarios/productossanitarios_invitro/">https://www.aemps.gob.es/productos-sanitarios/productossanitarios_invitro/</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact: — Email: —</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Committee includes a biomedical or clinical engineer: —</td>
<td></td>
<td></td>
</tr>
<tr>
<td>National regulatory authority:</td>
<td>Yes</td>
<td>National regulatory comments (...Annex 1):</td>
</tr>
<tr>
<td>Presence of national authority responsible for regulating medical devices:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name of regulatory agency: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Website(s): <a href="http://www.aemps.es">http://www.aemps.es</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact: Ms. Carmen Abad Luna Email: <a href="mailto:cabad@aemps.es">cabad@aemps.es</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name(s) of other regulatory agency eg. for radiation equipment etc.:</td>
<td>Consejo de Seguridad Nuclear; Ministerio para la Transicion Ecologica y el Reto Demografico.</td>
<td></td>
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</tbody>
</table>
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Many co-existence of nomenclatures  Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: No  Website: —
National level procurement: No  Website: —
Donations
Policy or guideline: No  Website: —
Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>805</td>
<td>17.22</td>
<td>Health posts:</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>895</td>
<td>19.14</td>
<td>Health centres:</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>84</td>
<td>1.8</td>
<td>General/district hospitals:</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>309</td>
<td>6.61</td>
<td>Specialized/regional/national hospitals:</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>760</td>
<td>120.64</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>434</td>
<td>9.28</td>
<td>n/a</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: —  Professionally trained biomedical/clinical engineers: No
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Use of management software: —  Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population):* 40.29
Number of biomedical/clinical engineers professionals in the country: 1000

Contacts
MOH focal point
Name: Mr. Antonio Sarria-Santamera
Department: Agencia de evaluacion de tecnologias sanitarias Inst. de Salud Carlos III
Email: sarria@isciii.es
Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liason Officer:
Name: —
Email: —

General comments (Annex 1): —
Sri Lanka

Country indicators

<table>
<thead>
<tr>
<th>Category</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>21,413 (57)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>68.9</td>
</tr>
</tbody>
</table>

National policy on health technology

- **Health technology (medical device) national policy:** No
- **Policy is part of the National Health Program/Plan:** No
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - **Lists available:** Yes
  - **Unit:** —
  - **Nomenclature systems used for devices and tests:** —

- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - **Lists available:** Yes
  - **Website - hospitals:** [https://nmra.gov.lk/images/PDF/Legislation/5e_nmdra_07.pdf](https://nmra.gov.lk/images/PDF/Legislation/5e_nmdra_07.pdf)
  - **Nomenclature systems used for devices and tests:** —

- **National list for specific clinical interventions/emergencies:**
  - **Lists available:** Yes
  - **Website:** —

National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):** Yes
- **National unit/department that includes HTA for medical devices:** No
- **Website(s):** —
- **Contact:** —
- **Email:** —
- **Committee includes a biomedical or clinical engineer:** —

HTA unit comments (...Annex 1):

The institutionalizing of an HTA as a mechanism for promoting health system integrity is in early stages.

National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** Yes
- **Name of regulatory agency:** Cosmetics, Devices and Drugs Authority.
- **Website(s):** [http://www.health.gov.lk](http://www.health.gov.lk)
- **Contact:** Dr. H. Beneragama
- **Email:** —
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** National Medicines Regulatory Authority.

National regulatory comments (...Annex 1):

...
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Based on UMDNS  Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: —
Donations
Policy or guideline: Yes  Website: —
Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility*</th>
<th>Total</th>
<th>Density per 100,000 population</th>
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<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>9</td>
<td>0.42</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
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<tr>
<td>Computerized Tomography Scanner:*</td>
<td>36</td>
<td>1.69</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
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<tr>
<td>Positron Emission Tomography Scanner*</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>18</td>
<td>0.08</td>
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<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>4</td>
<td>0.19</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>6</td>
<td>2.81</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
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<tr>
<td>Radiotherapy:*</td>
<td>23</td>
<td>1.07</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical device incorporation comments (...Annex 1): —

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Division of Biomedical Services  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 3

Inventories and medical equipment management software
Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: —
Use of management software: Yes  Software name: VH Temp.

Medical devices workforce
Density of medical doctors (per 10,000 population):* 11.54
Number of biomedical/clinical engineers professionals in the country: <10

Contacts
MOH focal point
Name: Mr. J.M.L.K. Jayathilake
Department: Division of Biomedical Engineering
Email: mudithaj@hotmail.com

Other country focal point
Name: Dr. Terance
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Alaka Singh
Email: singha@who.int

General comments (...Annex 1): —
Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>43,849 (34)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>68.8</td>
</tr>
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</table>

Under-five mortality (per 1000 live births): 58.4
Probability of dying aged 30-70 yrs of NCDs (%): 26.00%
Human Development Index (inequality adjusted HDI): 0.51 (0.33): low
ICT Development Index (rank): 2.6 (145)

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): Arabic and English
MOH responsible for health technology policy implementation: Health Development Unit.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —
National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Nomenclature systems used for devices and tests: —
National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: National Medicine and Poison Board.
Website(s): http://www.nmpb.gov.sd/
Contact: Dr. Mohamed Elhassan Mohamed Ahmed Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: Sudanese Nuclear and Radiological Regulatory Authority; National Medicines and Poisons Board (NMPB).

Approved devices lists comments (...Annex 1):

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):

HTA unit comments (...Annex 1):
A Health Technology Management system (HTM) has been developed. However, there is not current HTA system in place, but it is a goal to pursue towards the Universal Health Care country goal.

UHC - Service coverage index (1-100): 44
UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)
Global innovation index (rank): — (—)
High-technology exports (% of manufacture exports): —

Under-five mortality (per 1000 live births): 58.4
Probability of dying aged 30-70 yrs of NCDs (%): 26.00%
Human Development Index (inequality adjusted HDI): 0.51 (0.33): low
ICT Development Index (rank): 2.6 (145)

Population 000s (rank): 43,849 (34)
World Bank income group: Low
Life expectancy at birth (years): 68.8

Under-five mortality (per 1000 live births): 58.4
Probability of dying aged 30-70 yrs of NCDs (%): 26.00%
Human Development Index (inequality adjusted HDI): 0.51 (0.33): low
ICT Development Index (rank): 2.6 (145)

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): Arabic and English
MOH responsible for health technology policy implementation: Health Development Unit.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —
National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Nomenclature systems used for devices and tests: —
National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: National Medicine and Poison Board.
Website(s): http://www.nmpb.gov.sd/
Contact: Dr. Mohamed Elhassan Mohamed Ahmed Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: Sudanese Nuclear and Radiological Regulatory Authority; National Medicines and Poisons Board (NMPB).

Approved devices lists comments (...Annex 1):

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):

HTA unit comments (...Annex 1):
A Health Technology Management system (HTM) has been developed. However, there is not current HTA system in place, but it is a goal to pursue towards the Universal Health Care country goal.

UHC - Service coverage index (1-100): 44
UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)
Global innovation index (rank): — (—)
High-technology exports (% of manufacture exports): —

Under-five mortality (per 1000 live births): 58.4
Probability of dying aged 30-70 yrs of NCDs (%): 26.00%
Human Development Index (inequality adjusted HDI): 0.51 (0.33): low
ICT Development Index (rank): 2.6 (145)
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Based on UMDNS  Use: For procurement purposes  
Website: —

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes  
Publically available: No  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging*</td>
<td>12</td>
<td>0.32</td>
<td>Health posts:</td>
<td>4088</td>
<td>10.77</td>
</tr>
<tr>
<td>Computerized Tomography Scanner*</td>
<td>43</td>
<td>1.13</td>
<td>Health centres:</td>
<td>1398</td>
<td>3.68</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>242</td>
<td>0.64</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine*</td>
<td>5</td>
<td>0.13</td>
<td>Specialized/regional/national hospitals:</td>
<td>13</td>
<td>0.03</td>
</tr>
<tr>
<td>Mammograph*</td>
<td>20</td>
<td>12.18</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy*</td>
<td>12</td>
<td>0.27</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes  
Unit/Department: Medical Engineering Unit/ Curative Medicine Department.  Unit website: —
Contact name: Eng. Fatima Mohamed Fadol  Contact email: —  
Website with publically available technical specifications: —
Number of regional/state offices/units: 7

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)  
Website: —
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population):*  2.62
Number of biomedical/clinical engineers professionals in the country:* 365

Contacts

MOH focal point
Name: Mr. Mohamed Osman Hamid  
Department: Health Planning and Policy  
Email: osmanhamid72@gmail.com  
Other country focal point
Name: Eng. Fatima Mohamed Fadol  
Email: —

WHO health products focal point:
Name: Dr. Nahid Idris Salih Khalid  
Email: salihn@sud.emro.who.int  
WHO Representative/WHO Liaison Officer:
Name: Dr. Nima Saeed Abid  
Email: abidn@who.int

General comments (...Annex 1): —
## Suriname

### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>587 (164)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.1</td>
</tr>
</tbody>
</table>

### National policy on health technology

- Health technology (medical device) national policy: **No**
- Policy is part of the National Health Program/Plan: **No**
- Website: —
- Language(s): —
- MOH responsible for health technology policy implementation: —

### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: **No**
  - Unit: —
  - Website: —
  - Nomenclature systems used for devices and tests: —

- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - Lists available: **No**
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —

- **National list for specific clinical interventions/emergencies:**
  - Lists available: **No**
  - Website: —

### National health technology assessment unit

- Designated unit/department for health technology assessment (HTA): **No**
- National unit/department that includes HTA for medical devices: **No**
- Website(s): —
- Contact: — Email: —
- Committee includes a biomedical or clinical engineer: —

### National regulatory authority

- Presence of national authority responsible for regulating medical devices: **No**
- Name of regulatory agency: Ministry of Health.
- Contact: Secretariat of the Director of Health Email: secdirvolksgezondheid@gov.sr
- Name(s) of other regulatory agency eg. for radiation equipment etc.: —
- Other agency’s website: —

### Under-five mortality (per 1000 live births): 18

### UHC - Service coverage index (1-100): 71

### Probability of dying aged 30-70 yrs of NCDs (%): 21.70%

### UHC - Population with household spending >10% (>25%) of corresponding income (%): 4.9% (1.4%)

### Human Development Index (inequality adjusted HDI): 0.74 (0.54): high

### Global innovation index (rank): — (—)

### ICT Development Index (rank): 5.2 (88)

### High-technology exports (% of manufacture exports): 12.50%

### Under-five mortality (per 1000 live births): 18

### UHC - Service coverage index (1-100): 71

### Probability of dying aged 30-70 yrs of NCDs (%): 21.70%

### UHC - Population with household spending >10% (>25%) of corresponding income (%): 4.9% (1.4%)

### Human Development Index (inequality adjusted HDI): 0.74 (0.54): high

### Global innovation index (rank): — (—)

### ICT Development Index (rank): 5.2 (88)

### High-technology exports (% of manufacture exports): 12.50%
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified  Website: —

Medical device incorporation

Procurement

Policy or guideline: No  Website: —

National level procurement: No  Website: —

Donations

Policy or guideline: No  Website: —

Technical specifications

Technical specifications to support procurement or donations: No  Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>2</td>
<td>3.71</td>
<td>Health posts:</td>
<td>244</td>
<td>45.25</td>
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<tr>
<td>Computerized Tomography Scanner:*</td>
<td>4</td>
<td>7.42</td>
<td>Health centres:</td>
<td>6</td>
<td>1.11</td>
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<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>General/distict hospitals:</td>
<td>1</td>
<td>0.19</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>1</td>
<td>0.19</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>4</td>
<td>93.6</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>3</td>
<td>5.11</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged 50-69 old.

Medical equipment management unit

Unit present: —  Professionally trained biomedical/clinical engineers: No
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): 8.19
Number of biomedical/clinical engineers professionals in the country: <10

Contacts

MOH focal point
Name: Mrs. Mellenie Kasanredjo
Department: —
Email: mellenie.saimoen@gov.sr

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Karen Lewis-Bell
Email: lewisbek@paho.org

General comments (...Annex 1): —
## Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>10,099 (90)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>77.2</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births):</th>
<th>2.6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>9.10%</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI):</td>
<td>0.95 (0.88); very high</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>8.4 (11)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>UHC - Service coverage index (1-100):</th>
<th>86</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>— (—)</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>62.5 (2)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>14.60%</td>
</tr>
</tbody>
</table>

### National policy on health technology

Health technology (medical device) national policy:
- Policy is part of the National Health Program/Plan:
- Language(s):
- MOH responsible for health technology policy implementation:

### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement**
- Lists available: No
- Unit: —
- Website: —

**Nomenclature systems used for devices and tests:**
- National list for different types of healthcare facilities (hospitals, laboratories, etc)
  - Lists available: No
  - Website - hospitals: —
  - Website - IVD: —

**Nomenclature systems used for devices and tests:**
- National list for specific clinical interventions/emergencies:
  - Lists available: No
  - Website: —

### National health technology assessment unit

Designated unit/department for health technology assessment (HTA):
- Yes

National unit/department that includes HTA for medical devices:
- Yes, The Dental and Pharmaceutical Benefits Agency.

Website(s): [https://www.tlv.se/medicinteknik.html](https://www.tlv.se/medicinteknik.html); [https://lakemedelsverket.se/english/](https://lakemedelsverket.se/english/); [https://www.sbu.se/en/](https://www.sbu.se/en/)

Contact: Ms. Karin Melén  Email: Karin.Melen@tlv.se

Committee includes a biomedical or clinical engineer:
- —

### National regulatory authority

Presence of national authority responsible for regulating medical devices:
- Yes

Name of regulatory agency: Medical Products Agency.

Website(s): [http://www.lakemedelsverket.se/english/](http://www.lakemedelsverket.se/english/)

Contact: Ms. Malin Blixt  Email: registrator@mpa.se

Name(s) of other regulatory agency eg. for radiation equipment etc.: Swedish Radiation Safety Authority.

Other agency's website: [https://www.stralsakerhetsmyndigheten.se/en/](https://www.stralsakerhetsmyndigheten.se/en/)

### Approved devices lists comments

(...Annex 1):
- The devices must bear the CE-mark

### Health care facilities lists comments

(...Annex 1):
- —

### Specific lists comments

(...Annex 1):
- There is an ongoing project in order to create such a national list. It is the Dental and Pharmaceutical Benefits Agency that is working with that.

### HTA unit comments

(...Annex 1):
- Network of HTA agencies such as: the Dental and Pharmaceutical Benefits Agency (TLV); Agency for the HTA and Assessment of Social Services (SBU), and Medical Products Agency. Alternative email: registrator@tlv.se.

### National regulatory comments

(...Annex 1):
- —
### Medical Device Nomenclature System

Official nomenclature system for medical devices: Yes  
Type: Based on EMDN  
Use: Not specified  
Website: —

### Medical Device Incorporation

#### Procurement

Policy or guideline: No  
Website: —

National level procurement: No  
Website: —

#### Donations

Policy or guideline: No  
Website: —

#### Technical Specifications

Technical specifications to support procurement or donations: No  
Publically available: —  
Website: —

### Medical Equipment

<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging: a</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner: a</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner: a</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine: a</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph: a</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy: a</td>
<td>130</td>
<td>12.87</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

### Medical Equipment Management Unit

Unit present: Yes  
Professionally trained biomedical/clinical engineers: Yes  
Unit/Department: —  
Website: —

Contact name: —  
Contact email: —  
Website with publically available technical specifications: —  
Number of regional/state offices/units: —

### Inventories and Medical Equipment Management Software

Type of inventories available: —  
Website: —

Use of management software: Yes  
Software name: —

### Medical Devices Workforce

Density of medical doctors (per 10,000 population): 43.31

Number of biomedical/clinical engineers professionals in the country: 1137

### Contacts

**MOH focal point**

Name: —  
Department: —  
Email: —

**Other country focal point**

Name: —  
Email: —

WHO health products focal point:

Name: —  
Email: —  
WHO Representative/WHO Liaison Officer:

Name: —  
Email: —

### General Comments

—

### WHO European Region

Sweden

### Nomenclature Comments

The change from GMDN to EMDN will take place with regards to the implementation of the new EU regulation on medical devices that shall be applied from the 26th of May, 2021.

### Medical Device Incorporation Comments

The national law for procurement is based on the EU directive. Concerning procurement, it can be done at a country level or within a single hospital.

### Medical Equipment Comments

The national law for procurement is based on the EU directive. Concerning procurement, it can be done at a country level or within a single hospital.

### Medical Equipment Total Density per 1,000,000 population Healthcare facility Total Density per 100,000 population

- **Magnetic Resonance Imaging:** n/a n/a  Health posts: n/a n/a
- **Computerized Tomography Scanner:** n/a n/a  Health centres: n/a n/a
- **Positron Emission Tomography Scanner:** n/a n/a  General/district hospitals: n/a n/a
- **Gamma camera or nuclear medicine:** n/a n/a  Specialized/regional/national hospitals: n/a n/a
- **Mammograph:** n/a n/a  Estimation % of health facilities with none or very limited oxygen supply: n/a
- **Radiotherapy:** 130 12.87  | n/a | n/a |

—

### Medical Devices Workforce

Density of medical doctors (per 10,000 population): 43.31

Number of biomedical/clinical engineers professionals in the country: 1137

### Contacts

**MOH focal point**

Name: —  
Department: —  
Email: —

**Other country focal point**

Name: —  
Email: —

WHO health products focal point:

Name: —  
Email: —  
WHO Representative/WHO Liaison Officer:

Name: —  
Email: —

### General Comments

—

### WHO European Region

Sweden

### Nomenclature Comments

The change from GMDN to EMDN will take place with regards to the implementation of the new EU regulation on medical devices that shall be applied from the 26th of May, 2021.

### Medical Device Incorporation Comments

The national law for procurement is based on the EU directive. Concerning procurement, it can be done at a country level or within a single hospital.
### Switzerland

#### Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):*</th>
<th>8,655 (100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:*</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):*</td>
<td>83.6</td>
</tr>
</tbody>
</table>

#### National policy on health technology

**Health technology (medical device) national policy:** No  
**Policy is part of the National Health Program/Plan:** No  
**Website:** —  
**Language(s):** —  
**MOH responsible for health technology policy implementation:** —

#### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**  
Lists available: Yes  
**Unit:** Swiss Federal Office of Public Health.  
**Website:** [https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung.html](https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung.html)  
**Nomenclature systems used for devices and tests:** —

**National list for different types of healthcare facilities (hospitals, laboratories, etc)**  
Lists available: No  
**Website - hospitals:** —  
**Website - IVD:** —  
**Nomenclature systems used for devices and tests:** —

**National list for specific clinical interventions/emergencies:**  
Lists available: No  
**Website:** —

#### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** Yes  
**National unit/department that includes HTA for medical devices:** Yes, Health and Accident Insurance Directorate.  
**Contact:** —  
**Email:** ELGK-sekretariat@bag.admin.ch  
**Committee includes a biomedical or clinical engineer:** —

#### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes  
**Name of regulatory agency:** Swiss Agency for Therapeutic Products (Swissmedic).  
**Website(s):** [https://www.swissmedic.ch/swissmedic/en/home/](https://www.swissmedic.ch/swissmedic/en/home/)  
**Contact:** Dr. Karoline Mathys Badertscher  
**Email:** Karoline.Mathys@swissmedic.ch  
**Name(s) of other regulatory agency eg. for radiation equipment etc.:** Swiss Federal Nuclear Safety Inspectorate (ENSI); Federal Office of Public Health (FOPH).  

#### Approved devices lists comments  
(...Annex 1):

Reimbursement list for medical devices used by the patients themselves, and Reimbursement list for medical analyses are available on the corresponding website (see link).

#### Health care facilities lists comments  
(...Annex 1):

—

#### Specific lists comments  
(...Annex 1):

—

#### HTA unit comments  
(...Annex 1):

There is the swiss network of HTA entities focusing in various areas. Some institutions are: Health Insurance Benefits, State Secretariat for Education, Research and Innovation, etc.

#### National regulatory comments  
(...Annex 1):

—
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Many co-existence of nomenclatures  Use: Not specified
Website: —

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: No  Website: —
Donations
Policy or guideline: No  Website: —
Technical specifications
Technical specifications to support procurement or donations: Yes  Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcares facility*</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy*</td>
<td>111</td>
<td>12.82</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical devices workforce

Density of medical doctors (per 10,000 population): 43.33
Number of biomedical/clinical engineers professionals in the country: 120

Contacts

MOH focal point
Name: Mr. André Breisinger
Department: Swissmedic, Swiss Agency for Therapeutic Products, Market Surveillance
Email: questions.devices@swissmedic.ch
Other country focal point
Name: —
Email: —

General comments (Annex 1): —

Nomenclature comments (Annex 1): Swissmedic uses GMDN (no country specific nomenclature). If manufacturers do not know the GMDN number, a UMDNS code may be given.

WHO European Region

Medical device incorporation comments (Annex 1):
The medical devices must fulfil the requirements described in the European medical device directives. Legal basis: (Swiss Medical devices ordinance): http://www.admin.ch/ch/d/sr/c812_213.html. The hospital / high cost technology planning is done at a national level. Coordinated planning of certain highly specialized areas of health care is in progress (see https://www.gdk-cds.ch/de/).

Medical equipment Total Density per 1,000,000 Healthcares facility* Total Density per 100,000
population

Magnetic Resonance Imaging* n/a n/a Health posts: n/a n/a
Computerized Tomography Scanner* n/a n/a Health centres: n/a n/a
Positron Emission Tomography Scanner* n/a n/a General/district hospitals: n/a n/a
Gamma camera or nuclear medicine* n/a n/a Specialized/regional/national hospitals: n/a n/a
Mammograph* n/a n/a Estimation % of health facilities with none or very limited oxygen supply: n/a
Radiotherapy* 111 12.82

* Density per 1,000,000 females aged from 50-69 old.

Medical devices workforce Density of medical doctors (per 10,000 population): 43.33
Number of biomedical/clinical engineers professionals in the country: 120

Contacts

MOH focal point
Name: Mr. André Breisinger
Department: Swissmedic, Swiss Agency for Therapeutic Products, Market Surveillance
Email: questions.devices@swissmedic.ch
Other country focal point
Name: —
Email: —

General comments (Annex 1): —

a  UN POP/WPP 2019 (2020 POP)  f  UNDP 2019
b  WB FY21 2019  g  ITU 2017
c  UN POP/WPP 1990-2020 MOR  h  WHO GHO 2017
d  WHO GHO 2019  i  WHO GHO 2010-2018
e  WHO GHO 2016  j  WHO GHO 2013-2018
δ Latest (2015-2021): WHO HTA/HBP survey or WHO HTA 2015 survey or WHO 2021 survey

Software comments (Annex 1): Go to the gdk website and search for the 291.0.html documentation.
Syrian Arab Republic

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):a</th>
<th>17,501 (67)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:b</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years):c</td>
<td></td>
</tr>
</tbody>
</table>

| Under-five mortality (per 1000 live births):d | 21.5 |
| UHC - Service coverage index (1-100):e | 60 |
| Probability of dying aged 30-70 yrs of NCDs (%):f | 21.80% |
| UHC - Population with household spending >10% (>25%) of corresponding income (%):g | — (—) |
| Human Development Index (inequality adjusted HDI): rank:h | 0.57 (—): medium |
| Global innovation index (rank):i | — (—) |
| ICT Development Index (rank):j | 3.3 (126) |
| High-technology exports (% of manufacture exports):k | — |

National policy on health technology

Health technology (medical device) national policy: —
Policy is part of the National Health Program/Plan: —
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: —
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

Available devices lists comments (...Annex 1): —

Health care facilities lists comments (...Annex 1): —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):a Yes

HTA unit comments (...Annex 1): It exists the Planning and International Collaboration Directorate which performed HTA activities, but it is not specifically for medical devices.

National regulatory authority

Presence of national authority responsible for regulating medical devices: —

National regulatory comments (...Annex 1): —

Name of regulatory agency: —
Website(s): —
Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Syrian Atomic Energy Commission.
Other agency’s website: http://www.aec.org.sy/
Medical device nomenclature system
Official nomenclature system for medical devices: — Type: — Use: — Website: —

Medical device incorporation
Procurement
Policy or guideline: — Website: —
National level procurement: — Website: —
Donations
Policy or guideline: — Website: —
Technical specifications
Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility ¹</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging: n/a</td>
<td></td>
<td>n/a</td>
<td>Health posts: n/a</td>
<td></td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner: n/a</td>
<td></td>
<td>n/a</td>
<td>Health centres: n/a</td>
<td></td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner: n/a</td>
<td></td>
<td>n/a</td>
<td>General/district hospitals: n/a</td>
<td></td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine: n/a</td>
<td></td>
<td>n/a</td>
<td>Specialized/regional/national hospitals: n/a</td>
<td></td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph: n/a</td>
<td></td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply: n/a</td>
<td></td>
<td>n/a</td>
</tr>
<tr>
<td>Radiation therapy: 12</td>
<td></td>
<td>0.69</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹ Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: —
Website: —
Use of management software: — Software name: —

Medical devices workforce
Density of medical doctors (per 10,000 population): 12.87
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Akjemal Magtymova
Email: magtymova@who.int

General comments (...)Annex 1: —

Medical devices workforce
Density of medical doctors (per 10,000 population): 12.87
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Akjemal Magtymova
Email: magtymova@who.int

General comments (...)Annex 1: —
Tajikistan

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):*</th>
<th>9,538 (94)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:*</td>
<td>Low</td>
</tr>
</tbody>
</table>

Life expectancy at birth (years):*  
Graph showing life expectancy trends over the years.

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births):*</th>
<th>33.8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%)*</td>
<td>25.30%</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank¹</td>
<td>0.67 (0.58); medium</td>
</tr>
<tr>
<td>ICT Development Index (rank)²</td>
<td>— (—)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>UHC - Service coverage index (1-100):*</th>
<th>68</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%)</td>
<td>— (—)</td>
</tr>
<tr>
<td>Global innovation index (rank):³</td>
<td>22.2 (109)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):*</td>
<td>—</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: Yes  
Policy is part of the National Health Program/Plan: Yes  
Language(s): —  
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:  
Lists available: Yes  
Unit: —  
Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)  
Lists available: —  
Website - hospitals: [http://ncl.tj/](http://ncl.tj/)  
Website - IVD: —  
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:  
Lists available: —  
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):* Yes  
National unit/department that includes HTA for medical devices: No  
Website(s): —  
Contact: — Email: —  
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes  
Name of regulatory agency: State Supervision Service for Pharmaceutical Activities of the Republic of Tajikistan; Agency of Standardization, Metrology, Certification and Trade Inspection under the Government of Republic of Tajikistan.  
Contact: — Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Agency on Nuclear and Radiation Safety, National Academy of Sciences of Tajikistan.  

Approved devices lists comments  
(...Annex 1):

Health care facilities lists comments  
(...Annex 1):

Specific lists comments  
(...Annex 1):

Human Development Index (inequality adjusted HDI): rank¹  
Rank: 0.67 (0.58); medium

Global innovation index (rank):³

Human Development Index (inequality adjusted HDI): rank¹

Global innovation index (rank):³

High-technology exports (% of manufacture exports):* —
## Medical device nomenclature system

Official nomenclature system for medical devices: **Yes**  
**Type:** Based on GMDN  
**Use:** For procurement purposes  
[Website:](https://portal.eaeunion.org/sites/odata/redesign/Pages/MedicalDeviceNomenclature.aspx)

## Medical device incorporation

### Procurement

**Policy or guideline:** Yes  
**Website:** —  
**National level procurement:** Yes  
**Website:** —

### Donations

**Policy or guideline:** Yes  
**Website:** —

### Technical specifications

**Technical specifications to support procurement or donations:** Yes  
**Publicly available:** —  
**Website:** —

## Medical equipment

<table>
<thead>
<tr>
<th>Equipment Type</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare Facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>3</td>
<td>0.37</td>
<td>Health posts</td>
<td>1701</td>
<td>20.72</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>9</td>
<td>1.1</td>
<td>Health centres</td>
<td>840</td>
<td>10.23</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals</td>
<td>249</td>
<td>3.03</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals</td>
<td>3</td>
<td>0.04</td>
</tr>
<tr>
<td>Mammograph</td>
<td>5</td>
<td>12.59</td>
<td>Estimation % of health facilities with none or very limited oxygen supply</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>2</td>
<td>0.21</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged 50-69 old.

## Medical equipment management unit

**Unit present:** —  
**Professionally trained biomedical/clinical engineers:** —  
**Unit/Department:** Medical Devices Unit  
[Website:](http://www.pharmnadzor.tj/)

## Inventories and medical equipment management software

**Type of inventories available:** National inventory for medical equipment  
[Website:](https://admch.tj/en/home/)

## Medical devices workforce

**Density of medical doctors (per 10,000 population):** **17.23**  
**Number of biomedical/clinical engineers professionals in the country:** <10

## Contacts

**MOH focal point**  
**Name:** Mr. Salim Abdulazizov  
**Department:** —  
**Email:** abdu_salim@mail.ru  
**Other country focal point**  
**Name:** —  
**Email:** —

**WHO health products focal point**  
**Name:** —  
**Email:** —  
**WHO Representative/WHO Liaison Officer**  
**Name:** Dr. Victor Stefan Olsavszky  
**Email:** olsavszkyv@who.int

---

### WHO European Region

**WHO health products focal point**  
**Name:** —  
**Email:** —  
**WHO Representative/WHO Liaison Officer**  
**Name:** Dr. Victor Stefan Olsavszky  
**Email:** olsavszkyv@who.int

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### General comments

—

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### Medical device nomenclature comments

—

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### Medical device incorporation comments

—

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### Medical devices workforce comments

—

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### Nomenclature comments

—

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Country indicators

Population 000s (rank): 69,800 (20)
World Bank income group: Upper-Middle

Under-five mortality (per 1000 live births): 9
Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: No
Website: https://www.moph.go.th/
Language(s): Thai
MOH responsible for health technology policy implementation: Food and Drugs Administration.

National policy on health technology

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, Food and Drug Administration.
Website(s): https://www.hitap.net/en/organization/background
Contact: Dr. Pongpan Vongmanee Email: pongpan_v@fda.moph.go.th
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Food and Drugs Administration.
Contact: Dr. Pongpan Vongmanee Email: pongpan_v@fda.moph.go.th
Name(s) of other regulatory agency eg. for radiation equipment etc.: Office of Atoms for Peace, Ministry of Science and Technology.

Health care facilities lists comments (...Annex 1):

Specific lists comments (...Annex 1):

Timeframe: 2022

HTA unit comments (...Annex 1):
HTA is focused on several health technologies and programs, including pharmaceuticals, medical devices, interventions, and disease prevention as well as to inform policy decisions.

National regulatory comments (...Annex 1):

HTA is focused on several health technologies and programs, including pharmaceuticals, medical devices, interventions, and disease prevention as well as to inform policy decisions.

Approved devices lists comments (...Annex 1):
There are lists of recommended procedures in organization level such as the procedure of the Physical Therapy Council. The approved medical devices list is only available for the reimbursements of the three health insurances, namely the National Health Security Office, the Comptroller General’s Department, and the Social Security Office.

Population 000s (rank): 69,800 (20)
Life expectancy at birth (years): 72.3
World Bank income group: Upper-Middle

Probability of dying aged 30-70 yrs of NCDs (%): 14.50%
UHC - Service coverage index (1-100): 80
UHC - Population with household spending >10% (>25%) of corresponding income (%): 2.2% (0.4%)
Human Development Index (inequality adjusted HDI): 0.78 (0.65): high
Global innovation index (rank): 36.7 (44)
ICT Development Index (rank): 5.7 (78)
High-technology exports (% of manufacture exports): 23.60%

Under-five mortality (per 1000 live births): 9
Life expectancy at birth (years): 72.3

Probability of dying aged 30-70 yrs of NCDs (%): 14.50%
UHC - Service coverage index (1-100): 80
UHC - Population with household spending >10% (>25%) of corresponding income (%): 2.2% (0.4%)
Human Development Index (inequality adjusted HDI): 0.78 (0.65): high
Global innovation index (rank): 36.7 (44)
ICT Development Index (rank): 5.7 (78)
High-technology exports (% of manufacture exports): 23.60%
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: https://www.moph.go.th/
National level procurement: No  Website: —

Donations
Policy or guideline: Yes  Website: http://www.moph.go.th

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: Yes
Website: https://www.moph.go.th/index.php/

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>28339</td>
<td>42.29</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:</td>
<td>399</td>
<td>5.95</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:</td>
<td>5</td>
<td>0.07</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>11</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:</td>
<td>30</td>
<td>0.45</td>
<td>Specialized/regional/national hospitals:</td>
<td>86</td>
<td>0.13</td>
</tr>
<tr>
<td>Mammograph:</td>
<td>215</td>
<td>27.87</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Radiotherapy:</td>
<td>140</td>
<td>2.01</td>
<td>—</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 9

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: Yes  Software name: RMC2005.

Medical devices workforce
Density of medical doctors (per 10 000 population): 9.19
Number of biomedical/clinical engineers professionals in the country: <10

Contacts
MOH focal point
Name: Mr. Chapon Ratanapan
Department: Food and Drug Administration
Email: sonapan@fda.moph.go.th

Other country focal point
Name: Dr. Orasa Kovindha
Email: kovindha@yahoo.com

WHO health products focal point:
Name: —
Email: —
WHO Representative/WHO Liason Officer:
Name: Dr. Jos Vandelaer
Email: vandelaerjo@who.int

General comments (...Annex 1): —
### Timor-Leste

#### Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>1,318 (152)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>69.2</td>
</tr>
</tbody>
</table>

#### National policy on health technology

<table>
<thead>
<tr>
<th>Policy</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health technology (medical device) national policy:</td>
<td>No</td>
</tr>
<tr>
<td>Policy is part of the National Health Program/Plan:</td>
<td>No</td>
</tr>
<tr>
<td>Website:</td>
<td>—</td>
</tr>
<tr>
<td>Language(s):</td>
<td>—</td>
</tr>
<tr>
<td>MOH responsible for health technology policy implementation:</td>
<td>—</td>
</tr>
</tbody>
</table>

#### National lists of medical devices

<table>
<thead>
<tr>
<th>List Description</th>
<th>Availability</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:</td>
<td>No</td>
<td>—</td>
</tr>
<tr>
<td>National list for different types of healthcare facilities (hospitals, laboratories, etc)</td>
<td>No</td>
<td>—</td>
</tr>
<tr>
<td>National list for specific clinical interventions/emergencies:</td>
<td>Yes</td>
<td>—</td>
</tr>
</tbody>
</table>

#### National health technology assessment unit

| Designated unit/department for health technology assessment (HTA): | No          |
| National unit/department that includes HTA for medical devices: | No          |
| Contact: Email: Committee includes a biomedical or clinical engineer: | —           |

#### National regulatory authority

| Presence of national authority responsible for regulating medical devices: | No          |
| Name of regulatory agency: | —           |
| Website(s): Email: | —           |
| Name(s) of other regulatory agency eg. for radiation equipment etc.: | —           |
| Other agency’s website: | —           |

### Approved devices lists comments

(...Annex 1): —

### Health care facilities lists comments

(...Annex 1): —

### Specific lists comments

(...Annex 1):
- There is the Standart Medical Equipment from Australia Advisor of Medical Equipment. See Classification Minimum Standard equipment HP, CHC, DHC.

### HTA unit comments

(...Annex 1): —

### National regulatory comments

(...Annex 1): —
Medical device nomenclature system

Official nomenclature system for medical devices: No
Type: None
Use: Not specified
Website: —

Medical device incorporation

Procurement
Policy or guideline: No
Website: —
National level procurement: No
Website: —

Donations
Policy or guideline: No
Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged 50-69.

Medical equipment management unit

Unit present: Yes
Professionally trained biomedical/clinical engineers: Yes
Unit/Department: —
Contact name: —
Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No
Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): 7.69
Number of biomedical/clinical engineers professionals in the country: <10

Contacts

MOH focal point
Name: —
Department: —
Email: —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Arvind Mathur
Email: mathura@who.int

General comments (...Annex 1): The Health Technology of medical equipment does not have standards for Medical Equipment yet.
## Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):</th>
<th>8,279 (101)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>Low</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>63.7</td>
</tr>
<tr>
<td>World</td>
<td>72.1</td>
</tr>
</tbody>
</table>

### National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

### National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: Yes
Website: —

### National health technology assessment unit

Designated unit/department for health technology assessment (HTA): —
National unit/department that includes HTA for medical devices: —
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

### National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

## Approved devices lists comments
(Annex 1):
Aucune organisation en charge de ces listes existe, malgré toutes les propositions formulées dans ce sens. Il ne semble pas avoir la volonté politique à évoluer dans ce sens.

## Health care facilities lists comments
(Annex 1):
—

## Specific lists comments
(Annex 1):
—

## HTA unit comments
(Annex 1):
—

## National regulatory comments
(Annex 1):
—

## Additional indicators

- Under-five mortality (per 1000 live births): 66.9
- Probability of dying aged 30-70 yrs of NCDs (%): 23.60%
- Human Development Index (inequality adjusted HDI): 0.52 (0.35); low
- ICT Development Index (rank): 2.2 (156)
- UHC - Service coverage index (1-100): 43
- UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)
- Global innovation index (rank): 18.5 (125)
- High-technology exports (% of manufacture exports): 0.10%

## Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Year</th>
<th>Life expectancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>55.4</td>
</tr>
<tr>
<td>2010</td>
<td>58.0</td>
</tr>
<tr>
<td>2020</td>
<td>60.5</td>
</tr>
</tbody>
</table>

## Under-five mortality (per 1000 live births):

<table>
<thead>
<tr>
<th>Year</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>67.4</td>
</tr>
<tr>
<td>2010</td>
<td>66.9</td>
</tr>
<tr>
<td>2020</td>
<td>66.9</td>
</tr>
</tbody>
</table>

## Probability of dying aged 30-70 yrs of NCDs (%):

<table>
<thead>
<tr>
<th>Year</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>23.5</td>
</tr>
<tr>
<td>2010</td>
<td>23.6</td>
</tr>
<tr>
<td>2020</td>
<td>23.6</td>
</tr>
</tbody>
</table>

## Human Development Index (inequality adjusted HDI):

<table>
<thead>
<tr>
<th>Year</th>
<th>Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>0.52</td>
</tr>
<tr>
<td>2010</td>
<td>0.52</td>
</tr>
<tr>
<td>2020</td>
<td>0.52</td>
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</tbody>
</table>

## ICT Development Index (rank):

<table>
<thead>
<tr>
<th>Year</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>2.2</td>
</tr>
<tr>
<td>2010</td>
<td>2.2</td>
</tr>
<tr>
<td>2020</td>
<td>2.2</td>
</tr>
</tbody>
</table>

## UHC - Service coverage index (1-100):

<table>
<thead>
<tr>
<th>Year</th>
<th>Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>43</td>
</tr>
<tr>
<td>2010</td>
<td>43</td>
</tr>
<tr>
<td>2020</td>
<td>43</td>
</tr>
</tbody>
</table>

## UHC - Population with household spending >10% (>25%) of corresponding income (%):

<table>
<thead>
<tr>
<th>Year</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>— (—)</td>
</tr>
<tr>
<td>2010</td>
<td>— (—)</td>
</tr>
<tr>
<td>2020</td>
<td>— (—)</td>
</tr>
</tbody>
</table>

## Global innovation index (rank):

<table>
<thead>
<tr>
<th>Year</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>18.5</td>
</tr>
<tr>
<td>2010</td>
<td>18.5</td>
</tr>
<tr>
<td>2020</td>
<td>18.5</td>
</tr>
</tbody>
</table>

## High-technology exports (% of manufacture exports):

<table>
<thead>
<tr>
<th>Year</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>0.10%</td>
</tr>
<tr>
<td>2010</td>
<td>0.10%</td>
</tr>
<tr>
<td>2020</td>
<td>0.10%</td>
</tr>
</tbody>
</table>

## Other indicators

- Population 000s (rank): 8,279 (101)
- World Bank income group: Low
- Life expectancy at birth (years): 63.7
- Under-five mortality (per 1000 live births): 66.9
- Probability of dying aged 30-70 yrs of NCDs (%): 23.60%
- Human Development Index (inequality adjusted HDI): 0.52 (0.35); low
- ICT Development Index (rank): 2.2 (156)
- UHC - Service coverage index (1-100): 43
- UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)
- Global innovation index (rank): 18.5 (125)
- High-technology exports (% of manufacture exports): 0.10%

## Education indicators

- Population (rank): —
- Academic attainment (15+ yrs): —
- Adult literacy (%): —
- Pre-primary school (age 3-5 yrs): —
- Primary school (age 6-11 yrs): —
- Secondary school (age 12-15 yrs): —
- Tertiary education (%): —
Medical device nomenclature system

- Official nomenclature system for medical devices: No
- Type: None
- Use: Not specified
- Website: —

Medical device incorporation

- Procurement
  - Policy or guideline: Yes
  - National level procurement: No
  - Website: —
- Donations
  - Policy or guideline: No
  - Website: —

Technical specifications

- Technical specifications to support procurement or donations: No
- Publically available: —
- Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:</td>
<td>1</td>
<td>0.15</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:</td>
<td>5</td>
<td>0.73</td>
<td>Health centres:</td>
<td>746</td>
<td>10.94</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>35</td>
<td>0.51</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>6</td>
<td>0.09</td>
</tr>
<tr>
<td>Mammograph:</td>
<td>3</td>
<td>10.39</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:</td>
<td>n/a</td>
<td>n/a</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Software comments (...Annex 1):

Bien que cela soit le point de départ de toute gestion en terme de maintenance des parcs biomédicaux, cette opération n'existe pas au plan national sauf par endroit mais aussi de façon sommaire. Les données ainsi consignées ne permettent pas de l'exploiter pour proposer des plans de renouvellement ou de développement de parcs biomédicaux. En bref aucun inventaire digne de ce nom n'existe pas sur le plan national.

Medical equipment management unit

- Unit present: Yes
- Professionally trained biomedical/clinical engineers: Yes
- Unit/Department: Service de la Maintenance
- Unit website: —
- Contact name: Mr. Komlan Jean Edoh-kossi
- Contact email: kedohkos@yahoo.fr
- Website with publically available technical specifications: —
- Number of regional/state offices/units: 6

Inventories and medical equipment management software

- Type of inventories available: None
- Website: —
- Use of management software: No
- Software name: —

Medical devices workforce

- Density of medical doctors (per 10 000 population): 0.78
- Number of biomedical/clinical engineers professionals in the country: —

WHO health products focal point

- Name: Dr. Minzah Pekele
- Email: pekelem@who.int

WHO Representative/WHO Liaison Officer

- Name: Dr. Fatoumata Binta T. Diallo
- Email: diallof@who.int

General comments (...Annex 1):

Compte tenu des difficultés que nous rencontrons pour la prise en compte adéquate des plateaux techniques dans nos formations sanitaires malgré les recommandations régionales pour une politique commune en matière de maintenance et la gestion durable des infrastructures sociales je veux bien croire que cette enquête nous ouvrira l’horizon de nouvelles politiques adaptées à nos réalités.
### Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Tonga</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>106 (181)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.3 (34)</td>
</tr>
</tbody>
</table>

### National policy on health technology
- **Health technology (medical device) national policy:** No
- **Policy is part of the National Health Program/Plan:** No
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

### National lists of medical devices
- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - **Lists available:** Yes
  - **Unit:** Facility and Equipment Committee together with the Biomedical Engineering Unit of the Ministry of Health.
  - **Website:** —
  - **Nomenclature systems used for devices and tests:** —
- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - **Lists available:** No
  - **Website - hospitals:** —
  - **Website - IVD:** —
  - **Nomenclature systems used for devices and tests:** —
- **National list for specific clinical interventions/emergencies:**
  - **Lists available:** No
  - **Website:** —

### National health technology assessment unit
- **Designated unit/department for health technology assessment (HTA):**
  - **Website(s):** —
  - **Contact:** —
  - **Email:** —
  - **Committee includes a biomedical or clinical engineer:** —

### National regulatory authority
- **Presence of national authority responsible for regulating medical devices:** No
- **Name of regulatory agency:** —
- **Website(s):** —
- **Contact:** Mr. Feleti Eke  Email: feke@health.gov.to
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** —
- **Other agency’s website:** —

### National policy on health technology comments
- Approved devices lists comments
  - (...Annex 1): —
- Health care facilities lists comments
  - (...Annex 1): —
- Specific lists comments
  - (...Annex 1): There are no specific lists.

### National regulatory comments
- **HTA unit comments**: (...Annex 1): —
- **National regulatory comments**: (...Annex 1): Although there is no formal institution that oversees the implementation of any medical device regulation, there is the “Facility and Equipment Committee” of the Ministry of Health that oversees certain things such as the procurement of medical devices, the criteria of acceptance of donated equipment and the implementation of maintenance guidelines, etc.
Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: None  Use: Not specified  Website: —

Medical device incorporation
Procurement
Policy or guideline: No  Website: —  National level procurement: Yes  Website: —
Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes  Publically available: —  Website: —

Medical equipment
<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>0</td>
<td>0</td>
<td>Health posts:</td>
<td>15</td>
<td>14.24</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>Health centres:</td>
<td>14</td>
<td>13.29</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>—</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>0</td>
<td>0</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes  Unit/Department: Biomedical engineering  Unit website: —
Contact name: Mr. Feleti Eke  Contact email: feke@health.gov.to  Website with publically available technical specifications: —  Number of regional/state offices/units: 0

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment  Website: —  Use of management software: Yes  Software name: Equipment Management Systems.

Medical devices workforce
Density of medical doctors (per 10,000 population): 5.4
Number of biomedical/clinical engineers professionals in the country: —

Contacts
MOH focal point
Name: —  Department: —  Email: —
Other country focal point
Name: Mr. Feleti Eke  Email: feke@health.gov.to

WHO health products focal point
Name: —  Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Yutaro Setoya  Email: setoyay@who.int

General comments (Annex 1): —
Trinidad and Tobago

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):^a</th>
<th>1,399 (150)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:^h</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):^c</td>
<td></td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births):^d 17.5
UHC - Service coverage index (1-100):^h 74
Probability of dying aged 30-70 yrs of NCDs (%):^e 21.30%
UHC - Population with household spending >10% (>25%) of corresponding income (%):^f 3.9% (1.9%)
Human Development Index (inequality adjusted HDI): rank^i 0.8 (--); high
Global innovation index (rank):^j 24.1 (98)
ICT Development Index (rank):^k 6 (68)
High-technology exports (% of manufacture exports):^l —

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: http://www.health.gov.tt/
Language(s): English
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes, but it is only a recommendation
Unit: Ministry of Health.
Website: —
Nomenclature systems used for devices and tests: Other.
National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —
National list for specific clinical interventions/emergencies:
Lists available: Yes
Website: —

Approved devices lists comments (...Annex 1):
The nomenclature is part of the Computerized Maintenance Management System.

Health care facilities lists comments (...Annex 1):
Certification standards for equipment, e.g. European CE Marking and U.S. Food and Drug Administration.

Specific lists comments (...Annex 1):
The list exists for point of care testing equipment, namely, Diagnostic Screening and Laboratory Testing. The medical equipment requirements for specific procedures are done by the respective inhouse Hospital Biomedical Department and the clinicians. The American Hospital Association guidelines are used as a reference. Also, the Ministry has established requirements for Diagnostic Laboratory Point of Care Testing.

HTA unit comments (...Annex 1):
There are identified HTA activities at a national level. Furthermore a consultant is to be engaged to assists in the development of an HTA framework. Alternative contact for the Health Technology Management unit: pmu@health.gov.tt.

National health technology assessment unit

Described unit/department for health technology assessment (HTA):^d Yes
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: Mr. Kyron Lopez  Email: kyron.lopez@health.gov.tt
Committee includes a biomedical or clinical engineer: Yes

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Chemistry Food and Drug Division.
Contact: Mr. Adrian Mc Cathy  Email: adrianmccathy@health.gov.tt
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

National regulatory comments (...Annex 1):

Medical device nomenclature system
Official nomenclature system for medical devices: No  Type: Many co-existence of nomenclatures  Use: For procurement purposes  Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: —
National level procurement: No  Website: —
Donations
Policy or guideline: Yes  Website: —
Technical specifications
Technical specifications to support procurement or donations: Yes  Publically available: —  Website: —

Medical equipment
Total  Density per 1,000,000 population  Healthcare facility
Density per 100,000 population
Magnetic Resonance Imaging*: 7 5  Health posts: 105 7.51
Computerized Tomography Scanner*: 12 8.58  Health centres: 94 6.72
Positron Emission Tomography Scanner*: 1 0.71  General/district hospitals: 10 0.71
Gamma camera or nuclear medicine*: 4 2.86  Specialized/regional/national hospitals: 0 0
Mammograph*: 6 37.37  Estimation % of health facilities with none or very limited oxygen supply: 5%
Radiotherapy*: 11 7.86

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Biomedical Department, North Central Regional Health Authority.  Unit website: —
Contact name: Mr. Rusell Sooknanan  Contact email: rusel.sooknanan@ncrha.co.tt
Website with publically available technical specifications: —
Number of regional/state offices/units: 5

Inventories and medical equipment management software
Type of inventories available: National inventory only for high cost technologies (Diagnostic Imaging)  Website: —
Use of management software: Yes  Software name: WebTMA.

Medical devices workforce
Density of medical doctors (per 10,000 population):* 44.76
Number of biomedical/clinical engineers professionals in the country: 40

Contacts
MOH focal point
Name: Mr. Ronald Koylass  Department: Project Management Unit  Email: Ronald.Koylass@health.gov.tt
Other country focal point
Name: Mr. Rusell Sooknanan  Email: rusel.sooknanan@ncrha.co.tt

WHO health products focal point:
Name: —  Email: —
WHO Representative/WHO Liaison Officer:
Name: Dr. Erica Lynette Wheeler  Email: wheelereri@paho.org

General comments (...Annex 1): It is noted that several medical devices systems exist at the respective Regional Health Authorities (RHA) level. The MoH is currently working towards standardising these and in particular concerning the procurement guidelines for medical devices.
Country indicators

Population 000s (rank): 11,819 (78)
World Bank income group: Lower-Middle

Under-five mortality (per 1000 live births): 16.9
UHC - Service coverage index (1-100): 70

Probability of dying aged 30-70 yrs of NCDs (%): 16.10%
UHC - Population with household spending >10% (>25%) of corresponding income (%): 18.4% (2.7%)

Human Development Index (rank): 0.74 (0.6); high
Global innovation index (rank): 31.2 (65)

ICT Development Index (rank): 4.8 (99)
High-technology exports (% of manufacture exports): 6.90%

National policy on health technology
Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices
National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —
National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —
National list for specific clinical interventions/emergencies:
Lists available: Yes
Website: http://www.santetunisie.tn/images/docs/pop-up3.html

National health technology assessment unit
Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes
Website(s): https://www.ineas.tn/fr
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (Annex 1):
INEAS is under the auspices of the MoH. It evaluates health technologies and provide rigorous evidence-based recommendations to decision-makers on pharmaceuticals and other technologies’ uptake and use. As one internal policy trains it’s own staff, as well as HTA user’s.

National regulatory authority
Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Ministry of Health.
Website(s): http://www.santetunisie.rns.tn/fr/
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: Centre National des Sciences et Technologies Nucléaires (CNSTN) et Centre National Chalbi Belkahia de Pharmacovigilance (CNPV).
Other agency’s website: http://www.cnstn.rnrt.tn/radioprotection.php; http://www.pharmacovigilance.rns.tn/

Population 000s (rank): 11,819 (78)
World Bank income group: Lower-Middle

Approved devices lists comments (Annex 1):
L’acquisition et la mise en service des équipements lourds sont soumis à l’autorisation préalable du MoH pour les secteurs public et privé et ce conformément aux critères et normes fixés par les arrêtés sus-indiqués.
Arrêté. D’une manière générale la liste de matériel découle de l’activité préconisée sans liste préétablie. Seules les produits non conformes aux spécifications techniques fixés par les cahiers de charges (CCITP) des appels d’offres ou dont le contrôle technique à l’importation non concluant et ceux qui ne sont pas autorisés à être mis sur le marché dans leurs pays d’origine ne sont pas autorisés à être mis sur le marché Tunisien.

Health care facilities lists comments (Annex 1):
—

Specific lists comments (Annex 1):

HTA unit comments (Annex 1):
INEAS is under the auspices of the MoH. It evaluates health technologies and provide rigorous evidence-based recommendations to decision-makers on pharmaceuticals and other technologies’ uptake and use. As one internal policy trains it’s own staff, as well as HTA user’s.

National regulatory comments (Annex 1):
—

Under-five mortality (per 1000 live births): 16.9
UHC - Service coverage index (1-100): 70

Probability of dying aged 30-70 yrs of NCDs (%): 16.10%
UHC - Population with household spending >10% (>25%) of corresponding income (%): 18.4% (2.7%)

Human Development Index (rank): 0.74 (0.6); high
Global innovation index (rank): 31.2 (65)

ICT Development Index (rank): 4.8 (99)
High-technology exports (% of manufacture exports): 6.90%
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: Not specified
Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: www.santetunisie.rns.tn
Donations
Policy or guideline: No  Website: —
Technical specifications
Technical specifications to support procurement or donations: Yes
Publicly available: No
Website: —

Medical equipment
<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>22</td>
<td>2</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>98</td>
<td>8.91</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>13</td>
<td>1.18</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>21</td>
<td>22.58</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>29</td>
<td>2.45</td>
</tr>
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</table>

Healthcare facility
<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts:</td>
<td>2058</td>
</tr>
<tr>
<td>Health centres:</td>
<td>n/a</td>
</tr>
<tr>
<td>General/district hospitals:</td>
<td>131</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>30</td>
</tr>
<tr>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Contact name: Dir. General  Contact email: ancsep.rns.tn
Website with publically available technical specifications: http://www.santetunisie.rns.tn/fr/
Number of regional/state offices/units: 3

Inventories and medical equipment management software
Type of inventories available: —
Website: —
Use of management software: Yes  Software name: G.M.B.H.

Medical devices workforce
Density of medical doctors (per 10 000 population):* 13.03
Number of biomedical/clinical engineers professionals in the country: 20

Contacts
MOH focal point
Name: Mr. Fathi Amous
Department: CETEM-BH
Email: fathi.amous@rns.tn
Other country focal point
Name: Dir. General
Email: ancsep@rns.tn

WHO health products focal point:
Name: Dr. Ramzi Ouhichi
Email: ouhichi@tun.emro.who.int

WHO Representative/WHO Liaison Officer:
Name: Dr. Yves Souteyrand
Email: souteyrand@who.int

General comments (...Annex 1): La structure publique de santé en Tunisie est composé de établissements publics de santé (CHU.H. Spécialisés) dans les sièges de faculté de médecine des hôpitaux régionaux des hôpitaux de circonscription des groupements de santé de base des centres de santé de base et des centres régionaux de médecine scolaire et universitaire en plus des trois hôpitaux militaires et un hôpital des forces de sécurité intérieure publics et six centres de d’hémodialyse et six polycliniques para-publique ne relevant pas du ministère de la santé le secteur privé compte 3371 unités réparties entre cliniques, cabinets dentaires, officines, cabinets de radiologie, centres d’imagerie médicale laboratoires et centres d’hémodialyse.

a UN POP/WPP 2019 (2020 POP)
b WB FY2 2019
c UN POP/WPP 2019 (1990-2020 MOR)
d WHO GHO 2019
e WHO GHO 2016
f UNDP 2019
g ITU 2017
h WHO GHO 2017
i WHO GHO 2010-2018
j WIPO 2020
k UN and WB 2017-2019
f WHO GHO 2017 survey or IAEA (2017-2021)
g WHO GHO 2021 survey or OECD (2017-2019)
h WHO GHO 2010-2018
i n/a not applicable/not available
## Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank)</td>
<td>84,339 (17)</td>
</tr>
<tr>
<td>Life expectancy at birth (years)</td>
<td>71.3</td>
</tr>
</tbody>
</table>

## National policy on health technology

- **Health technology (medical device) national policy:** No
- **Policy is part of the National Health Program/Plan:** No
- **Website:** —
- **Language(s):** —
- **MOH responsible for health technology policy implementation:** —

## National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: Yes
  - Unit: Social Security Institution.
  - Nomenclature systems used for devices and tests: —

- **National list for different types of healthcare facilities (hospitals, laboratories, etc)**
  - Lists available: Yes
  - Website - IVD: [https://www.titck.gov.tr/dinamikmodul/85](https://www.titck.gov.tr/dinamikmodul/85)
  - Nomenclature systems used for devices and tests: —

- **National list for specific clinical interventions/emergencies:**
  - Lists available: Yes

## National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):** Yes
- **National unit/department that includes HTA for medical devices:** Yes, General Directorate of Curative Services.
- **Website(s):** [https://shgmargestddb.saglik.gov.tr/](https://shgmargestddb.saglik.gov.tr/)
- **Contact:** Mr. Irfan Sencan  Email: irfan.sencan@saglik.gov.tr

## National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** Yes
- **Name of regulatory agency:** Directorate of Pharmacy and Pharmaceuticals
- **Website(s):** [https://www.titck.gov.tr/faaliyetalanlari/tibbicihaz](https://www.titck.gov.tr/faaliyetalanlari/tibbicihaz)
- **Contact:** Mr. Bilgehan Karadayi  Email: bilgehan.karadayi@iegm.gov.tr
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** Nuclear Regulatory Authority (NDK); Turkish Medicines and Medical Devices Agency (TITCK).

## Approved devices lists comments

(Annex 1): The Ministry of Health is closely involved in the decision making but the main responsible unit is the Social Security Institution of the Republic of Turkey. The Directorate of Curative Services is the main responsible unit in the Ministry of Health.

## Health care facilities lists comments

(Annex 1):

Specific lists comments (Annex 1): These standards are not centrally organized and published. Each department has its own and they can be found in the second link under Saglik Mevzuati>Genelgeler, Tebligler, Yönergeler, Yönetmelikler>… Relevant departments and headlines. Each Directorate and department has its relevant health technology reference documents (guidelines, circulars, regulatory statute etc) in its links on the website.

## HTA unit comments

(Annex 1): Generic email of the HTA department shgm.argestd@saglik.gov.tr

## National regulatory comments

(Annex 1): —

## Demographic indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under-five mortality (per 1000 live births)</td>
<td>10.1</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%)</td>
<td>16.10%</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank</td>
<td>0.82 (0.68): very high</td>
</tr>
<tr>
<td>ICT Development Index (rank)</td>
<td>6.1 (67)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports)</td>
<td>3.00%</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100)</td>
<td>74</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%)</td>
<td>3.2% (0.4%)</td>
</tr>
<tr>
<td>Global innovation index (rank)</td>
<td>34.9 (51)</td>
</tr>
</tbody>
</table>
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: Not specified
Website: https://www.saglik.gov.tr/?_Dil=2

Nomenclature comments (...Annex 1):
Huab is the Turkish registry system for medical devices. Both GMDN and UNSPSC are used in this system. For reimbursement purposes another nomenclature mentioned in the corresponding link is also used.

Medical device incorporation

Procurement
Policy or guideline: Yes  Website: https://www.saglik.gov.tr/?_Dil=2
National level procurement: No  Website: —

Donations
Policy or guideline: Yes  Website: http://www.saglik.gov.tr/

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

Medical device incorporation comments (...Annex 1):

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Directorate of Pharmacy and Pharmaceuticals.  Unit website: https://www.hssgm.gov.tr/
Contact name: Mr. Saim Kerman  Contact email: s aim.kerman@iegm.gov.tr
Website with publically available technical specifications: https://www.hssgm.gov.tr/TuzuklerYonetmelikler
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: http://www.saglik.gov.tr/
Use of management software: —  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): ε 18.07
Number of biomedical/clinical engineers professionals in the country: γ 960

Contacts

MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: Mr. Saim Kerman
Email: saim.kerman@iegm.gov.tr

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Batyr Berdyklychev
Email: berdyklychev.b@who.int

General comments (...Annex 1):
Concerning the medical equipment and structure section: there is a draft document (Health Statistics Yearbook) at the link: https://hsgm.saglik.gov.tr/tr/ , but it is not appropriate to use it as a reference since the original document will be available in the future. Some numbers can be variable because of the dynamic situation in Turkey. Especially for the last 5-7 years, the health technology situation is changing and developing rapidly.

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging a</td>
<td>915</td>
<td>10.85</td>
<td>Health posts:</td>
<td>7518</td>
<td>10.03</td>
</tr>
<tr>
<td>Computerized Tomography Scanner a</td>
<td>1211</td>
<td>14.36</td>
<td>Health centres:</td>
<td>203</td>
<td>0.27</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner a</td>
<td>131</td>
<td>1.55</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine a</td>
<td>299</td>
<td>3.55</td>
<td>Specialized/regional/national hospitals:</td>
<td>237</td>
<td>0.32</td>
</tr>
<tr>
<td>Mammograph a</td>
<td>966</td>
<td>120.72</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy a</td>
<td>300</td>
<td>3.56</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a Density per 1,000,000 females aged from 50-69 old.

Software comments (...Annex 1):
Go to the previous website and search for sbhb. However, the full online inventory databank, with restricted use to the authorities, is on the following site: http://sbu.saglik.gov.tr/sbhbf/
Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):a</th>
<th>6,031 (111)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:b</td>
<td>Upper-Middle</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Life expectancy at birth (years):c</th>
<th>72.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>TTM</td>
<td>World</td>
</tr>
<tr>
<td>69.7</td>
<td>72.8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births):d</th>
<th>42</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Probability of dying aged 30-70 yrs of NCDs (%):e</th>
<th>29.50%</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Human Development Index (inequality adjusted HDI): rank:f</th>
<th>0.72 (0.59): high</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>ICT Development Index (rank):g</th>
<th>— (—)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Health care facilities lists comments (Annex 1):</th>
<th>—</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Specific lists comments (Annex 1):</th>
<th>—</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>HTA unit comments (Annex 1):</th>
<th>There is no systematic programme of health technology assessment, but an informed decision is mainly used for pharmaceutics but no for medical devices.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>National health technology assessment unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designated unit/department for health technology assessment (HTA):a No</td>
</tr>
<tr>
<td>National unit/department that includes HTA for medical devices: No</td>
</tr>
<tr>
<td>Website(s):</td>
</tr>
<tr>
<td>Contact: Email:</td>
</tr>
<tr>
<td>Committee includes a biomedical or clinical engineer:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>National regulatory authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presence of national authority responsible for regulating medical devices:</td>
</tr>
<tr>
<td>Name of regulatory agency: Ministry of Health and Medical Industry of Turkmenistan.</td>
</tr>
<tr>
<td>Website(s): <a href="https://www.saglykhm.gov.tm/home">https://www.saglykhm.gov.tm/home</a></td>
</tr>
<tr>
<td>Contact: Email:</td>
</tr>
<tr>
<td>Name(s) of other regulatory agency eg. for radiation equipment etc.:</td>
</tr>
<tr>
<td>Other agency’s website:</td>
</tr>
</tbody>
</table>

Global policy on health technology

Health technology (medical device) national policy: —
Policy is part of the National Health Program/Plan: —
Website: https://www.saglykhm.gov.tm/home
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: —
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

Approved devices lists comments (Annex 1): —

Health care facilities lists comments (Annex 1): —

Specific lists comments (Annex 1): —

National regulatory comments (Annex 1): —

Population 000s (rank):a 6,031 (111)
World Bank income group:b Upper-Middle

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<td>Contact: Email:</td>
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</tr>
<tr>
<td>Name(s) of other regulatory agency eg. for radiation equipment etc.:</td>
</tr>
<tr>
<td>Other agency’s website:</td>
</tr>
</tbody>
</table>
Medical device nomenclature system

Official nomenclature system for medical devices:

Type: 
Use: 

Website: —

Medical device incorporation

Procurement

Policy or guideline: —
Website: —

National level procurement: —
Website: —

Donations

Policy or guideline: —
Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/Regional/National hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>11</td>
<td>1.82</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: —
Professionally trained biomedical/clinical engineers: —

Unit/Department: —
Unit website: —

Contact name: —
Contact email: —

Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: https://www.saglykhm.gov.tm/home
Use of management software: —
Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): 22.25
Number of biomedical/clinical engineers professionals in the country: —

Contacts

MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: —
Email: —

General comments (Annex 1): —

Medical device incorporation comments (Annex 1): —

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr Egor Zaitsev
Email: zaitseve@who.int

General comments (Annex 1): —
## Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):a</th>
<th>12 (192)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:bi</td>
<td>Upper-Middle</td>
</tr>
</tbody>
</table>

| Life expectancy at birth (years):i | 72.3 |

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births):a</th>
<th>23.9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):ii</td>
<td>—</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): ranki</td>
<td>(—)</td>
</tr>
<tr>
<td>ICT Development Index (rank):ii</td>
<td>(—)</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):b</td>
<td>—</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):i</td>
<td>(—)</td>
</tr>
<tr>
<td>Global innovation index (rank):j</td>
<td>(—)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):k</td>
<td>—</td>
</tr>
</tbody>
</table>

### National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): English
MOH responsible for health technology policy implementation: —

### National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Approved devices lists comments (...Annex 1):
—

Health care facilities lists comments (...Annex 1):
—

Specific lists comments (...Annex 1):
—

### National health technology assessment unit

Designated unit/department for health technology assessment (HTA):i Yes
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
National Drug and Therapeutic Committee (NDTC) has done HTA activities mainly in pharmaceutics; however, there is no a national HTA unit.

### National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Ministry of Health.
Website(s): —
Contact: Director of Health Email: pphs@tuvalu.tv
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

National regulatory comments (...Annex 1):
—
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  
Type: Based on UMDNS  
Use: Not specified  
Website: —

Medical device incorporation
Procurement
Policy or guideline: Yes  
Website: —
National level procurement: Yes  
Website: —

Donations
Policy or guideline: Yes  
Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes  
Publically available: No  
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>11</td>
<td>111.38</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>1</td>
<td>10.13</td>
</tr>
<tr>
<td>Mammograph:</td>
<td>n/a</td>
<td>n/a</td>
<td>Expansion % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical device incorporation comments (...Annex 1):
Guidelines on Donations exist, they are nationally developed but they are not publicly available.

Medical tools

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>CT Scanner:</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>11</td>
<td>111.38</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>1</td>
<td>10.13</td>
</tr>
<tr>
<td>Mammograph:</td>
<td>n/a</td>
<td>n/a</td>
<td>Expansion % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
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<tr>
<td>Radiotherapy:</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical devices workforce
Density of medical doctors (per 10,000 population): 9.09
Number of biomedical/clinical engineers professionals in the country: —

Contacts

MOH focal point
Name: Mr. Nelson Morikao Vaguna  
Department: Biomedical Department  
Email: wallabies.donny@gmail.com

Other country focal point
Name: Mr. Natano Elisala  
Email: pharmacyintovalu@gmail.com

WHO health products focal point:
Name: —  
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Mark Andrew Jacobs  
Email: jacobsma@who.int

General comments (...Annex 1): —
Uganda

Country indicators

Population 000s (rank): 45,741 (31)
World Bank income group: Low
Life expectancy at birth (years): 62.8

National policy on health technology
Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: https://www.health.go.ug/
Language(s): English
MOH responsible for health technology policy implementation: Health Infrastructure Department.

National lists of medical devices
National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes, but it is only a recommendation
Unit: National Advisory Committee on Medical Equipment (NACME).
Website: www.health.go.ug
Nomenclature systems used for devices and tests: Nationally developed.
National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: https://www.nda.or.ug/medical-devices-guidelines/
Website - IVD: https://www.nda.or.ug/drug-register-downloads/
Nomenclature systems used for devices and tests: —
National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit
Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No, Health Infrastructure Division.
Website(s): http://www.health.go.ug
Contact: Eng. George Otim Odongcoo Email: otimodongcoo@gmail.com
Committee includes a biomedical or clinical engineer: Yes

National regulatory authority
Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: National Drug Authority.
Website(s): https://www.nda.or.ug/
Contact: Mr. Gordon K. Sematiko Email: gsematiko@nda.or.ug
Name(s) of other regulatory agency eg. for radiation equipment etc.: Uganda National Bureau of Standards.
Other agency’s website: https://www.nda.or.ug/medical-devices/

approved devices lists comments
(Annex 1):
Usually we use the WHO recommendations. List of equipment by health care level is available in the website.

Health care facilities lists comments
(Annex 1):
Standard Medical Equipment list is under review.

Specific lists comments (Annex 1):
There are no national lists recommending health technology for specific procedures.
We usually adhere to the World Health Organization recommendations.

HTA unit comments (Annex 1):
There are identified HTA activities but there is not a national unit.

Population 000s (rank):
Under-five mortality (per 1000 live births):
Probability of dying aged 30-70 yrs of NCDs (%):
Human Development Index (inequality adjusted HDI): rank:
ICT Development Index (rank):

UHC - Service coverage index (1-100):
UHC - Population with household spending >10% (>25%) of corresponding income (%):
Global innovation index (rank):
High-technology exports (% of manufacture exports):

UHC - Service coverage index (1-100):
15.3% (3.8%)
Global innovation index (rank):
20.5 (114)
High-technology exports (% of manufacture exports):
3.50%
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: For various purposes above-mentioned
Website: www.health.go.ug

Medical device incorporation
Procurement
Policy or guideline: Yes  Website: www.ppda.go.ug
National level procurement: Yes  Website: http://www.health.go.ug
Donations
Policy or guideline: Yes  Website: http://www.health.go.ug
Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical equipment
| Total | Density per 1,000,000 population | Healthcare facility
|-------|-----------------------------|-----------------------------
| Magnetic Resonance Imaging: | 6 | 0.13 |
| Computerized Tomography Scanner: | 20 | 0.44 |
| Positron Emission Tomography Scanner: | 0 | 0 |
| Gamma camera or nuclear medicine: | 3 | 0.07 |
| Mammograph:* | 5 | 3.3 |
| Radiotherapy:* | 4 | 0.09 |

Health posts: 4929 10.78
Health centres: 1796 3.93
General/district hospitals: 163 0.36
Specialized/regional/national hospitals: 2 0.01
Estimation % of health facilities with none or very limited oxygen supply: 50%

Medical equipment management unit
Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Health Infrastructure Department. Unit website: http://www.health.go.ug
http://mrh.igad.int/production/index_ug
Contact name: Eng. Sitra Mulepo  Contact email: sitraik@hotmail.com
Website with publically available technical specifications: https://www.nda.or.ug/medical-devices/
Number of regional/state offices/units: 13

Inventories and medical equipment management software
Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: Yes  Software name: New order for managing anything data (NOMAD) software.

Medical devices workforce
Density of medical doctors (per 10 000 population): 1.68
Number of biomedical/clinical engineers professionals in the country: 500

Contacts
MOH focal point
Name: Mr. Sitra Mulepo C. S.
Department: Health Infrastructure Department
Email: sitraik@hotmail.com
Other country focal point
Name: Eng. Sitra Mulepo
Email: sitraik@hotmail.com

General comments (...Annex 1): The policy guidelines on donations is at Chapter 5.1.5 of the medical equipment policy (see documentations). The Medical Equipment Policy is under review.
**Country indicators**

<table>
<thead>
<tr>
<th>Population 000s (rank):a</th>
<th>43,734 (35)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:b</td>
<td>Lower-Middle</td>
</tr>
</tbody>
</table>

**Life expectancy at birth (years):c**

<table>
<thead>
<tr>
<th>Probability of dying aged 30-70 yrs of NCDs (%):c</th>
<th>24.70%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Development Index (inequality adjusted HDI):c</td>
<td>0.78 (0.73): high</td>
</tr>
<tr>
<td>ICT Development Index (rank):c</td>
<td>5.6 (79)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births):d</th>
<th>8.4</th>
</tr>
</thead>
<tbody>
<tr>
<td>UHC - Service coverage index (1-100):e</td>
<td>68</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):f</td>
<td>7.8% (0.9%)</td>
</tr>
<tr>
<td>Global innovation index (rank):g</td>
<td>36.3 (45)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):h</td>
<td>5.60%</td>
</tr>
</tbody>
</table>

**National policy on health technology**

Health technology (medical device) national policy: Yes

Policy is part of the National Health Program/Plan: No


Language(s): Ukrainian

MOH responsible for health technology policy implementation: Department of Regulatory Policy in the Treatment of Drugs and Products in the Health Care System of the Ministry of Health.

**National lists of medical devices**

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**

Lists available: Yes

Unit: Department of Medical Care; the Department of Motherhood, and Childhood.


Nomenclature systems used for devices and tests: —

**National list for different types of healthcare facilities (hospitals, laboratories, etc)**

Lists available: Yes

Website - hospitals: [https://moz.gov.ua/dokumenti](https://moz.gov.ua/dokumenti); [https://zakon.rada.gov.ua/rada/show/v0153282-98#Text](https://zakon.rada.gov.ua/rada/show/v0153282-98#Text)

Website - IVD: [https://moz.gov.ua/dokumenti](https://moz.gov.ua/dokumenti)

Nomenclature systems used for devices and tests: —

**National list for specific clinical interventions/emergencies:**

Lists available: —

Website: —

**National health technology assessment unit**

Designated unit/department for health technology assessment (HTA):a Yes

National unit/department that includes HTA for medical devices: Yes, HTA Department State Expert Center (SEC), MoH.


Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

**National regulatory authority**

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: State Administration of Ukraine on Medicinal Products (SAUMP).


Contact: Mr. Alexey Soloviev S. Email: —

Name(s) of other regulatory agency eg. for radiation equipment etc.: Ministry of Energy and Environment Protection of Ukraine

Other agency’s website: [https://mepr.gov.ua/en/](https://mepr.gov.ua/en/)

**Approved devices lists comments**

(...Annex 1):

—

**Health care facilities lists comments**

(...Annex 1):

—

**Specific lists comments**

(...Annex 1):

There are many files, namely, the orders MSS. Orders of the Ministry of Health approval of protocols of care for various diseases.

**HTA unit comments**

(...Annex 1):

In 2019 was established the national HTA within the MoH to power the National Essential Medicines List and to inform the National Benefits Package towards the Universal Health Care. The HTA is focused on a wide range of health products, interventions, but till now is rarely focused in medical devices.

**National regulatory comments**

(...Annex 1):

—
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified


Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: https://moz.gov.ua/zakupivli-likiv

Donations
Policy or guideline: Yes  Website: https://en.moz.gov.ua/uploads/0/16-strategy_eng.pdf

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facilityγ</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>198</td>
<td>4.53</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: —  Professionally trained biomedical/clinical engineers: No
Unit/Department: Control of Monitoring and Maintenance of State Programs.
Unit website: https://moz.gov.ua/; https://www.dls.gov.ua/
Contact name: Ms. Elena Efimenko  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: https://moz.gov.ua/derzhavnij-reestr-medichnoi-tehniki-ta-virobiv-medichnogo-priznachennja
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population):* 29.92
Number of biomedical/clinical engineers professionals in the country: 350

Contacts

MOH focal point
Name: Dr. Sergei Danilov
Department: Department of Regulatory Policy in the treatment of drugs and products in the health care system of the Ministry of Health
Email: sergdanilov@mail.ru

Other country focal point
Name: Ms. Svetlana Zgonnik
Email: sz2212@gmail.com

WHO health products focal point:
Name: Dr. Igor Pokanevych
Email: pokanevychi@who.int

WHO Representative/WHO Liaison Officer:
Name: Dr. Jarno Habicht
Email: habichtj@who.int

General comments (...Annex 1): —

Medical device incorporation comments (...Annex 1): —

Medical device comments (...Annex 1): —

Medical device workforce comments (...Annex 1): —

General comments (...Annex 1): —

a  UN POP/WPP 2019 (2020 POP)  f  UNDP 2019
b  WB FY21 2019  g  ITU 2017
c  UN POP/WPP 1990-2020 MOR  h  WHO GHO 2017
d  WHO GHO 2019  i  WHO GHO 2010-2018
e  WHO GHO 2016  j  WIPO 2020
k  UN and WB 2017-2019

δ  Latest (2015-2021): WHO HTA/HBP survey or WHO HTA 2015 survey or WHO 2021 survey
ε  WHO GHO 2010-2018
ω  WHO GHO 2010-2018

n/a not applicable/not available
United Arab Emirates

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank):*</th>
<th>9,890 (92)</th>
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<tbody>
<tr>
<td>World Bank income group:**</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):*</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Under-five mortality (per 1000 live births):*</th>
<th>7.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):*</td>
<td>16.80%</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank:</td>
<td>0.89 (#); very high</td>
</tr>
<tr>
<td>ICT Development Index (rank):*</td>
<td>7.2 (40)</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):*</td>
<td>76</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>— (—)</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>41.8 (34)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):*</td>
<td>137.60%</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: —
Policy is part of the National Health Program/Plan: —
Website: https://www.mohap.gov.ae/en/aboutus/Pages/PublicHealthPolicies.aspx
Language(s): —
MOH responsible for health technology policy implementation: —

Approved devices lists comments (...Annex 1): —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: —
Unit: —
Website: —
Nomenclature systems used for devices and tests: —
National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —
National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

Health care facilities lists comments (...Annex 1): —

Specific lists comments (...Annex 1): —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):* Yes
National unit/department that includes HTA for medical devices: No
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1): HTA activities have been identified within the MoH. It exists the Health Authority Abu Dhabi, the Dubai Health Authority and the Department of Health (DoH) but there is not a national unit. The main activities of the HTA are in health products pricing and reimbursement decisions. Also, the private sector is playing an increasing role in health care coverage.

National regulatory authority

Presence of national authority responsible for regulating medical devices: —
Name of regulatory agency: Ministry of Health & Prevention.
Website(s): https://www.mohap.gov.ae/en/
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: Federal Authority for Nuclear Regulation (FANR) and Department of Health (DoH).
Other agency's website: https://www.fanr.gov.ae/ www.doh.gov.ae

National regulatory comments (...Annex 1): —
Medical device nomenclature system

Official nomenclature system for medical devices:
- Type: 
- Use: 
- Website: —

Medical device incorporation

Procurement
Policy or guideline: — Website: —
National level procurement: — Website: —

Donations
Policy or guideline: — Website: —

Technical specifications
Technical specifications to support procurement or donations: —
Publically available: — Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility¹</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:¹</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:²</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:³</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:⁴</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:⁵</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy:⁶</td>
<td>7</td>
<td>0.71</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹ Density per 1,000,000 females aged from 50-69 old.

Medical device incorporation comments (...Annex 1):

Medical devices workforce

Density of medical doctors (per 10 000 population): 25.28
Number of biomedical/clinical engineers professionals in the country: <10

Contacts

MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: —
Email: —

General comments (...Annex 1): —
United Kingdom of Great Britain and Northern Ireland

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank): 67,886 (21)</th>
<th>Under-five mortality (per 1000 live births): 4.3</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group: High</td>
<td>UHC - Service coverage index (1-100): 87</td>
</tr>
<tr>
<td>Life expectancy at birth (years):  83.3</td>
<td></td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%): 10.90%</td>
<td></td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank: 0.93 (0.86); very high</td>
<td></td>
</tr>
<tr>
<td>ICT Development Index (rank): 8.7 (5)</td>
<td></td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: Yes

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, National Institute for Health and Care Excellence (NICE).
Website(s): http://www.nice.org.uk/; http://awttc.org; http://www.healthcareimprovementscotland.org
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: The Medicines and Healthcare products Regulatory Agency (MHRA).
Contact: Mr. Steve Owen Email: Steve.owen@mhra.gsi.gov.uk
Name(s) of other regulatory agency eg. for radiation equipment etc.: Office for Nuclear Regulation (ONR); Department for Business, Energy & Industrial Strategy; Health and Safety Executive; Office for Nuclear Regulation; Medicines and Healthcare products Regulatory Agency (MHRA).

Approved devices lists comments (...)Annex 1):
There is no approved list of medical devices for procurement. However we have lists for communicable and non communicable diseases, and public health emergency situations. Guidance is produced by NICE and CEP which was disbanded 31 March 2010. NHS Supply Chain provides a catalogue of products that can be purchased by the NHS which are approved by way of meeting EU directives.

Health care facilities lists comments (...)Annex 1):

Specific lists comments (...)Annex 1):
The Centre for Evidence Based Purchasing (CEP) website is a portal containing over 600 and therefore too numerous for specific reference in this document. Please note CEP was disbanded end of March 2010 but the reports still apply to clinical professionals.

HTA unit comments (...)Annex 1):
Evidence-based recommendations are developed in a wide range of areas: clinical guidelines, diagnostic technologies, interventional procedures, cost effectiveness, highly specialised, and medical technologies guidance.

Global innovation index (rank): 59.8 (4)
High-technology exports (% of exports): 23.50%
**Medical device incorporation**

**Procurement**

Policy or guideline: Yes  
Website: https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market

National level procurement: Yes  
Website: http://www.supplychain.nhs.uk; http://www.nhsclass.nhs.uk

**Donations**

Policy or guideline:  
Website: —

**Technical specifications**

Technical specifications to support procurement or donations: Yes  
Publically available: Yes  
Website: https://www.gov.uk/government/publications/technical-specifications-for-personal-protective-equipment-ppe/

**Medical equipment**

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>465</td>
<td>6.85</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged 50-69 old.

**Medical devices workforce**

Density of medical doctors (per 10,000 population): 58.23

Number of biomedical/clinical engineers professionals in the country: 3500

**Contacts**

**MOH focal point**

Name: —
Department: —
Email: —

**Other country focal point**

Name: —
Email: —

**WHO health products focal point**

Name: —
Email: —

**Software comments (Annex 1):**

A recent amendment of the Medical Devices Directive has lifted the confidentiality requirement on information supplied by manufacturers to Competent Authorities under their obligation to register certain types of medical devices. The devices include low-risk class I devices CE marked based on a self-declaration of conformity by the manufacturer, custom-made devices made according to a prescription from a healthcare professional for an individual patient,
### United Republic of Tanzania

#### Country indicators

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):*</td>
<td>59,734 (24)</td>
</tr>
<tr>
<td>World Bank income group:†</td>
<td>Lower-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):*</td>
<td>50.7</td>
</tr>
</tbody>
</table>

#### National policy on health technology

**Health technology (medical device) national policy:** Yes

- Policy is part of the National Health Program/Plan: No
- Website: [https://www.moh.go.tz/en/](https://www.moh.go.tz/en/)
- Language(s): English
- MOH responsible for health technology policy implementation: Diagnostic Services, Healthcare Technical Services under Directorate of Curative Services.

#### National lists of medical devices

**National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**

- Lists available: Yes
- Unit: Tanzania Food and Drugs Authority.
- Website: [https://www.tmda.go.tz/publications/39](https://www.tmda.go.tz/publications/39)
- Nomenclature systems used for devices and tests: 

**National list for different types of healthcare facilities (hospitals, laboratories, etc)**

- Lists available: No
- Website - hospitals: 
- Website - IVD: 
- Nomenclature systems used for devices and tests: 

**National list for specific clinical interventions/emergencies:**

- Lists available: No
- Website: 

#### National health technology assessment unit

**Designated unit/department for health technology assessment (HTA):** No

- National unit/department that includes HTA for medical devices: No

- Website(s): 
- Contact: Email: 
- Committee includes a biomedical or clinical engineer: 

#### National regulatory authority

**Presence of national authority responsible for regulating medical devices:** Yes

- Name of regulatory agency: Tanzania Food and Drugs Authority (TFDA).
- Website(s): [https://www.tmda.go.tz/](https://www.tmda.go.tz/)
- Contact: Ms. Agnes Sitta Kijo  Email: agneskijo@tfda.or.tz
- Name(s) of other regulatory agency eg. for radiation equipment etc.: Tanzania Atomic Energy Commission.
- Other agency’s website: [https://taec.go.tz/inspection-information/](https://taec.go.tz/inspection-information/)

### National lists of medical devices comments

- Approved devices lists comments (...Annex 1):

- Specific lists comments (...Annex 1):

### National health technology assessment unit comments (...Annex 1):

- HTA unit comments (...Annex 1):

### National regulatory comments (...Annex 1):

- National regulatory comments: 

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*Note: *Numbers are approximate and may vary.

†Source: [World Bank World Development Indicators Database](https://databank.worldbank.org/)

*Source: [United Nations Department of Economic and Social Affairs, Population Division](https://unsd.un.org/)

‡Source: [World Health Organization (WHO)](https://www.who.int)

§Source: [United Nations Conference on Trade and Development (UNCTAD)](https://unctad.org)

### Demographic and development indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>50.3</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>43</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>17.90%</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>3.8% (1.2%)</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI):</td>
<td>0.53 (0.4): low</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>25.6 (88)</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>1.8 (165)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>6.90%</td>
</tr>
</tbody>
</table>

### Health care facilities lists comments

- Health care facilities lists comments (...Annex 1): 

### Specific lists comments

- Specific lists comments (...Annex 1): 

---

*Note: *Numbers are approximate and may vary.
Medical device nomenclature system

Official nomenclature system for medical devices: Yes
Type: Many co-existence of nomenclatures
Use: For various purposes above-mentioned
Website: http://www.gmdnagency.org

Medical device incorporation

Procurement
Policy or guideline: Yes
Website: https://trade.business.go.tz/media/THE%20TANZANIA%20FOOD,%20DRUGS%20AND%20COSMETICS%20medical%20device%20regulation.pdf

National level procurement: Yes
Website: https://www.moh.go.tz/en/departments/procurement

Donations
Policy or guideline: Yes
Website: —

Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>4</td>
<td>0.07</td>
<td>Health posts:</td>
<td>8175</td>
<td>13.69</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>10</td>
<td>0.17</td>
<td>Health centres:</td>
<td>994</td>
<td>1.66</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>1</td>
<td>0.02</td>
<td>General/district hospitals:</td>
<td>182</td>
<td>0.3</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>4</td>
<td>0.07</td>
<td>Specialized/regional/national hospitals:</td>
<td>49</td>
<td>0.08</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>8</td>
<td>3.38</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>9</td>
<td>0.15</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes
Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Healthcare Technical Services
Unit website: —
Contact name: Mr. Valentino Mvanga
Contact email: vmvanga@yahoo.com
Website with publically available technical specifications: —
Number of regional/state offices/units: 0

Inventories and medical equipment management software

Type of inventories available: National inventory only for high cost technologies (such as MRI, CT or PET scanners)
Website: —
Use of management software: No
Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): 0.6
Number of biomedical/clinical engineers professionals in the country: 20

Contacts

MOH focal point
Name: Mr. Valentino Mvanga
Department: Health Care Technical Services - MOHCDGEC
Email: valentino.mvanga@afya.go.tz
Other country focal point
Name: —
Email: —

WHO health products focal point:
Name: Ms. Rose Shija Muhangwa
Email: shijar@who.int

WHO Representative/WHO Liaison Officer:
Name: Dr. Tigest Ketsela Mengestu
Email: ketselat@who.int

General comments (…Annex 1): —
United States of America

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank): 331,003 (3)</th>
<th>Under-five mortality (per 1000 live births): 6.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group: High</td>
<td>UHC - Service coverage index (1-100): 84</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td></td>
</tr>
</tbody>
</table>

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

Approved devices lists comments (...Annex 1):
—

Health care facilities lists comments (...Annex 1):
—

Specific lists comments (...Annex 1):
—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No
Website(s): https://www.ahrq.gov/research/findings/ta/index.html
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):
There is not a single body nor a national institution to evaluate health technologies. However, there is an extensive network of HTA institutions such as the Advisory Committee on Immunization Practices (ACIP), the Preventive Services Task Force (USPSTF), the Medicare Evidence Development & Coverage Advisory Committee (MedCAC), the Agency for Healthcare Research and Quality (AHRQ), etc.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH).
Website(s): http://www.fda.gov/MedicalDevices/default.htm
Contact: Dr. Jeffery Shuren Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: United States Nuclear Regulatory Commission (U.S. NRC); United States Environmental Protection Agency (EPA).

National regulatory comments (...Annex 1):
—
### Medical device nomenclature system

**Official nomenclature system for medical devices:** Yes  
**Type:** Based on GMDN  
**Use:** Not specified  

### Medical device incorporation

#### Procurement

**Policy or guideline:** No  
**Website:** —

**National level procurement:** No  
**Website:** —

#### Donations

**Policy or guideline:** No  
**Website:** —

#### Technical specifications

**Technical specifications to support procurement or donations:** No  
**Publically available:** —  
**Website:** —

### Medical equipment

<table>
<thead>
<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>13275</td>
<td>40.11</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner</td>
<td>14750</td>
<td>44.56</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner</td>
<td>1790</td>
<td>5.41</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine</td>
<td>16010</td>
<td>48.37</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph</td>
<td>21421</td>
<td>521.55</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>4356</td>
<td>1316</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

### Medical equipment management unit

**Unit present:** —  
**Professionally trained biomedical/clinical engineers:** —  
**Unit/Department:** —  
**Contact name:** —  
**Contact email:** —  
**Website with publically available technical specifications:** —  
**Number of regional/state offices/units:** 0

### Inventories and medical equipment management software

**Type of inventories available:** None  
**Website:** —  
**Use of management software:** —  
**Software name:** —

### Medical devices workforce

**Density of medical doctors (per 10,000 population):** 26.04  
**Number of biomedical/clinical engineers professionals in the country:** 22000

### Contacts

#### MOH focal point

**Name:** Ms. Tammie Bell  
**Department:** Office of International Programs Office of the Commissioner U.S. Food and Drug Administration  
**Email:** Tammie.Bell2@fda.hhs.gov  
**Other country focal point**  
**Name:** Mr. David E. Hohman

WHO health products focal point:

**Name:** —  
**Email:** —  
**WHO Representative/WHO Liaison Officer:**  
**Name:** Ms. Mary Lou Valdez  
**Email:** valdezmar@paho.org

### General comments

Unfortunately, we are only able to respond to numeric country statistics. As is often the case, they are too much difficulty for Federal States to answer; furthermore, is largely irrelevant for a system like ours that is so based on private sector.

---

a UN POP/WPP 2019 (2020 POP)  
b WB FY1 2019  
c UN POP/WPP 2019 (1990-2020 MOR)  
d WHO GHO 2019  
e WHO GHO 2016  
f UNDP 2019  
g ITU 2017  
h WHO GHO 2017  
i WHO GHO 2010-2018  
j WIPO 2020  
k UN and WB 2017-2019  
 n/a not applicable/not available
### Uruguay

#### Country indicators

<table>
<thead>
<tr>
<th>Population O00s (rank):</th>
<th>3,474 (131)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group:</td>
<td>High</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>72.1</td>
</tr>
</tbody>
</table>

#### National policy on health technology

- **Health technology (medical device) national policy:** Yes
- **Policy is part of the National Health Program/Plan:** Yes
- **Website:** [https://www.gub.uy/ministerio-salud-publica/](https://www.gub.uy/ministerio-salud-publica/)
- **Language(s):** Español
- **MOH responsible for health technology policy implementation:** Departamento de Evaluación de Tecnología.

#### National lists of medical devices

- **National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:**
  - Lists available: Yes
  - Unit: Departamento de Evaluación de Tecnología.
  - Website: —
  - Nomenclature systems used for devices and tests: —
- **National list for different types of healthcare facilities (hospitals, laboratories, etc):**
  - Lists available: Yes
  - Website - hospitals: —
  - Website - IVD: —
  - Nomenclature systems used for devices and tests: —
- **National list for specific clinical interventions/emergencies:**
  - Lists available: No
  - Website: —

#### National health technology assessment unit

- **Designated unit/department for health technology assessment (HTA):** Yes
- **National unit/department that includes HTA for medical devices:** Yes, Departamento de Evaluación de Tecnología, MoH.
- **Website(s):** [https://www.gub.uy/ministerio-salud-publica/evaluacion-tecnologia](https://www.gub.uy/ministerio-salud-publica/evaluacion-tecnologia)
- **Contact:** — Email: —
  - Committee includes a biomedical or clinical engineer: —

#### National regulatory authority

- **Presence of national authority responsible for regulating medical devices:** Yes
- **Name of regulatory agency:** Ministerio de Salud Pública - Departamento de Evaluación de Tecnología.
- **Website(s):** [https://www.gub.uy/ministerio-salud-publica/evaluacion-tecnologia](https://www.gub.uy/ministerio-salud-publica/evaluacion-tecnologia)
- **Contact:** Mr. Juan Manuel Jones  Email: tecnologia@msp.gub.uy
- **Name(s) of other regulatory agency eg. for radiation equipment etc.:** Autoridad Reguladora Nacional en Radioprotección (Ministerio de Industria, Energía y Minería).
- **Other agency’s website:** [https://www.gub.uy/ministerio-industria-energia-mineria/institucional/estructura-del-organismo/autoridad-reguladora-nacional-radioproteccion](https://www.gub.uy/ministerio-industria-energia-mineria/institucional/estructura-del-organismo/autoridad-reguladora-nacional-radioproteccion)

#### Under-five mortality (per 1000 live births): 7.1

#### UHC - Service coverage index (1-100): 80

#### Probability of dying aged 30-70 yrs of NCDs (%): 16.7%

#### UHC - Population with household spending >10% (>25%) of corresponding income (%): — (~)

#### Human Development Index (inequality adjusted HDI): 0.82 (0.71); very high

#### Global innovation index (rank): 30.8 (69)

#### ICT Development Index (rank): 8.30%

#### Under-five mortality (per 1000 live births): 7.1

#### UHC - Service coverage index (1-100): 80

#### Probability of dying aged 30-70 yrs of NCDs (%): 16.7%

#### UHC - Population with household spending >10% (>25%) of corresponding income (%): — (~)

#### Human Development Index (inequality adjusted HDI): 0.82 (0.71); very high

#### Global innovation index (rank): 30.8 (69)

#### ICT Development Index (rank): 8.30%
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  
Type: Based on UMDNS  
Use: For procurement purposes
Website: http://www.msp.gub.uy

Medical device incorporation

Procurement
Policy or guideline: Yes  
Website: —
National level procurement: Yes  
Website: http://www.cocemi.com.uy/

Donations
Policy or guideline: Yes  
Website: https://www.gub.uy/tramites/donaciones-especiales

Technical specifications
Technical specifications to support procurement or donations: No  
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:a</td>
<td>10</td>
<td>2.94</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:a</td>
<td>44</td>
<td>12.91</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:a</td>
<td>1</td>
<td>0.29</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:a</td>
<td>10</td>
<td>2.94</td>
</tr>
<tr>
<td>Mammograph:a</td>
<td>62</td>
<td>172.42</td>
</tr>
<tr>
<td>Radiotherapy:a</td>
<td>24</td>
<td>6.91</td>
</tr>
<tr>
<td>Health posts:</td>
<td>600</td>
<td>17.61</td>
</tr>
<tr>
<td>Health centres:</td>
<td>40</td>
<td>1.17</td>
</tr>
<tr>
<td>General/district hospitals: n/a</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specialized/regional/national hospitals:</td>
<td>14</td>
<td>0.41</td>
</tr>
</tbody>
</table>

Medical equipment management unit

Unit present: Yes  
Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Departamento de Evaluación de Tecnología.  
Unit website: —
Contact name: Mr. Juan Manuel Jones.  
Contact email: Jones@msp.gub.uy
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National functional inventory for medical equipment
Website: —
Use of management software: —  
Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): 49.4
Number of biomedical/clinical engineers professionals in the country: 10

Contacts

MOH focal point
Name: Dr. Juan Manuel Jones  
Department: Departamento de Evaluación de Tecnología
Email: tecnologia@msp.gub.uy
Other country focal point  
Name: Mr. Juan Manuel Jones  
Email: jjones@msp.gub.uy

WHO health products focal point:
Name: —
Email: —
WHO Representative/WHO Liason Officer:
Name: Dr. Hernan J. Montenegro  
Email: monteneher@paho.org

General comments (...Annex 1): —
Uzbekistan

Country indicators

Population 000s (rank): 33,469 (42)
World Bank income group: Lower-Middle

Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Year</th>
<th>Uzbekistan</th>
<th>World</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990</td>
<td>65.1</td>
<td>69.2</td>
</tr>
<tr>
<td>2000</td>
<td>67.8</td>
<td>72.7</td>
</tr>
<tr>
<td>2010</td>
<td>69.5</td>
<td>74.3</td>
</tr>
<tr>
<td>2020</td>
<td>71.3</td>
<td>75.8</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 17.4
UHC - Service coverage index (1-100): 73

Probability of dying aged 30-70 yrs of NCDs (%): 24.50%
UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)

Human Development Index (inequality adjusted HDI): 0.72 (—); Global innovation index (rank): 24.5 (93)

ICT Development Index (rank): 4.9 (95)
High-technology exports (% of manufacture exports): 0.70%

National policy on health technology

Health technology (medical device) national policy: —
Policy is part of the National Health Program/Plan: —
Website: https://www.uzpharm-control.uz/en/; http://ssvuz/ru
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: —
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No
Website(s): http://tipme.uz/
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Ministry of Health, General Directorate for the Quality Control of Medicines and Medical Equipment (GDQC).
Website(s): https://ssvuz/ru
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

Approved devices lists comments (…Annex 1):

Health care facilities lists comments (…Annex 1):

Specific lists comments (…Annex 1):

HTA unit comments (…Annex 1):
HTA activities are carried out mainly by the MoH, and the Evidence-Based Medicine Centre within the Tashkent Institute for Advanced Medical Education. HTA is done for various health topics: pharmaceutics, medical devices, and also the in pharmaceutics field but not specifically for medical devices, guidelines, etc. However, a national HTA is still in progress as well as unified national mechanisms for developing and implementing clinical standards, guidelines and protocols.

National regulatory comments (…Annex 1):

Population 000s (rank): 33,469 (42)
World Bank income group: Lower-Middle

Under-five mortality (per 1000 live births): 17.4
UHC - Service coverage index (1-100): 73

Probability of dying aged 30-70 yrs of NCDs (%): 24.50%
UHC - Population with household spending >10% (>25%) of corresponding income (%): — (—)

Human Development Index (inequality adjusted HDI): 0.72 (—); Global innovation index (rank): 24.5 (93)

ICT Development Index (rank): 4.9 (95)
High-technology exports (% of manufacture exports): 0.70%
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Many co-existence of nomenclatures  Use: Not specified  Website: —

Medical device incorporation

Procurement

Policy or guideline: —  Website: —
National level procurement: —  Website: —

Donations

Policy or guideline: —  Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>9</td>
<td>0.27</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical devices workforce

Density of medical doctors (per 10,000 population): 23.74
Number of biomedical/clinical engineers professionals in the country: —

Medical equipment management unit

Unit present: —  Professionally trained biomedical/clinical engineers: —
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment  Website: https://www.uzpharm-control.uz/en/
Use of management software: —  Software name: —

Medical devices workforce

Density of medical doctors (per 10,000 population): 23.74
Number of biomedical/clinical engineers professionals in the country: —

Contacts

**MOH focal point**
Name: —
Department: —
Email: —

**WHO health products focal point**
Name: —
Email: —

**WHO Representative/WHO Liaison Officer**
Name: Dr. Lianne Kuppens
Email: kuppensl@who.int

General comments (...Annex 1): —
Vanuatu

Country indicators

Population 000s (rank): 307 (172)
World Bank income group: Lower-Middle

Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Year</th>
<th>Vanuatu</th>
<th>World</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020</td>
<td>68.7</td>
<td>73.7</td>
</tr>
</tbody>
</table>

National policy on health technology

Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: Yes
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): No
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

Specific lists comments (...Annex 1):
This list exists as part of another document -e.g. essential drug list or an inventory list of a health facility- but there is no separate nor specific document of the guideline on its own. No list exists for any of the conditions above (different diseases/situations).

HTA unit comments (...Annex 1): —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

Approved devices lists comments (...Annex 1): —

Health care facilities lists comments (...Annex 1): —

Specific lists comments (...Annex 1): —

HTA unit comments (...Annex 1): —

National regulatory comments (...Annex 1): —
Medical device nomenclature system
Official nomenclature system for medical devices: Yes  Type: Nationally developed
Use: For procurement purposes
Website: —

Medical device incorporation
Procurement
Policy or guideline: No  Website: —
National level procurement: No  Website: —
Donations
Policy or guideline: No  Website: —
Technical specifications
Technical specifications to support procurement or donations: No
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>0</td>
<td>0</td>
<td>Health posts:</td>
<td>300</td>
<td>118.69</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>Health centres:</td>
<td>39</td>
<td>15.43</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
<td>General/district hospitals:</td>
<td>4</td>
<td>1.58</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>0</td>
<td>0</td>
<td>Specialized/regional/national hospitals:</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>0</td>
<td>0</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit
Unit present: —  Professionally trained biomedical/clinical engineers: No
Unit/Department: —  Unit website: —
Contact name: —  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software
Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medical devices workforce
Density of medical doctors (per 10 000 population):* 1.65
Number of biomedical/clinical engineers professionals in the country:* <10

Contacts
MOH focal point
Name: Dr. Willie Tokon
Department: Vila Central Hospital
Email: wtokon@vanuatu.gov.vu

WHO health products focal point:
Name: —
Email: —

WHO Representative/WHO Liaison Officer:
Name: Dr. Eunyoung Ko
Email: koe@who.int

Other country focal point
Name: —
Email: —

General comments (...Annex 1): Vanuatu is a small island country in the Pacific region with a population of less than 350,000: this explains the low level of health facilities available.
Venezuela (Bolivarian Republic of)

Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population 000s (rank):</td>
<td>28,436 (50)</td>
</tr>
<tr>
<td>World Bank income group:</td>
<td>Upper-Middle</td>
</tr>
<tr>
<td>Life expectancy at birth (years):</td>
<td>70.2</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%):</td>
<td>18.1%</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI):</td>
<td>0.71 (0.59): high</td>
</tr>
<tr>
<td>ICT Development Index (rank):</td>
<td>5.2 (86)</td>
</tr>
<tr>
<td>Under-five mortality (per 1000 live births):</td>
<td>24.2</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100):</td>
<td>74</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%):</td>
<td>— (—)</td>
</tr>
<tr>
<td>Global innovation index (rank):</td>
<td>— (—)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports):</td>
<td>— (—)</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy:

Policy is part of the National Health Program/Plan: —
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: —
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: —
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, Comisión Nacional de Evaluación de Tecnología enSalud (CONETS).
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: Yes

HTA unit comments (Annex 1):
Las actividades de evaluación de tecnologías médicas se han desarrollado en el marco de la Comisión Nacional de Evaluación de Tecnología en Salud (CONETS) dentro del Ministerio del Poder Popular de la Salud.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Servicio Autónomo de Contraloría Sanitaria: Dirección de Regulación y Control de Materiales, Equipos, Establecimientos y Profesiones de Salud.
Website(s): —
Contact: — Email: atencion@sacs.gob.ve
Name(s) of other regulatory agency eg. for radiation equipment etc.: Dirección de Regulación y Control de Materiales, Equipos, Establecimientos y Profesiones de Salud.
Other agency’s website: http://sacs.gob.ve/site/index.php/advanced-stuff/direccion-de-regulacion-y-control-de-materiales-equipos-establecimientos-y-profesiones-de-salud

Approved devices lists comments (Annex 1): —
Health care facilities lists comments (Annex 1): —
Specific lists comments (Annex 1): —
Medical device nomenclature system

Official nomenclature system for medical devices: No. Type: Many co-existence of nomenclatures. Use: For various purposes above-mentioned.

Website: https://www.fda.gov/medical-devices/classify-your-medical-device/product-code-classification-database

Medical device incorporation

Procurement

Policy or guideline: — Website: —
National level procurement: — Website: —

Donations

Policy or guideline: — Website: —

Technical specifications

Technical specifications to support procurement or donations: —
Publically available: —
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Equipment Type</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts: n/a n/a Health centres: n/a n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals: n/a n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals: n/a n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply: n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>61</td>
<td>2.15</td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: — Professionally trained biomedical/clinical engineers: —
Unit/Department: — Unit website: —
Contact name: — Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: http://www.sacs.gob.ve/site/
Use of management software: — Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): 17.3
Number of biomedical/clinical engineers professionals in the country: 60

Medical device incorporation comments (...Annex 1):

Funindes (Univ. Simon Bolivar) is authorized by the Autonomous Service of the Sanitary Comptroller to carry out equipment analysis for subsequent sanitary registration.

Nomenclature comments (...Annex 1):

Does not have one specific nomenclature. For the certification of the medical device, the nomenclature used is the U.S FDA product classification.

WHO health products focal point:
Name: Dr. Joel Caraballo
Email: carabaljoe@paho.org

WHO Representative/WHO Liaison Officer:
Name: Dr. Pier Paolo Balladelli
Email: balladep@paho.org

General comments (...Annex 1): —
Viet Nam

Country indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under-five mortality (per 1000 live births)</td>
<td>19.9</td>
</tr>
<tr>
<td>UHC - Service coverage index (1-100)</td>
<td>75</td>
</tr>
<tr>
<td>Probability of dying aged 30-70 yrs of NCDs (%)</td>
<td>17.1%</td>
</tr>
<tr>
<td>UHC - Population with household spending &gt;10% (&gt;25%) of corresponding income (%)</td>
<td>9.4% (1.9%)</td>
</tr>
<tr>
<td>Human Development Index (inequality adjusted HDI): rank</td>
<td>0.7 (0.59); high</td>
</tr>
<tr>
<td>Global innovation index (rank)</td>
<td>37.1 (42)</td>
</tr>
<tr>
<td>ICT Development Index (rank)</td>
<td>4.4 (108)</td>
</tr>
<tr>
<td>High-technology exports (% of manufacture exports)</td>
<td>40.40%</td>
</tr>
</tbody>
</table>

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): Vietnamese
MOH responsible for health technology policy implementation: Department of Medical Equipment and Construction.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - IVD: https://dav.gov.vn/procedures.html
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: Yes
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes
National unit/department that includes HTA for medical devices: Yes, Health Strategy and Policy Institute (HSPI).
Contact: — Email: hsativietnam@hspi.org.vn
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: Department of Medical Equipment and Construction.
Website(s): http://www.nimec.gov.vn/
Contact: Mr. Nguyen Minh Tuan - General director Email: Ngmtuan_tt@vnn.com
Name(s) of other regulatory agency eg. for radiation equipment etc.: Institute of Medical Equipment and Construction.

Approved devices lists comments
(...Annex 1): —

Health care facilities lists comments
(...Annex 1): —

Specific lists comments (...Annex 1):
There are for all general procedures but they are not complete. We have enacted medical device list for procedures which shall be covered by medical insurance only.

HTA unit comments (...Annex 1):
The HTA system has been developed by establishing nodal agencies within MoH, moving towards the Universal Health Care country goal. Priority-setting mechanisms and HTA processes are at a nascent stage. HTA is rarely applied to medical devices.

National regulatory comments
(...Annex 1):
Contact person: Hoang Mai Bui - Director of the Department of medical equipment verification and calibration.
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation

Procurement
Policy or guideline: No  Website: —
National level procurement: Yes  Website: http://www.moh.gov.vn/

Donations
Policy or guideline: —  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: No
Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health posts:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Health centres:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>n/a</td>
<td>n/a</td>
<td>General/district hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Specialized/regional/national hospitals:</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>n/a</td>
<td>n/a</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>47</td>
<td>0.48</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical device management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Department of Medical Equipment and Construction.  Unit website: —
Contact name: Mr. Nguyen Minh Tuan - General director.  Contact email: —
Website with publically available technical specifications: —
Number of regional/state offices/units: —

Inventories and medical equipment management software

Type of inventories available: —
Website: —
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population): 8.28
Number of biomedical/clinical engineers professionals in the country: 1000

Contacts

MOH focal point
Name: —
Department: —
Email: —

Other country focal point
Name: Mr. Nguyen Minh Tuan - General director
Email: —

WHO health products focal point:
Name: Dr. Socorro Escalante
Email: escalantes@wpro.who.int

WHO Representative/WHO Liason Officer:
Name: Dr. Kidong Park
Email: parkk@who.int

General comments (...Annex 1): —

Viet Nam
Yemen

Country indicators

Population 000s (rank): 29,826 (48)
World Bank income group: Low
Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Year</th>
<th>Yemen</th>
<th>World</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990</td>
<td>60.9</td>
<td>68.1</td>
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<tr>
<td>2000</td>
<td>63.0</td>
<td>71.1</td>
</tr>
<tr>
<td>2010</td>
<td>66.0</td>
<td>73.1</td>
</tr>
<tr>
<td>2020</td>
<td>68.0</td>
<td>75.1</td>
</tr>
<tr>
<td>2022</td>
<td>69.7</td>
<td>76.3</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 58.4
UHC - Service coverage index (1-100): 42

Probability of dying aged 30-70 yrs of NCDs (%): 30.60%
UHC - Population with household spending >10% (>25%) of corresponding income (%): 15.8% (4.2%)

Human Development Index (inequality adjusted HDI): 0.47 (0.32): low
Global innovation index (rank): 13.6 (131)

ICT Development Index (rank): — (—)
High-technology exports (% of manufacture exports): —

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: —
Website: —
Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: Yes
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: — Email: —
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: Ministry of Industry & The Supreme board for Drugs & Medical Appliance.
Website(s): www.sbd-ye.org; www.moit.gov.ye
Contact: Dr. Alhakmi Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: Ministry of industry & The Supreme board for Drugs & Medical Appliance.

Approved devices lists comments (...Annex 1):
—

Health care facilities lists comments (...Annex 1):
—

Specific lists comments (...Annex 1):
There is a need of financial, technical support and cooperation to put national standards or lists of recommended medical devices for specific procedures. For different diseases/situations there are no existing lists; MOPH must do that by cooperation of specialist administrations.

HTA unit comments (...Annex 1):
—

National regulatory comments (...Annex 1):
There are Authorities only for the registration of agents for medical equipment.
### Medical device nomenclature system

**Official nomenclature system for medical devices:** No  
**Type:** None  
**Use:** Not specified  
**Website:** —

### Medical device incorporation

#### Procurement

**Policy or guideline:** Yes  
**Website:** [www.htb.gov.ye](http://www.htb.gov.ye)

**National level procurement:** Yes  
**Website:** —

#### Donations

**Policy or guideline:** Yes  

### Technical specifications

**Technical specifications to support procurement or donations:** Yes  
**Publically available:** No  
**Website:** —

#### Magnetic Resonance Imaging

**Total:** 28  
**Density per 1,000,000 population:** 1.15

#### Computerized Tomography Scanner

**Total:** 88  
**Density per 1,000,000 population:** 3.61

#### Positron Emission Tomography Scanner

**Total:** 0  
**Density per 1,000,000 population:** 0

#### Gamma camera or nuclear medicine

**Total:** 3  
**Density per 1,000,000 population:** 0.12

#### Mammograph

**Total:** 18  
**Density per 1,000,000 population:** 17.62

#### Radiotherapy

**Total:** 1  
**Density per 1,000,000 population:** 0.03

### Medical equipment management unit

**Unit present:** Yes  
**Professionally trained biomedical/clinical engineers:** Yes  
**Unit/Department:** The General Directorate of Medical Equipment and Maintenance  
**Unit website:** —

**Contact name:** Mr. Faisal Ali Mujamal  
**Contact email:** eng-alfaisal@hotmail.com  
**Website with publically available technical specifications:** —  
**Number of regional/state offices/units:** 6

### Inventories and medical equipment management software

**Type of inventories available:** None  
**Use of management software:** No  
**Software name:** —

### Medical devices workforce

**Density of medical doctors (per 10 000 population):** 5.25  
**Number of biomedical/clinical engineers professionals in the country:** 150

### Contacts

**MOH focal point**

**Name:** Mr. Faisal Ali Mujamal  
**Department:** The General Director of Medical Equipment and Maintenance Directorate  
**Email:** eng-alfaisal@hotmail.com

**WHO health products focal point**

**Name:** —  
**Email:** —

**WHO Representative/WHO Liaison Officer**

**Name:** Dr. Adham Rashad Ismail Abdel Moneim  
**Email:** ismaila@who.int

### General comments

There was a deficiency about maintenance and calibrations of medical devices.
Country indicators

Population 000s (rank): 18,384 (64)

World Bank income group: Lower-Middle

Life expectancy at birth (years):

<table>
<thead>
<tr>
<th>Year</th>
<th>ZMB</th>
<th>World</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990</td>
<td>53.8</td>
<td>70.3</td>
</tr>
<tr>
<td>2000</td>
<td>56.8</td>
<td>72.1</td>
</tr>
<tr>
<td>2010</td>
<td>59.3</td>
<td>74.3</td>
</tr>
</tbody>
</table>

Under-five mortality (per 1000 live births): 61.7

UHC - Service coverage index (1-100): 53

Probability of dying aged 30-70 yrs of NCDs (%): 17.90%

UHC - Population with household spending >10% (>25%) of corresponding income (%): 0.3% (0.0%)

Human Development Index (inequality adjusted HDI): 0.58 (0.4); medium

Global innovation index (rank): 19.4 (122)

ICT Development Index (rank): 2.5 (146)

High-technology exports (% of manufacture exports): 2.30%

National policy on health technology

Health technology (medical device) national policy: No

Policy is part of the National Health Program/Plan: No

Website: —

Language(s): —

MOH responsible for health technology policy implementation: Medical Equipment Unit.

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:

Lists available: Yes, but it is only a recommendation

Unit: Ministry of Health, Directorate of Clinical Care and Diagnostic Services-Medical Equipment Unit.

Website: —

Nomenclature systems used for devices and tests: —

National list for different types of healthcare facilities (hospitals, laboratories, etc)

Lists available: Yes

Website - hospitals: —

Website - IVD: —

Nomenclature systems used for devices and tests: —

National list for specific clinical interventions/emergencies:

Lists available: Yes

Website: —

Approved devices lists comments (...Annex 1):

The MoH has developed the Standard Equipment Lists (SEL) for District facilities such as Health Posts, Health Centres and Level One Hospitals. The SEL are not yet done, because the Basic Health Care Package, which is the blueprint for health service delivery in Zambia, has neither been developed.

Health care facilities lists comments (...Annex 1):

—

Specific lists comments (...Annex 1):

—

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): Yes

National unit/department that includes HTA for medical devices: No

Website(s): —

Contact: — Email: —

Committee includes a biomedical or clinical engineer: —

HTA unit comments (...Annex 1):

Evidence-informed healthcare priority setting via HTA is at early stages. Currently, HTA is being used by the MoH to build the Health Benefits Package.

National regulatory authority

Presence of national authority responsible for regulating medical devices: Yes

Name of regulatory agency: Ministry of Health-Directorate of Clinical Care and Diagnostic services-Medical Equipment Unit.

Website(s): http://www.moh.gov.zm

Contact: Dr. Zuma Munkombwe Email: zmunkombwe@pra.gov.zm

Name(s) of other regulatory agency eg. for radiation equipment etc.: Zambia Medicines Regulatory Authority (ZAMRA).

Other agency’s website: http://www.zamra.co.zm/
Medical device nomenclature system

Official nomenclature system for medical devices: Yes  Type: Based on UMDNS  Use: For regulatory and procurement purposes

Website: —

Medical device incorporation

Procedures

Policy or guideline: Yes  Website: https://www.moh.gov.zm/docs/reports/Medical%20Equipment%20Management%20Guidelines.pdf


Donations

Policy or guideline: Yes  Website: —

Technical specifications

Technical specifications to support procurement or donations: Yes

Publically available: —  Website: —

Medical equipment

<table>
<thead>
<tr>
<th>Equipment Type</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>1</td>
<td>0.07</td>
</tr>
<tr>
<td>Computerized Tomography Scanner:*</td>
<td>3</td>
<td>0.21</td>
</tr>
<tr>
<td>Positron Emission Tomography Scanner:*</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gamma camera or nuclear medicine:*</td>
<td>1</td>
<td>0.07</td>
</tr>
<tr>
<td>Mammograph:*</td>
<td>2</td>
<td>4.56</td>
</tr>
<tr>
<td>Radiotherapy:*</td>
<td>5</td>
<td>0.27</td>
</tr>
</tbody>
</table>

* Density per 1,000,000 females aged from 50-69 old.

Healthcare facility

<table>
<thead>
<tr>
<th>Total</th>
<th>Density per 100,000 population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health posts</td>
<td>171 1.18</td>
</tr>
<tr>
<td>Health centres</td>
<td>121 8.33</td>
</tr>
<tr>
<td>General/district hospitals</td>
<td>43 0.3</td>
</tr>
<tr>
<td>Specialized/regional/national hospitals</td>
<td>5 0.03</td>
</tr>
<tr>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Medical equipment management unit

Unit present: Yes  Professional trained biomedical/clinical engineers: Yes

Unit/Department: Medical Equipment Unit  Unit website: —

Contact name: —  Contact email: —

Website with publically available technical specifications: —

Number of regional/state offices/units: 9

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment

Website: —

Use of management software: Yes  Software name: ECRI and other nationally developed

Medical devices workforce

Density of medical doctors (per 10 000 population): 0.93

Number of biomedical/clinical engineers professionals in the country: 18

Contacts

MOH focal point

Name: Mr. Fales Mwamba
Department: Ministry of Health Headquarters, Directorate of Clinical Care and Diagnostic Services, Medical Equipment Unit.
Email: Mwamba@moh.gov.zm

Other country focal point

Name: Mr. Chipalo Kaliki
Email: ckaliki@moh.gov.zm

WHO health products focal point:

Name: —
Email: —

WHO Representative/WHO Liaison Officer:

Name: Dr. Nathan Nsubuga Bakyaita
Email: bakyaitan@who.int

General comments (...Annex 1): The WHO used to run training programs for maintenance technicians but stopped long ago, this has affected this field. There is a need for the WHO to come in strongly in support of maintenance of Medical equipment. The main problems in developing countries are lack of skilled manpower, inadequate budgets for maintenance, and lack of software that is compatible with the procurement system.

Software comments (...Annex 1):

The national data bank for equipment is in its infancy; the data was collected three years ago during a project that was funded by the Japan International Cooperation Agency (JICA). Currently, this data will be upgraded this year. The information captured includes Equipment Description, Model, Maker, Serial Number, Location, Functional Status, Age of Equipment. There are however hard copies at the facility level which maintenance units use. This needs to be computerised and accessible from anywhere which is not the case now. There is no software for equipment management but have tried ECRI and another software developed by a professional in Holland.
Zimbabwe

Country indicators

<table>
<thead>
<tr>
<th>Population 000s (rank): a</th>
<th>14,863 (73)</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Bank income group: b</td>
<td>Lower-Middle</td>
</tr>
</tbody>
</table>

Life expectancy at birth (years): c

| Under-five mortality (per 1000 live births): d | 54.6 |
| Probability of dying aged 30-70 yrs of NCDs (％): e | 19.30% |
| Human Development Index (inequality adjusted HDI): rank: f | 0.57 (0.44): medium |
| ICT Development Index (rank): g | 2.9 (136) |

| UHC - Service coverage index (1-100): h | 54 |
| UHC - Population with household spending >10% (>25%) of corresponding income (％): i | — (—) |
| Global innovation index (rank): j | 20 (120) |
| High-technology exports (% of manufacture exports): k | 5.00% |

National policy on health technology

Health technology (medical device) national policy: No
Policy is part of the National Health Program/Plan: No
Website: —
Language(s): —
MOH responsible for health technology policy implementation: —

National lists of medical devices

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: Yes, but it is only a recommendation
Unit: Hospital Equipment Unit.
Website: —
Nomenclature systems used for devices and tests: —
National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: —
Website - IVD: —
Nomenclature systems used for devices and tests: —
National list for specific clinical interventions/emergencies:
Lists available: No
Website: —

Approved devices lists comments (...Annex 1):
—

Health care facilities lists comments (...Annex 1):
—

Specific lists comments (...Annex 1):
—

HTA unit comments (...Annex 1):
It has been started the building capacity and the HTA will be a fundamental tool to achieve the Universal Health Care goal.

National health technology assessment unit

Designated unit/department for health technology assessment (HTA): a No
National unit/department that includes HTA for medical devices: No
Website(s): —
Contact: Mr. Martin Nhorivo Email: mnhorivo@yahoo.co.uk
Committee includes a biomedical or clinical engineer: —

National regulatory authority

Presence of national authority responsible for regulating medical devices: No
Name of regulatory agency: —
Website(s): —
Contact: — Email: —
Name(s) of other regulatory agency eg. for radiation equipment etc.: —
Other agency’s website: —

National regulatory comments (...Annex 1):
—
Medical device nomenclature system

Official nomenclature system for medical devices: No  Type: None  Use: Not specified
Website: —

Medical device incorporation

Procurement
Policy or guideline: Yes  Website: —
National level procurement: Yes  Website: —

Donations
Policy or guideline: Yes  Website: —

Technical specifications
Technical specifications to support procurement or donations: Yes
Publically available: —
Website: —

Medical equipment

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<tr>
<th>Medical equipment</th>
<th>Total</th>
<th>Density per 1,000,000 population</th>
<th>Healthcare facility</th>
<th>Total</th>
<th>Density per 100,000 population</th>
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<tbody>
<tr>
<td>Magnetic Resonance Imaging:*</td>
<td>4</td>
<td>0.28</td>
<td>Health posts:</td>
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<td>Computerized Tomography Scanner:*</td>
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<td>0.42</td>
<td>Health centres:</td>
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<tr>
<td>Positron Emission Tomography Scanner:*</td>
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<td>General/district hospitals:</td>
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<td>Gamma camera or nuclear medicine:*</td>
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<td>Specialized/regional/national hospitals:</td>
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<td>Mammograph:*</td>
<td>4</td>
<td>6.89</td>
<td>Estimation % of health facilities with none or very limited oxygen supply:</td>
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<td>Radiotherapy:*</td>
<td>10</td>
<td>0.67</td>
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</table>

* Density per 1,000,000 females aged from 50-69 old.

Medical equipment management unit

Unit present: Yes  Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Hospital Equipment Unit.  Unit website: —
Contact name: Mr. Martin Nhorivo  Contact email: mnhorivo@yahoo.co.uk
Website with publically available technical specifications: —
Number of regional/state offices/units: 8

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: —
Use of management software: No  Software name: —

Medical devices workforce

Density of medical doctors (per 10 000 population):* 2.1
Number of biomedical/clinical engineers professionals in the country: —

Contacts

MOH focal point
Name: Dr. Christopher Tapfumaneyi
Department: Ministry of Health Curative Services
Email: tapfuman@gmail.com
Other country focal point
Name: Mr. Martin Nhorivo
Email: mnhorivo@yahoo.co.uk

WHO health products focal point:
Name: Dr. Stanley M. Midzi
Email: midzis@who.int

WHO Representative/WHO Liason Officer:
Name: Dr. Alex Gasasira
Email: gasasiraa@who.int

General comments (...Annex 1): The country health technology policy document was initiated in 2007 with funding from the US. This is currently being formulated into a policy document for diagnostic imaging and medical devices.
Annex I
Additional comments
<table>
<thead>
<tr>
<th>Country</th>
<th>WHO region</th>
<th>National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement</th>
<th>National list for different types of healthcare facilities (hospitals, laboratories, etc)</th>
<th>National list for specific clinical interventions/emergencies</th>
<th>National health technology assessment unit</th>
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<tr>
<td>Afghanistan</td>
<td>EMR</td>
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<td>—</td>
<td>—</td>
<td>The National HTA unit is not yet established.</td>
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<td>There is not yet an HTA national unit but it has been acknowledged at a political level by the MoH. There is a centralized system for managing health products pricing and reimbursement via the Ministry of Health, the National Agency for Drugs and Device, and the Drug Price Commission.</td>
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<tr>
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<td>Adopted EMA (European Medicines Agency) and ICH (International Council for Harmonisation for Pharmaceuticals) guidelines. Inspector General Office performs health economics HTA. Within the MoH HTA is focused on pharmaceutics but not in medical devices.</td>
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<td>There are identified HTA activities but not a national unit.</td>
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<td>AMR</td>
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<tr>
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<td>Existe una base de datos que contiene a las tecnologías sanitarias registradas(denominados productos médicos) y disponibles en el sitio- ver tercera liga web- ( accesible con colocar nombre g nérico de producto (por ej; apósito) o con su identificación (Nº de PM).</td>
<td>Cirugía, diagnóstico por imágenes, laboratorio, terapia intensiva.</td>
<td>Actualmente existen lineamientos para la elaboración de guías. Disponible en la segunda página web proporcionada.</td>
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<td>Country</td>
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<td>Switzerland</td>
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<td>Syria</td>
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<td>United Arab Emirates</td>
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<td>United Kingdom</td>
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<td>United States</td>
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<td>Uruguay</td>
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<td>Vietnam</td>
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**General Comments**

Concerning the HT national policy, it can be found the following document, within the provided website: [ley-18211-dec-5-2007 SNIS.pdf](http://www.who.int/medical_devices/survey_resources/health_technology_national_policy_albania.pdf).

June 4, 2021: With Presidential Decree 136/21 the extinction of the Direcção Nacional de Medicamentos e Equipamentos is announced and the Regulatory Agency for Medicines and Health Technologies (ARMED) is created, which will have its headquarters in Luanda, Angola and will be supervised by the Ministry of Health.

— For the registration of medical devices. For procurement of medical devices at national level we use the: "lista licitaciones". The MoH wants to push awareness/surveillance about health technology quality, technical specifications, etc.
<table>
<thead>
<tr>
<th>Country</th>
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<th>National health technology assessment unit</th>
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<tbody>
<tr>
<td>Armenia</td>
<td>EUR</td>
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<td>—</td>
<td>Informing decisions of the cited institutions are not specifically HTA. Alternative email: <a href="mailto:info@healthpiu.arm">info@healthpiu.arm</a>.</td>
</tr>
<tr>
<td>Australia</td>
<td>WPR</td>
<td>—</td>
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<td>The Therapeutic Goods Administration (TGA), the Medical Services Advisory Committee (MSAC), the Pharmaceutical Advisory Committee (PBAC), and the Prostheses List Advisory Committee (PLAC) perform Health Technology Assessment (HTA) processes to provide advice to the Australian Government Department of Health.</td>
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<tr>
<td>Austria</td>
<td>EUR</td>
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<td>Österreichischer Strukturplan Gesundheit (up mentioned link) and various guidelines of the medical societies, internal guidelines of the hospitals, etc. Also, there is the Austrian Influenza Pandemic Plan. Only for the hospital benefit catalogue there is a national HTA process in place, but not for drugs. It is expected that it will be a process in place in the next 1-2 years.</td>
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<td>Azerbaijan</td>
<td>EUR</td>
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<td>The HTA activities in pharmaceutics are not specifically for medical devices.</td>
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<tr>
<td>Bahamas</td>
<td>AMR</td>
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<td>There are no lists recommending health technology for any of the above.</td>
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<tr>
<td>Bahrain</td>
<td>EMR</td>
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<td>There are identified HTA activities but not a national unit.</td>
</tr>
<tr>
<td>National regulatory authority</td>
<td>Medical device nomenclature system</td>
<td>Medical Device incorporation: procurement/donations/technical specifications:</td>
<td>Inventories and medical equipment management software comments:</td>
<td>General Comments</td>
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<td>“National Institute of Metrology”; National Institute of Standards”; “ArmAtomInspection”; and “Scientific Center of Drug and Medical Technology Expertise”.</td>
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<td>The technical specifications are developed by the Health Project Implementation Unit (HPIU) biomedical engineer in cooperation with international consultants.</td>
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<td>The use of GMDN is a legal mandatory requirement for devices supplied in Australia, including IVDs.</td>
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<td></td>
<td>The Austrian Medical Devices Register uses the UMDNS and the EDMA Code.</td>
<td>The procurement is done with internal guidelines of the Hauptverband, insurance funds, hospitals, Bundesbeschaffungs GmbH, etc.</td>
<td>There are various software for the maintenance and inspection of medical devices in the hospital. Additionally, there is the implementation of a National Plan for high-cost technologies called: “Großgeräteplan”.</td>
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<td>The Procurement guidelines are under development. For donations guidelines the WHO are the ones used. The corresponding technical specifications are under the responsibility of the Innovation and Supply Centre.</td>
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<td>The Public Hospitals Authority, the corporate entity of the Ministry of Health, is responsible for managing the three Public Hospitals within the Bahamas. It uses the services of the ECRI Institute to assist in the procurement of medical devices.</td>
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<td>It is needed the GMDN code for registration of medical devices, as well as the HS code.</td>
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<tr>
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<tr>
<td>Bangladesh</td>
<td>SEAR</td>
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<tr>
<td>Barbados</td>
<td>AMR</td>
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</table>

HTA activities have been identified, but there is not a national unit.

| Belarus | EUR | Documents: N° “2007 ” and N° “458” in the specified website. | — | — | — |

In BELCMT there are not informing decisions specifically for medical devices.
<table>
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<tr>
<th>Country</th>
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<th>Medical Device incorporation: procurement/donations/technical specifications:</th>
<th>Medical device incorporation: procurement/donations/technical specifications:</th>
<th>General Comments</th>
</tr>
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</table>
| Bangladesh | SEAR | — | — | — | — | Ms. S. M. Sabrina Yesmin is the Assistant Director of DGDA. | Technical specifications are not publically available. | Central Medical Stores Depot, Tejgaon, Dhaka-1208. Dhaka has all the data in this regards. | — | }
| Barbados | AMR | — | — | — | — | Procurement queries, comments, and information should be addresses to the Chief Supply Officer (email: joness@gob.bb). | There is not a national inventory but the Queen Elizabeth Hospital Engineering Services maintains an inventory of high-cost technologies and medical equipment; thus, there is an institutional inventory there. Also, all the polyclinics keep institutional inventory for medical equipment only. The institutional inventories at the hospital and the polyclinics are audited annually. Additionally, the Equipment management software is currently being installed at the Queen Elizabeth Hospital. | There is not a national inventory but the Queen Elizabeth Hospital Engineering Services maintains an inventory of high-cost technologies and medical equipment; thus, there is an institutional inventory there. Also, all the polyclinics keep institutional inventory for medical equipment only. The institutional inventories at the hospital and the polyclinics are audited annually. Additionally, the Equipment management software is currently being installed at the Queen Elizabeth Hospital. | Concerning the Healthcare Infrastructure section: there are many single and grouped medical centres and general practice clinics/offices which perform primary care that includes emergency services. Some medical centres of the private sector perform secondary care services as well. |
| Belarus | EUR | — | — | — | — | State register of medical equipment and medical supplies of Belarus. | Public procurement of medical devices and their specifications for each procurement procedure can be found in our website. | Go to website (first link) and find the document titled “mfindr”. | — | }
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<td>Belgium</td>
<td>EUR</td>
<td>Ces listes existent indirectement par le remboursement de certains dispositifs médicaux et/ou le remboursement de certains tests cliniques effectués. Les dispositifs médicaux implantaibles et invasifs à long terme doivent se trouver dans ce listing de l’INAMI pour pouvoir être facturés par l’hôpital aux patients. La liste est disponible sur internet via le lien signalé. Approvement for reimbursement by type of IVD device or analysis, not a product-specific list.</td>
<td>—</td>
<td>Ces listes existent indirectement par le remboursement de certains dispositifs médicaux et/ou le remboursement de certains tests cliniques effectués.</td>
<td>The assessment includes pre-market clinical evaluation of innovative high-risk medical devices.</td>
</tr>
<tr>
<td>Belize</td>
<td>AMR</td>
<td>—</td>
<td>Policy Analysis &amp; Planning Unit, Ministry of Health.</td>
<td>There is no information about which lists are available.</td>
<td>HTA activities have been identified, but there is not a specific national unit.</td>
</tr>
<tr>
<td>Benin</td>
<td>AFR</td>
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<td>—</td>
<td>Ilya la Direction de la programmation et de la prospective (DPP) et Direction des hôpitaux (fait HTA), mais n'est pas spécifiquement pour des dispositifs médicaux.</td>
</tr>
<tr>
<td>National regulatory authority</td>
<td>Medical device nomenclature system</td>
<td>Medical Device incorporation: procurement/donations/technical specifications</td>
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<td>L’Agence fédérale de Contrôle nucléaire (AFCN) est en train de réviser les inventaires des dispositifs médicaux émettant des rayonnements ionisants présents en Belgique. Cet inventaire provient en partie de données fournies par les Organismes Agréés (AV Controlatom, TechniTest, ....). COCIR (European Coordination Committee of the Radiological, Electromedical and Medical IT Industries) peut également fournir des informations utiles sur les dispositifs d’imagerie diagnostique médicale en incluant l’âge de l’équipement (age profile). Rappelons que l’OECD a aussi mené une enquête avec des questions similaires, organisation à laquelle les données ont été mentionnées par l’AFCN.</td>
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<tr>
<td>Agence Fédérale de Contrôle Nucléaire en Belgique.</td>
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La nomenclature CNEH: Centre National d’Expertise Hospitalière Nomenclature (from France) est utilisée de façon informelle dans certains de nos hôpitaux.
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</thead>
<tbody>
<tr>
<td>Bhutan</td>
<td>SEAR</td>
<td>We have a list for each level of health centre used for annual identification for non drug items which includes equipments but we have not uploaded it in a website.</td>
<td>—</td>
<td>At present we do not have national lists of recommended medical devices but we are developing a standard list of Equipment and non-drug items for each level of health facilities in Bhutan (national, regional, district hospital, Basic health unit I and Basic health unit II). The standard list of equipment will be based on the standard services that will be provided at each level of the health centre. The standard list is available since 2012.</td>
<td>HTA is focused on pharmaceutics and vaccines but not in medical devices.</td>
</tr>
<tr>
<td>Bosnia and Herzegovina</td>
<td>EUR</td>
<td>There are the lists of medical devices for procurement regarding the each general hospital as well as clinical centres (situation analysis of health care institutions). At the primary health care level, there is a list of medical equipments that is necessary for family medicine.</td>
<td>The Rulebook on Normative Standards for Establishment of Health Institutions.</td>
<td>There are documents that regulate the necessary knowledge, skills, procedures and equipment (definition of medical technology) which are used by those group of diseases. Also, there are Guides for specific medical conditions, and there are adequate contingency plans for responding for public health threats as needed. The Rulebook on National Standards for Establishment of Health Institutions, Standards for Primary Care and Hospitals.</td>
<td>The HTA is acknowledged in decentralized legislation, and present at a national level.</td>
</tr>
<tr>
<td>Botswana</td>
<td>AFR</td>
<td>—</td>
<td>Documents are in constant revision and update.</td>
<td>—</td>
<td>It is needed to strengthen the research to improve the HTA capacity.</td>
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<tr>
<td>National regulatory authority</td>
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<tr>
<td>The DRA has no assigned responsibilities for regulating medical devices.</td>
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<td>All medical devices are procured by the Ministry of Health (MoH) following the Procurement Rules and Regulations of the Ministry of Finance Bhutan (see: procurementmanual1.pdf). Drug Vaccine and Equipment Division (DVED) is the agency in the MoH that does the procurement of drugs and medical devices for the whole country.</td>
<td>The Biomedical Engineering Division under the Department of Medical Services has maintained an Inventory of equipment above 25,000 rupees only.</td>
<td>Concerning the Infrastructure section: there is 1 National Referral Hospital with 350 beds, 2 Regional referral hospitals with 150 beds each, 10 district hospitals with 60 to 40 beds, 12 district hospitals with 20 beds. Out of 192 health posts, 18 are Basic Health Unit grade I with 10 beds, and the remaining 174 health centres with 2 to 5 beds are Basic Health Unit grade II.</td>
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</tr>
<tr>
<td>Unidad de Seguros Públicos de Salud - Dante Ergueta tel. 591-22495053; Unidad de Servicios de Salud - Javier Luna Orozco tel. 591-22495053.</td>
<td>—</td>
<td>Se cuenta con la propuesta de la norma &quot;Pliego de especificaciones técnicas para la adquisición de dispositivos médicos&quot; DBC. La adquisición se realiza a través de los gobiernos municipales (Ley del Medicamento 1737, Reglamento a la ley del Medicamento 25235).</td>
<td>El inventario de equipos y la aplicación del plan para la adquisición de equipo médico solo se realizó para los departamentos de Oruro, Beni y Pando.</td>
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<tr>
<td>For the Republika Srpska: Regarding the procurement of various medical devices, the company that generally provides the medical device must ensure capable suppliers who can implement a proper assessment and who can carry out the certification of medical devices.</td>
<td>Our nomenclature is based on GMDN and EDMA codes. In our instructions we ask for our manufacturer and representative of manufacturers to use GMDN or EDMA codes for making generic name. We have free access to GMDN base, and we found a new version of EDMA codes in internet.</td>
<td>Responsible authority in both entities. Ministry of Health of Republika Srpska is responsible for the procurement of high-cost technologies while the Health Care Institutions can provide procurement of other medical equipment.</td>
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<td>There is a drug regulatory unit. It has a draft for an Act that will regulate medicines and medical devices.</td>
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<td>There is the Medical Equipment Asset Register which was completed in December 2009. The Custom Solution is being implemented; the contract was signed on May 19th 2010.</td>
<td>Concerning the Infrastructure section: there are 800 clinics, healthposts and mobile clinics.</td>
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<td>Brazil</td>
<td>AMR</td>
<td>Lists for diseases are Health Attention Secretariat (SAS) unit competence. Other lists are not available for the moment.</td>
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<td>Competencia de la Health Attention Secretariat (SAS).</td>
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<td>Brunei Darussalam</td>
<td>WPR</td>
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<td>Bulgaria</td>
<td>EUR</td>
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<td>It is a established system for setting healthcare priorities, which involves HTA.</td>
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<tr>
<td>Burkina Faso</td>
<td>AFR</td>
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<td>It exists a limited number of trained HTA experts. Relevant health economic education is available at several universities in the region, and HTA experts or health economists work as consultants for the government (more info see third link).</td>
</tr>
<tr>
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<td>Anvisa started working to internalize the GMDN. So far, 100 of Anvisa’s technical names are compatible with GMDN. Anvisa also works in the implementation of the Unique Device Identification (UDI) in Brazil. Anvisa is currently preparing a draft proposal in a working group with the participation of the private sector, that should be sent to the Public Consultation later this year (2021).</td>
<td>In the given website search for the corresponding documents in procurement field. There are Lists of OPM, Procedures and Protocols.</td>
<td>Even though there is no standardized software for the medical equipment management in Brazil, some hospitals and other health facilities have developed and implemented their own. Besides that, the Post Market Surveillance of Medical Devices Unit of ANVISA, the Brazilian Regulatory Authority, intends to develop a software to address the main needs related to medical electrical equipment management (information related to the history of the medical equipment).</td>
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<td>-</td>
<td>Use of GMDN and UMDNS.</td>
<td>Only for the devices which are supplied through a centralized procedure accomplished by the Ministry of Health.</td>
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<td>The RPNS within the NRA is in the process of institutionalization.</td>
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<td>Les achats se font selon plusieurs procédures en fonction de la source de financement (les projets font des appels d’offres de façon indépendante, les hôpitaux exécutent en interne une partie du budget achat, les achats groupés au niveau national sont en train d’être expérimentés par la CAMEG: Centrale d’Achat des Médicaments Génériques); des appels d’offres internationaux sont quelquefois lancés par les projets.</td>
<td>Inventaire technique au niveau national a été fait par la DGIEM en 2003 avec l’appui de la GTZ; un inventaire non technique a été fait par la DAF en 2007 suivant une procédure du Ministère de l’Economie et des Finances. La mise à jour de ces inventaires n’est pas effective. Il y a les deux types d’inventaire: national fonctionnel pour certain équipement médicale et non-fonctionnel pour d’autres.</td>
<td>Concerning the HT national policy, a 2010 version was provided. Concerning the Section Infrastructure: There are 3 CHU and 1 Hôpital national.</td>
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<td>Burundi</td>
<td>AFR</td>
<td>Nous avons des listes préétablies suivant le type de catégories conformes aux normes en vigueur au MoH.</td>
<td>Nous avons également de la documentation sur la normalisation des équipements par structures de soins.</td>
<td>Lists available for communicable and non communicable diseases, injuries, and public health emergency situations.</td>
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<tr>
<td>Cambodia</td>
<td>WPR</td>
<td>—</td>
<td>a) Medical Equipment Standard list for CPA referral Hospitals; b) Medical Equipment Standard list for Minimum Package of activity (MPA) (Health Centre).</td>
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<td>It has been started the development of HTA systems by establishing nodal agencies and conducting ad-hoc activities.</td>
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<td>Cameroon</td>
<td>AFR</td>
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<td>Procédé aux achats/Système d'appel d'offres ouvert national/international. Il existe des entreprises nationales spécialisées dans la vente de ces produits.</td>
<td>The software was originally developed by the Ministry of Health (MoH). The Department of Hospital service is managing inventories for medical equipment of four National hospitals and 18 CPA3 level hospitals. The Controlled medical equipment requires management (monitoring), maintenance and repair.</td>
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<td>—</td>
<td>Hospital Service Bureau has developed standard medical equipment nomenclature for public hospitals in Cambodia and it has been utilized for medical equipment management and maintenance.</td>
<td>Procurement: Health Sector Support Program (HSSP2) is the implementation project team under the direction of Health Sector Strategic Plan (HSP2) of the Ministry of Health. Medical Equipment standard list for CPA1,2,3 referral hospitals.</td>
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<tr>
<td>Il existe un organisme chargé de la réglementation concernant les équipements qui émettent les rayonnements ionisants. l’Agence Nationale de Radioprotection. Contact: Dr. SimoAugustin, e-mail: <a href="mailto:augsimo@yahoo.fr">augsimo@yahoo.fr</a>.</td>
<td>Procurement: Il existe des directives générales concernant tous les marchés publics. Les hôpitaux et autres formations disposent aussi de budgets propres pour l'achat de dispositifs médicaux.</td>
<td>Les bailleurs de fonds réalisent des inventaires dans leurs zones d'intervention, mais il n'existe pas d'inventaire national.</td>
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<tr>
<td>Canada</td>
<td>AMR</td>
<td>Given the nature of the Canadian Constitution, these are of provincial jurisdiction and not at the federal or national jurisdictional level.</td>
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<td>There are several HTA agencies, mainly regional.</td>
<td>There are several HTA agencies, mainly regional.</td>
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</table>

**Cape Verde**  
AFR  
No, it is done according to the needs and the procedures of our action plan for the next years.  
HTA is focused on pharmaceutics but not in medical devices.
Annex 1. Additional comments

<table>
<thead>
<tr>
<th>National regulatory authority</th>
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</thead>
<tbody>
<tr>
<td>Canada uses both: Preferred Name Codes (based on US FDA Panel Codes) and GMDN. Not publicly available.</td>
<td>Given the nature of the Canadian Constitution, these are of provincial jurisdiction and not at the federal or national jurisdictional level.</td>
<td>Given the nature of the Canadian Constitution, these are of provincial jurisdiction and not at the federal or national jurisdictional level.</td>
<td>In several survey’s sections (e.g. section health policy), we were not able to reflect the shared governance approach that Canada has evolved towards as several as the key organisations, namely, the Canadian Agency for Drugs and Technology in Health are neither national nor provincial but entities whose governance and financing is shared among the Deputy Minister of Health of Canada’s 14 jurisdictions (e.g. Federal, 10 provinces and 3 Territories). In addition, the survey did not allow for the identification of existing provincial capacities which would have resulted in having to fill 13 separate surveys to accurately reflect Canada’s reality. Concerning HT national policy, it was provided the following document: <a href="http://www.who.int/medical_devices/survey_resources/health_technology_national_policy_canada.pdf">http://www.who.int/medical_devices/survey_resources/health_technology_national_policy_canada.pdf</a>.</td>
<td>In conclusion, there is a need to organize the park of medical devices. We would like to make a national inventory for medical equipment, assess the needs, and organizing technical guidelines for procurement to elaborate a clear plan of medical devices management. We think it is time to develop legislation for medical devices.</td>
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There is a department in charge of medical devices, but there is no legislation nor registration of medical devices yet.

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There is no national inventory of medical equipment. There’s a plan to do it soon.
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<td>Central African Republic</td>
<td>AFR</td>
<td>En concernant acquisition il ya une longue durée entre la commande et la réception.</td>
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<td>Chad</td>
<td>AFR</td>
<td>It is needed to revise the list.</td>
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<tr>
<td>Chile</td>
<td>AMR</td>
<td>Existen cinco listas de los dispositivos médicos que están bajo control obligatorio en el país (guantes de examinación, guantes quirúrgicos, preservativos, agujas hipodérmicas y jeringas hipodérmicas de un solo uso). Se encuentran disponibles en la dirección proporcionada.</td>
<td>—</td>
<td>No se dispone de las listas de tecnologías sanitarias de este apartado.</td>
<td>—</td>
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<td>No.</td>
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<td><strong>Achat groupé par les partenaires, passation de marché. Longue durée entre la commande et la réception.</strong></td>
<td><strong>Réalisée par la direction des infrastructures sanitaires. Il y a les deux types d’inventaire: national fonctionnel pour certain équipement médicale et non-fonctionnel pour d’autres.</strong></td>
<td><strong>Concerning the HT national policy it is stated in the following document: POLITINACIONALSAUDE_VERSAOVALIDADA 2020.</strong></td>
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<td><strong>There is a need to update the guideline.</strong></td>
<td></td>
<td><strong>The lack of a national policy in matters of health technology does not allow access to information on medical devices that could support the action plan with regards to training of users, specialists and maintenance technicians.</strong></td>
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<td><strong><a href="http://www.minsal.cl">http://www.minsal.cl</a></strong></td>
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<td><strong>Concerning the Infrastructure section: Los 21 centros de salud están incorporados en los 100 hospitales distritales/rurales. Los Centros de Referencia de Salud (CRS) = 7 considera a los Hospitales de Chile denominados de Mediana Complejidad y que se ubican en la región metropolitana y demás regiones del país. [Tambien existen tambièn los hospitales de Chile denominados de Alta Complejidad. Se ubican en la región metropolitana y demás regiones del país. Estos hospitales tienen la calidad de “Establecimientos Autogestionados en red”, incluyendo los Hospitales base de regiones y los Institutos de especialidades, que se concentran en la Región Metropolitana. [En lo que concierne a los Centros de Salud de atención ambulatoria de especialidades. Son 5 de la Región Metropolitana y dos ubicados en regiones del norte y sur del país.</strong></td>
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<td>China</td>
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<td>Colombia</td>
<td>AMR</td>
<td>No existe un listado oficial. El acuerdo No.008 de La Comisión de Regulación en Salud (CRES) establece que los dispositivos médicos usados en los procedimientos listados son reembolsados dentro del Plan de Beneficios en Salud.</td>
<td>--</td>
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<td>The INVIMA (Instituto Nacional de Vigilancia en Medicamentos y Alimentos) and the IETS (Instituto de Evaluación Tecnológica en Salud) perform HTA.</td>
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<td>Comoros</td>
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<tr>
<td>Congo</td>
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<tr>
<td>Cook Islands</td>
<td>WPR</td>
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<td>There are identified HTA activities but not a national unit.</td>
</tr>
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<tr>
<td>El INVIMA tiene dos dependencias relacionadas, la Subdirección de Registros Sanitarios que tiene un grupo funcional específico de dispositivos médicos y se encarga de la evaluación y autorización pre-mercado de los dispositivos médicos; y la Subdirección de Insumos para la Salud que se encarga de la vigilancia posmercado y de auditar sistemas de calidad de los fabricantes y condicion de calidad de los importadores de los dispositivos médicos en Colombia. También existe la Dirección de Dispositivos Médicos y otras Tecnologías.</td>
<td>Nationally developed. It is in phase of implementation.</td>
<td>—</td>
<td>Actualmente no hay inventario nacional, se ha intentado elaborar mediante el catastro de equipamiento físico. En la normatividad vigente, el Decreto 4725 de 2005, establece que los equipos biomédicos de tecnología controlada deben contar con registro sanitario o con permiso de comercialización en Colombia.</td>
<td>Actualmente se tiene reglamentado y en fase de implementación el Programa Nacional de Tecnovigilancia Post-mercado liderado por el Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA) (importantes para la gestión y manejo de los dispositivos médicos), también es importante establecer normas sobre los productos importados (que son la mayoría). Otros temas relevantes son la trazabilidad y el manejo de los dispositivos médicos en el territorio nacional, al igual que el manejo y la aprobación de los equipos repotenciados, su control y uso (este mercado necesita formas alternativas de control, la definición de los requisitos para su uso, etc.).</td>
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<td>Inspection Général de la Santé.</td>
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<td>La Evaluación de Tecnologías se reglamentó en el año 2011 mediante la Ley 1438, la cual será competencia del Instituto Nacional de Evaluación de Tecnologías que está en proceso de creación.</td>
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<td>La Nomenclature officiel n'existe pas. Mais sinon, on utilise ce qui peut être à la portée de la main et selon les circonstances.</td>
<td>L'achat des dispositifs médicaux est décentralisé. Il peut se faire au niveau national comme à l'étranger.</td>
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<td>AMR</td>
<td>Existen protocolos y procedimientos para las enfermedades y situaciones de emergencias en mención, pero no existen listas de dispositivos médicos como tales.</td>
<td>—</td>
<td>—</td>
<td>Two entities perform HTA: Caja Costarricense de Seguro Social (CCSS) and DDCTS. The extension of the HTA entities is at subnational level, not at national level.</td>
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**Côte d'Ivoire**  
AFR  
Les listes d'acquisition proviennent du Plan National de développement Sanitaire PNDS.  
Document de travail de la Direction des Infrastructures, de l'Equipement et de la Maintenance (DIEM): ListeTypeEquip CHR_HG_CSU_CSR.  
Les procédures et directives sont dans le manuel de directives à l'attention du personnel des des établissements de soins. Il n'existe pas de liste spécifique à un domaine ou un programme de santé.  
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<td>Two entities perform HTA: Caja Costarricense de Seguro Social (CCSS) and DDCTS. The extension of the HTA entities is at subnational level, not at national level.</td>
<td>El Ministerio de Salud tiene a su cargo el registro y control del equipo y material biomédico mediante el Reglamento Nº 34482-S para el uso, registro, clasificación, importación y control de equipo y material biomédico. El Sistema Integrado de Compras Públicas sigue la regulacion vigente para hacer sus respectivas compras de productos de salud.</td>
<td>The GMDN has been adapted to the national needs.</td>
<td>La Caja Costarricense de Seguro Social brinda cobertura universal a la población y es el mayor proveedor de servicios de salud del país, tanto en hospitales, clínicas y áreas de salud, por lo que se considera que hace la adquisición a nivel nacional. También hay adquisiciones en el sector privado de dispositivos médicos en menor escala; de esta última no se tiene acceso al inventario.</td>
<td>El Ministerio de Salud cuenta con la base de datos de los productos de equipo y material biomédico registrados para el país. Para cualquier adquisición dentro del país es necesario contar con su registro, pero no es del tipo inventario pues no se contabiliza; el registro tiene cinco años de vigencia. En el caso de la CCSS (ver <a href="https://www.ccss.sa.cr/">https://www.ccss.sa.cr/</a>) se tiene un inventario por establecimiento (en los tres niveles de atención) tanto a nivel hospitalario como en clínicas y áreas de salud. Del sector privado se ha reportado que cuentan con inventarios de equipos por institución, sin embargo no se tiene acceso a ese inventario pues se maneja como información discrecional en algunos de los casos y es difícil de monitorearlo en su totalidad. En el Ministerio de Salud para el registro de equipo y material biomédico se utiliza el programa Visual Basic 6.0, Base de datos SQL Server 2005; mientras que en la Caja Costarricense de Seguro Social se utiliza el programa ACCESS para la gestión del equipo médico.</td>
<td>Es difícil que las instituciones den cierta información que consideran es confidencial, por el ejemplo: el acceso a sus inventarios de equipo. En el caso de la Caja Costarricense de Seguro Social, que es el mayor prestador de servicios de salud del país, se pudo obtener dicha información con las autoridades correspondientes, pero resulta complicado.</td>
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<td>Croatia</td>
<td>EUR</td>
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<td>In 2007 the Ministry of Health and Social Welfare issued Ordinance on the organization and work procedures of the Ministry of Health and Social Welfare’s Crisis Headquarters (<a href="http://narodne-novine.nn.hr/clanci/sluzbeni/2007_05_46_1563.html">http://narodne-novine.nn.hr/clanci/sluzbeni/2007_05_46_1563.html</a>) which determines organization scheme and work procedure of the Ministry of Health and Social Welfare’s Crisis Headquarters as well as actions of other health care institutions and private health workers in case of major crisis. Major crisis is described as any event which constitutes a serious threat to health of a certain community and results (or might result) in large number of victims who cannot be taken care of by usual work organization of public and private health care institutions or private health workers.</td>
<td>HTA is focused on pharmaceutics, not specifically in medical devices. HTA has three partners: the MoH, Health Insurance Fond (HIF) and Croatian Institute of Public Health (CIPH). However systematic use of HTA to support healthcare decision-making is in still in process, but expected over the next years.</td>
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<td>Ministry of Health and Social Welfare currently conducts joined procurement of several groups of medical devices for more than 20 hospitals in the Republic of Croatia. The procurement procedure is managed by the expert divisions within the Ministry in collaboration with all hospitals included in the Procurement Plan and top medical experts for every group of the equipment. Due to continuous advancement in medical devices technology, a special commission is formed before every procurement procedure. The commission defines the required technical specifications of the device based on the most recent available data.</td>
<td>The Ministry of Health and Social Welfare has a national informal and internal inventory for medical devices in all public health institutions. This inventory is used mainly for analytical purposes and planning strategies within the Ministry. In 2008 Croatian National Institute of Public Health, as part of a pilot project under EUROSTAT guidelines, made an inventory of 10 most expensive medical devices (MRI, Computed Tomography, Linear Accelerator, etc.).</td>
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<tr>
<td>Cuba</td>
<td>AMR</td>
<td>Existe un listado de modelo de equipamiento médico destinado para cada nivel de atención. No está refrendado en ninguna web (no disponible).</td>
<td></td>
<td>Cada especialidad médica tiene establecidas normas y programas a través de las recomendaciones de los grupos nacionales y apoyo del Consejo de Sociedades Científicas. En cuanto a las listas para diferentes enfermedades y/o situaciones no están refrendadas en ninguna web (no disponible).</td>
<td>It also exists the Department of Innovation and Evaluation of Health Technologies attached to the National Directorate of Science and Technology of the Ministry of Public Health (MINSAP). Evaluations are made mainly for pharmaceutics not for medical devices.</td>
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<td>Cyprus</td>
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<td>Pharmaceutical Services within the Ministry of Health performs HTA evaluation of pharmaceutics.</td>
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<td>Czechia</td>
<td>EUR</td>
<td>—</td>
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<td>—</td>
<td>There are HTA activities in pharmaceutics, not specifically for medical devices.</td>
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<td>National regulatory authority</td>
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<tr>
<td>Cuba</td>
<td>SUCNEM is based on UMDNS. It is also in use the GMDN.</td>
<td>Basado en la política de salud, los equipos médicos deben contar con el Registro Sanitario para su utilización en el Sistema Nacional de Salud (see: <a href="http://www.bvscuba.sld.cu">www.bvscuba.sld.cu</a>) y en la Gaceta Oficial de la República de Cuba (<a href="http://www.gacetaoficial.cu">www.gacetaoficial.cu</a>). Para el proceso de importación se realiza una evaluación entre las autoridades competentes donde se efectúa previamente un análisis entre asistencia médica y electromedicina. Las fichas técnicas para facilitar el proceso de adquisición no están publicadas.</td>
<td>El Programa de Informatización de la Salud se encuentra en fase de desarrollo. There are 3 types of inventory for medical equipment: National for high cost technologies (such as MRI, CT or PET scanners), National for medical equipment and National functional for medical equipment.</td>
<td>En términos de aclaración general indicamos que en Cuba, como es conocido, el Sistema de Salud tiene características de ser único, centralizado, público, gratuito y universal, refrendado en la Constitución de la República. La demanda de equipos médicos se realiza sobre la base de requerimientos acorde al desarrollo científico-técnico mundial y de los índices de consumo para los insumos y obedece a las políticas sanitarias establecidas. Con relación al 3.3.1 las Directrices se basan en la Resolución del Ministerio del Comercio Exterior No. 15 del 2006, no obstante se conocen las Directrices de la Organización Mundial de la Salud.</td>
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<tr>
<td>Cyprus</td>
<td>Use of UMDNS and GMDN. Procurement guidelines apply to the Public Sector only.</td>
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<tr>
<td>Czechia</td>
<td>GMDN and UMDNS remain the historically used nomenclatures. Three national specific systems (categorizations) of medical devices are used for reimbursement and statistical purposes. The GMDN remains a comprehensively recognized system for the registration and notification of medical devices in the Czech Republic. GMDN codes are used in the Register of Medical Devices (RZPRO) administered by the State Institute for Drug Control (SUKL) for regulatory purposes, adverse events reporting, safety corrective measures, and information on clinical trials.</td>
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<tr>
<td>Democratic People’s Republic of Korea</td>
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<tr>
<td>Democratic Republic of the Congo</td>
<td>AFR</td>
<td>Il existe des listes de matériel dressé au niveau périphérique approuvé (district sanitaire). Pour le niveau intermédiaire et niveau tertiaire cette liste est en élaboration.</td>
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<tr>
<td>Denmark</td>
<td>EUR</td>
<td>—</td>
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<td>In the case of lists for different diseases and situations, there are some more general plans, but no specific medical devices recommended.</td>
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<tr>
<td>Djibouti</td>
<td>EMR</td>
<td>—</td>
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<td>—</td>
<td>The development of the HTA unit is in progress, as well as the human resources to fill the workforce gap within the MoH.</td>
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<tr>
<td>Democratic Republic of the Congo</td>
<td>Il existe des listes de matériel dressé au niveau périphérique approuvé (district sanitaire). Pour le niveau intermédiaire et niveau tertiaire, cette liste est en élaboration.</td>
<td>La Direction des laboratoires de Santé veuille surtout au respect des normes de autres équipements des laboratoires et des services d'imagerie médicales. Tandis la Direction des Equipements et Matériels Médicaux s'occupes des autres matériel médicaux et non médicaux. Un autre organisme non du ressort de la santé, c'est le Comité National de Protection Contre les Rayonnements Ionisants (CNPRI) qui s'occupe essentiellement des équipements émettant des rayonnements non seulement médicaux mais tout. Il faut dire qu'il y a manque notoire des textes qui doivent réglementer tout ceci. C'est avec les quelques notions appris par ici et par là qu'on essaye de faire tant qu'on peut. Sinon, le secteur est très peu réglementé ou carrément non réglementé.</td>
<td>En R.D.Congo, les achats se font à tous les niveaux. L'État n'a pas pu réglementer ce secteur les achats se font à tous les niveaux et surtout les bailleurs de fonds pour leurs programmes spécifiques qu'ils appuient. Le directives à ce niveau sont fonction d'un appel offre, c'est en ce moment que celui qui lance l'offre dresse un certains critères des dispositifs qu'il veut acquérir.</td>
<td>En tant pays post-conflit, dans le processus de l'organisation de son système national de santé, le gouvernement dispose déjà d'une stratégie de renforcement du système de santé qui est une stratégie sectorielle. Ensuite, le pays vient de se doter d'un plan stratégique de développement sanitaire pour 5 ans avec un cadre des dépenses à moyen terme ou toutes ces technologies sont planifiées.</td>
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<tr>
<td>Denmark</td>
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<td>The National Institute of Radiation Protection is in charge. The inventory covers all x-ray equipment, equipment for nuclear medicine and radiation therapy.</td>
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<td>Djibouti</td>
<td>EMR</td>
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<td>The National Board of Health is issuing some Health Technology Assessments, including but not limited to medical devices. Only a minority of technologies are handled, so this is regarded as being outside the scope of the Policy section.</td>
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<tr>
<td>Dominica</td>
<td>AMR</td>
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<td>HTA activities have been identified, but there is not a specific national unit.</td>
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<tr>
<td>Dominican Republic</td>
<td>AMR</td>
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<tr>
<td>Ecuador</td>
<td>AMR</td>
<td>—</td>
<td>Estatuto del MSP; Licenciamiento por Área en el I y II nivel.</td>
<td>Reglamento para el registro y control sanitario de dispositivos médicos, reactivos bioquímicos y de diagnóstico y productos dentales. Reg. Oficial 573 del 20 de abril de 2009.</td>
<td>There are HTA activities for health products, not specified for medical devices.</td>
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<tr>
<td>Egypt</td>
<td>EMR</td>
<td>Were counted by the sector ministry and therapeutic medicine, the National Information Center Ministry</td>
<td>—</td>
<td>—</td>
<td>A pharmacoeconomics unit was officially established in 2011 under the Central Administration of Pharmaceutical Affairs within the Ministry of Health, but HTA is not obligatory for pricing or reimbursement. However, the recent universal health insurance law from 2018 mandates the representation of health economists in the governing boards of the new Universal Health Insurance Authority and the health care provider body.</td>
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<td>The Software is currently awaiting for the setting-up.</td>
<td>A manual exists in draft form to govern issues related to medical devices. It is still supposed to have a final review to begin the process of it's adoption and implementation.</td>
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**La Ley General de Salud 42-01 y el Reglamento de Medicamentos Decreto 246-06 son el marco legal que fundamenta el accionar del Viceministerio de Garantía de la Calidad.**

La nomenclatura oficial. Sin embargo, existe una propuesta que data del año 2006 que respondió a un proyecto de mantenimiento preventivo de equipos médicos. En cuanto a la adquisición solo existen recomendaciones dadas en fichas técnicas y de acuerdo a la complejidad del establecimiento.

**Eco. Ruth Lucio, Coordinadora Nacional de Desarrollo Estratégico en Salud Dirección Nacional de Vigilancia y Control Sanitario en lo relativo a Publicidad y vigilancia. Dr. Liliana Sacoto es la Directora Nacional. Así como la Dra. Amelia Prieto del Instituto Nacional de Higiene y Medicina Tropical.**

Las políticas de adquisición están en proceso de implementación por la Dirección de Inteligencia y Economía de la salud. Programa Mi hospital: Adquisición de equipos para 8 hospitales declarados en emergencia sanitaria. Se está actualizando el inventario de los Hospitales declarados en emergencia. Hay "National inventory only for high cost technologies (such as MRI, CT or PET scanners)" tambien.

La regulación y el control de la publicidad de dispositivos médicos se realiza mediante el "Reglamento para la publicidad y promoción de medicamentos en General, Productos Naturales procesados de uso medicinal, medicamentos homeopáticos y dispositivos médicos". Reg. Oficial 416, acuerdo ministerial 179 del 30 de marzo de 2011.

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Concerning the Infrastructure section: the proposed names are not totally compatible with ours. Thus, the number of units is under the Ministry of Health only and is not confined to Tfsalia to the private sector in 2010.
<table>
<thead>
<tr>
<th>Country</th>
<th>WHO region</th>
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</thead>
<tbody>
<tr>
<td>El Salvador</td>
<td>AMR</td>
<td>Norma técnica para el diseño y equipamiento de Casas de Salud.</td>
<td>Tomadas de la pagina web del MINSAL (ver link proporcionado). Norma técnica para radiología diagnóstica e intervencionista; Norma técnica para uso de fuentes radiactivas en braquiterapia; Norma técnica para la operación de equipos de teleterapia; Norma técnica uso de fuentes radiactivas no selladas en medicina nuclear; Norma de procedimientos de control de calidad para equipos de rayos-x de uso en diagnóstico médico y dental; Norma técnica sobre anestesiología P.I; Norma técnica sobre anestesiología P.II.</td>
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<tr>
<td>Equatorial Guinea</td>
<td>AFR</td>
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<td>—</td>
<td>—</td>
<td>There are identified HTA activities but not a national unit.</td>
</tr>
<tr>
<td>National regulatory authority</td>
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<tr>
<td>El departamento está a cargo del Dr. Rivera, Director de Regulación y Legislación en Salud del Ministerio de Salud.</td>
<td>El catálogo desarrollado es de equipo médico en general y sólo es para fines de compra. No existe distinción o clasificación de equipos de tecnología médica por su aplicación o incidencia en la salud del paciente.</td>
<td>Para el control de equipos con fuente de radiaciones ionizantes, la Dirección de Regulación a través de la Unidad Reguladora de Radiaciones Ionizantes (UNRA) tiene el inventario de los equipos como TC, Rayos X, Angiografía, Gamma Cámara, etc. Autorizados a nivel nacional en la actualidad, se remitirá el listado actualizado a la fecha a la OMS.</td>
<td>Las respuestas proporcionadas corresponden exclusivamente a la información disponible en la Unidad de Proyectos del Ministerio de Salud Pública y Asistencia Social. Agradecemos permitirnos participar de tan importante encuesta que nos permite establecer un enlace que estamos seguros contribuirá a mejorar nuestra gestión en la planificación, evaluación, adquisición y mantenimiento de los dispositivos médicos de nuestro sistema nacional de salud; así como a contribuir en el desarrollo de una política nacional de tecnología sanitaria en El Salvador. Este trabajo servirá de referencia mundial en materia de tecnologías sanitarias, en particular en lo que se refiere a políticas, gestión, regulación y uso de dispositivos médicos. Esta encuesta se convertirá en la información de base para las actividades con que se llevarán a la práctica las intervenciones que prevea la OMS en respuesta a las peticiones de los Estados Miembros, de acuerdo con lo establecido en la resolución sobre las tecnologías sanitarias aprobada en 2007 (WHA60.29). Nos ponemos a su total disposición.</td>
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<tr>
<td>Eritrea</td>
<td>AFR</td>
<td>Ministry of Health, Department of Regulatory Services, Medicine and Medical Devices Control Division.</td>
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<tr>
<td>Estonia</td>
<td>EUR</td>
<td>The list about reimbursed medical devices used in outpatient conditions is available on web-site (second link). Medical devices used in inpatient conditions are financed though the prices of healthcare services (these prices include also costs of workforce, area, etc). List of healthcare services is available on web-site (third link).</td>
<td>Recommended medical devices for specific procedures are described in diagnostic (and treatment) guidelines. They are composed and/or approved by specialists organizations.</td>
<td>The HTA for medical products, mainly pharmaceutics, and treatments. There is mention of medical equipment too.</td>
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<tr>
<td>Eswatini</td>
<td>AFR</td>
<td>The list is still being developed by the Emergency Preparedness Group.</td>
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<tr>
<td>Ethiopia</td>
<td>AFR</td>
<td>The list of healthcare facilities is currently in progress.</td>
<td>A revision has started for each. It is use the WHO guidelines and other documents.</td>
<td>An HTA unit is not yet established. Within the FMoH the Pharmaceutical and Medical Device Directorate and HEFA team are primary driving forces to generate and promote HTA based evidence. The HEFA team is tasked with spearheading the application of evidence-based health care decision making by organizing available evidence, costing interventions, and defining effectiveness measures of the different health programs and then supporting policymakers at the national and regional levels.</td>
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</table>

AFR — Ministry of Health, Department of Regulatory Services, Medicine and Medical Devices Control Division.
EUR — Recommended medical devices for specific procedures are described in diagnostic (and treatment) guidelines. They are composed and/or approved by specialists organizations.
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<tr>
<td>Ethiopia</td>
<td>Official nomenclature system for medical devices is currently on the process of development.</td>
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<td>National medical devices inventory on the six zones has started in 2008 and, currently, it is in the process of finalization (only one zone is partially remaining).</td>
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<tr>
<td>Eswatini</td>
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<td>The procurement of medical devices is regulated by the Public procurement law, as well as all other commodities (see specified website: riigiteataja).</td>
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<tr>
<td>Estonia</td>
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<td>The National guidelines on procurement are yet to be developed. The unit together with the bio-medical department forms a committee that recommends purchasing the needed equipment or rather requested equipment.</td>
<td>Though this inventory is still under development, we have only covered hospitals and health centres and will proceed to clinics (health posts for Swaziland).</td>
<td>Concerning the Infrastructure section: In Swaziland Health Centres may have more than 20 beds. The referral levels are being defined by the ongoing essential health care package that is being developed.</td>
</tr>
<tr>
<td>Radiation &amp; Protection Authority</td>
<td>Nationally developed and adapted from both UMDN and GMDN. This nomenclature is done by EPSA, ESDA and FMOH in collaboration with stakeholders. The nomenclature is mainly use for procurement and regulatory purposes. Established the Public Infrastructure Directorate are now started inventory to identify the type, source and status of the devices.</td>
<td>The Plan, Monitoring and Evaluation Directorate (PMED), within Federal Ministry of Health (FMOH) is in charge of the procurement.</td>
<td>AAU, Tikur Anbesa specialized Hospital update medical Inventory and Equipment history file in 2013.</td>
<td>Concerning National policy on health technology: National Medical device strategy under development (draft) and National Medical device directive (final draft) will approved within 3 or 4 months. Concerning the HT national policy, it is stated in the corresponding National Health Policy document. Concerning the Infrastructure section: the targets of the government are to expand the current infrastructure capacity.</td>
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<tr>
<td>Fiji</td>
<td>WPR</td>
<td>The biomedical catalogue for procurement can be obtained by the Fiji Health Sector Improvement Program (FHSIP).</td>
<td>CSN &amp; CSP lists can be obtained from ministry of health, HQ.</td>
<td>CSN &amp; CSP. Can be obtained from Ministry of Health, HQ.</td>
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<tr>
<td>Finland</td>
<td>EUR</td>
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<tr>
<td>France</td>
<td>EUR</td>
<td>La liste des dispositifs médicaux et prestations pris en charge par l’assurance maladie est accessible à l’adresse donnée en ameli (chercher fournisseurs-de-biens-medicaux/exercer-au-quotidien/liste-des-produits-et-prestations-lpp/liste-des-produits-et-prestations-lpp/).</td>
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<td>Also, supported by the divisional biomedical engineering units.</td>
<td>—</td>
<td>Mainly standardization of all medical equipment as per the national biomedical catalogue. Also, supported by the Ministry of Health central procurement centre at Fiji Pharmaceutical Services.</td>
<td>BME Equipment Inventory. The inventory has more than 8,600 items.</td>
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<td>—</td>
<td>Funding CA will implement the European Medical Device Nomenclature (EMDN) used by manufacturers/ARs when registering their medical devices in the EUDAMED database. The EMDN system will be based on the Italian CND nomenclature system. This will be the only official nomenclature system for medical devices in Finland. Also, some other commercial nomenclature systems are used in healthcare organizations and health technology companies. Healthcare organizations use these nomenclatures in, for example, public procurement, product information retrieval, ERP, and cost accounting.</td>
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<td>La classification des dispositions des dispositifs médicaux est prévue à l'article R. 5211-7 du code de la santé publique. Les règles sont précisées dans l'arrêté du 15 mars 2010 modifiant l'arrêté du 20 avril 2006 fixant les règles de classification des dispositifs médicaux. La nomenclature utilisée est la CNEH: Centre National d’Expertise Hospitalière Nomenclature.</td>
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<td>Dans cette enquête, nous avons mentionnées la HAS et l’ANSM qui sont deux agences qui sont chargées: HAS: Agence d’évaluation des dispositifs médicaux</td>
<td>ANSM : Agence nationale de sécurité du médicament qui est chargée de la sécurité sanitaire des dispositifs médicaux.</td>
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<td>Georgia</td>
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<td>Germany</td>
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<td>The Medical Research Council (UK) unit “the Gambia” (refer to specified link) uses the UMDNS system via the ECRI Health Devices Sourcebook (ECRI website). Note that this is not used by the Ministry of Health.</td>
<td>Recently inventories have been compiled for the National Laboratory Services. However, those for Hospital/Clinical equipment are not available yet. The Medical Research Council (UK) the Gambia has a full inventory of its biomedical equipment. It is comprised of 1,500 devices including minor clinical equipment, high-cost diagnostic and research laboratory equipment. We use a proprietary equipment management program from Phoenix Data Systems Inc. called AIMS (<a href="http://www.goaims.com">www.goaims.com</a>).</td>
<td>Concerning the Infrastructure section: the private sector section correspond to the responses for the Medical Research Council (UK) the Gambia; Concerning HT national policy we provide the following doc.: Medical Equipment and Devices Policy 2010 March.doc. Concerning Section Infrastructure: We have 3 CHU and 1 Hôpital national.</td>
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<td></td>
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<td>Georgi National Agency For Standards, Technical Regulations and Metrology is responsible for standardization and metrology as well as calibration and accreditation of facilities, providing inspection of medical devices.</td>
<td>Nuclear and Radiation Safety Service, Ministry of Environment and Natural Resources.</td>
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<td>According to Georgian legislation, Georgia recognises international or national (according on a list of certain countries) certificates of medical devices there.</td>
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<td>There are more than 30 regional Competent Authorities.</td>
<td>At the German Institute for Medical Documentation and Information (DIMDI) German manufacturers or an authorised representative of non-EU manufacturers have to register themselves or their products. The database served by DIMDI uses today the UMDNS.</td>
<td></td>
<td>Germany does not complete the whole survey because of their federal system, which will imply to make the whole survey in their 16 states. Regarding the Regulations section: they follow the EU system, other matters are state’s competency.</td>
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<td>Ghana</td>
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<td>The standard list serves as a guide. The actual procurement is based on the need of health facility, availability of utilities, and availability of professional user staff.</td>
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<td>Greece</td>
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<td>Grenada</td>
<td>AMR</td>
<td>The list can be requested from the management of the Hospital services. However there is no web to guideline because was never used as a policy of the MoH.</td>
<td>-</td>
<td>No lists available.</td>
</tr>
<tr>
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<tr>
<td>Ghana</td>
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<td>The Ghana National Procurement law as well as the Ministry of Health (MoH). Depending on the value of the procurement package, the health facilities are allowed to procure sometimes, the unit of the MoH also procures some of the capital equipment especially from other projects. All procurement of medical devices is carried out with the technical support of the Clinical Engineering Department of the Ghana Health Service or the Biomedical Engineering Unit of the MoH.</td>
<td>Most inventories are held at a regional and an institutional level. We are yet to acquire the software for the management of the inventory at the national level.</td>
<td>There is no written nor published national health technology policy yet but there are policies available that have been established by the systems and structures unit for health technology in Ghana. Ghana Health Service has drafted its operational policy for healthcare equipment and needs to be finalized.</td>
</tr>
<tr>
<td>Greece</td>
<td></td>
<td>The EU Directive for public procurement and national specific legislation for health procurement (law 3580/2007). A part of procurement of medical devices is carried out at a national level, by the Health Procurement Committee.</td>
<td>&quot;Praxis&quot;, was developed by the Institute of Biomedical Technology (INBIT), and it is a specific one. Also, it is used the Asset Management Software.</td>
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<tr>
<td>Grenada</td>
<td></td>
<td>A specific technical committee is responsible for the correlation of Nomenclature, Classification and Codification of Medical Devices. The final deliverable is expected in 2014.</td>
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<td></td>
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<td>A system was develop but it was not supported by management. There is no URL because this software was locally developed.</td>
<td>The inventory for all medical equipment in the island can be found in the Biomedical Engineering Department, General Hospital. The system was locally developed, installed and called The Medical Device Management System Software.</td>
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</table>

The Radiation Protection Institute is responsible for the regulation of equipment with radiation sources such as X-Ray machines.
<table>
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<tbody>
<tr>
<td>Guatemala</td>
<td>AMR</td>
<td>Ver: Norma Técnica Vigente para inscripción sanitaria de dispositivos médicos. Especificamente la Normativa 37.</td>
<td>—</td>
<td>—</td>
<td>HTA activities have been identified, but there is not a specific national unit. Currently, the HTA unit is in progress towards the Universal Health Care (UHC) country goal. There are the following units: Planificación Estratégica (SIGSA), Observatorio en Salud Reproductiva (OPSOMS/OSAR) y Sistema Informático de Gestión (SIGES).</td>
</tr>
<tr>
<td>Guinea</td>
<td>AFR</td>
<td>Les Normes ont été définies pour les formations sanitaires de base (postes, centres de santé), les Centres de santé améliorés, les Hôpitaux préfectoraux / districts sanitaires et les Hôpitaux Régionaux. Ces normes ne sont pas disponibles pour toutes les unités fonctionnelles des hôpitaux nationaux.</td>
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<td>Guinea-</td>
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<td>Bissau</td>
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<td>Guyana</td>
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<tr>
<td>Haïti</td>
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<td>Guinea-Bissau</td>
<td>AFR — — — —</td>
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<td>Honduras</td>
<td>AMR</td>
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<td>—</td>
<td>HTA activities have been identified, but there is not a specific national unit.</td>
</tr>
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</table>

- El Reglamento para el Control Sanitario de Productos, Servicios y Establecimientos de Interés Sanitario, establece una nomenclatura con fines de Registro.
- Ley de Contratación del Estado y Reglamento de Ley de Contratación del Estado (more information under https://www.arsa.gob.hn/).
- Cada uno de los Programas de Salud dependientes de la Dirección antes mencionada o entes cooperantes realizan compras de dispositivos médicos para proveer a nivel nacional, como pueden ser pruebas de laboratorio y anticonceptivos.
- El Programa de Equipamiento se elabora por demanda y por complejidad.
- El inventario es por Objeto de Gasto. Existe el SIAFI que es un sistema informático para fines de presupuesto, el cual actualmente se encuentra en proceso de ampliación ya que permitirá la gestión del equipamiento en todas sus fases.
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<tr>
<td>Hungary</td>
<td>EUR</td>
<td>The uploaded Ministerial Decree lays down the minimum requirements for the provision of healthcare services. The criteria are equally specified for healthcare facilities (1.2.1) and specific procedures. The document has been uploaded only once. The decree is only available in Hungarian. The assigned URLs contain protocols for pandemic situation according to the National Influenza Pandemic Preparedness Plan (second link). Also, see the Decree 60_2003 on minimum requirements of healthcare services.</td>
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<tr>
<td>Iceland</td>
<td>EUR</td>
<td>Only CE marked medical devices are approved.</td>
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<tr>
<td>India</td>
<td>SEAR</td>
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| —                              | The coding is not available on the Internet. | For procurement guidelines see the “Decree of the Minister of Welfare” (No. 9/1993 NM) on the specific aspects of the financing of healthcare insurance services. In respect of certain medical devices procured at a national level over a certain amount, procurement is carried out by the Central Services Directorate General of the Prime Minister’s Office. In the remaining cases, hospitals procure medical devices subject to itemized accounting individually and the National Health Insurance fund reimburses a certain level of the costs (see the list in the corresponding website, but with exception of pacemakers, heart valves, cochlear implants). | Under high-cost (amounts exceeding EUR 400). Unfortunately, the real state is not a public registry. The access is ensured only for data providers, manufacturers and conformity assessment bodies. Most of the public institutions use the software CT-EcoSTAT. | Concerning the HT policies: “Safety and Partnership Program” - the health program adopted by the Hungarian government on July 9th, 2008 - the acceptance of medical devices and health technologies into the social insurance scheme was defined in the context of improvement of insurance tasks until 2010. |}

According to Directives 93/42, 90/385 and 98/79.
Notified medical devices are regulated under the Drugs and Cosmetics Act and Rules under the 14 rule of medical devices as notified under the corresponding Act.
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<tr>
<td>Indonesia</td>
<td>SEAR</td>
<td>We do not have lists for different diseases/situations, but we use WHO recommendations.</td>
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<td></td>
<td>It has been started the development of HTA systems by establishing nodal agencies and conducting ad-hoc activities. Social Security Management Agency for the Health Sector (BPJS) is focus on HTA for health products. Komite Penilaian Teknologi Kesehatan (Komite PTK) performs economic HTA (not for medical equipment). HTA for medical equipment is rarely performed.</td>
</tr>
<tr>
<td>Iran (Islamic Republic of)</td>
<td>EMR</td>
<td></td>
<td></td>
<td></td>
<td>The HTA office under the umbrella of the Ministry of Health and Education (MOHME) was established in 2008, it produces HTA over health products and medical equipment.</td>
</tr>
<tr>
<td>Iraq</td>
<td>EMR</td>
<td>The lists of medical equipments have been announced on annual basis.</td>
<td></td>
<td></td>
<td>It has been adopted the EMA (European Medicines Agency) and the ICH (International Council for Harmonisation for Pharmaceuticals) guidelines. Inspector General Office performs health economics HTA. Within the MoH, HTA is focused on pharmaceutics not in medical devices.</td>
</tr>
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<td>It is used a Harmonization System code (HS) at the moment. After harmonization GMDN will be used.</td>
<td>We follow the Presidential Decree No. 80 for general procurement. Both, yes and no. Yes, for vertical public hospitals, procurement conducted at national level. No, since re-centralization, procurement of medical devices at province/district's hospital conducted at local level (province and district level); see yanmed on the website.</td>
<td>Inventories are still ongoing.</td>
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The company KIMADIA is responsible for the bulk purchase of medicines, drugs, medical supplies and equipment for whole Iraq on behalf of the MoH. The regulations are pertaining to the procurement aspects.

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The company provides storage, distribution and marketing of medicines and supplies for all Iraq where it is the sole importer of the public sector as well as developing the basic rules for setting the prices for each class of drugs, chemicals and medical supplies to ensure the right price to the citizens and pharmacies and the relevant authorities. Works as well as the allocation of quantities of medicine (drugs and emergency life-saving drugs) as well as the necessary supplies to be used in exceptional emergency circumstances. In addition, to cover part of the needs of the health institutions of medicine and supplies is through national production.

The MoH is working on adapting a national nomenclature system and linking it to the UMDNS.

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The Ministry of Health at a central level keeps updated records on monthly basis for the functional status of the high-cost technologies. 2- World Health Organization is supporting the procurement of 3 CMMS (from GE - Asset Plus) for three Central Maintenance Repair shops in Baghdad, Erbil and AL-Muthanna Provinces. 3- The Inventories for 6 provinces out of 18 are completed and 6 provinces will be supported to carry out a functional inventory for their medical equipment during the current biennium 2010/11. Finally, MS Excel is been used at the hospitals where inventory was carried out.

Data were obtained from the annual report from 2010, issued by the Department of Planning and Human Resource Development at the MoH Iraq.
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<tbody>
<tr>
<td>Ireland</td>
<td>EUR</td>
<td>There are also several National Framework Agreement contracts for the supply of medical devices and equipment. List of reimbursable devices from Primary Care Reimbursement Service (PCRS). List of reimbursable devices from PCRS is available at pcrs website under -&gt; online services -&gt; list of reimbursable items.</td>
<td></td>
<td></td>
<td>Additional HTA contact: deirdre_o’<a href="mailto:halloran@health.gov.ie">halloran@health.gov.ie</a>.</td>
</tr>
<tr>
<td>Israel</td>
<td>EUR</td>
<td>List for procurement/reimbursement — It is part of the National Insurance Law.</td>
<td></td>
<td>It is in the Israeli legislation.</td>
<td>The HTA within the MoH, as well as research centers such as the Israeli Center for Technology Assessment in Health Care (ICTAHC).</td>
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## Annex 1. Additional comments

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<td>Ireland</td>
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<td>Portfolio &amp; Category Management approach involves the development of medical devices/equipment procurement strategies at a national level and the facilitation of regional and local decision making consistent with these strategies and accompanying procedures. Go to the website and search for: services/Publications/corporate/procurementpolicy.pdf. Health Service Executive (HSE).</td>
<td>There are no national inventories available to date. Inventories of medical equipment (including functional inventories) are maintained at a local level. Often there are separate asset management and medical equipment management inventories. There is an initiative to compile this data into regional/national inventories in the near future. There is no common software but a variety of systems are employed including HEX, SAP, MS Access.</td>
<td>Concerning the Infrastructure section: the breakdown of infrastructures does not match to our public sector. We have 7 Hospital Groups.</td>
</tr>
<tr>
<td>Israel</td>
<td>EUR</td>
<td>Contact person: Avi Kravel within the Medical Devices department.</td>
<td>Technical specifications are available only in hardcopy.</td>
<td>All the divisions and departments mentioned in this survey are part of the Medical Technology Administration of the Ministry of Health in Israel. The Administration is in charge of the regulation, licencing and policy making regarding all medical technologies in Israel (including medical devices).</td>
</tr>
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<td>Country</td>
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<tr>
<td>Italy</td>
<td>EUR</td>
<td>Documents are available at the websites. Documents are often updated, and many of them under revision.</td>
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<td>National regulatory authority</td>
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<td>Medical Device incorporation: procurement/donations/technical specifications</td>
<td>Inventories and medical equipment management software comments</td>
<td>General Comments</td>
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<td>Address and contact of the Medical Devices Directorate: Via Molise 2, 00187 Roma, Italy. Tel. +390647051.</td>
<td>CND Classificazione Nazionale dei Dispositivi Medici (correlated with GMDN). CND was nationally developed, and it is the base for EMDN. As mentioned on several occasions in the past, a map of correspondence between the GMDN nomenclature and the Italian CND classification has been created since 2007 to allow manufacturers to register in the Italian database of medical devices. This map is subject to ongoing maintenance even today at the request of manufacturers. This map was introduced at the beginning because the GMDN code was originally the mandatory registration key in the Italian system. Subsequently, the mandatory use of the GMND code was removed at the request of the manufacturers, due to the difficulty of using it and, in many cases, due to its unavailability. In any case, the possibility of using the GMDN code and its connection with the CND is still allowed, but it appears that, despite this possibility of use, the GMDN code is rarely used in the registration in the Italian system. A new version of the Italian medical device nomenclature (CND) will be published within the next months. Because the CND has been chosen as the basis of the EMDN nomenclature, a huge update has been done to create the European nomenclature.</td>
<td>Go to the website and look for: dispositivi/dispomed.jsp documents.</td>
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<td>Country</td>
<td>WHO region</td>
<td>National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement</td>
<td>National list for different types of healthcare facilities (hospitals, laboratories, etc)</td>
<td>National list for specific clinical interventions/ emergencies</td>
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<tr>
<td>Jamaica</td>
<td>AMR</td>
<td>—</td>
<td>—</td>
<td>Not available at present.</td>
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<tr>
<td>Japan</td>
<td>WPR</td>
<td>New medical devices which begin to be reimbursed have been published by the Central Social Insurance Medical Council.</td>
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<td>National regulatory authority</td>
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<tr>
<td>Jamaica</td>
<td>-</td>
<td>The procurement is done at regional and hospital levels.</td>
<td>-</td>
<td>Concerning the HT national policy is stated in the document Ritza 04.</td>
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<tr>
<td>Japan</td>
<td>Japanese Medical Device Nomenclature was developed from the GMDN 2003 version.</td>
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All the updates have been acquired in the new version of the CND, that has been approved by the Italian Technical Committee on 21st December 2020. One of the most important inputs for the CND update was the comparison with GMDN and so an alignment between the first level of the CND 2018 version and GMDN (dataset 01/05/2019) has been done. A list of GMDN codes not covered by CND has been defined and then used to create some new codes in CND. In the Meeting of the Medical Device Nomenclature Working Group-04, OCTOBER 2019 of the European Commission, the state of the art of mapping between CND and GMDN was a point of the agenda. Any further other mapping activities must be agreed upon with the European Commission in line with the provisions of the project itself.
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<th>Country</th>
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<th>National list for different types of healthcare facilities (hospitals, laboratories, etc)</th>
<th>National list for specific clinical interventions/ emergencies</th>
<th>National health technology assessment unit</th>
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<tr>
<td>Jordan</td>
<td>EMR</td>
<td>The list is not published. It is within the updated document of the study department.</td>
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<td>—</td>
<td>We have a list but for a specific departments, it is not published. It is only updated and kept in the Study &amp; Project Department. In the near future it will be published the Essential list at our website.</td>
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<tr>
<td>Kazakhstan</td>
<td>EUR</td>
<td>For list of approved medical devices for procurement we have the Medical State Register of Lekarstennyh.</td>
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<td>Structured HTA capacity building is being developed and implemented in the Department of the Pharmacy Center for Drug Policy and Technology Assessment (CDPTA), King Hussein Cancer Center (third link). Jordan started a hospital-level HTA at King Hussein Cancer Center (KHCC). The CDPTA at KHCC is responsible for conducting HTAs, their assessments are appraised by the Pharmacy and Therapeutic (P&amp;T) Committee and HTA results are currently utilized to support formulary listing decisions.</td>
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<tr>
<td>Kenya</td>
<td>AFR</td>
<td>Lists are developed locally and available in hard copy only. Lists for procedures only cover surgical procedures.</td>
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<td>—</td>
<td>Additional HTA contact: Zaid Zholdassov: <a href="mailto:zholdassov_z@rcrz.kz">zholdassov_z@rcrz.kz</a>. The HTA is focused on pharmaceutics, sometimes performed for medical devices.</td>
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</table>

Kenya: Lists are developed locally and available in hard copy only. Lists for procedures only cover surgical procedures.

It only covers surgical procedures which are locally developed. No available.

The development of HTA framework for health products is in progress.
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<td>It also exists the Energy &amp; Minerals Regulatory Commission.</td>
<td>We support the WHO to adopt a standard nomenclature for medical devices. We used a nomenclature based on UMDNS for management in the CMMS system, and the government procurement department uses UNSPSC nomenclature for procurement purposes.</td>
<td>The procurement is done at a national level by Ministry of Health. Some manufacturers have guidelines and technical specifications such as: ECRI, AAMI, HTM (See: <a href="http://dbe.gov.jo">http://dbe.gov.jo</a>). Although the list is not published neither available online, it’s within the updated document of the study department.</td>
<td>—</td>
<td>Concerning medical equipment management section: we have around 700 type medical equipment tech., spec., updated only in tenders are published; and we have 30 medical equipment, workshops MOH Hospitals.</td>
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<td>National center of examination of drugs (RGP), medical devices and medical equipment nazancheniya (MH RK).</td>
<td>Medical State Register of lekarstennyy.</td>
<td>The procurement is done at a national level with the register of procurement of medical equipment. We have the National Register of medical devices.</td>
<td>Medical State Register of lekarstennyy.</td>
<td>Concerning the Infrastructure section: the division for 20 beds on health centres is not applicable for the Kazakhstan centres network.</td>
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<td>Kenya has demonstrated its commitment to improve the national legal and regulatory framework for radiation safety. Currently, The Radiation Protection Board (RPB) regulates such activities in Kenya, including those with sealed and unsealed radioactive sources as well as X-ray and other radiation-emitting devices.</td>
<td>The GMDN is used for regulatory purposes.</td>
<td>The procurement at a national level is specifically done at the Ministry of Health. Guidelines for donations: IEC 60601, ISO 13485, Directive 93/42/EEC.</td>
<td>Locally developed.</td>
<td>The corresponding technical specifications, as well as donation guidelines are available upon request in soft copy (not pdf versions).</td>
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<td>Kiribati</td>
<td>WPR</td>
<td>We do not have a standard list in place but we do overseas and local procurement for specific medical devices needed for MoH; e.g., in 2009 overseas procurement for medical devices was made through medical healthcare prioritization according to doctors and head nurses. The selection and orders of medical devices were made to medical suppliers (such as South Austral and Braun) taking into account quality, affordability and critical need to meet quality health care services and patient’s safety and satisfaction.</td>
<td>—</td>
<td>We do not have a standard list in place but we do overseas and local procurement for specific medical devices needed for MoH; e.g., in 2009 overseas procurement for medical devices was made through medical healthcare prioritization according to doctors and head nurses. The selection and orders of medical devices were made to medical suppliers (such as South Austral and Braun) taking into account quality, affordability and critical need to meet quality health care services and patient’s safety and satisfaction. In 2010 (8/3/2010) we received some medical devices. Kiribati outbreak manual for public health nurses and curative: national pandemic guidelines, national disaster guideline.</td>
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<td>Kuwait</td>
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<td>The donations are second-hand medical devices from churches (LDS &amp; CCatholics); such as defibrillator, computer, patient monitor-propaq, dressing trolleys.</td>
<td>We have the inventory record and monitoring system with medical stores/clinical wards/community health centres. In the case there is no inventory for specific medical equipment we refer to overseas medical supplier for assistance and good advices. In some cases there is inventory only for high cost technologies (such as MRI, CT or PET scanners).</td>
<td>Medical devices components such as tools, knowledge, skills, repair and maintenance are very crucial and essential therefore Kiribati is very fortunate to be part of this surveillance thus is the only way to maintain our QA/QI (quality assurance and quality improvement) to achieve MoH objectives (utilization of quality medical/nursing care to all Kiribati individual patient/client to provide patient’s safety, quality health care services and patient’ satisfaction). We would appreciate being advised in ongoing training especially for nurses.</td>
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<td>Kyrgyzstan</td>
<td>EUR</td>
<td>Standards: The law on the Health Care institutions. We have lists for communicable diseases, and public health emergency situations, as well as clinical protocols. The register of registered medical equipment is made at the website of the Department of Drug Provision and Medical Equipment MoH of the Kyrgyz Republic.</td>
<td>Equipment timesheets are available, but without the use of nomenclature.</td>
<td>Clinical protocols.</td>
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<td>Lao People’s Democratic Republic</td>
<td>WPR</td>
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<tr>
<td>Latvia</td>
<td>EUR</td>
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<td>Regulation of Cabinet of Ministers No. 60.</td>
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<td>National regulatory authority</td>
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<td>The nomenclature is used for various purposes: regulation, procurement, in-vitro diagnostics lists and inventory.</td>
<td>Kyrgyz Republic National Health Care Reform Program “Manas taalimi”. Procurements are carry out through the National (budget) or donor projects.</td>
<td>The National Register for Medical Equipment and the National Functional Register for Medical Equipment. The National Functional Register for the Medical Equipment is a database for medical facilities of the public health institutions; meanwhile, the National Register of the Medical Equipment is a national list of pharmaceuticals and medical equipment authorized and registered for utilization in the Kyrgyz Republic. A database is employed for material and technical facilities and medical facilities of public health institutions.</td>
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<td>There is the political will to strengthen the Nuclear and radiation safety and security, as well as the corresponding legal framework (as seen in the 2020-2025 plan).</td>
<td>The procurement at a national level is only for sophisticate and high-value equipment.</td>
<td>In the whole country, the inventories are ongoing.</td>
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<td>The procurement of national devices at a national level started from the year 2010.</td>
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<td>Lebanon</td>
<td>EMR</td>
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<td>Lesotho</td>
<td>AFR</td>
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<tr>
<td>Liberia</td>
<td>AFR</td>
<td>Lists of standards and lists are: “Basic Package of Health Services” which contains a list of the equipment at the “annexe”. However, the list is subject to revision. The WHO guidelines are being used for donations. The process has been initiated for the adaptation of the guidelines.</td>
<td>-</td>
<td>The list of equipment can be found in the index of the following document: Basic Package of Health Services. However, the list is subject to revision.</td>
</tr>
<tr>
<td>Libya</td>
<td>EMR</td>
<td>There are national standards lists but they are not written. There are lists for Sundries Hospital consumable- Diagnostics Laboratory 37/3.</td>
<td>-</td>
<td>There are national standards lists but are not written. It exists also lists for interventions, and emergencies. See the following file: General_terms_and_conditions_for_medicines_and_medical_consumables_and_equipment.</td>
</tr>
<tr>
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<td>It controls the importation of all radiological devices (x-ray devices, tracers for nuclear medicine, etc.).</td>
<td>The Ministry of Health is planning to acquire the Global Medical Devices Nomenclature system to adopt it and use it for regulatory and procurement purposes.</td>
<td>The procurement of medical equipment for public hospitals is done by the Council for Development and Reconstruction in coordination with the Ministry of Public Health. A procurement procedure and bidding documents are used and adapted according to the specific project and considering the government rules for procurement. No guidelines exist in the private sector that is dominating the health sector (80% of beds are private).</td>
<td>The Ministry of Health has acquired a GIS licence to establish a database which will include the available high-cost technologies.</td>
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<td>Currently, there is a National Drug Regulatory Authority that is in the process of institutionalization.</td>
<td>No comments as the nomenclature does not exist.</td>
<td>The procurements are based on the WHO guidelines and they are mainly organized through partners.</td>
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<td>The Medical Supply Organization (MSO) is responsible for the procurement of medical appliances for the public sector.</td>
<td>For the medical equipment list, it is used a nomenclature based on the UMDNS. The nomenclature is used for inventory systems of healthcare facilities and lists.</td>
<td>In regards to the technical specifications of medical devices, we depend mainly on the technical committees which consist of experts in medicine, pharmacy and biomedical engineer. These committees set up decrees issued by the Secretariat of Health.</td>
<td>The last version is from 2006.</td>
<td>This is the first time for us to participate in this survey. Our standards and policies are under development and/or being updated. Many issues in this survey are available but still not documented.</td>
</tr>
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<tr>
<td>Lithuania</td>
<td>EUR</td>
<td>Licensing regulations for health care facilities. General and specific requirements for institutional health care services. There is a list of medical devices that are mandatory for specialized and surgical health care services. Public Procurement Office operating under the Ministry of Economy, compiles the list of drugs and medical supplies, annually. The list is approved by the Minister of Health. The items included in this list are procured in a centralized way. The procurement expenses are disbursed from the National Health Insurance Fund Budget. The National Health Insurance Fund under the Ministry of Health is responsible for public procurement of the items of the list, mentioned above.</td>
<td>These are lists of indications and reimbursement regulations for expensive health technology examination techniques (e.g. CT, MRI) and diagnostic procedures (e.g. diagnostic interventional procedures). Only available in Lithuanian language. General and specific requirements for institutional health care services. There is a list of medical devices that are mandatory for specialized and surgical health care services. There are no separate lists of communicable or non-communicable diseases.</td>
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<tr>
<td>Luxembourg</td>
<td>EUR</td>
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<tr>
<td>Madagascar</td>
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Luxembourg: Contains particularly in the plan pandemic grippe qui n’est pas sur l’internet public.
### Annex 1. Additional comments

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<td>Guidelines for procurement of expensive health technologies (i.e. MRI, CT etc.). Guidelines are in the Lithuanian language only. There are basic requirements for technical specification of medical devices that are procured in a public centralized way.</td>
<td>The State Health Care Accreditation Agency, under the Ministry of Health, is responsible for the management of national data regarding expensive health technologies (i.e. MRI, CT, etc.).</td>
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<td></td>
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<td>Software choisi par chaque hôpital individuellement.</td>
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<td>Nomenclature nationale pour la comptabilité matière du patrimoine de l’État (codification pour l’inventaire technique).</td>
<td>Specifications techniques pour: Matériels et équipements pour les Centres de Santé de base; matériels et équipements de laboratoire pour les Centres Hospitaliers de Districts de niveau 2; matériels et équipements biomédicaux et hospitaliers pour les Centres Hospitaliers de Districts de niveau 2.</td>
<td>Inventaire effectué en 2007 avec le projet CRESAN 2 (55 Centre Hospitalier de District de niveau 1 (CHD1), 29 Centres Hopsitaliers de Districts de niveau 2 (CHD2), 18 Centres Hospitalier de Référence Régionale (CHRR), 10 Centre Hospitalier Universitaire (CHU) et Etablissements Sanitaires. Mise à jour en cours.</td>
<td>Formation en maintenance biomédicale à Madagascar: Depuis 1980, la multiplication des établissements hospitaliers et l’avènement des nouvelles technologies au service de santé ont induit une arrivée massive et diversifiée d’appareillages biomédicaux et ont fait apparaître le problème crucial de leur maintenance. La dernière action de recyclage (formation continue) des techniciens date de 2001.</td>
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<tr>
<td>Country</td>
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<td>Malawi</td>
<td>AFR</td>
<td>The standard list provided is for health centres, community hospitals and district hospitals. The standard list for central hospitals is being developed and will be published very soon (file names: &quot;jica&quot; and &quot;customer&quot;, respectively).</td>
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<tr>
<td>Malaysia</td>
<td>WPR</td>
<td>The corresponding lists are only prepared based on the needs.</td>
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<td>There is no standardized list. It is based on needs.</td>
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<td>Maldives</td>
<td>SEAR</td>
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| Radiation protection and nuclear safety is done via AERA and it is in process of institutionalization. | | There are the following pdf files: the "Public Procurement Act (2003)", the "Desk Instructions", and the "Procurement Regulations". | The inventory is in a database known as "Planning and Management of Assets in Health Sector (PLAMAHS)" and is not yet online. | |}

The Medical Device Act 2012 (Act 737) has come into force on June 30th 2013, while the effective date for its subsidiary legislations, the Medical Device Regulations (MDR) 2012 was on July 1st 2013. Act 737 provides two and one years, respectively, of a transition period for the industry to submit applications for medical device registration and establishment licensing before the law is fully enforced. It exists a separate unit for the regulation of radiological equipment (i.e. within the Ministry of Energy): Radiation Health and Safety Section, Engineering Services Division, Ministry of Health Malaysia: https://radia.moh.gov.my/. The Atomic Energy Licensing Act 1984 (Act 304) provides the regulation and control of irradiating apparatus.

Depending on the types of Medical Devices. Some are procured at a national level, some at the state level and some at the hospital level.

The procurement is done at a national level as well as for government health facilities.
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<tr>
<td>Mali</td>
<td>AFR</td>
<td>Il n’existe pas de normes nationales pour des procedures spécifiques, en général elles sont traitées au cas par cas. Non, comme décrit précédemment, il n’existe pas de liste spécifique de dispositifs médicaux pour les cas cités. La liste de dispositifs médicaux approuvée est en fait par niveau de structures sanitaires. À ce jour nous disposons de listes standard d’équipements pour les structures de base (CSCOM - centre de santé communautaire) et les structures de première référence (CSREF - centre de santé de référence) que nous utilisons dans nos différents dossiers d’appel d’offres d’acquisition de dispositifs pour celles ci. Pour les hôpitaux nous essayons d’harmoniser, car les structures diffèrent un peu, en fonction de la population, de l’éloignement et de la position géographique.</td>
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The HTA is at initial stages to inform health policy and products but not for medical equipment.
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<td>Il existe dans le document de la comptabilité matière une rubrique nomenclature sommaire ou les différents produits sont classés par catégories, mais c’est un domaine très important qui mérite une action.</td>
<td>Guidelines for procurement: existe un document de projet de politique nationale en matière d’équipements et d’infrastructures sanitaires qui traite ces cas, mais il reste à être validé. Jusqu’à l’adoption de la loi hospitalière. La DFM était le seul organe d’achat de dispositifs médicaux. Vue que cette loi accorde un statut particulier à certaines structures sanitaires notamment l’autonomie de gestion, mais aussi dans le cadre de la décentralisation il y a le transfert de compétences entre le Ministère de la Santé et les collectivités territoriales, de sorte que ces structures peuvent acheter indépendamment</td>
<td>Chaque année le Ministère de la santé à travers la DFM organise des inventaires mixtes dans lesquels participent comptables matières et techniciens biomédicaux, dans toutes les structures sanitaires du pays (centres de santé communautaire (cscom), centre de santé de référence (csréf) et hôpitaux régionaux (HR). Ensuite les différentes fiches sont compilées et informatisés au niveau de la division comptabilité matières.</td>
<td>Concerning the Infrastructure section: nous n’avons pas encore une politique nationale pour les équipements mais nous y travaillons, nous avons tenu deux ateliers: l’un pour l’élaboration des éléments de la politique et l’autre pour la rédaction du document de politique. Le document attend sa validation lors d’un atelier national pour être soumis à l’Assemblée Nationale. Concerning the Section Infrastructure: la Division établissements sanitaires et réglementation (DESR) à la Direction Nationale de la Santé s’occupe également des établissements privés de santé mais ne dispose pas de données à jour (2010) sur leur nombre exact.</td>
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<td>Malta</td>
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<td>Marshall Islands</td>
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<td>Procurement at national level: there is a strong collaboration between the two. For capital expenditure for new technologies it is usually the department, for others it is usually coordinated by the hospital itself.</td>
<td>The name of the Software is Clingo from the company Carestream Health Italia SRL.</td>
<td>The Ministry of Health has started to provide emphasis on new health technology and its assessment. Over the last 2 years, it has been developed a short form and guidelines for the completion of all the requests for the implementation of new health technologies and services. Together, the Director Generals for Strategy &amp; Sustainability, and Healthcare Services have met three times a year to evaluate the proposals received. It is envisaged that a health technology evaluation unit will be developed in the short term.</td>
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<tr>
<td>Malta</td>
<td>EUR</td>
<td>Office of the Chief Medical Officer is in charge to perform HTA, mainly in pharmaceutics.</td>
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<tr>
<td>Marshall Islands</td>
<td>WPR</td>
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<td>Inventory is not available.</td>
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<td>Mauritania</td>
<td>AFR</td>
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<td>Il existe des paquets d'activités par niveau des soins de la pyramide sanitaire.</td>
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<td>Direction de la Medecine Hospitaliere qui a l’attribution de élaborer et suit la réglementation et les normes hospitalières, et prépare l’autorisation d’ouverture a titre privé des cliniques et des cabinets de soins infirmier. Inspection General de la Santé (IGS) a l’attribution de vérifier la gestion des activités de l’ensembles des services du departement et des organes sous tutelles, et leurs conformité aux lois et reglement en vigueur cf voir organigramme du ministere de la santé qui se trouve dans le site web du ministere.</td>
<td>Il existe un plan de passation des Marchés (search for the document admin07 in the specified website). Il existe le Centrale d’Achat des Médicaments, Equipements et Consommables Médicaux (CAMEC) en ce qui concerne la procuration des équipements médicaux: <a href="http://www.camec.mr/">http://www.camec.mr/</a></td>
<td>Un inventaire technique national était disponible dans une base de donnée informatisée (GMAO) qui est malheureusement défectueuse depuis 2004, et qui n’a jamais été actualisé au niveau national.</td>
<td>Le suivi de la maintenance des équipements est une mission confiée à la Direction des Infrastructures, du Matériel et de la Maintenance (DIMM) et mis en œuvre par le service de la Maintenance.</td>
<td>Le service de la maintenance comprend deux divisions :- Division de la maintenance des infrastructures; - Division de la maintenance des équipements et des matériels. Le service de la maintenance dispose d’un plateau technique composé, au niveau central de 7. techniciens biomédicaux, de 2 ingénieurs biomédicaux et d’un ingénieur électrotechnicien, au niveau périphérique de : 5 unités régionales, qui assurent une maintenance de proximité. La qualité du service est insuffisante dans la quasi-totalité des structures de maintenance lié à la perception même de la composante maintenance, qui n’est généralement pas prise en compte lors de l’élaboration des projets et de certaines défaillances au niveau du développement des compétences (formations spécialisées, stages de perfectionnement pour les experts etc.) et autres moyens (financier, outillages etc.) pour l’exécution des activités de maintenance (préventive, curative etc.).</td>
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<tr>
<td>Mauritius</td>
<td>AFR</td>
<td>Some lists are available for certain specific conditions e.g pandemic, fogging, sprayers, etc. (an specific Plan is in preparation), there are no specific lists for non-comunicable nor communicable diseases. It must be pointed out that the Ministry does not accept all donations except from friendly countries.</td>
<td>—</td>
<td>Some lists are available for certain specific conditions e.g Pandemic, fogging, sprayers, etc. There is no specific list for Communicable Diseases but a PLAN is in preparation.</td>
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<td>Mexico</td>
<td>AMR</td>
<td>See “cuadro básico”. The list is under new policies.</td>
<td>The lists are updated constantly.</td>
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<tr>
<td>Radiation Protection Authority for Radiation.</td>
<td>We import all our devices.</td>
<td>Central Procurement Board has a policy. However, there is an equipment committee which looks after procurement of equipment spare parts. For public sector procurement is done at a level of the Ministry of Health and the central procurement board. Private equipment is done by direct purchase. In the public sector, we recommend certification based on the FDA, CE and TUV approved systems.</td>
<td>Each hospital has a separate inventory. Concerning Software there is one developed locally which is currently on trial. E-health is in preparation.</td>
<td>Concerning the HT national police it is stated in following document: politique santé.</td>
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<td>—</td>
<td>The nomenclature system is established and organized in charts for health technologies that can be used in public/social health services. As for the government administration for 2018-2024, the charts will be organized now as a compendium and it is in process of depuration (<a href="http://www.csg.gob.mx/Compendio/CNIS/cnis.html">http://www.csg.gob.mx/Compendio/CNIS/cnis.html</a>). The nationally developed nomenclature has been tailored to regional terms adopted by hospitals based on the same coding as the GMDN.</td>
<td>There are some recommendations for this topic, but they are not policies. The specifications are only recommendations.</td>
<td>Subsistema de Información de Equipamiento, Recursos Humanos e Infraestructura para la Atención a la Salud (Subsystem of Equipment, Human Resources and Infrastructure in Health). There are not only one, in general these are made in each one of the units for their particular needs.</td>
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<tr>
<td>Country</td>
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<tr>
<td>Micronesia (Federated States of)</td>
<td>WPR</td>
<td>—</td>
<td>—</td>
<td>There are no lists available.</td>
<td>The unit of Budget and Planning with the department of finance and administration (DOFA) performs economic analysis, however, there is no HTA for medical products.</td>
</tr>
<tr>
<td>Monaco</td>
<td>EUR</td>
<td>—</td>
<td>—</td>
<td>There are &quot;Plans d’urgence&quot;.</td>
<td>La Direction de l’Action Sanitaire pourrait commander évaluations des technologies de Santé.</td>
</tr>
<tr>
<td>Mongolia</td>
<td>WPR</td>
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<tr>
<td>Montenegro</td>
<td>EUR</td>
<td>There is a list of medical devices (based on the opinion of a team of doctors) that are provided or reimbursed to the patient by the Health Insurance Fond. The list is created as a result of different indications mostly for treatment, alleviation or compensation for an injury or disability. There is the Law on Protection of Population against Communicable Diseases. Also, we have a national strategy for an emergency which is involved as a part of the public health emergencies policy (see link).</td>
<td>—</td>
<td>There are no national standards for medical devices, but Competent Authority, in accordance with the law on medical devices recognize appropriate international standards (EC, ISO). There is the Law on Protection of Population against Communicable Diseases. Also, we have National strategy for emergency situation, which involves part about public health emergency situations (see link). The lists are published in Montenegrin language.</td>
<td>There is no HTA framework yet, but there is positive political will.</td>
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<tr>
<td>National regulatory authority</td>
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<td>Medical devices may be purchased by the National Department of Health &amp; Social Affairs, or the State Health Services. At a national level purchases are made by the coordinator of the program receiving the grant or funds for the purchase in consultation with the department to receive the device (e.g. manager of state hospital radiography department, or chief of ancillary services). Guidelines are only for competitive quotes or bidding processes.</td>
<td>The National Department of Health and Social Affairs, as well as state health services, keep assets registries for fixed assets over $1,000. Medical Devices will be included on these registers. Individual units (e.g. state laboratory) should have a functional inventory of devices/equipment.</td>
<td>There is limited expertise in the country. There are no qualified radiographers nor pathologists. Only 3 over 30 laboratory technicians have a bachelors degree in medical laboratory science.</td>
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<td>“Register (notification) of medical devices” that contains information on medical devices which are available for use in Montenegro has just recently been set up. As it is at the start of its operations, it will use GMDN as a referent nomenclature system and based on this, it will be developed a system that will be in Montenegrin language so that all users can use it properly and they will have information what is on Montenegrin market as well.</td>
<td>The procurements of medical devices for public health institutions are in conformity with Law on public procurements. We recognize international standards in accordance with a law on medical devices.</td>
<td>There are no specific national inventories but every year the Government of Montenegro provides a specific amount of money that can be used in special cases (public health emergency etc.).</td>
<td>Concerning the Infrastructure section: We would like to inform you that we have specialized hospitals for only one speciality as psychiatric, orthopaedic and lungs diseases. We have 3 institutions like this.</td>
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<tr>
<td>Morocco</td>
<td>EMR</td>
<td>Des listes standardisées de dispositifs médicaux pour différents établissements de soins sont établies au niveau de la DEM.</td>
<td>—</td>
<td>Concernant les points &quot;b&quot; et &quot;c&quot; des listes sont établies au niveau de la DEM. La DELM prend en charge les points &quot;a&quot; et &quot;b&quot; aussi (see comments of other lists).</td>
<td>Adopted EMA (European Medicines Agency) and ICH (International Council for Harmonisation for Pharmaceuticals) guidelines. Inspector General Office performs health economics HTA. Within the MoH, HTA is focused on pharmaceutics but not in medical devices.</td>
</tr>
<tr>
<td>Mozambique</td>
<td>AFR</td>
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<td>—</td>
<td>The Department of Health Information (DIS), Ministry of Health (MISAU), performs HTA for technologies related to prevention and control of diseases, but no specifically for medical devices.</td>
</tr>
<tr>
<td>Myanmar</td>
<td>SEAR</td>
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<td>It has started the development of HTA systems by establishing nodal agencies and conducting ad-hoc activities.</td>
</tr>
<tr>
<td>Namibia</td>
<td>AFR</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>MoH uses HTA for both regulatory and coverage purposes. Not performed for medical devices. However, an HTA has yet to be elevated to the national agenda. There is a written HTA guideline, and formal identification of technologies for HTA.</td>
</tr>
<tr>
<td>Nauru</td>
<td>WPR</td>
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<td>SPC assist us with our supplies for the Pandemic preparedness but we do not have a list as most of these are consumables.</td>
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</table>

Global atlas of medical devices 2022

A78
<table>
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<tr>
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<tr>
<td>—</td>
<td>Nomenclature basée sur l'ECRI et le CNEH.</td>
<td>Un projet de mise en place d'une stratégie Nationale en matière de gestion des T.S est en cours. Les spécifications techniques sont établies selon les besoins des utilisateurs (grands projets de CHUs) et standardisées pour chaque type d'établissement de soins.</td>
<td>La majorité des inventaires des régions sont sur support papier et non encore informatisé. L'alimentation de la base de données du progiciel de gestion des dispositifs médicaux est en cours.</td>
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According to the Atomic Energy and Radiation Protection Act No. 5 of 2005.

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There are guidelines for Implementation of the National Health care Technology Policy & Medical Equipment Management. Since finances have been decentralised, each of the 13 political regions is responsible for budgeting and procuring medical equipment for the health facilities in that region. Advise on budgeting and tender specifications can be obtained from MEM at a National Level.

Medical Equipment Management System Software (MEMS).

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The procurement for the medical devices is based on the Hospital’s Senior Management Team decision and the availability of the fund.

We keep an asset register at the Administration Office and the Pharmaceutical Store which include all the medical equipment in the hospital.

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<tr>
<td>Nepal</td>
<td>SEAR</td>
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<td>There are identified HTA activities but not national unit per se. However, there is research in the health unit within the MoH. The HTA under the government umbrella is in progress and a requirement to reach the Universal Health Care country goal.</td>
</tr>
<tr>
<td>Netherlands</td>
<td>EUR</td>
<td>The health insurance scheme takes care of the reimbursement of extramural medical devices in the Netherlands. The reimbursement of medical devices is function orientated.</td>
<td>-</td>
<td>In the Netherlands, the professional has to decide, recommend or indicate a medical device. The cupola of the professionals can publish a guideline for specific procedures. There is no national policy on diseases or situations.</td>
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<tr>
<td>New Zealand</td>
<td>WPR</td>
<td>Under New Zealand law there is no approval system for medical devices and hence no pre-market scrutiny of their safety and performance. There is a legal requirement for the sponsor (importer/exporter/supplier) of a medical device (with some exceptions) to notify the device to a database maintained by Medsafe within 30 working days of becoming the sponsor for the device.</td>
<td>-</td>
<td>-</td>
<td>National Health Committee performs HTA in several areas, but not for medical devices.</td>
</tr>
<tr>
<td>Nicaragua</td>
<td>AMR</td>
<td>-</td>
<td>-</td>
<td>The Ministry of Health does not have lists recommending health technology for different diseases or situations.</td>
<td>There are identified HTA activities but not a national unit.</td>
</tr>
<tr>
<td>National regulatory authority</td>
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<td>We follow the Public Procurement Act and the regulation of Nepal for procurement of medical devices also. Also, it is partially carried out at national level procurement of medical devices.</td>
<td>Working on to develop national inventories.</td>
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<td>Nu</td>
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<td>For vigilance and post market surveillance (more info in the medische-hulpmiddelen corresponding link).</td>
<td>There is the Commission decision of 7 May 2002 on common technical specifications for in vitro-diagnostic medical devices.</td>
<td>The Netherlands has no national inventory for medical devices.</td>
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<td>National requirements apply only to procurement of electro-medical devices through a set of AS/NZ standards such as AS/NZ3551:2004 which are mandated under a national law. Government publishes standards that are applicable to some devices.</td>
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<td>Although we do have an official nomenclature system for medical devices, it is not use for various reasons.</td>
<td>The procurement department works as a team with the Health Services Department, the Sanitary Regulations Department and the Acquisition Unit of the Ministry of Health.</td>
<td>This inventory was carried out for the maintenance unit (CEMED). The last update was in 2009.</td>
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<td>The definition of medical device used in NZ law (the Medicines Act 1981) is not currently aligned with the GHTF approach. Consequently, some products that are regarded as devices in other countries are currently regulated as medicines in NZ. Examples include pregnancy tests, condoms with spermicide, IUCDs with copper and nasal irrigation solutions.</td>
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<td>Our Ministry of Health is doing big efforts to normalize and regulate the procurement of medical devices, but we do require training for our personnel to perform a better job. We also have limitations in providing maintenance to the acquired equipment.</td>
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</tr>
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<td>Niger</td>
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<td>Nigeria</td>
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<tr>
<td>Niue</td>
<td>WPR</td>
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<tr>
<td>North Macedonia</td>
<td>EUR</td>
<td>The reimbursement is performed by the National Health Insurance Fund, the list of medical devices that are reimbursed are posted on the &quot;fzo website&quot;. In public health facilities the procurement is currently going through a public competition with those medical devices that have entered the register of medical devices.</td>
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</table>

Three organisms perform HTA at a national level: The Agency for Food and Drugs Administration and Control (NAFDAC), Nigeria Institute for Pharmaceutical Research and Development (NIPRD) and the National Health Insurance Scheme,(NHIS). The action plan 2018-2021 of the MoH states the progress to a National Quality Review & Health Technology Assessment Systems to determine which health interventions are cost effective including medical devices (see fourth link). HTA is a pillar for UHC’s goal.

There is not an HTA national unit yet per se but it has been acknowledged at a political level by the MoH. There are HTA activities for the selection of specific medicines. It exists a Centralized System for external price referencing and decentralized procurement prices of non-prescription medicines and devices.
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<td>No, but we are recognising GMDN code.</td>
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<tr>
<td>Norway</td>
<td>EUR</td>
<td>A few devices - those being reimbursed via the blue prescription system i- are listed. Lists are made by The Norwegian Labour and Welfare Administration, refer to the procurement of medical devices at national level section.</td>
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<tr>
<td>Oman</td>
<td>EMR</td>
<td>—</td>
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<td>Medical devices for specific procedures, whenever required, are prepared or modified based on the requirement from end users. Available at Directorate of Medical Technologies.</td>
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<tr>
<td>Pakistan</td>
<td>EMR</td>
<td>—</td>
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<td>The provinces develop their lists of equipment based on their health facilities, the available funds, and according to the Priced Vocabulary of Medical Stores (PVMS) (Available). World Health Organization Pakistan share such lists with the Ministry of Health at time of emergency.</td>
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<tr>
<td>Palau</td>
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<tr>
<td>The Directorate of Health, Department of medical devices and medicinal products is the Competent Authority for medical devices in Norway, it has the tasks of the competent authority as they are given in the European directives for medical devices. These tasks, however, are not identical with those listed under the corresponding ones of this survey.</td>
<td>The use of GMDN is not imposed by law.</td>
<td>Only procurement of devices being reimbursed via the blue prescription system is carried out at a national level, by The Norwegian Labour and Welfare Administration.</td>
<td>—</td>
<td>Concerning the HT national policy, it was provided the following document: plan van aanpak patientveiligheid medische technologie.pdf. Concerning the infrastructure section: As of 01.01.2009: 11 885 beds in specialised healthcare. 117 of these are in the private sector.</td>
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<td>The WHO country team helped the Ministry of Health in drafting rules for regulations of medical devices, but they are not applicable after the 18th amendment.</td>
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<td>The procurement guidelines are available at the Directorate of Medical Technologies.</td>
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<tr>
<td>The procurement service rules 2003 (KPK) issued by the finance department. The procurement is carried out at a provincial level and identified by SPRA etc. There is a National inventory for medical equipment.</td>
<td>A national inventory was previously maintained but now is at a province/region level, it is in pipeline.</td>
<td>—</td>
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<tr>
<td>After the 18th amendment and devolution of the MoH, no person nor authority can provide information, the WHO as convening body of health systems in Pakistan collected the information separately from all regions/provinces then the information was compiled by the WHO focal person of health technologies.</td>
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<tr>
<td>Panama</td>
<td>AMR</td>
<td>Available at the specified website.</td>
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<td>Papua New Guinea</td>
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<td>Paraguay</td>
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<td>Peru</td>
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<td>El sistema UMDNS ha sido adoptado en la legislación. Su implementación está aún en proceso.</td>
<td>La Caja de Seguro Social hace sus procesos de adquisición de forma independiente del Ministerio de Salud pero sujeto al sistema de Fichas Técnicas Nacionales en cuyas confecciones también participa.</td>
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<td>Se está elaborando un plan para proceder con la instalación de un sistema de nomenclatura.</td>
<td>Procurement guidelines: se inició la elaboración de directrices.</td>
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<td>Ley Nº29459-D.S and the D.S. Nº 016-2011-SA.</td>
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<tr>
<td>Philippines</td>
<td>WPR</td>
<td>The lists are limited to diagnostics, no interventional equipment noted (i.e., ECMO, DaVinci, etc.)</td>
<td>—</td>
<td>This is part of the requirements for the licensing of health facilities. The given URL is for general surgery. The indicated website can be browsed for other recommended medical devices for other procedures.</td>
<td>HTAC has one biomedical engineer and one medical physicist.</td>
</tr>
<tr>
<td>Poland</td>
<td>EUR</td>
<td>The Polish competent authority for medical devices is the Office for Registration of Medicinal products, Medical devices and Biocidal products, which keeps the register of medical devices in a database; it is only used for market surveillance and vigilance purposes. On Polish market can be placed all CE-marked medical devices according to current EU regulatory framework and directives (90/385/EEC; 93/42/EC; 98/79/EC).</td>
<td>There are no lists, but basic (minimal) requirements regarding the necessary medical devices that are a part of the health benefit package regulations and are created concerning the type of facility (including specialisation) and with clear-cut requirements on specialised health care services.</td>
<td>There are no lists, but basic (minimal) requirements regarding the necessary medical devices that are a part of the health benefit package regulations and are created concerning the type of facility (including specialisation) and with clear-cut requirements on specialised health care services.</td>
<td>AOTMiT evaluates pharmaceutical and non-pharmaceutical technologies including medical devices assessment. The Agency for Health Technology Assessment and Tariff System evaluates pharmaceutical and non-pharmaceutical technologies including medical devices assessment.</td>
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<tr>
<td>Portugal</td>
<td>EUR</td>
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<td>Functions of Infarmed: Research, assessment, registration, monitoring and supervision of health products. Clinical research evaluation, assessment and registration of CE marked medical devices, notification of health care products and market supervision activities.</td>
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<td>The Philippines will be using the Nomenclature that will be decided by the member states of the ASEAN who are working on the harmonization of medical device regulation in the region, where medical device nomenclature is one of the concerns.</td>
<td>The procurement for a medical device is part of the National Procurements system of the Philippine Government (see website). Procurement of medical devices can be done at a national level, at a regional level and local government units.</td>
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<td>The Ministry of Health is the national regulatory authority in the area of the health system and The Office for registration of Medicinal Products, Medical Devices and Biocidal Products is the polish competent authority responsible for cooperation with European Commission in the medical device regulatory area. Another regulatory agency is the Market Surveillance, Vigilance system, Clinical trial registration and Inspection, Cooperation with the European Commission and other Competent Authorities.</td>
<td>The GMDN code is mentioned as a basic medical device nomenclature system in Polish legislation: Act of 20 May 2010 on Medical Devices; however, the use of other nomenclatures is allowed. Poland is part of the EU medical device regulatory framework so a new obligation from the European Commission in the area of medical device nomenclature and Eudamed will be implemented, e.g. adopting the European Medical Device Nomenclature (EMDN) when available. Nevertheless, according to the EC statement, this nomenclature will still share some features with the GMDN code.</td>
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<td>-</td>
<td>Nomenclature is used for the registration of Medical Devices &amp; IVDs.</td>
<td>Go to the website and search for the &quot;contratoasequisicoes&quot; documents.</td>
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<tr>
<td>Qatar</td>
<td>EMR</td>
<td>There are functional inventory of medical devices for procurement and/or reimbursement in HMC hospitals. HMC disciplines occupies functional inventory of medical devices for prompt delivery of patient care services. Emergency preparedness policy reference.</td>
<td>-</td>
<td>HMC disciplines occupies functional inventory of medical devices for prompt delivery of patient care services. It exists the emergency preparedness policy reference (including lists) too.</td>
<td>There are identified HTA activities. HTA consultancy is required for building high-level infrastructure and there is the formation of an HTA workforce but there is not a national unit. Drugs pricing falls on External Reference Pricing stated in the national objectives towards Universal Health Care (UHC) implementation goal.</td>
</tr>
<tr>
<td>Republic of Korea</td>
<td>WPR</td>
<td>The Health Insurance and Review Assessment (HIRA) is responsible for listing treatment materials for public insurance.</td>
<td>-</td>
<td>-</td>
<td>HTA is performed in a variety of health areas including medical technologies, devices, interventions, etc.</td>
</tr>
<tr>
<td>Republic of Moldova</td>
<td>EUR</td>
<td>A special group of Agency of Medicines and Medical Devices organise the procurement of medical equipment from the state budget.</td>
<td>-</td>
<td>Medical standards on diagnostic and treatment for pathological conditions in surgery, therapeutic profile for adults and children, have been developed. Also, development of guidelines is based on international recommendations for family physicians and blood transfusion agencies.</td>
<td>There are identified HTA activities but not a national unit per se.</td>
</tr>
<tr>
<td>Romania</td>
<td>EUR</td>
<td>-</td>
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<td>-</td>
<td>Several national entities are in charge of performing HTA activities, each one focus in various areas (see corresponding links).</td>
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<td>If ever a private agency, hospital or clinic needs a specific product they should approach the Medical Licensing which in turn seeks technical evaluation (such as specification, safety, compliance, etc.) from the Bio-Medical Engineering to import the product to the country. Bio-Eng does verify FDA, CE and/ or equivalent compliance on medical device/ equipment for safety, especially for Hamad Medical Corporation (HMC) hospitals.</td>
<td>This is used for planning of medical equipment for new / upcoming projects.</td>
<td>The specification compliance on safety and clinical requisites is regularly updated. The Hamad Medical Corporation (HMC) Materials Management and Tender committee take over the procurement activities of Medical and Non-Medical Equipment/ items for HMC hospitals, and the ministry upon request, as deem necessary. Specification of equipment formulated in cooperation with end-user prepared by Bio-eng.</td>
<td>Maintained GE AssetPlus for the functional inventory of Medical equipment for the Hamad Medical Corporation (HMC), hospitals and Public Health Care Centers.</td>
<td>List of accredited HMC hospitals: Hamad General Hospital, Women's Hospital, Rumailah Hospital, Al Amal Hospital, and Al Khor Hospital. Emergency Medical Services (EMS), Pediatric Emergency, Trauma Centers, Orthopedic Center, Dental and School Health, Home Healthcare, Primary Health Centers, Skilled Nursing Facility. Upcoming projects: Qatar Heart Center, New Children's Hospital, Al-Wakra Hospital. Please visit the Hamad Medical Corporation website (<a href="http://www.hamad.qa">www.hamad.qa</a>) and the Qatar Supreme Council of Health website (<a href="https://www.moph.gov.qa/">https://www.moph.gov.qa/</a>) for more details.</td>
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<tr>
<td>The National Center of Public Health is ensuring the control of the rules of utilization of X-Ray equipment in all medical institutions of the country.</td>
<td>National and public hospitals purchase medical equipments according to the general procurement procedures.</td>
<td>The inventories for medical devices are not managed by the government.</td>
<td>Concerning the Infrastructure section: Korea Health Center is down to 29 beds.</td>
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<td>Procurement guidelines: Government Decree No. 568 (10.09.09). Guidelines on technical specifications: Decree 190 from 25.06.2009 establishes standard specifications for biochemical and immunology test.</td>
<td>It is not developed. A project to support management of medical equipment is being developed: openMedis.</td>
<td>The strategy to develop Health System during the period 2005-2017 as well as the Plan of Action contains specific goals on strengthening the bases of technical material for healthcare.</td>
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<td>The procurement of high technologies devices is carried out at national level. Go to the website and search for the corresponding documents.</td>
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<td>The HTA system development is inserted in the Russian Federation healthcare legislation. Currently, the procedure for a comprehensive assessment of drugs has been approved and is constantly being improved. However it is still at their start phase for medical devices and biomedical products.</td>
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<td>Rwanda</td>
<td>AFR</td>
<td>—</td>
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<td>—</td>
<td>There are identified HTA activities which are specifically done in pharmaceutics for pricing and reimbursements as well as health economics; however, there is no national unit.</td>
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<td>Saint Vincent and the Grenadines</td>
<td>AMR</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>There are identified HTA activities but not a national unit. The development of one is in progress.</td>
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<tr>
<td>Samoa</td>
<td>WPR</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>Please refer to Biomedical Engineering Unit Head, Mr. Galuafi Vaoga at email: <a href="mailto:biomed@nhs.gov.ws">biomed@nhs.gov.ws</a>.</td>
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<td>There are identified HTA activities but not a national unit. MoH together with National Health Services (NHS) intend to develop one, but it is still on progress.</td>
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- **Russian Federation**
  - EUR — — — The HTA system development is inserted in the Russian Federation healthcare legislation. Currently, the procedure for a comprehensive assessment of drugs has been approved and is constantly being improved. However it is still at their start phase for medical devices and biomedical products.

- **Rwanda**
  - There are identified HTA activities which are specifically done in pharmaceutics for pricing and reimbursements as well as health economics; however, there is no national unit.
  - Rwanda has started to use Online Public Procurement, each device should have an unique identification code (mainly based on UMDNS). But it is challenging when dealing with different code nomenclature such as the sterilizer, autoclave or medical gases. Rwanda uses UMDNS for inventory and maintenance of medical equipment.

- **Saint Kitts and Nevis**
  - There is the Bureau of Standards which will do the regulatory activities.
  - Hospital management purchases devices directly from vendors.

- **Saint Lucia**
  - There is the Bureau of Standards which will do the regulatory activities.
  - The procurement at a national level is not for medical equipment, but for pharmaceuticals.

- **Saint Vincent and the Grenadines**
  - There are identified HTA activities but not a national unit. The development of one is in progress.

- **Samoa**
  - There are identified HTA activities but not a national unit. MoH together with National Health Services (NHS) intend to develop one, but it is still on progress.

- **Concerning the Infrastructure section**: there are 18 General Practitioner Clinics in the Private sector.
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<td>San Marino</td>
<td>EUR</td>
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<td>There are identified HTA activities but not a national unit.</td>
</tr>
<tr>
<td>Sao Tome and Principe</td>
<td>AFR</td>
<td>—</td>
<td>—</td>
<td>Il n'existe pas au niveau national aucune liste recommandant des technologies de sante.</td>
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<tr>
<td>Saudi Arabia</td>
<td>EMR</td>
<td>—</td>
<td>—</td>
<td>Food and Drug Administration - Specification and Measurement Administration.</td>
<td>The Ministry of Health supports the creation of a national entity for HTA in healthcare as part of the National Transformation Program. The new HTA entity will deal mainly with pharmaceutics but is intended to extends to other health products such as devices. Informed HTA decisions were rarely identified for medical devices.</td>
</tr>
<tr>
<td>Senegal</td>
<td>AFR</td>
<td>—</td>
<td>—</td>
<td>Il existe une liste standard de base pour toutes les structures sanitaires. Pour la plupart des acquisitions, les specifications techniques des équipements sont réalisées par la Direction des Equipements et de la Maintenance. Voir aussi les spécifications techniques des équipements médicaux.</td>
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<td>For specialized care and diagnostics, patients can be treated in Italian hospitals that have agreements with San Marino.</td>
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<td>—</td>
<td>A committee inside NUPCO has been established for that purpose and the work is in progress.</td>
<td>National Unified Procurement Company for Medical Supplies (NUPCO).</td>
<td>For every hospital and health centre there is a maintenance-specialized company contracted to make the inventory and perform necessary maintenance activities for all medical devices within the facility. Also, there is a National inventory for high cost technologies (such as MRI, CT or PET scanners).</td>
<td>Concerning the HT national policy it is stated on the Medical Egypt Management Plan (Corporate).</td>
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<tr>
<td>Serbia</td>
<td>EUR</td>
<td>Not available at the moment.</td>
<td>—</td>
<td>There are no specific national standards nor recommended medical devices for specific procedures. And there are no lists recommending health technology for different diseases/situations.</td>
<td>It conducts centralized public procurement for health products including devices. HTA is in the law and with a centralized national unit either MoH sector for inspection affairs or Public Health Institute (NIS).</td>
</tr>
<tr>
<td>Seychelles</td>
<td>AFR</td>
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<tr>
<td>Sierra Leone</td>
<td>AFR</td>
<td>Lists for procurements are still being worked on not yet completed. However we do have public health emergency situations lists.</td>
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</tr>
<tr>
<td>Singapore</td>
<td>WPR</td>
<td>A list is available in the form of the Singapore Medical Device Register (SMDR). This shows all approved medical devices in Singapore and provides information on them. It is not a list of recommended devices for procurement.</td>
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<td>National nomenclature is in the process of updating and amendment.</td>
<td>Go to the website and search for the corresponding documents.</td>
<td>The inventory was made, in 2000, according to methodology. In 2003, European Agency for Reconstruction commissioned a project performed by IPH Serbia, but the methodology was not included in the national Law on Health Records and Statistics and has not been adopted, so the inventory continued to be performed on annual basis based on the existing Law on Health Records and classification of medical equipment (1980's). The inventory is not available.</td>
<td>The Institute of Public Health of Serbia has a department for health technology assessment mainly responsible for updating nomenclature and type of technology.</td>
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<td>It is a small committee that meets to discuss equipment request by the various units within the Ministry of Health. Please note that Seychelles has a small population and we do not purchase equipment on a big scale.</td>
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<td>The document is not available for the Facilities and Maintenance Unit.</td>
<td>Most of the equipment has been used and found incomplete, and this is the reason why its installation is difficult. Procurement of medical devices is carried out without involving the specialists.</td>
<td>The last inventory was done twelve years ago. Looking forward to start another one.</td>
<td>There is a limited number of technical personnel to meet the service demand. Most of the equipment supplied by donors are obsolete and out of order.</td>
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<td>—</td>
<td>There the Global Medical Device Nomenclature (GMDN) which we only use as an internal reference. It is not required for medical device product registration in Singapore.</td>
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</tr>
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<tr>
<td>Slovakia</td>
<td>EUR</td>
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<td>There is no list recommending health technology for above mentioned diseases/situations.</td>
<td>The Working Group for Pharmacoeconomics, Clinical Outcomes and Health Technology Assessment of the Slovak Ministry of Health perform HTA, but not specifically for medical devices.</td>
</tr>
<tr>
<td>Slovenia</td>
<td>EUR</td>
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<td>There are many boards (Slovenian Collegiate Boards) each responsible for one area of medicine. Those bodies produce recommendations on specific procedures where deemed necessary. Currently, recommendations are under development at the Ministry of Health.</td>
<td>HTA framework is not done yet, but HTA processes are in an existing framework. HTA decision-taking is done by the following institutions: MoH, National Institute of Public Health, and the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP).</td>
</tr>
<tr>
<td>Solomon Islands</td>
<td>WPR</td>
<td>—</td>
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<td>Unfortunately, there are no such lists. Donation equipment have various brands.</td>
<td>There is no formalized HTA available and it relies heavily on other institutions assessment mechanisms, such as the WHO.</td>
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<td>When medical devices are being produced by the manufacturers of medical devices with their registered place of business in the Republic of Slovenia, are notified to the national competent authority, GMDN code should be submitted, if available.</td>
<td>The CPV establishes a single classification system for public procurement aimed at standardising the references used by contracting authorities and entities to describe the subject of the procurement contracts. Thus, we are using various co-existent types of nomenclature systems, mainly for procurement and regulatory purposes, such as EUDAMED, GMDN, and CPV.</td>
<td>The inventories website is still in development and is not yet available to the public.</td>
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<td>The National Referral Hospital (NHR) performs most of the procurement, planning and allocation for the Provincial Hospital. There is a disposable procurement by the Ministry of Finance.</td>
<td>There is virtually none of this currently in place.</td>
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<td>The procurement Unit, Ministry of Health &amp; Medical Service, has mainly to do with the finance but no with the technical aspect of the equipment. The Committee is Ad hoc and meets only to allocate equipment base on Departmental requests.</td>
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<tr>
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<tr>
<td>Somalia</td>
<td>EMR</td>
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<td>National Medicines Regulatory Authority (NMRA) under Department of Medical Services has an HTA role. However, even if the designated unit is present in the organigram is not yet well established. There are scarce HTA activities, but the plans are to expand, specially in pharmaceutics. The UHC country goal is in progress.</td>
</tr>
<tr>
<td>South Africa</td>
<td>AFR</td>
<td>There are no lists of the mentioned above. The list is only for the private sector funders (not the government). The National Department of Health is engaging with the private sector to establish a national system.</td>
<td>Both UMNDS and GMDN have been used.</td>
<td>There are none of the cited lists mentioned above.</td>
<td>The institutionalization of a national HTA as part of the ongoing National Health Insurance (NHI) is in the process towards the National Department of Health (NDoH) and the Universal Health Care (UHC) goal.</td>
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<td>South Sudan</td>
<td>AFR</td>
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<tr>
<td>Spain</td>
<td>EUR</td>
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<td>—</td>
<td>There is a network of Agencies for HTA and services of the National Health System. The HTA is for decision-making within the health system, as well as for medical products, including medical devices.</td>
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<tr>
<td>Sri Lanka</td>
<td>SEAR</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>The institutionalizing of an HTA as a mechanism for promoting health system integrity is in early stages.</td>
</tr>
<tr>
<td>Sudan</td>
<td>EMR</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>A Health Technology Management system (HTM) has been developed. However, there is not current HTA system in place, but it is a goal to pursue towards the Universal Health Care country goal.</td>
</tr>
<tr>
<td>Suriname</td>
<td>AMR</td>
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<td>The definition of medical devices is included in the national medicines law which is not yet ratified.</td>
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<td>Somalia</td>
<td>The radiation control is now part of the tasks of the South African Health Products Regulatory Authority (SAHPRA).</td>
<td>The regulator has adopted the use of GMDN which will be a nationally accepted nomenclature.</td>
<td>The Office of the Chief Procurement Officer is in charge of the procurement of medical devices.</td>
<td>There are no national inventory nor management systems but some hospitals do have. Currently, we are compiling a national inventory and acquiring a system to be implemented at a national level. Thus, we are progressing to acquire the national system.</td>
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<tr>
<td>South Africa</td>
<td>The institutionalization of a national HTA as part of the ongoing National Health Insurance (NHI) is in the process towards the National Department of Health (NDoH) and the Universal Health Care (UHC) goal.</td>
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<tr>
<td>Spain</td>
<td>There is a network of Agencies for HTA and services of the National Health System. The HTA is for decision-making within the health system, as well as for medical products, including medical devices.</td>
<td>Se ha utilizado el código UMNDS, pero se sustituirá por GMDN cuando esté disponible la versión en español.</td>
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<tr>
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<tr>
<td><strong>Sweden</strong></td>
<td>EUR</td>
<td>The devices must bear the CE-mark. — There is an ongoing project in order to create such a national list. It is the Dental and Pharmaceutical Benefits Agency that is working with that.</td>
<td>—</td>
<td>Network of HTA agencies such as: the Dental and Pharmaceutical Benefits Agency (TLV); Agency for the HTA and Assessment of Social Services (SBU), and Medical Products Agency. Alternative email: <a href="mailto:registrator@tlv.se">registrator@tlv.se</a>.</td>
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<tr>
<td><strong>Switzerland</strong></td>
<td>EUR</td>
<td>Reimbursement list for medical devices used by the patients themselves, and Reimbursement list for medical analyses are available on the corresponding website (see link).</td>
<td>—</td>
<td>—</td>
<td>There is the swiss network of HTA entities focusing in various areas. Some institutions are: Health Insurance Benefits, State Secretariat for Education, Research and Innovation, etc.</td>
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<tr>
<td><strong>Syrian Arab Republic</strong></td>
<td>EMR</td>
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<td>It exists the Planning and International Collaboration Directorate which performed HTA activities, but it is not specifically for medical devices.</td>
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<tr>
<td><strong>Tajikistan</strong></td>
<td>EUR</td>
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<td>The change from GMDN to EMDN will take place with regards to the implementation of the new EU regulation on medical devices that shall be applied from the 26th of May, 2021.</td>
<td>The national law for procurement is based on the EU directive. Concerning procurement, it can be done at a country level or within a single hospital.</td>
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<td>Swissmedic uses GMDN (no country specific nomenclature), if manufacturers do not know the GMDN number, a UMDNS code may be given.</td>
<td>The medical devices must fulfil the requirements described in the European medical device directives. Legal basis (Swiss Medical devices ordinance): <a href="http://www.admin.ch/ch/d/sr/c812_213.html">http://www.admin.ch/ch/d/sr/c812_213.html</a>. The hospital / high cost technology planning is done at a national level. Coordinated planning of certain highly specialized areas of health care is in progress (see <a href="https://www.gdk-cds.ch/de/">https://www.gdk-cds.ch/de/</a>).</td>
<td>Go to the gdk website and search for the 291.0.html documentation.</td>
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<tr>
<td>Thailand</td>
<td>SEAR</td>
<td>There are lists of recommended procedures in organization level such as the procedure of the Physical Therapy Council. The approved medical devices list is only available for the reimbursements of the three health insurances, namely the National Health Security Office, the Comptroller General's Department, and the Social Security Office.</td>
<td></td>
<td>There are lists of recommended procedures in organization level such as the procedure of the Physical Therapy Council.</td>
<td>HTA is focused on several health technologies and programs, including pharmaceuticals, medical devices, interventions, and disease prevention as well as to inform policy decisions.</td>
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<tr>
<td>Timor-Leste</td>
<td>SEAR</td>
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There is the Standart Medical Equipment from Australia Advisor of Medical Equipment. See Classification Minimum Standard equipment HP, CHC, DHC.
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<tr>
<th>National regulatory authority</th>
<th>Medical device nomenclature system</th>
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<th>Inventories and medical equipment management software comments:</th>
<th>General Comments</th>
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<tr>
<td>The Office of Atoms for Peace (OAP), within the Ministry of Science and Technology, is the responsible agency for strengthening regulatory control of sources that involve radioactive activities such as manufacturing, radiation processing, radiation application (medical, industrial, research, etc.), importation and exportation of radioactive sources and radioactive waste management under the Atomic Energy for Peace Law, BE2504 (1961) and the Nuclear Energy for Peace Law, BE 2559. It also guarantees the safety of users and the public against radiation and nuclear use by regulating the use of nuclear energy and by educating the public.</td>
<td>—</td>
<td>The procurement was performed by individual agencies. For technical specifications go to the web site and find the law section, search for the corresponding documents.</td>
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| The Inventory is from 2002-2009. | The Health Technology of medical equipment does not have standards for Medical Equipment yet.
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<tbody>
<tr>
<td>Togo</td>
<td>AFR</td>
<td>Aucune organisation en charge de ces listes existe, malgré toutes les propositions formulées dans ce sens. Il ne semble pas avoir la volonté politique à évoluer dans ce sens.</td>
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<tr>
<td>Tonga</td>
<td>WPR</td>
<td>There are no specific lists.</td>
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</table>
### National regulatory authority

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### Medical device nomenclature system

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### Medical Device incorporation: procurement/donations/technical specifications:

- Le niveau du sous service chargé chargé des équipements est trop bas pour être lisible. Les supériorus hiérarchique ne portent pas l'intérêt nécessaire pour la mise en œuvre de la gestion qui s'impose pour les dispositifs médicaux.

### Inventories and medical equipment management software comments:

- Bien que cela soit le point de départ de toute gestion en terme de maintenance des parcs biomédicaux, cette opération n'existe pas au plan national sauf par endroit mais aussi de façon sommaire. Les données ainsi consignées ne permettent pas de l'exploiter pour proposer des plans de renouvellement ou de développement de parcs biomédicaux. En bref aucun inventaire digne de ce nom n'existe pas sur le plan national.

### General Comments

- Compte tenue des difficultés que nous rencontrons pour la prise en compte adéquate des plateaux techniques dans nos formations sanitaires malgré les recommandations régionales pour une politique commune en matière de maintenance et la gestion durable des infrastructures sociales je veux bien croire que cette enquête nous ouvrira l'horizon de nouvelles politiques adaptées à nos réalités.

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**Although there is no formal institution that oversees the implementation of any medical device regulation, there is the “Facility and Equipment Committee” of the Ministry of Health that oversees certain things such as the procurement of medical devices, the criteria of acceptance of donated equipment and the implementation of maintenance guidelines, etc.**
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<tbody>
<tr>
<td>Trinidad and Tobago</td>
<td>AMR</td>
<td>The nomenclature is part of the Computerized Maintenance Management System.</td>
<td>Certification standards for equipment, e.g. European CE Marking and U.S. Food and Drug Administration.</td>
<td>The list exists for point of care testing equipment, namely, Diagnostic Screening and Laboratory Testing. The medical equipment requirements for specific procedures are done by the respective inhouse Hospital Biomedical Department and the clinicians. The American Hospital Association guidelines are used as a reference. Also, the Ministry has established requirements for Diagnostic Laboratory Point of Care Testing.</td>
<td>There are identified HTA activities at a national level. Furthermore a consultant is to be engaged to assists in the development of an HTA framework. Alternative contact for the Health Technology Management unit: <a href="mailto:pmu@health.gov.tt">pmu@health.gov.tt</a>.</td>
</tr>
<tr>
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<td>Developed and in use as “Fixed Asset Inventory and Facilities Management”, TMA Systems Maintenance Management Software (the nomenclature of medical devices are generally developed by the respective Regional Health Authorities for procurement purposes).</td>
<td>There are guidelines based on the Regional Health Authorities (RHAs) internal policies and procedures on the procurement process and in particular for the need of the development of specifications. The Ministry of Health is presently moving towards standardising policies and procedures for all technical areas which would include the procurement of medical devices. Technical specifications are developed as part of all equipment procurement for public open tender. In general, there are recommended technical specifications used by each RHA for procurement of equipment as part of public tendering requirements. This is an area that the ministry is working with the RHAs towards standardising. For procurement information contact via mail to <a href="mailto:pmu@health.gov.tt">pmu@health.gov.tt</a> (Project Management Unit).</td>
<td>The inventories of other medical devices exist at each respective Regional Health Authorities (RHA) and for high-cost technologies such as diagnostic imaging.</td>
<td>It is noted that several medical devices systems exist at the respective Regional Health Authorities (RHA) level. The MoH is currently working towards standardising these and in particular concerning the procurement guidelines for medical devices.</td>
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<tr>
<td>Tunisia</td>
<td>EMR</td>
<td>L’acquisition et la mise en service des équipements lourds sont soumis à l’autorisation préalable du MoH pour les secteurs publique et privé et ce conformément aux critères et normes fixés par les arrêtés sus-indiqués. -Arrêté. Dune manière générale la liste de matériel découle de l’activité préconisée sans liste préétablue. Seules les produits non conformes aux spécifications techniques fixés par les cahiers de charges (CCTP) des appels d’offres ou dont le contrôle technique à l’importation non concluant et ceux qui ne sont pas autorisés a être mis sur le marché dans leurs pays d’origine ne sont pas autorisés a être mis sur le marché Tunisien.</td>
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<tr>
<td>Turkey</td>
<td>EUR</td>
<td>The Ministry of Health is closely involved in the decision making but the main responsible unit is the Social Security Institution of the Republic of Turkey. The directorate of Curative Services is the main responsible unit in the Ministry of Health but other directorates also give their opinion on the subject. There is the new version (2010) of the relevant document. Specific lists can be reached by opening EKLER Appendix (see in website).</td>
<td>—</td>
<td>These standards are not centrally organized and published. Each department has its own and they can be found in the second link under Sağlık Mevzuatı&gt;Genelgeler, Tebliger, Yönetgeler, Yönetmelikler&gt;... Relevant departments and headlines. Each directorate and department has its relevant health technology reference documents (guidelines, circulars, regulatory statute etc) in its links on the website.</td>
<td>Generic email of the HTA department <a href="mailto:shgm.argestd@saglik.gov.tr">shgm.argestd@saglik.gov.tr</a></td>
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<tr>
<td>Turkmenistan</td>
<td>EUR</td>
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<td>There is no systematic programme of health technology assessment, but an informed decision is mainly used for pharmaceutics but no for medical devices.</td>
</tr>
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<td>La nomenclature des dispositifs médicaux fait partie intégrante du Manuel des procédures de gestion de la maintenance biomédicale et hospitalière élaboré en 1996 et amélioré en 2007 par le Ministère de la santé publique qui a fait l'objet d'un arrêté.</td>
<td>L'achat des dispositifs médicaux obéit en plus des procédures réglementaires (Règlement des marchés publics) d'une part et passe par des commissions techniques spécialisés (commissions d'élaboration des cahiers des clauses techniques particulières, fiches techniques, commissions de sélection, des commissions de réception provisoire et définitifs du matériel fiches techniques). Il n'y a pas de fiches techniques standard mais elles sont préparées au cas par cas en fonction du besoin (caractéristiques opérationnelles).</td>
<td>Conformément au manuel des procédures de gestion de la maintenance chaque établissement de santé est dans l'obligation de tenir un inventaire technique des équipements et des infrastructures techniques, remplir la fiche d'identification et une fiche de santé (maintenance) par appareil. Un applicatif informatique dédié a été développé à cet effet. Management Software: G.M.B.H. développé en local par le ctembh et le centre informatique du msp.</td>
<td>La structure publique de santé en Tunisie est composée d'établissements publics de santé (CHU,H. Spécialisés) dans les sièges de faculté de médecine des hôpitaux régionaux des hôpitaux de circonscription des groupements de santé de base des centres de santé de base et des centres régionaux de médecine scolaire et universitaire en plus des trois hôpitaux militaires et un hôpital des forces de sécurité intérieure publics et six centres de d'hémodialyse et six polycliniques para-publique ne relevant pas du ministère de la santé le secteur privé compte 3371 unités réparties entre cliniques, cabinets dentaires, officines, cabinets de radiologie, centres d'imagerie médicale laboratoires et centres d'hémodialyse.</td>
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<td>Huab is the Turkish registry system for medical devices. Both GMDN and UNSPSC are used in this system. For reimbursement purposes another nomenclature mentioned in the corresponding link is also used.</td>
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<td>Go to the previous website and search for sbhbt. However, the full online inventory databank, with restricted use to the authorities, is on the following site: <a href="http://sbu.saglik.gov.tr/sbhbf/">http://sbu.saglik.gov.tr/sbhbf/</a></td>
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Annex 1: Additional comments
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<td>Tuvalu</td>
<td>WPR</td>
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<td>National Drug and Therapeutic Committee (NDTC) has done HTA activities mainly in pharmaceutics; however, there is no a national HTA unit.</td>
</tr>
<tr>
<td>Uganda</td>
<td>AFR</td>
<td>Usually we use the WHO recommendations. List of equipment by health care level is available in the website.</td>
<td>Standard Medical Equipment List is under review.</td>
<td>There are no national lists recommending health technology for specific procedures. We usually adhere to the World Health Organization recommendations.</td>
<td>There are identified HTA activities but there is not a national unit.</td>
</tr>
<tr>
<td>Ukraine</td>
<td>EUR</td>
<td>—</td>
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<td>There are many files, namely, the orders MSS. Orders of the Ministry of Health approval of protocols of care for various diseases.</td>
<td>In 2019 was established the national HTA within the MoH to power the National Essential Medicines List and to inform the National Benefits Package towards the Universal Health Care. The HTA is focused on a wide range of health products, interventions, but till now is rarely focused in medical devices.</td>
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<td>Tuvalu</td>
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<td>Guidelines on Donations exist, they are nationally developed but they are not publicly available.</td>
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<td>See the list of medical equipment by level, and the Standard Medical Equipment Lists and Specifications by healthcare level are under review (as in sample formats in the corresponding websites). The main uses of the nomenclature system are for procurement purposes, and inventory systems in healthcare facilities.</td>
<td>The Ministry acquires resources and procures in bulk; although for the last 2 years development funds for infrastructure have been directly allocated to regional referral hospitals which procure equipment with the guidance of the health infrastructure division and national advisory committee on medical equipment (NACME). The Public Procurement and Disposal of Public Assets Authority (within the MoH, specified website).</td>
<td>Currently, is being updated.</td>
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<td>Ukraine</td>
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<tr>
<td>United Arab Emirates</td>
<td>EMR</td>
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<td>HTA activities have been identified within the MoH. It exists the Health Authority Abu Dhabi, the Dubai Health Authority and the Department of Health (DoH) but there is not a national unit. The main activities of the HTA are in health products pricing and reimbursement decisions. Also, the private sector is playing an increasing role in health care coverage.</td>
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<td>Inventories and medical equipment management software comments</td>
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<tr>
<td>United Kingdom of Great Britain and Northern Ireland</td>
<td>EUR</td>
<td>There is no approved list of medical devices for procurement. However we have lists for communicable and non-communicable diseases, and public health emergency situations. Guidance is produced by NICE and CEP which was disbanded 31 March 2010. NHS Supply Chain provides a catalogue of products that can be purchased by the NHS which are approved by way of meeting EU directives.</td>
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<td>The Centre for Evidence Based Purchasing (CEP) website is a portal containing over 600 and therefore too numerous for specific reference in this document. Please note CEP was disbanded end of March 2010 but the reports still apply to clinical professionals UK wide. Also, NICE Interventional Procedures (IP) Programme develops guidance on interventional (mainly surgical) procedures, and approx two-thirds of these involve a medical device or devices developed specifically for the procedure (see second link). In addition to the IP guidance referenced the previous lists, NICE has produced guidance on use of devices in the following non-communicable high burden diseases: ICDs, drug-eluting stents, endovascular stent grafts for AAA, inhaler devices for asthma and insulin pumps (see third link). The website is a portal containing the full set of reports most of which will be relevant to either a, b, or c. They are too numerous to mention here please also see comments of previous lists.</td>
<td>Evidence-based recommendations are developed in a wide range of areas: clinical guidelines, diagnostic technologies, interventional procedures, cost effectiveness, highly specialised, and medical technologies guidance.</td>
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### National regulatory authority
The Medicines and Healthcare products Regulatory Agency (MHRA) are the UK Competent Authority with respect to the safety, quality and performance placed on the market by manufacturers in the UK under the EU Medical Devices Directives. Trading Standards Departments based in local authorities also have enforcement responsibility in respect of medical devices available over the counter direct to the public.

### Medical device nomenclature system
The Medicines and Healthcare products Regulatory Agency (MHRA) will be moving forward to use solely the GMDN with their system being phased out. The nomenclature used by the National Health System (NHS) for the procurement of medical devices is that used by the “Official Journal of the European Union” (OJEU) CPV codes. The NHS also has a national system known as “e-class” which is a classification system for products and services.

### Medical Device incorporation: procurement/donations/technical specifications:
Medical devices may be procured at a number of levels, either locally (NHS Trust level), regionally (collaborative procurement hub level) or nationally (NHS Supply chain). Also in Scotland, there is a system for National Procurement for the NHS.

### Inventories and medical equipment management software comments:
A recent amendment of the Medical Devices Directive has lifted the confidentiality requirement on information supplied by manufacturers to Competent Authorities under their obligation to register certain types of medical devices. The devices include low-risk class I, devices CE marked based on a self-declaration of conformity by the manufacturer, custom-made devices made according to a prescription from a healthcare professional for an individual patient, assembled procedure packs, re-usable sterile devices and in vitro diagnostic devices. EU member states including the UK are currently working on how these registers can be published. Higher risk devices are CE marked based on a conformity assessment conducted by a third party certification organisation designated as competent to undertake this function by an EU member state. CE marking denotes that the device meets safety, quality and performance requirements accepted across Europe and allows access to member states markets without further restrictions. In addition, there also two national implant registries in operation. One for hip and knee implants covering England & Wales. The other for pacemakers for the whole of the UK. Both record information on individual devices, who they were implanted in and when both the original implant and any revision procedure were undertaken. Both Registries produce annual reports which contain all this data apart from individual patients names and other personal details.

### General Comments
Concerning the HT national policy, it was provided the following document: http://www.president.gov.ua/docs/Programa_reform_FINAL_1.pdf; www.rada.gov.ua. The UK comprises 4 devolved administrations: England, Wales, Northern Ireland and Scotland. Each Administration is responsible for the delivery of its own healthcare system as well as collating and maintaining its own data. Therefore, there is no centrally held data that covers the whole of the UK. A range of initiatives around the more widespread use of clinically and cost-effective medical devices is underway. The work is in early stages but once fully operational should improve patients' access to the latest health technologies.
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<thead>
<tr>
<th>Country</th>
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<tbody>
<tr>
<td>United Republic of Tanzania</td>
<td>AFR</td>
<td>Lists recommending health technology for different categories of diseases is not available. The Ministry is however planning to develop it. Registration of medical devices in Tanzania has started in January 2010. Registration will be carried out phasewise and 1st phase involves single use devices. The first phase involves limited number of devices in particular single use devices. Prior to the start of first phase of registration applicants were requested to notify they are dealing with and the list of notified devices is used as a basis for approval during the transition period. The guideline for registration can be accessed at the tfda website.</td>
<td>—</td>
<td>Lists recommending health technology for different categories of diseases are not available. However, the Ministry is planning to develop it.</td>
<td>The institutionalizing of HTA for decision making and priority setting for guidelines, essential medicines list, and cost-effective treatments is in progress. The Tanzania HTA committee (THTAC) is essential in the progress towards the Universal Health Care country goal.</td>
</tr>
<tr>
<td>National regulatory authority</td>
<td>Medical device nomenclature system</td>
<td>Medical Device incorporation: procurement/donations/technical specifications</td>
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<td>TMDA is using GMDN as the nomenclature system for the registration of medical devices in Tanzania. The main types of nomenclature used are GMDN and UMDNS. The main uses of the nomenclature system are for procurement purposes and inventory systems in healthcare facilities.</td>
<td>Medical Store Department (MSD) is responsible for procuring pharmaceuticals and medical devices for the public but not for profit organization. It should also be noted that individual entities can also procure medical devices on their own as not all devices are covered by MSD. The private sector imports medical devices after obtaining approval from TFDA. The list of recommendations is not available. However, the guidelines for registration recommend the use of ISO standards and national standards if available.</td>
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<tr>
<td>United States of America</td>
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</table>

There is not a single body nor a national institution to evaluate health technologies. However, there is an extensive network of HTA institutions such as the Advisory Committee on Immunization Practices (ACIP), the Preventive Services Task Force (USPSTF), the Medicare Evidence Development & Coverage Advisory Committee (MedCAC), the Agency for Healthcare Research and Quality (AHRQ), etc.
### National regulatory authority

**Medical device nomenclature system**

1. Product Code. FDA-The Center for Devices and Radiological Health (CDRH) uses a nomenclature by assigning a 3-letter code to identify a device into a generic type or category. This nomenclature system is known as product code classification. The short name is ProCode. The Product Code Classification Database contains medical device names and associated information developed by the CDRH in support of its mission. This database contains device names and their associated product codes. The name and product code identify the generic category of a device for the FDA. The Product Code assigned to a device is based upon the medical device product classification designated under 21 Code of Federal Regulations (CFR) Parts 862-892.

2. Problem code FDA-CDRH also has a nomenclature for CDRH Event Problem Codes for Medical Devices used in reporting adverse device events. The adverse event vocabulary codes were developed in cooperation with the National Cancer Institute Enterprise Vocabulary Service (NCI-EVS); see the second link.

### Medical Device incorporation: procurement/donations/technical specifications:

### Inventories and medical equipment management software comments:

### General Comments

Unfortunately, we are only able to respond to numeric country statistics. As is often the case, they are too much difficulty for Federal States to answer; furthermore, is largely irrelevant for a system like ours that is so based on private sector.
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<tbody>
<tr>
<td>Uruguay</td>
<td>AMR</td>
<td>Las listas aún no se encuentran disponibles públicamente.</td>
<td>—</td>
<td>—</td>
<td>HTA is performed by the department of Health Assessment (MOH), and the National Resources Fund (FNR) in several areas concerning health products, and healthcare, including medical devices.</td>
</tr>
<tr>
<td>Uzbekistan</td>
<td>EUR</td>
<td>—</td>
<td>—</td>
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<td>HTA activities are carried out mainly by the MoH, and the Evidence-Based Medicine Centre within the Tashkent Institute for Advanced Medical Education. HTA is done for various health topics: pharmaceutics, medical devices, and also the in pharmaceutics field but not specifically for medical devices, guidelines, etc. However, a national HTA is still in progress as well as unified national mechanisms for developing and implementing clinical standards, guidelines and protocols.</td>
</tr>
<tr>
<td>Vanuatu</td>
<td>WPR</td>
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<td>This list exists as part of another document -e.g. essential drug list or an inventory list of a health facility- but there is no separate nor specific document of the guideline on its own. No list exists for any of the conditions above (different diseases/situations).</td>
</tr>
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<td>When there is a plan to procure a medical device, only then is the technical nomenclature required.</td>
<td>An updated complete list of medical equipment does not exist at national level; but at subnational levels and at facility level, health managers maintain their own inventory for various commodities including medical devices.</td>
<td>Vanuatu is a small island country in the Pacific region with a population of less than 350,000: this explains the low level of health facilities available.</td>
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<tr>
<td>Venezuela (Bolivarian Republic of)</td>
<td>AMR</td>
<td>Las actividades de evaluación de tecnologías médicas se han desarrollado en el marco de la Comisión Nacional de Evaluación de Tecnología en Salud (CONETS) dentro del Ministerio del Poder Popular de la Salud.</td>
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<td>Viet Nam</td>
<td>WPR</td>
<td>There are for all general procedures but they are not complete. We have enacted medical device list for procedures which shall be covered by medical insurance only.</td>
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<td>The HTA system has been developed by establishing nodal agencies within MoH, moving towards the Universal Health Care country goal. Priority-setting mechanisms and HTA processes are at a nascent stage. HTA is rarely applied to medical devices.</td>
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<td>—</td>
<td>Does not have one specific nomenclature. For the certification of the medical device, the nomenclature used is the U.S FDA product classification.</td>
<td>Funindes (Univ. Simon Bolivar) is authorized by the Autonomous Service of the Sanitary Comptroller to carry out equipment analysis for subsequent sanitary registration.</td>
<td>—</td>
<td>The most important problems of the hospitals in Venezuela were: the electrical system, the air conditioning and the vertical system (for 2001). In 2019 the most serious problems were water, sanitation and hygiene: 79% of hospitals reported failures in the drinking water service; most had the service intermittently, only two or three days a week. By 2011 there were 1,366 intensive care units. By 2019 there were 36 intensive care beds in Venezuela. Currently, MRI, CT, and Gamma Camera specialized service is not performed in Venezuelan hospitals.</td>
<td>We as Funindes USB are authorized by the Autonomos Service of the Sanitary Controller, it is authorized to carry out equipment analysis for subsequent sanitary registration: see Paper Quality Certification of Medical Devices in Venezuela (<a href="https://globalce.org/index.php/GlobalCE/article/view/83">https://globalce.org/index.php/GlobalCE/article/view/83</a>).</td>
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Contact person: Hoang Mai Bui - Director of the Department of medical equipment verification and calibration.
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<tr>
<th>Country</th>
<th>WHO region</th>
<th>Description</th>
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<tbody>
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<td>EMR</td>
<td>There is a need of financial, technical support and cooperation to put national standards or lists of recommended medical devices for specific procedures. For different diseases/situations there are no existing lists; MOPH must do that by cooperation of specialist administrations.</td>
</tr>
<tr>
<td>Zambia</td>
<td>AFR</td>
<td>The MoH has developed the Standard Equipment Lists (SEL) for District facilities such as Health Posts, Health Centres and Level One Hospitals. The SEL are not yet done, because the Basic Health Care Package, which is the blueprint for health service delivery in Zambia, has neither been developed.</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>AFR</td>
<td>Evidence-informed healthcare priority setting via HTA is at early stages. Currently, HTA is being used by the MoH to build the Health Benefits Package.</td>
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<td>It has been started the building capacity and the HTA will be a fundamental tool to achieve the Universal Health Care goal.</td>
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This is in reference to the guidelines on procurement, donations, replacement of equipment at end of the lifespan. The Ministry of Health procures, under Mandate from ZPPA; the Ministry of Health develops the list, quantities and specifications. Public Procurement Authority sets the framework for the procurement mostly International Competitive Bidding. These are provided by the Medical equipment Unit but the developed SEL for the District facilities have specifications as well which are part of the planning documents used by the facilities for planning.

The national data bank for equipment is in its infancy; the data was collected three years ago during a project that was funded by the Japan International Cooperation Agency (JICA). Currently, this data will be upgraded this year. The information captured includes Equipment Description, Model, Maker, Serial Number, Location, Functional Status, Age of Equipment. There are however hard copies at the facility level which maintenance units use. This needs to be computerised and accessible from anywhere which is not the case now. There is no software for equipment management but have tried ECRI and another software developed by a professional in Holland.

The WHO used to run training programs for maintenance technicians but stopped long ago, this has affected this field. There is a need for the WHO to come in strongly in support of maintenance of Medical equipment. The main problems in developing countries are lack of skilled manpower, inadequate budgets for maintenance, lack of proper maintenance facilities equipped with tools, test and calibration equipment, lack of supportive policies. Coupled with a lack of local agents for the supply of equipment the traders take advantage and dump equipment which tomorrow will need services.

The country health technology policy document was initiated in 2007 with funding from the US. This is currently being formulated into a policy document for diagnostic imaging and medical devices.
Annex 2
Overview of nomenclature systems for medical devices in WHO member states
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GAMD 2021 - - - - - - - - B18 India - - - - - - - - B25
Congo - - - - - - - - B18 Indonesia - - - - - - - - B26
Cook Islands - - - - - - - - B18 Iran (Islamic Republic of) - - - - - B26
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Cuba - - - - - - - - B19 Israel - - - - - - - - B27
Czech Republic - - - - - - - - B19 Italy - - - - - - - - B27
Denmark - - - - - - - - B19 Jamaica - - - - - - - - B27
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**Conclusion** 46

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For a long time, the need of a common Medical Devices nomenclature available for all WHO member countries has been acknowledged, and recently during the covid-19 pandemic its absence has been painfully felt. During the past WHO Executive Board 145 and 148 and World Health Assembly WHA74, WHO member states are exploring the current status of global medical device nomenclature systems and opportunities to harmonize approaches. The objective of this work is to present and summarize the information available concerning the existence and use of nomenclatures in the world.

Analysis of the nomenclature systems

The Baseline Country Survey of Medical Devices (BCSoMD) is of particular interest in the context of our research since BCSoMD covered several cross-cutting themes concerning medical devices and collected a significant amount of data during the following periods: 2010-2013, 2014-2017, 2020-2021.

Since the nomenclature data gathered from the BCSoMD 2021 was considered rather incomplete, it was decided to conduct an email consultation to ask the countries focal points to kindly confirm and complete the information we had from their countries. We sent the request on February 21 setting a first deadline of March 21st, and continued follow up receiving and updating answers up to the end of May.

In some cases, it was discovered the contact person had changed and a follow up continued in order to find the information required. The information we acquired from this consultation was integrated into the GAMD 21 and used for this review.

The information of the Atlas has been updated later on 2021 with the following sources:

- August 2021 Survey “Questions for Biomedical / Clinical Engineers”
- September 2021 Survey for the GAMD 2021 Update
- Comments and precisions emailed in reaction to the publication of the First Draft Nomenclature Overview during October and November 2021

The latest BCSoMD update, in which 180 countries took part, comprises data summarized in the Global Atlas of Medical Devices 2021 regarding the key points of our research that are listed as follows:

- countries that had a nomenclature system;
- type of a nomenclature system;
- nature of the use of a nomenclature system;
- variability of the mentioned above parameters by region.

An overview of the results of our analysis can be seen in Map 1.
More than a half of the responding member states, i.e., 101 (52%) had an official nomenclature, and 41% did not have an official one. A total of 14 countries (7%) did not participate in the survey (see Fig. 1).

Figure 1. Existence of an official nomenclature system for medical devices (updated with the MD 2021 country consultation)

Less than a half of the responding member states, i.e., 79 countries (44%) do not have an official system for medical devices. In contrast, 101 member states use, at least, one nomenclature system with the following types: 21.1% have developed a national nomenclature system, 10.6% use the Universal Medical Device Nomenclature System (UMDNS), 11.1% use the Global Medical Device Nomenclature (GMDN), 10.6% use more than one system and 2.8% uses the Italian Classificazione Nazionale Dispositivi medici (CND) or the European Medical Device Nomenclature (EMDN) (see Fig. 2).

Figure 2. Existence and type of an official nomenclature system for medical devices (data from the GAMD December 2021 update)

In most of the regions —African (AFR), Region of the Americas (AMR), Eastern-Mediterranean (EMR), European (EUR)— it was reported that the use of medical device nomenclature systems comprises mainly: regulatory, procurement, and a combination of both purposes. Although, most of the countries of all regions had not specified the purpose of use of its medical nomenclature system (see Fig. 3).
Annex 2. Overview of nomenclature systems for medical devices in WHO member states

Figure 3. Nomenclature system use by WHO regions (data updated with the MD 2021 country consultation)

**Desk review**

**Methodology**

We collected and compared information about whether state members of the WHO had a nomenclature system in place and publicly available through the web, as well as the type and use of the nomenclature. There were three main sources of information:

- Country answers, comments and websites shared by the member countries within the BCSoMD 2021 (the Baseline Survey of Medical Devices that served to create the Global Atlas of Medical Devices or GAMD 21) and the subsequent consultation updates.
- Desk Review
  - Search for webpages
  - Search for studies such as journal articles, reports, and thesis using Medline and Google scholar

The Desk Review search was conducted during the months of February, March and April 2021. The following search string was used in Google and Medline search engines:

```
COUNTRY NAME AND ("NOMENCLATURE" OR "CLASSIFICATION" OR "REGULATION" OR "SYSTEM") AND ("MEDICAL DEVICES" OR "MEDICAL EQUIPMENT")
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If no relevant hits were found in English, a reviewer would translate to the country’s official language. When reviewers did not yet find an answer, they tried synonyms, and then proceeded by searching and reading anything related to laws and commercial sites on medical devices in order to find the appropriate wording for the search terms in the target language and adjust the search accordingly. In many cases, they also looked for clues into the Ministry of Health website, searched for dedicated agencies and eventually for procedures regarding import of medical equipment.
International and regional agreements

In addition to country-by-country analysis we also examined the regulation of medical devices, in particular in terms of nomenclature systems, at the international and regional level.

Various countries as well as corporations use the United Nations Standard Products and Services Code (UNSPSC) alongside the Harmonized Commodity Description and Coding Systems (HS) to trade products, including medical devices.

European Union

The member states of the European Union use different nomenclature systems of medical devices (for more details by country, please, consult Annex 2 - Findings by country), however, the EU is currently developing a common nomenclature system - the European Medical Device Nomenclature - (FAQ on EMDN) that will be based primarily on Classificazione Nazionale Dispositivi medici (CND).

As a Regulatory requirement in the European Union, set by the publication to the Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), the EMDN (European Medical Device Nomenclature) is the nomenclature that manufacturers shall use for the registration of medical devices in EUDAMED, where it is associated to each Unique Device Identifier - Device Identifier (UDI-DI)³.

When all European Union countries effectively comply with these regulations, 15% of the world’s countries would be using EMDN.

Eurasian Economic Union (EEU)

In March, 2019 the Eurasian Economic Commission (EEC), whose members are Armenia, Belarus, Kazakhstan, the Kyrgyz Republic, the Russian Federation, and the Global Medical Device Nomenclature Agency (GMDNA) signed the Memorandum of Understanding with a primary goal to start harmonizing Eurasian Economic Union’s nomenclature system with the one developed by the Agency.

The common market of medical products within the Eurasian Economic Union begins to function in full from 2022. In order to implement the Agreement on common principles and rules for the circulation of medical devices (medical products and medical equipment), more than 20 general regulatory documents have been developed; two of them are devoted to the creation and maintenance of the medical device nomenclature of the Union (link).

The Southern Common Market (MERCOSUR)

MERCOSUR has developed the Mercosur Common Nomenclature (MCN) that is based on the Harmonized Commodity Description and Coding System developed by the World Customs Organization (WCO). The MCN provides information concerning a wide range of products including medical devices.

The member countries of MERCOSUR agreed to use the MCN in terms of importing and exporting commodities, however, some of the countries use nationally developed or other types of nomenclature systems, for more detailed information about each member of MERCOSUR, please, consult Annex 2 - Findings by country.

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Association of Southeast Asian Nations (ASEAN)

One of the key documents that addresses several issues concerning medical devices regulation within ASEAN is the ASEAN Medical Device Directive (AMDD). The AMDD includes provisions under which the member states committed themselves to harmonize the sphere of medical devices regulation to facilitate trade and cooperation. Today, ASEAN is working on the development of a common nomenclature. For further information, please, consult the Medical Device Guidance and The 1st Asian Medical Device Committee Meeting and Related Events.

United States-Mexico-Canada Agreement (USMCA)

Although the USA, Canada, Mexico within the United States-Mexico-Canada Agreement (USMCA) are advancing towards more integrated environment in terms of regulatory framework convergence (the USITC document), in particular developing the same risk-based classification of medical devices, countries do not use a common nomenclature system of medical devices yet.

African Medical Devices Forum (AMDF)

The African Medical Devices Forum (AMDF), under the auspices of the African Union, serves as a platform for enhancing integration and regulatory framework convergence in the context of medical devices. The issue of a common nomenclature system has not been addressed yet.

Asian Harmonization Working Party (AHWP)

Global Harmonization Working Party (formerly known as the Asian harmonization working party: the AHWP) with members from Asia, Africa, Middle East and South America facilitates the process of regulatory framework convergence, encouraging its member states to use GMDN, although no common nomenclature has been adopted yet. Related links below:

- Playbook for Implementation of a Medical Device Regulatory Framework
- Requirements of Medical Devices Nomenclature for the AHWP
- Asian Harmonization Working Party (AHWP)

The Global Harmonization Task Force on Medical Devices (GHTF) and the International Medical Device Regulators Forum (IMDRF)

The Global Harmonization Task Force on Medical Devices (GHTF) established the International Medical Device Regulators Forum (IMDRF) in order to accelerate international medical device regulatory harmonization and convergence. The IMDRF is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and aims to accelerate international medical device regulatory harmonization and convergence. IMDRF Adverse Events Working Group developed a nomenclature for the adverse events reporting, including terminology and codes (see the IMDRF Terminologies for Categorized Adverse Event Reporting). IMDRF strategic plan for 2021-2025 can be found here.
Comparison of desk review and BCSoMD

The BCSoMD collected data about 180 countries and the desk review gathered information about 5 more, bringing the total number of countries that we have information about to 184. Nevertheless, the nomenclature system status of 9 countries remains unknown. Although some gaps in the data provided by the member states on the BCSoMD21 were covered through the web and literature search of the desk review, the difference between both data sets can also provide some insight about the accessibility of such information, either public or through the country itself.

For example, there is a 9% difference between countries that answered that they do not have any official nomenclature system for their medical devices and the data found via desk review i.e., 79 countries (43.9%) versus 64 countries (35%), respectively. Concerning the use of more than one system, there is a difference of 21% between what countries indicated through their responses, i.e., 19 countries (10.6%) and what was found through the desk review 58 countries (32%).

Both the BCSoMD21 and the desk review showed that at least a third of the member states (41% for the former, 33% for the last) do not have an official nomenclature coding structure for the proper management of their medical devices.

For specific types of nomenclature, the percentage differences were less than 4%. The UMDNS showed a usage difference of 3.6% (BCSoMD21: 10.6% versus desk review: 7%, corresponding to 19 and 12 countries, respectively); the nomenclature developed at a national level showed a difference of 4.1% (BCSoMD21: 21.1% vs. desk review: 17%, corresponding to 38 and 31 countries, respectively); a percentage difference of 0.8% was found between the countries that use the CND/EMDN nomenclature, i.e., 5 respondent countries (2.8%) versus 4 countries (2%) whose information was found through the desk review.

Finally, the countries whose nomenclature was based on GMDN showed a 3.1% difference between the data from the survey, i.e., 20 countries (11.1%) versus the data collected through desk review, i.e., 15 countries (8%).

Many of the differences can be explained by the following:

- Existence of a nomenclature system, type and use is a continuous and rapidly evolving area of medical devices.
- Important to note that around a third of the country’s answers from the BCSoMD dated back from the period 2010-2013, another third from the period 2013-2017, and the last third were recently collected in 2021. Thus, it is expected to see the changes in the three studied parameters: existence, type and use of the nomenclature system.
- Nomenclature system of medical devices is a cross-cutting subject that depends on many factors such as legislation, commerce, management, political will, economy etc.

Regarding nomenclature system use, and comparing the results between the data obtained through the BCSoMD21 and the desk review 2021, we obtain the following:

By merging the ‘not defined’ and ‘nor specified’ country answers into a single ‘unknown’ category, this would correspond to the largest number of countries by region. This can be explained by the difficulty to specify the various uses of the nomenclature system of medical devices within a country’s health system. The number of ‘unknown’ answers was rather similar for the European Region (EUR), Eastern Mediterranean Region (EMR) and African Region (AFR), with a difference no greater than 2 countries between the responding countries and the information collected from the desk review. The Region of the Americas (AMR), the South-East Asia Region (SEAR) and the Western Pacific Region (WPR) showed no difference between the number of the responding countries (BCSoMD21) and the collected information (desk-review).

- Concerning other specific purposes of use of nomenclature systems: in all WHO regions the desk review and the BCSoMD21 found more countries using their nomenclature for regulatory, procurement or both purposes, i.e., 36 in both type of answers, than countries using their nomenclature for various purposes, i.e., 27 (desk review) and 13 (BCSoMD21).
• Concerning the set of countries found to use regulatory, procurement or both nomenclatures for specific purposes, the WHO regions appeared as follows: i.e., the AFR-BCSoMD21: 6 countries and the AFR-desk review: 4 countries; the EMR-BCSoMD21: 4 countries versus the EMR-desk review: 5 countries; the EUR-BCSoMD21: 11 countries and the EUR-desk review: 8 countries; the WPR-BCSoMD21: 4 countries and the WPR-desk review: 8 countries; and the 11 countries found in both AMR-BCSoMD21 and desk review.

• Concerning South-East Asia, neither SEAR-BCSoMD21 nor the desk review found evidence about any of the nomenclature specific purposes specified above, while it was reported one country using their nomenclature for various purposes in the SEAR-BCSoMD21 and two for the SEAR-desk review.

As previously shown the specific purposes for the use of the nomenclature system, if any, are rarely mentioned such as the following: For reimbursement purposes; For in-vitro diagnostics Lists/Inventory; For inventory systems in healthcare facilities.

Findings by country

The desk review findings by country concern qualitative national information. As stated in the Methodology, they include the GAMD 2021 country comments and the internet search (labeled Desk Review). Although most of the GAMD 2021 country comments come from the GAMD 2021 country survey, some of them have been updated with related Nomenclature country consultations which have also been used to update the GAMD 2021 data and qualitative analysis. When this is the case, the source is been specified as a footnote.

Concerning regional nomenclature agreements, the information can be found in the dedicated International Agreements section. For quantitative data, check the full answers in this spreadsheet.

Countries without comments

No qualitative information was found during the desk review (nor sent during the GAMD survey) about the nomenclature use of the following countries: Gabon
Afghanistan
Antigua and Barbuda
Bahamas
Barbados
Belize
Burkina Faso
Burundi
Cameroon
Cape Verde
Central African Republic
Chad
Chile
Comoros
Côte d’Ivoire
Cyprus
Democratic People’s Republic of Korea
Ecuador
Guinea-Bissau
Haiti
Liberia
Malawi
Malta*
Marshall Islands
Mauritania
Mauritius
Micronesia (Federated States of)
Mongolia
Mozambique
Myanmar
Nauru
Pakistan
Papua New Guinea
Saint Kitts and Nevis
Saint Lucia
Saint Vincent and the Grenadines  
Samoa  
San Marino  
Seychelles  
Solomon Islands  
Somalia  
Suriname  
Swaziland (Eswatini)  
Tonga  
Vanuatu  

Vietnam  
Algeria  
Andorra  
Kuwait  
Lesotho  
Niue  
Palau  
Turkmenistan  
Tuvalu  

*Note on the European Union  

Members of the European Union such as Malta may not have information available on the web or GAMD survey but from the EU regulations 745 and 746 they are required to implement EMDN.
Albania

**GAMD 2021**

This Italian nomenclature system CIVAB comes with the Inventory system called CLINGO.

**Desk review**

The registration list for medical devices in Albania and the codes that appeared belong to CIVAB nomenclature. Nomenclature is used mainly for registration and inventory purposes.


Angola

**Desk review**

Access to the information is restricted since user accounts and passwords are required to access the website of the Ministry of Health.

Argentina

**GAMD 2021**

The Administración Nacional de Medicamentos Alimentos y Tecnología Médica (ANMAT), reported the use of the Universal Medical Device Nomenclature System (UMDNS) for regulatory purposes of the medical devices in this country.

**Desk review**

Medical equipment research in the national inventory revealed that identification codes and technical names of medical equipment are similar to the ones that are used in UMDNS.

[When searching for medical equipment in the national inventory, identification codes and technical names are UMDNS.]


Armenia

**Desk review**

Armenia uses a nomenclature that was developed within the Eurasian Economic Union (see first link, paragraph 8, an official website). The Eurasian Economic Commission (EEC) and the GMDN Agency signed the Memorandum of Understanding (2nd link) to support the harmonization of Eurasian Economic Union’s (EAEU) medical device nomenclature with the GMDN. The common market of medical products within the Eurasian Economic Union (EAEU) begins to function in full in 2022. From 2022 an EAEU nomenclature will be developed and based on the GMDN for various purposes mentioned in the purpose of use question. By now, some enterprises use GMDN for procurement in the country.

[https://portal.eaeunion.org/sites/odata/redesign/Pages/MedicalDeviceNomenclature.aspx](https://portal.eaeunion.org/sites/odata/redesign/Pages/MedicalDeviceNomenclature.aspx)
[https://www.e-draft.am/projects/222/about](https://www.e-draft.am/projects/222/about)

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Answered to the September 2021 Survey for the GAMD 2021 Update.
Australia

Desk review
The Therapeutic Goods Administration site (Australian Regulatory Agency) states the use of GMDN. Also, for IVDs the GMDN is recommended.


After publication of the first draft of this Overview, the Therapeutic Goods Administration (the responsible agency for regulating medical devices in this country) pointed out that the nomenclature used in Australia for medical devices, including IVDs, is the Global Medical Device Nomenclature System (GMDN), which is a legal and mandatory requirement for the devices supplied in this country.5

Austria

GAMD 2021
The Austrian Medical Devices Register uses the UMDNS and the EDMA Code.
https://goeg.at/Medizinproduktregister

Desk review
The Austrian Medical Devices Register uses the UMDNS, GMDN and EDMA Code for IVDs. In the future, the CND/EMDN will be used as part of the European Commission Standard.
https://goeg.at/Medizinproduktregister
https://medizinproduktregister.at/Nomenklaturen

Azerbaijan

Desk review
State registration of medical devices is not carried out by the government. For import of medical products and medical equipment, it is necessary to obtain a confirmation letter regarding the classification of an imported product, and then obtain a hygienic certificate from the Republican Center for Hygiene and Epidemiology of the Republic of Azerbaijan.
http://www.pharma.az/

Bahrain

GAMD 2021
It is needed the GMDN code for registration of medical devices, as well as the HS code.

https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/forms/Medical%20Device%20Registration%20Form%20%20Dec%202020.pdf
https://www.gmdnagency.org/Services/Members#N

Desk review
According to the 19 sub-section of the Registration Guideline for medical devices (from the National Health Regulatory Authority), it is needed the GMDN code for registration of medical devices; for registration purposes, it is needed the GMND and the HS code. In some cases, it might be required to fulfil the classification criteria issued by the NHRA Medical Devices Regulations department (it should be provided). The National Health Regulatory Authority has been found as a member of the GMND agency.

Commented by email to the publication of the Draft Nomenclature Overview
Bangladesh

**Desk review**
A medical equipment price list can be found on the website of the Directorate General of Drug Administration, but naming systems are not provided.


Belarus

**GAMD 2021**
State register of medical equipment and medical supplies of Belarus.

https://www.rceth.by/Documents/3mz3prNl32420141216.pdf

**Desk review**
Country uses the EEU’s nomenclature system alongside the nationally developed one. The Eurasian Economic Commission (EEC) and the GMDN Agency signed the Memorandum of Understanding (2nd link) to support the harmonization of Eurasian Economic Union’s (EAEU) medical device nomenclature with the GMDN.

https://www.rceth.by/Documents/3mz3prNl32420141216.pdf
https://pravo.by/document/?guid=3871&p0=F918000087

Belgium

**GAMD 2021**
The GMDN code is used during the notification of the placing on the market of class I medical devices, it is also used in the form for the transmission of material vigilance incidents. This code is also used for the registration of diagnostic medical devices in vitro in the European database Eudamed; in Belgium, several agencies are involved in the evaluation and regulation of devices.

(Original in French) Le code GMDN est utilisé lors de la notification de mise sur le marché des dispositifs médicaux de classe I, il est également utilisé dans le formulaire de transmission des incidents en matériovigilance. Ce code est également utilisé pour l’enregistrement des dispositifs médicaux de diagnostic in vitro dans la base de données européennes Eudamed; in Belgium, several agencies are involved in the evaluation and regulation of devices.

https://kce.fgov.be/en
https://www.famhp.be/en

**Desk review**
The country uses the GMDN, and as it is a member of the EU it will be used in parallel with CND/EMDN.


Benin

**GAMD 2021**
The CNEH nomenclature is used informally in some of the country’s hospitals.

(Original in French) La nomenclature CNEH est utilisée de façon informelle dans certains de nos hôpitaux.

http://www.sante.gouv.bj/

**Desk review**
The adoption of national and / or international nomenclatures for the identification of infrastructure, biomedical equipment and care structures is an important prerequisite for the establishment of harmonized management of health assets across the country.
(Original in French) L’adoption de nomenclatures nationales et/ou internationales pour l’identification des infrastructures, des équipements biomédicaux et des structures de soins est un préalable important pour la mise en place d’une gestion harmonisée du patrimoine sanitaire à travers le pays

http://www.sante.gouv.bj/
https://www.jhia-online.org/index.php/jhia/article/download/179/110/664

**Bhutan**

**Desk review**
There is a national medical devices list that is based on the nationally developed nomenclature.

**Bolivia (Plurinational State of)**

**Desk review**
Country uses the UMDNS as well as the Mercosur Common Nomenclature (MCN).
http://www.agemed.gob.bo/
https://www.mercosur.int/bolivia-ingresa-al-mercosur/

**Bosnia and Herzegovina**

**GAMD 2021**
Our nomenclature is based on GMDN and EDMA codes; In our instructions we ask for our manufacturer and representative of manufactures to use GMDN or EDMA codes for making generic names. We have free access to the GMDN base, and we found a new version of EDMA codes on the internet.

**Internal comment Desk review**
The country's law on medicines and health products was revised; it does not contain information on the use of nomenclature.

**Desk review**
Our nomenclature is based on the GMDN and the EDMA codes.

**Botswana**

**Desk review**
Country uses the UMDNS.
https://www.bomra.co.bw/index.php/bomra-downloads/guidelines-manuals

**Brazil**

**GAMD 2021**
Anvisa started working to internalize the GMDN. So far, 100 of Anvisa’s technical names are compatible with GMDN. Anvisa also works in the implementation of the Unique Device Identification (UDI) in Brazil. Anvisa is currently preparing a draft proposal in a working group with the participation of the private sector, which should be sent to the Public Consultation later this year (2021).
Desk review
Brazil’s regulatory agency uses the GMDN system. For importation the Mercosur Common Nomenclature is used.
https://www.gov.br/anvisa/pt-br

Brunei Darussalam

Desk review
The UMDNS is used for regulatory purposes (see second link). Country is a Member of the Asian Harmonization Working Party (AHWP). Within the AHWP efforts are being made to start developing a unified medical devices nomenclature system for regulatory purposes.
http://www.ahwp.info/index.php/node/57
https://www.dgra.de/media/pdf/studium/masterthesis/master_matthies_c.pdf

Bulgaria

GAMD 2021
Use of GMDN and UMDNS.
https://www.mh.government.bg/en/

Desk review
It uses the GMDN and the UMDNS, and as a member of the EU it will use the CND/EMDN.
https://www.mh.government.bg/en/

Cambodia

GAMD 2021
The Hospital Service Bureau has developed standard medical equipment nomenclature for public hospitals in Cambodia and it has been utilized for medical equipment management and maintenance.

Canada

GAMD 2021
Not publically available. Used internally for coding products in the database. Preferred Name Codes are based on US FDA Panel Codes.

Desk review
Health Canada is initiating the transition from its current medical device categorization method to the Global Medical Device Nomenclature (GMDN) to improve the availability, access to, and quality of information available on medical devices in Canada (see first link). However, it is planned to develop a national nomenclature that can be used alongside the UMDNS.

After publication of the first draft of this Overview, the Directorate of Medical Devices/Health Canada specified that two types of nomenclatures for medical devices coexist in this country: the Global Medical Device Nomenclature System (GMDN) and preferred name codes. In addition, it was clarified that although Canada continues to accept PNC and encourage manufacturers to use the GMDN, it has never been the intention to use any other nomenclature other than those mentioned above, nor to develop a national one.6

Commented by email to the publication of the first Draft Nomenclature Overview
China
Desk review
Based on the UMDNS (China has plans to develop a uniquely identifiable database for medical equipment).

Colombia
GAMD 2021
Nationally developed. It is in the phase of implementation.
Desk review
Currently, the country is in resolutions to generate a new nomenclature.

Democratic Republic of the Congo
GAMD 2021
The official nomenclature does not exist. We use what can be at hand depending on the circumstances.

Congo
Via the “Questions for Biomedical / Clinical Engineers” survey, the private HTM-Consulting pointed out the coexistence of many nomenclature systems within this country, as there is not a specific one in official use. As reported by the private agency, this situation has caused errors and mismatches regarding the purchase of specific medical devices. 7

Cook Islands
Desk review
Regulated by MOH
https://www.health.gov.ck/policies-guidelines/

Costa Rica
GAMD 2021
The GMDN has been adapted to the national needs.
Desk review
Costa Rica has a national nomenclature system for classifying medical equipment.
http://www.pgrweb.go.cr/sci/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NRTC&nValor1=1&nValor2=62959&nValor3=99850&strTipM=TC

7 Answered to the August 2021 Survey “Questions for Biomedical / Clinical Engineers”
Croatia

Desk review
Croatia uses the GMDN nomenclature for the national registration of medical equipment. As an EU member, it will adopt the use of CND/EMDN too.

https://www.halmed.hr/Medicinski-proizvodi/Upute-za-podnositelje-zahtjeva-41/Proizvodnja-medicinskih-proizvoda/

Cuba

GAMD 2021
The Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos (CECMED) reported the coexistence and use for procurement purposes of two nomenclature systems: the SUCNEM, a nationally developed nomenclature, based on the Universal Medical Device Nomenclature System (UMDNS) and the Global Medical Device Nomenclature (GMDN).https://www.cecmed.cu/
http://www.electromedicina.sld.cu

Desk review
Cuba has its system for classifying medical equipment: SUCNEM, which is based on the UMDNS. Additionally, the country uses the GMDN.

https://www.cecmed.cu/registro/equipos-medicos

Czech Republic

GAMD 2021
The GMDN and UMDNS remain the historically used nomenclatures. Three national specific systems (categorizations) of medical devices are used for reimbursement and statistical purposes. The GMDN remains a comprehensively recognized system for the registration and notification of medical devices in the Czech Republic. GMDN codes are used in the Register of Medical Devices (RZPRO) administered by the State Institute for Drug Control (SUKL) for regulatory purposes, adverse events reporting, safety corrective measures, and information on clinical trials.

Desk review
It is used by the UMDNS for registration, and other types of medical device nomenclature for reimbursement purposes. As a EU member it will adopt the use of CND/EMDN too.


Denmark

Desk review
The use of the GMDN system is in the law, but soon it will be used alongside the CND/EMDN, as the EU nomenclature.

https://laegemiddelstyrelsen.dk/en/devices/

Djibouti

Desk review
Regulated by MOH

https://sante.gov.dj/reglements

8 Answered to the September 2021 Survey for the GAMD 2021 Update.
Dominica

**Desk review**
No change. Neither in the web portal of the government nor the Ministry of Health, Wellness and New Health Investment (the latest is in development) there’s no information about nomenclature of medical devices.

http://health.gov.dm/

**Dominican Republic**

**GAMD 2021**
There is no official nomenclature. However, there is a proposal dating from 2006 that responded to a project for preventive maintenance of medical equipment.

(Original in Spanish) *No existe una nomenclatura oficial. Sin embargo, existe una propuesta que data del año 2006 que respondió a un proyecto de mantenimiento preventivo de equipos médicos.*

**Desk review**
There is no official nomenclature system. The access to the Dirección General de Medicamentos, Alimentos y Productos Sanitarios have only three windows of information about the process and certification of medical devices, medicines and cosmetics; none of them is available for public navigation as a supplier registration and password are needed; the only available classification (but not nomenclature system) of medical devices is in the Oficial Decret No. 246-06, Book 2, chapter 1, articles 11 to 20.

https://digemaps.msp.gob.do/menu/

**Egypt**

**GAMD 2021**
Used in the database of geographical information system health.

https://www.edaegypt.gov.eg/

**Desk review**
Medical devices registration requires use of a nomenclature (not specified, link 2).

https://www.edaegypt.gov.eg/
https://www.wikiprocedure.com/index.php/Egypt_-_Register_with_Central_Administration_of_Pharmaceutical_Affairs_(CAPA)

**El Salvador**

**GAMD 2021**
The catalog developed is for medical equipment in general and is for purchase purposes only. There is no distinction or classification of medical technology equipment based on its application or impact on the health of the patient

(Original in Spanish) *El catálogo desarrollado es de equipo médico en general y sólo es para fines de compra. No existe distinción o clasificación de equipos de tecnología médica por su aplicación o incidencia en la salud del paciente.*

**Desk review**
In the Dirección Nacional de Medicamentos is available the guide for medical devices registration. It includes the classification of medical devices (see link).

https://www.transparencia.gob_sv/institutions/h-zacamil/documents/207883/download
Equatorial Guinea

Desk review
Regulated by MOH

Eritrea

GAMD 2021
Official nomenclature system for medical devices is currently in the process of development.
https://shabait.com/

Estonia

Desk review
It uses the MSA code (nationally developed) although it also uses the GMDN, both for various purposes such as regulation and procurement.
https://msa.sm.ee/eng/search/
https://msa.sm.ee/ctrl/en/Fail/laadi_alla_mall/96968
https://haigekassa.ee/en/people/medical-devices

Ethiopia

GAMD 2021
Nationally developed and based on both the UMDN and the GMDN. This nomenclature is developed by EPSA, ESDA and FMoH in collaboration with stakeholders. The nomenclature is mainly used for procurement and regulatory purposes. The Established Public Infrastructure Directorate is now starting an inventory to identify the type, source and status of the devices.
www.fmhaca.gov.et
https://epsa.gov.et/featured-services/procurement-list/

Desk review
The Guideline for Registration of Medical Devices includes the medical devices’ essential safety and performance requirements, and risk classification I to IV. As well as a nationally developed nomenclature as stated in the Ethiopian Food and Drug Administration (first link and third link). The second link shows the registration form for medical devices.

Fiji

Desk review
There is no specific nomenclature system. The procurement, management, inventory and registration use the generic name or the trade name of the product (according to the 2013 policy).
Finland

**GAMD 2021**

Finland CA will implement the European Medical Device Nomenclature (EMDN) used by manufacturers/ARs when registering their medical devices in the EUDAMED database. The EMDN system will be based on the Italian CND nomenclature system. This will be the only official nomenclature system for medical devices in Finland.


**Desk review**

The EMDN system will be based on the Italian CND nomenclature system. This will be the only official nomenclature system for medical devices in Finland.


France

**GAMD 2021**

The classification of the provisions of medical devices is provided for in Article R. 5211-7 of the Public Health Code. The rules are specified in the order of March 15, 2010 amending the order of April 20, 2006 setting the classification rules for medical devices.


http://www.legifrance.gouv.fr/affichCode.do;jsessionid=3DA99E55SFOAB933E0B91227088DB46C _tpdo04v_3?idSectionTA=LEGISCTA000006190738&cidTexte=LEGITEXT000006072665&dateTexte=20100330

https://www.gmdnagency.org/

**Desk review**

It is used as a nomenclature based on the GMDN (for procurement and commercialization), and as it is in the EU it will be used in parallel with the EMDN (for different purposes such as regulation, registration, procurement, surveillance, etc.).

https://www.legifrance.gouv.fr/codes/id/LEGISCTA000006190738/


After publication of the first draft of this Overview, the Hôpitaux de Haute-Savoie/AFIB have expressed the use, for more than 30 years, of the CNEH code nomenclature system (developed by the Center National d’Expertise Hospitalière) for the identification and management of any biomedical devices and medical infrastructures in this country. This nomenclature in French language, is publicly available. In addition, the inventory and management software system for medical devices (CMMS) uses the CNEH codes to identify any medical device. It has also been specified that the Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM), formerly the AFSSAPS, is the agency in charge of giving marketing authorizations for CE-marked medical devices, which in no case takes into consideration the use of the GMDN nor the UMDN for classifying or identifying any medical device.9

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9 Answered to the August 2021 Survey “Questions for Biomedical / Clinical Engineers” and commented by email to the publication of the first Draft Nomenclature Overview.
The Republic of The Gambia

**GAMD 2021**
The Medical Research Council (UK) in Gambia (refer to specific link) uses the UMDNS system via the ECRI Health Devices Sourcebook (ECRI website). Note that this is not used by the Ministry of Health.

http://www.mrc.gm/

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Georgia

**GAMD 2021**
According to Georgian legislation, Georgia recognises international or national (according to a list of certain countries) certificates of medical devices there.

https://matsne.gov.ge/ru

**Desk review**
The Law of Medicines and Pharmaceutical Activities (which includes the regulation of medical goods or medical devices) proposes three groups on the classification of pharmaceutical products (article 11, superindex 2) for advertising and retailing purposes. But there is no nomenclature system for medical devices.


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Germany

**GAMD 2021**
At the German Institute for Medical Documentation and Information (DIMDI) German manufacturers or an authorised representative of non-EU manufacturers have to register their products themselves. The database is served by DIMDI and today uses UMDNS.

http://www.dimdi.de

**Desk review**
According to the information of the regulatory agency of Medical devices (BfARM) and the Ministry of Health two systems are used: UMDS (for medical devices in general) and EMDN for IVD. Although it is announced that both of them will be replaced (in May 2021) with the EMDN (European Nomenclature system for medical devices) which itself is based on the Italian CND system.

https://www.dimdi.de/dynamic/de/medizinprodukte/bezeichnungssysteme/

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Ghana

**Desk review**
According to the “Guideline for registration of medical devices”, the GMDN will be required for registration just in case it is previously coded. The nomenclature is used for registration purposes.

Greece

GAMD 2021
A specific technical committee is responsible for the correlation of Nomenclature, Classification and Codification of Medical Devices. The final deliverable is expected in 2014.
https://www.gmdnagency.org/

Desk review
A specific technical committee is responsible for the correlation of the nomenclature, the classification and codification of medical devices. The final deliverable is expected in 2014. The novel EMDN which is based on CND nomenclature will be introduced soon as the official EU's system. The National regulatory authority is the National Organization for Medicines in charge of medical products and devices.
https://www.eunethta.eu/eof/

Grenada

GAMD 2021
A system was developed but was not supported by management. There is no URL because this software was locally developed.

Desk review
The Ministry of Health website is not available for this country, nor the “Biomedical unit”, which is responsible for the identification, procurement and maintenance of the medical equipment at the Hospitals and the Community Health facilities; nevertheless, the Strategic Plan for Health 2016-2025 is available and provides an in which it is mentioned the lack of material and human resources.

Guatemala

GAMD 2021
La Clasificación se encuentra contemplada en el Anexo de la Norma Técnica No. 37. In Vivo y según clase.
(Original in Spanish) The Classification is contemplated in the Annex of Technical Standard No. 37. In Vivo and According to class.
https://www.mspas.gob.gt/
https://medicamentos.mspas.gob.gt/

Desk review
In accordance to the “Norma Técnica 37 versión 5-2016 Para la inscripción sanitaria de dispositivos médicos” the nomenclature system use for regulation, surveillance and control of medical devices has been nationally developed.
https://medicamentos.mspas.gob.gt/index.php/legislacion-vigente/normas-tecnicas?download=262%3Ainscripcion-sanitaria-de-dispositivos-medicos&start=40

Guinea

Desk review
In the Medicines and Cosmetics Regulation 2002 Act it is indicated that medicinal products for importation, manufacture, processing or packing should be done with the generic, official or approved non-proprietary name found in official pharmacopoeias or formularies alongside the brand name.
https://wipolex.wipo.int/en/text/199156
Guyana

**Desk review**
There is no official nomenclature for medical devices. The Regulation Agency (GAFDD) is in charge of the registration of devices.

https://gafdd.gy/inspectorate/

Honduras

**GAMD 2021**
El Reglamento para el Control Sanitario de Productos, Servicios y Establecimientos de Interés Sanitario, establece una nomenclatura con fines de Registro.

(Original in Spanish) *The Regulation for the Sanitary Control of Products, Services and Establishments of Sanitary Interest, establishes a nomenclature for registration purposes.*

http://www.salud.gob.hn/site/

**Desk review**
The ‘Reglamento de control sanitario 2005’ proposes a nomenclature system for sanitary license (art. 133/ unidad III) and for registration (art. 159, unidad V).


Hungary

**GAMD 2021**
The coding is not available on the Internet.

**Desk review**
A national nomenclature system (and classification) has been developed for medical devices on “4/2009. (III. 17.) Decree”; also the acceptance of another nomenclature system such as the “Global device name” for registration of products (see: “Annex II”). Although, as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too.

https://net.jogtar.hu/jogszabaly?docid=A0900004.EUM&celpara=#xcelparam
https://net.jogtar.hu/jogszabaly?docid=a0300008.esc

Iceland

**Desk review**
It uses a nomenclature system for registration (see link). Although, as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too.

https://www.ima.is/medical_devices/about_medical_devices/

India

**Desk review**
Regulated by the Central Drugs Standard Control Organization: CDSCO. The GMDN nomenclature system is used for regulation in the private sector.

https://cdsco.gov.in/opencms/opencms/en/Home/
Indonesia

**GAMD 2021**
It uses a Harmonization System code (HS) at the moment. After harmonization, GMDN will be used.

**Desk review**
There are classification guidelines and a policy for the distribution of medical devices and IVDs. The nomenclature systems mentioned in the regulation documents are the Harmonization System code (HS) and the GMDN (see two links).

http://regalkes.kemkes.go.id/informasi_alkes/Pedoman%20Klasifikasi.pdf

Iran (Islamic Republic of)

**Desk review**
Regulated by IMDR (first link). For its registration, any medical device needs a declaration of conformity as stated in GHTF STED which is accepted in the report in one of the following nomenclatures: National developed classification (IRC Code: Iran Registration Code); EU classification or US-FDA classification. However, in order to fulfil the whole documentation, the UMDNS classification is used.

http://imed.ir/

Iraq

**GAMD 2021**
The MoH is working on adapting a national nomenclature system and linking it to the UMDNS.

https://kimadia.iq/en

**Desk review**
No official nomenclature system, but several such as UMDNS are accepted. The State Company for Provision of Medicines and Medical Appliances (KIMADIA) oversees imported medical devices. Tecmoh registers all medical devices in Iraq.

https://kimadia.iq/assets/files/1613646335_67-2021-2-%D8%A7%D8%B3%D8%B9%D8%A7%D8%B1-%D8%A7%D9%84%D9%85%D8%A7%D8%AD%D8%A9-%D8%A7%D9%84%D9%85%D8%B1%D9%82%D9%85%D8%A9_1613646335.pdf
https://www.facebook.com/Iraqi-Pharmacovigilance-Center-IPhvC/?ref=ARSHWx4DaLIQXMMAOzGGWzyBji1p90GRSRgwilp1tcc_P7hppyjNAGTxdXOsm7KiQ&refn&tn=kC-R

Ireland

**Desk review**
For registration of medical devices, it is recommended to use the GMND nomenclature system (see link 1), even if other nomenclatures are also accepted. Although as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too.

Annex 2. Overview of nomenclature systems for medical devices in WHO member states

**Israel**

**Desk review**
There is no official nomenclature, but the use of several nomenclatures is accepted, such as UMDNS, for the registration of medical technologies (regulated by the Division of Medical Equipment (see first link)). Risk Classification often uses the same as EC states. As in agreement with EC states, it may use the EMDN (European Nomenclature system for medical devices) too. The risk classification for medical devices used is divided into the following classes: I, IIa, IIb, and III (Decreto Legislativo 24 febbraio 1997, Art. 8). [From (Samadi)]

https://www.health.gov.il/English/MinistryUnits/HealthDivision/MedicalTechnologies/MLD/Pages/default.aspx

https://medicaldevices.health.gov.il/

**Italy**

**GAMD 2021**
As mentioned on several occasions in the past, a map of correspondence between the GMDN nomenclature and the Italian CND classification has been created since 2007 to allow manufacturers to register in the Italian database of medical devices. This map is subject to ongoing maintenance even today at the request of manufacturers. This map was introduced at the beginning because the GMDN code was originally the mandatory registration key in the Italian system. Subsequently, the mandatory use of the GMND code was removed at the request of the manufacturers, due to the difficulty of using it and, in many cases, due to its unavailability. In any case, the possibility of using the GMDN code and its connection with the CND is still allowed, but it appears that, despite this possibility of use, the GMDN code is rarely used in the registration in the Italian system.

http://www.salute.gov.it/imgs/C_17_pagineAree_328_listFile_itemName_15_file.pdf

http://www.salute.gov.it/portale/temi/p2_3_dispositivi.html

**Desk review**
The Italian classification system (CND Classificazione Nazionale dei Dispositivi Medici) has been correlated to the GMDN nomenclature, as well as it will be the basis for the future EMDN (European Nomenclature system for medical devices) too, that will be the one used soon for EC states.

http://www.salute.gov.it/imgs/C_17_pagineAree_328_listFile_itemName_15_file.pdf

http://www.salute.gov.it/portale/temi/p2_3_dispositivi.html

**Jamaica**

**Desk review**
There is the Standards & Regulations Division within the MoH. However, there is not mentioned a specific nomenclature for registration of medical devices, nor for risk classification.


Japan

**GAMD 2021**
Japanese Medical Device Nomenclature was developed from the GMDN 2003 version.


**Desk review**
It uses a national nomenclature system called Japanese Medical device nomenclature (JMDN) - see PMDA regulatory agency link for more details

https://www.std.pmda.go.jp/stdDB/index_en.html

Jordan

**GAMD 2021**
We support the WHO to adopt a standard nomenclature for medical devices. We used a nomenclature based on UMDNS for management in the CMMS system, and the government procurement department uses UNSPSC nomenclature for procurement purposes.


**Desk review**
Jordan relies on the EU directives to classify its devices, namely, the Medical Devices Directives 93/42/EEC and the Active Implantable MDD 90/385/EEC and the Medical Devices Importation Directives, Art. 2.


Kazakhstan

**GAMD 2021**
Medical State Register of lekarstennyyh.

https://www.ndda.kz/category/nomenklatura_men_izd

**Desk review**
It uses a nationally developed nomenclature system that is harmonized with the GMDN.

https://www.ndda.kz/category/nomenklatura_men_izd
http://nmirk.dari.kz/

Kenya

**GAMD 2021**
The GMDN is used for regulatory purposes.

https://www.gmdnagency.org

**Desk review**
The nomenclature is used for registration purposes. The following systems are allowed for registration purposes: nationally developed, GMDN, UDI and UMDNS; as stated in the guidelines, at least, one system must be used for registration of medical devices or IVDs (see link 1) alongside the risk classification for medical devices A-D (see link 2).

https://www.ghspjournal.org/content/ghsp/early/2021/03/24/GHSP-D-20-00578.full.pdf
Kiribati

**Desk review**
The Medical Equipment Management Committee within the MoH is in charge of the registration of medical equipment. There is no specific nomenclature used nor a risk classification system.

Kyrgyzstan

**GAMD 2021**
The nomenclature is used for various purposes: regulation, procurement, in-vitro diagnostics lists and inventory.

http://www.pharm.kg/ru/about

Lao People’s Democratic Republic

**Desk review**
No change as no nomenclature system is mentioned on any guidelines, policy, rules or acts; in this country, it is used the generic name of medical products or the active ingredients officially recognized by the World Health Organization which are used worldwide and have no copyright owner, according to “Law on drugs and medical products (Amended)(2011); Medical Devices risk classification A- D (law on Drugs and Medical Products, Art. 11.).


Latvia

**Desk review**
t. 119.3. from the “Procedimientos de registro, evaluación de la conformidad, distribución, operación y supervisión técnica de dispositivos médicos” regulation it is used a nomenclature system for the registration of medical devices and it is also accepted the GMDN for registration purposes (see link 1)


Lebanon

**GAMD 2021**
The Ministry of Health is planning to acquire the Global Medical Devices Nomenclature system to adopt it and use it for regulatory and procurement purposes.


**Desk review**
There is no official nomenclature for medical devices, but GMND is accepted as stated in the “Minister Decision No. 1506 date 1/9/2014” page 1 (see link).

**Libya**

**GAMD 2021**
For the medical equipment list it uses a nomenclature based on UMDNS. Nomenclature is used for inventory systems in healthcare facilities and lists.

http://www.mhtc.ly

**Desk review**
It is accepted the use of various nomenclature systems of medical devices for procurement and donations (see link 2).


**Lithuania**

**Desk review**
Medical devices are divided into classes I-III according to their risk (MS 102, 17-19). The State Health Care Accreditation Agency, MoH, is in charge of regulation. Although, as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too (see link 2).

https://vaspvlt.gov.lt/node/78
http://vaspvlt.taduliz.lt/node/44
https://vaspvlt.gov.lt/node/1166

**Luxembourg**

**Desk review**
Although as part of the EC they will use the (European Nomenclature system for medical devices) too.

https://sante.public.lu/fr/support/recherche/index.php?=do&from=search&s=desc%28score%29&r%5B0%5D=f%2Fsection%2Flegislation&res_length=20&q=dispositifs+m%C3%A9dicaux#main

**Madagascar**

**GAMD 2021**
Nomenclature nationale pour la comptabilité matière du patrimoine de l'Etat (codification pour l'inventaire technique).

(Original in French) National nomenclature for the material accounting of State assets (codification for the technical inventory).

http://www.agmed.mg/

**Desk review**
There is a nationally developed nomenclature. The regulation is in charge of L'Agence du Médicament de Madagascar (AGMED).

http://www.agmed.mg/PDF/SI/doss/ARRETE-14993_2013_MSANP-modalit%C3%A9s_fabrication_information-au_public_vente_dispositifs_m%C3%A9dicaux.pdf

**Malaysia**

**Desk review**
For medical devices registration it is used the HS Code (Harmonized Tariff Nomenclature and Coding System) as well as the GMDN code (see link).

Maldives

**Desk review**

There is a project to develop a national nomenclature system based on the UMDNS (see: Situation analysis report, Link 3).

http://health.gov.mv/
https://www.facebook.com/mfdamv-102808298333472/
https://www.researchgate.net/publication/260766912_Situation_Analysis_on_medical_equipment_in_Maldives#fullTextFileContent

Mali

**GAMD 2021**

Il existe dans le document de la comptabilité matièrre une rubrique nomenclature sommaire ou les différents produits sont classés par catégories, mais c’est un domaine très important qui mérite une action.

(Original in French) There is a summary nomenclature section in the stock accounting document where the different products are classified by categories, but this is a very important area that deserves action.

**Desk review**


Mexico

**GAMD 2021**

The nomenclature system is established and organized in charts for health technologies that can be used in public/social health services. As for the government administration for 2018-2024, the charts will be organized now as a compendium and it is in the process of depuration.


**Desk review**

https://www.gob.mx/cofepris
http://www.csg.gob.mx/contenidos/priorizacion/cuadro-basico.html

Via the “Questions for Biomedical / Clinical Engineers” survey, a private institution (TINC) specified that the Global Medical Device Nomenclature (GMDN) has been tailored to regional terms in order to standardize a single terminology adopted by hospitals. Also, they created a free inventory management tool which automatically makes the correlation to the tailored GMDN nomenclature.

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10 Answered to the August 2021 Survey “Questions for Biomedical / Clinical Engineers”
**Monaco**

**GAMD 2021**
Directives 93/42/CEE.

https://www.gouv.mc/Gouvernement-et-Institutions/Le-Gouvernement/Departement-des-Affaires-Sociales-et-de-la-Sante/Direction-de-l-Action-et-de-l-Aide-Sociales

**Desk review**
There is a nationally developed nomenclature for medical devices. Medical devices and IVDs are grouped by risk category: class I-III (arrêté ministériel n. 2003-581, Sec. I, Art. 1er). The Direction de l’Action Sanitaire et Sociale within the MoH is in charge of the regulation of medical devices.

https://www.gouv.mc/Gouvernement-et-Institutions/Le-Gouvernement/Departement-des-Affaires-Sociales-et-de-la-Sante/Direction-de-l-Action-et-de-l-Aide-Sociales

**Montenegro**

**GAMD 2021**
“Register (notification) of medical devices” that contains information on medical devices which are available for use in Montenegro has just recently been set up. As it is at the start of its operations, it will use GMDN as a referent nomenclature system and based on this, it will be developed a system that will be in Montenegrin language so that all users can use it properly and they will have information what is on Montenegrin market as well.

https://www.calims.me/Portal/faces/e?=4618826366059702&paramPut=%3E+Medical+Devices+%3E+Definitions+and+Classification&paramRender=2&paramS=70&_adf.ctrl-state=wn7tyvskb_894

**Desk review**
It has recently developed a nomenclature system of medical devices based on GMDN.

https://www.calims.me/Portal/faces/dinamickeStrane?_59702&paramPut=%3E+Medical+Devices+%3E+Definitions+and+Classification&paramRender=2&paramS=70&_adf.ctrl-state=wn7tyvskh_894

**Morocco**

**GAMD 2021**
Nomenclature basée sur l’ECRI et le CNEH.

(Original in French) Nomenclature based on ECRI and CNEH.

http://dmp.sante.gov.ma/classification?rlc=587d5c&tirt=Dispositifs%20m%C3%A9dicaux&id=8

**Desk review**
It is based on the UMDNS.

http://dmp.sante.gov.ma/classification?rlc=587d5c&tirt=Dispositifs%20m%C3%A9dicaux&id=8

**Namibia**

**Desk review**
Many nomenclatures are accepted as stated in the second link

http://www.nmrc.com.na/
Nepal

**Desk review**

A national nomenclature system is based on the GMDN and the UMDNS.

[Links]

Via the “Questions for Biomedical / Clinical Engineers” survey, the IFMBE-Clinical Engineering Division (CED) explained that the lack of mandatory guidelines or official documents demanding the use of one specific nomenclature system, as well as the coexistence of many nomenclatures in different government health facilities in Nepal, has led to wrong procurements and mismanagement of medical device inventories.11

Netherlands

**Desk review**

There is a national nomenclature system based on the GMDN. Although, as a part of the EC it will use the EMDN (European Nomenclature system for medical devices) too.

[Links]

New Zealand

**Desk review**

New Zealand uses a nomenclature based on the GMDN. The Global Medical Device Nomenclature (GMDN) codes are required to identify types of medical devices notified to the WAND database.

[Links]

Nicaragua

**GAMD 2021**

Although we do have an official nomenclature system for medical devices, it is not used for various reasons.

**Desk review**

Nicaragua has its own nomenclature system based on the GMDN.

[Links]

Niger

**GAMD 2021**

There are several types of codification tested. The first were inspired by the French CNEH code (national code for hospital equipment). There is no single codification adopted at the national level.

(Original in French) Il y a plusieurs types de codification testés. Les premières se sont inspirées du code CNEH (code national pour l’équipement hospitalier) français. Il n’y a pas de codification unique retenue au niveau national.

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11 Answered to the August 2021 Survey “Questions for Biomedical / Clinical Engineers”
Nigeria
Desk review
There is no official nomenclature system. Medical devices are regulated by the National Agency for Food and Drug, Administration and Control (NAFDAC). Compliance with the classification of the country where the device is manufactured (link 2).
https://www.nafdac.gov.ng/drugs/
https://www.nafdac.gov.ng/

North Macedonia
GAMD 2021
No, but we are recognising the GMDN code.
Desk review
There is a nationally developed nomenclature but it is allowed the co-existence of several nomenclatures such as GMDN.
https://lekovi.zdravstvo.gov.mk/medicaldevices

Norway
GAMD 2021
The use of GMDN is not imposed by law.
https://www.gmdnagency.org/
Desk review
Norway uses a nomenclature system based on the GMDN. However, as a part of the EC it will use the EMDN (European Nomenclature system for medical devices) too.
https://legemiddelverket.no/English

Oman
Desk review
The GMDN is used for regulatory purposes. However, UMDNS and GMDN are both accepted nomenclature systems.

Panama
GAMD 2021
The UMDNS system has been adopted into legislation. Its implementation is still in process.
(Original in Spanish) El sistema UMDNS ha sido adoptado en la legislación. Su implementación está aún en proceso.
http://www.minsa.gob.pa/
http://minsabcdn.net/sites/default/files/normatividad/decreto_468_de_2007_para_publicar_en_gaceta_2.pdf
Desk review
Panama is now in the process of adopting both the GMDN and the UMDNS for regulation purposes.
http://www.minsa.gob.pa/direccion/direccion-nacional-de-farmacia-y-drogas
**Paraguay**

**GAMD 2021**
A plan is being developed to proceed with the installation of a naming system.

(Original in Spanish) *Se está elaborando un plan para proceder con la instalación de un sistema de nomenclatura.*

**Desk review**
The national regulatory authority is the Dirección de Vigilancia Sanitaria del Ministerio de Salud Pública y Bienestar Social.


**Peru**

**GAMD 2021**
Ley N°29459-D.S and the D.S. N° 016-2011-SA.


[https://www.gmdnagency.org/](https://www.gmdnagency.org/)

**Desk review**
According to the form DMEB-002 published on the official website, Peru uses the GMDN in the private sector, although the use of UMDNS or other systems is legally accepted (Ley N°29459-D.S and the D.S. N° 016-2011-SA). The national regulatory authority is the Dirección de Vigilancia Sanitaria del Ministerio de Salud Pública y Bienestar Social. Advance Scientific del Perú.

[http://www.digemid.minsa.gob.pe](http://www.digemid.minsa.gob.pe)

**Philippines**

**GAMD 2021**
The Philippines will be using the Nomenclature that will be decided by the member states of the ASEAN who are working on the harmonization of medical device regulation in the region, where medical device nomenclature is one of the concerns.

**Desk review**
The national regulatory authority is the Bureau of Health Devices and Technology (BHDT), Department of Health.

[https://doh.gov.ph/node/266](https://doh.gov.ph/node/266)

**Poland**

**GAMD 2021**
The GMDN code is mentioned as a basic medical device nomenclature system in Polish legislation: Act of 20 May 2010 on Medical Devices; however, the use of other nomenclatures is allowed. Poland is part of the EU medical device regulatory framework so a new obligation from the European Commission in the area of medical device nomenclature and Eudamed will be implemented, e.g. adopting the European Medical Device Nomenclature (EMDN) when available.

Nevertheless, according to the EC statement, this nomenclature will still share some features with the GMDN code.
Desk review

In the private sector, Poland uses a nomenclature system of medical devices based on the GMDN. Although, as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too. The national regulatory authority is the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products.


Portugal

GAMD 2021
The Directorate-General of Health/Ministry of Health of this country pointed out that the official nomenclature system for medical devices and IVDs for registry purposes is based on the European Medical Device Nomenclature (EMDN).12

Desk review
In the private sector Portugal uses a nomenclature system of medical devices based on GMDN. Although, as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too. The national regulatory authority is the National Authority of Medicines and Health Products (INFARMEDC, IP).

https://www.infarmed.pt/

Qatar

GAMD 2021
This is used for planning medical equipment for new / upcoming projects.

https://www.ecri.org/solutions/umdns/

Desk review
Medical devices are regulated by the MOHP but registered by the Ministry of Economy and Commerce (MEC). It uses the UMDNS for planning for new/upcoming projects, but the GMDN is also accepted. The national regulatory authority is the Medical Device Registration Unit, Pharmacy & Drug Control, Supreme Council of Health.

https://www.mfds.go.kr/eng/index.do

Republic of Korea

Desk review
Undefined nomenclature but uses medical devices classification and medical devices are regulated by the Korean Food and Drug Administration (KFDA).

https://www.mfds.go.kr/eng/wpge/m_39/denofile.do
https://www.mfds.go.kr/eng/index.do
https://www.mfds.go.kr/eng/brd/m_61/view.do?seq=74

12 Answered to the September 2021 Survey for the GAMD 2021 Update
Republic of Moldova

Desk review
It uses its own developed nomenclature that, nevertheless, is harmonized with the EU’s regulation. The nomenclature is based on the GMDN (as seen in the second link, second page point 3c) but the use of other nomenclature is accepted too. The national regulatory authority is the AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE.

http://nomenclator.amdm.gov.md
https://amdm.gov.md/ro

Romania

Desk review
There is the European regulatory provision on medical devices Regulated by ANM (see first link) and a national database of medical devices. There is also an own nomenclature system. Although, as part of the EC it will use the EMDN (European Nomenclature system for medical devices) too.

https://www.anm.ro/en/
https://www.anm.ro/nomenclator-dm/

Russian Federation

Desk review
There is an own developed nomenclature system but according to the fact that the state is a member of the EEU, which signed an agreement with the GMDN about nomenclature systems harmonization. The common market of medical products within the Eurasian Economic Union (EAEU) begins to function in full in 2022. From 2022 an EAEU nomenclature will be done based on the GMDN for various purposes mentioned in this question. The national regulatory authority is Roszdravnadzor.

https://roszdravnadzor.gov.ru/services/mi_reesetr

Rwanda

Desk review
It uses the GMDN to register medical devices (see first link page 24).


Via the “Questions for Biomedical / Clinical Engineers” survey, the Nabel HealthCare Engineering Ltd. pointed out the main use of the Universal Medical Device Nomenclature System (UMDNS) for Rwanda's medical devices, as well as the coexistence of many nomenclatures for specific procedures. Also, it has been expressed that even with the progress that this country has made in collaboration with the ECRI Institute, there are major challenges caused by the many identification codes used for medical devices.13

Sao Tome and Principe

Desk review
Regulated by the Central de Aprovisionamiento de Medicamentos:CAME (see link).

http://ms.gov.st/?p=57

13 Answered to the August 2021 Survey “Questions for Biomedical / Clinical Engineers”
Saudi Arabia

GAMD 2021
A committee inside NUPCO has been established for that purpose and the work is in progress.
http://www.nupco.com

Desk review
Medical devices are regulated by the MOH (first link) via the unit NUPCO (second link) which manages tenders for medical devices. Medical devices are Regulated by the Saudi Food and Drug Authority (third link). Private industry uses the GMDN.
https://www.moh.gov.sa/
https://www.nupco.com/
https://udi.sfda.gov.sa

Senegal

Desk review
Private industry uses the GMDN. The national regulatory authority is the Direction des Infrastructures, d’équipement et de la Maintenance.
https://sante.sec.gouv.sn/les-directions/la-direction-des-infrastructures-des-equipements-et-de-la-maintenance

Serbia

GAMD 2021
National nomenclature is in the process of updating and amendment.
http://www.zdravlje.gov.rs

Desk review
The national regulatory authority is the Medicines and Medical Devices Agency (ALIMS) which assures the use of the official nomenclature.
https://www.zdravlje.gov.rs/tekst/335365/medicinska-sredstva.php

Sierra Leone

Desk review
Medical devices are regulated by a national regulatory authority which is the Pharmacy Board (PBSL). The GMDN is used for registration of medical devices, and it is regularly used by the private industry.
http://www.pharmacyboard.gov.sl/

Singapore

GAMD 2021
There is a Global Medical Device Nomenclature (GMDN) which we only use as an internal reference. It is not required for medical device product registration in Singapore.

Desk review
The GMDN is used for internal reference but not for the registration of medical products. In addition, since the country is a member of ASEAN, other nomenclature systems are also used. The national regulatory authority is the Health Science Authority.
https://www.hsa.gov.sg/medical-devices
Slovakia

**Desk review**
Regulated by the MoH, it uses the SNOMED system. The national regulatory authority is the Ministry of Health.

https://www.health.gov.sk/Titulka

**Slovenia**

**GAMD 2021**
When medical devices are being produced by the manufacturers of medical devices with their registered place of business in the Republic of Slovenia, are notified to the national competent authority, GMDN code should be submitted, if available.

http://www.jazmp.si
https://simap.ted.europa.eu/cpv

**Desk review**
No changes. The official information is regulated by the JAZMP. The private industry uses the GMDN. The national regulatory authority is the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia.

https://www.jazmp.si/

**South Africa**

**GAMD 2021**
The regulator has adopted the use of GMDN which will be a nationally accepted nomenclature.

**Desk review**
There are many co-existent nomenclatures. In many hospitals UMDNS is used. According to the country’s legislature the GMDN can be used for special equipment, and IVDs (see first/second link). For medium and high-risk devices it is obligatory to use the GMDN for manufacturing, importing, exporting and distribution (see first/second link). South Africa, for example, regulates medical devices according to 3 distinct pieces of legislation and guidelines most closely resembling those of the IMDRF founding members (see link 3). The national regulatory authority is the South African Health Products Regulatory Authority.

https://www.ghspjournal.org/content/ghsp/early/2021/03/24/GHSP-D-20-00578.full.pdf

**South Sudan**

**Desk review**
There is no official nomenclature system in South Sudan (first link 1st paragraph from the beginning of page 6: The South Sudanese Drug and Food Control Authority Act, 2012). One of the nomenclatures that may be used for the registration of medical devices is the one developed by US-FDA (second link: registration requirement’s section).

https://www.ghspjournal.org/content/ghsp/early/2021/03/24/GHSP-D-20-00578.full.pdf
https://www.wikiprocedure.com/index.php/Sudan_-_Registration_of_medical_device_and_In_Vitro_devices_(IVDs)
Spain

**GAMD 2021**
The code UMDNS has been used, but will be replaced by GMDN when the Spanish version is available.

(Original in Spanish) *Se ha utilizado el código UMDNS, pero se sustituirá por GMDN cuando esté disponible la versión en español.*

**Desk review**
It uses the UMDNS as the main nomenclature system. The GMDN is used for the regulation of medical devices in the private sector. Both GMDN and UMDNS are proposed on the official website (AEMPS). Uses the CIMA for medicine (see 2nd link). Regularly, private industry uses the GMDN system. The national regulatory authority is the Agencia Española de medicamentos y productos sanitarios.

https://www.aemps.gob.es/
https://cima.aemps.es/cima/publico/home.html

Sri Lanka

**Desk review**
Medical devices are regulated by the National Medicines Regulatory Authority (NMRA).


Sudan

**Desk review**
It uses the UMDNS system, and since 2011 it has officially recommended the use of the GMDN. There is a risk-based classification system (link 4).

https://fmoh.gov.sd/
https://www.ghspjournal.org/content/ghsp/early/2021/03/24/GHSP-D-20-00578.full.pdf

Syrian Arab Republic

**Desk review**
Medical devices are regulated by the MOH (see link). There is no specific information about the nomenclature system used.

http://www.moh.gov.sy/

Sweden

**GAMD 2021**
The change from GMDN to EMDN will take place with regards to the implementation of the new EU regulation on medical devices that shall be applied from the 26th of May, 2021.

**Desk review**
Switzerland

**GAMD 2021**
Swissmedic uses GMDN (no country specific nomenclature); if manufacturers do not know the GMDN number, a UMDNS code may be given.

**Desk review**
Both UMDNS and GMDN are used (the preference is given to GMDN, however, if manufacturers do not know GMDN, then UMDNS is used). Currently, there is a transition to EMDN (based on CND), as well as the corresponding mapping with the GMDN. The national regulatory authority is the Swiss Agency for Therapeutic Products, Swissmedic.


Tajikistan

**GAMD 2021**
https://portal.eaeunion.org/sites/odata/redesign/Pages/MedicalDeviceNomenclature.aspx

**Desk review**
It uses the EAEU nomenclature, and the GMDN nomenclature, as well as others. The nomenclature of the manufactured drugs and medical products is determined by the manufacturers themselves as the official website states. The national regulatory authority is the Ministry of Health and Social Protection of the Population of the Republic of Tajikistan.

https://portal.eaeunion.org/sites/odata/redesign/Pages/MedicalDeviceNomenclature.aspx

Thailand

**Desk review**
In Thailand, the sphere of medical devices is regulated by the Thai-FDA in cooperation with the Association of Southeast Asian Nations (ASEAN) that works together with the AHWP Asian on the harmonization of medical devices regulation. The GMDN is used for the regulation of medical devices in the private industry.

https://www.fda.moph.go.th/sites/fda_en/SitePages/Medical.aspx?IDitem=index
https://asiaactual.com/blog/thailand-implements-new-medical-device-regulations/

Timor-Leste

**Desk review**
There is an ongoing project for a nomenclature for MD, however there is scarce information.

http://timor-leste.gov.tl/?lang=en
Togo

**GAMD 2021**
The level of the sub-service responsible for the equipment is too low to be read. The hierarchical superiors do not show the necessary interest for the implementation of the management which is essential for medical devices.

**Desk review**
https://www.wahooas.org/web-ooas/

Trinidad and Tobago

**GAMD 2021**
Developed and in use as “Fixed Asset Inventory and Facilities Management”. TMA Systems Maintenance Management Software (the nomenclature of medical devices are generally developed by the respective Regional Health Authorities for procurement purposes).

Via the “Questions for Biomedical / Clinical Engineers” survey, the Ministry of Health of Trinidad and Tobago has established that no specific or official nomenclature system is used in this country, but the nomenclature codes given by manufacturers.  

Tunisia

**GAMD 2021**
The nomenclature of medical devices is an integral part of the Manual of biomedical and hospital maintenance management procedures drawn up in 1996 and improved in 2007 by the Ministry of Public Health, which was the subject of an order.

(Original in French) La nomenclature des dispositifs médicaux fait partie intégrante du Manuel des procédures de gestion de la maintenance biomédicale et hospitalière élaboré en 1996 et amélioré en 2007 par le Ministère de la santé publique qui a fait l’objet d’un arrêté.

**Desk review**
It uses a nationally developed nomenclature system, as well as the GMDN for the regulation of medical devices in the private sector.
http://www.dpm.tn/

Turkey

**GAMD 2021**
Huab (see second link) is the Turkish registry system for medical devices. Both GMDN and UNSPSC are used in this system. For reimbursement purposes another nomenclature mentioned in the corresponding link is also used.

https://www.saglik.gov.tr/?_Dil=2
http://www.huap.org.tr/ubb/

**Desk review**
It uses a nomenclature system that is based on the UNSPSC and GMDN, however, they are adapted to national needs. Turkey is in the process of using the EU regulation. The national regulatory authority is the Turkey Medicines and Medical Devices Agency, Ministry of Health.

https://www.gs1.org/docs/healthcare/events/220610/8_Turkey_Goksin.pdf
https://www.ispartaeo.org.tr/haber-9
https://www.saglik.gov.tr/TR/

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14 Answered to the August 2021 Survey “Questions for Biomedical / Clinical Engineers”
Uganda

**GAMD 2021**

See the list of medical equipment by level, and the Standard Medical Equipment Lists and Specifications by healthcare level are under review (as in sample formats in the corresponding websites). The main uses of the nomenclature system are for procurement purposes, and inventory systems in healthcare facilities.

[www.health.go.ug](http://www.health.go.ug)

**Desk review**

There exists a regulatory framework for medical devices registration, importation and use (link 3). However, Risk-based classification does not exist, and the application of the MD regulation is still limited (link 4).

[https://www.health.go.ug/download-attachment/ivZtalade9SPz4To_dbsBqwckPflb2S57yGgoi0ITo8](https://www.health.go.ug/download-attachment/ivZtalade9SPz4To_dbsBqwckPflb2S57yGgoi0ITo8)
[https://www.health.go.ug/download-attachment/wxVPCKlsDLk3NkJJyYkpYY-ohGwUXSeQMm7srlIbMM](https://www.health.go.ug/download-attachment/wxVPCKlsDLk3NkJJyYkpYY-ohGwUXSeQMm7srlIbMM)
[https://www.nda.or.ug/medical-devices/#1603100276960-871cf845-bab3](https://www.nda.or.ug/medical-devices/#1603100276960-871cf845-bab3)
[https://www.ghspjournal.org/content/ghsp/early/2021/03/24/GHSP-D-20-00578.full.pdf](https://www.ghspjournal.org/content/ghsp/early/2021/03/24/GHSP-D-20-00578.full.pdf)

Ukraine

**GAMD 2021**

[https://zakon.rada.gov.ua/rada/show/v0331282-01#Text](https://zakon.rada.gov.ua/rada/show/v0331282-01#Text)

**Desk review**

The incorporation of the GMDN is in progress. The national regulatory authority is the State Administration of Ukraine on Medicinal Products (SMDC).


United Kingdom of Great Britain and Northern Ireland

**GAMD 2021**

The Medicines and Healthcare products Regulatory Agency (MHRA) will be moving forward to use solely the GMDN with their system being phased out. The nomenclature used by the National Health System (NHS) for the procurement of medical devices is that used by the “Official Journal of the European Union” (OJEU) CPV codes. The NHS also has a national system known as “e-class” which is a classification system for products and services.

[www.nhssec.nhs.uk](http://www.nhssec.nhs.uk)

**Desk review**

The MHRA will be moving forward to solely use the GMDN with its previous system being phased out. The nomenclature used by the NHS is for the procurement of medical devices that are used by the “Official Journal of the European Union” (OJEU) CPV codes. Also, the NHS has a national system known as “e-class” which is a classification system for products and services. The national regulatory authority is the Medicines & Healthcare products Regulatory Agency (MHRA).

[https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#history](https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market#history)
United Republic of Tanzania

**GAMD 2021**

TMDA is using GMDN as the nomenclature system for the registration of medical devices in Tanzania. The main types of nomenclature used are GMDN and UMDNS. The main uses of the nomenclature system are for procurement purposes and inventory systems in healthcare facilities.

http://www.gmdnagency.org

**Desk review**

It has been used by the GMDN since 2015, but there is no access to the nomenclature code from the official website. It is obligatory to use a nomenclature system as it has been stated in the guidelines for the registration of medical devices.

https://www.tmda.go.tz/publications/24

https://www.ghspjournal.org/content/ghsp/early/2021/03/24/GHSP-D-20-00578.full.pdf

United Arab Emirates

**Desk review**

There is a nationally developed nomenclature but it is allowed the co-existence of several nomenclatures (often suggested by the importer -see first two links-). Regulated by the MOH (see links).


https://www.mohap.gov.ae/Files/MOH_Service/373/09%20Classification%20of%20a%20ProductEN.pdf


United States of America

**GAMD 2021**

1. **Product Code.** FDA- The Center for Devices and Radiological Health (CDRH) uses a nomenclature by assigning a 3-letter code to identify a device into a generic type or category. This nomenclature system is known as product code classification. The short name is ProCode. The Product Code Classification Database contains medical device names and associated information developed by the CDRH in support of its mission. This database contains device names and their associated product codes. The name and product code identify the generic category of a device for the FDA. The Product Code assigned to a device is based upon the medical device product classification designated under 21 Code of Federal Regulations (CFR) Parts 862-892.2. Problem code FDA-CDRH also has a nomenclature for CDRH Event Problem Codes for Medical Devices used in reporting adverse device events. The adverse event vocabulary codes were developed in cooperation with the National Cancer Institute Enterprise Vocabulary Service (NCI-EVS); see the second link.

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051637.htm

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/EventProblemCodes/default.htm

**Desk review**


Via the “Questions for Biomedical / Clinical Engineers” survey, the U.S. Food and Drug Administration has specified that, besides their product codes for medical device classification, the Global Medical Devices Nomenclature (GMDN) is the official nomenclature used in the UDI system and for all medical device requirements in this country.15

15 Answered to the August 2021 Survey “Questions for Biomedical / Clinical Engineers”
Uruguay
Desk review
The nomenclature commonly used in the Mercosur bloc is used.
https://www.gub.uy/ministerio-salud-publica/home

Uzbekistan
Desk review
It uses its own nomenclature system (see first link). Used nomenclature correlates with one used by the EU (second link).
https://data.gov.uz/uz/datasets/3514?dp-1-sort=G1

Venezuela (Bolivarian Republic of)
GAMD 2021
There is no specific nomenclature. The nomenclature used for the certification of medical devices is the FDA product classification.
Via the “Questions for Biomedical / Clinical Engineers” survey, the Simon Bolivar University informed that it has defined the U.S. Food and Drug Administration product codes as the official nomenclature system used for medical devices in this country. Also, this institution has developed the “Quality Certification Process for Medical Equipment”, which has been authorized by the Ministry of Health of Venezuela.16

Yemen
Desk review
Regulated by the Supreme Board for Medicines & Medical Appliances (SBDMA)/ MoPHP.
www.sbd-ye.org

Zambia
Desk review
Regulated by the Zambia Medicines Regulatory Authority (ZAMRA).
https://www.zamra.co.zm

Zimbabwe
Desk review
Regulated by the Medicines Control Authority of Zimbabwe (MCAZ).
https://www.mcaz.co.zw

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16 Answered to the August 2021 Survey “Questions for Biomedical / Clinical Engineers”
Conclusion

As presented in this report there are various nomenclature systems (national developed, UMDNS, GMDN, EMDN, etc.) used around the world for different purposes (regulation, procurement, reimbursements, lists, healthcare facilities, inventories). Around one third of the world does not have yet an official nomenclature to manage medical devices, one third uses various systems simultaneously, and another third either national developed nomenclature or EMDN, GMDN or UMDNS. This situation has been continuously evolving in the past ten years with promising signals of more countries acquiring an official(s) nomenclature(s) and also signals of multiple nomenclatures used for different purposes around the world. Several efforts are currently in place to harmonize not only the heterogenous regulatory framework worldwide, but more specifically universal nomenclature system. Until now these efforts have not been achieved due mainly to lack of agreement between the main stakeholders and member states. As indicated before, the nomenclature system of medical devices is a cross-cutting issue that interrelates the national health system with other areas such as economy, commerce, politics within a country, as well as with other countries due to globalization and regional agreements between countries. Thus, the actors, and interrelations multiply, the chances of agreement seem to diminish.

However, we observe a positive trend of countries strengthening their regulatory frameworks, harmonization of procedures, and adoption of an official nomenclature of medical devices. In the measure that the health system is strengthened it will facilitate the service delivery in order to achieve faster Universal Health Coverage.

Other limitations: More often than not, several regulations and agreements may be in use in a country for different purposes, but also for a single purpose. For instance, it is possible to have more than one agreement regarding imports and exports depending on the destination or origin of merchandise. In consequence sometimes there may be more than one answer to the questions we ask.

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Annex 2. Overview of nomenclature systems for medical devices in WHO member states

References


