Agency / Organization	GMDN Agency
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WHO thanks you very much for your participation in the meeting to discuss the standardization of medical devices nomenclature, as mandated by WHA74.

Please find below the survey for the Nomenclature Agencies, as mentioned during our meeting. Please provide all the evidence required for every statement provided (for example, website screenshots, links to your website or attach the documents required).

I.   General questions on nomenclature structure, access, and copyright

1. Please provide an overview of the processes used for: code development and maintenance, requests for updates, change control procedures, communication, and distribution of update versions. Who performs them and the periodicity?
How we update the GMDN   There is a huge range of technologies used in the MedTech industry, everything from specialist metals and plastics, machinery, electronics, chemicals, software and more. The industry is especially innovative and request us to update the GMDN to include their latest device or product features every day.   The GMDN Agency employs a team of highly qualified technical authors to investigate how the technology works and to create a concise description, not too vague and not too prescriptive or proprietary. The language used should be accessible to non-experts, with no jargon or too many complex acronyms and the terminology and style should be consistent.   The GMDN has been used for many years and therefore there is large existing set of descriptions. As new products enter the market, the descriptions for these need to be 'fitted-in' to the nomenclature, not just added to the bottom of the list, as that risks the duplication of Terms. If a product is innovative and truly unique, the procedure is quite straightforward to add a new Term. Often the product is a small variant of an existing product and an amendment to the Term Name or Definition is allowed, but only if the original scope of the Term is not reduced, which might exclude products that may have previously been described by the Term.   Occasionally technology leaps forward and we may need to review a set of GMDN Terms to determine if they reflect the current devices on the market, especially if the older technology is still commonly in circulation. In this case we may introduce several new Terms and amend Terms and may obsolete a Term, but this is quite rare (annually less than 1% of Terms are obsoleted). Obsoleted Terms remain available for historic reference / analysis purposes and remain linked to our higher-level Collective Terms too.

With so many variables, there is not a simple set of rules to determine when a new GMDN Term is created or amended. The following case studies describe some common scenarios we often come across.

For a New Product

Company A is planning to launch a new product which is very innovative. They search through all the relevant existing Terms in the GMDN website by carefully reviewing the Term Definition and none adequately describe their new product. They send us an Enquiry and attach the relevant product description. A GMDN Term Developer who is experienced in the product technology and application, reviews the product specification, and reviews the existing GMDN Terms for similar products. If we consider that the product requires a new GMDN Term and enough information is provided, a draft GMDN Term is provided to Company A to review. At the same time, the new GMDN Term is displayed on the GMDN website 'Proposed' Term's list for any GMDN Member to provide a comment. Once the consultation period ends, the new Term is linked to the relevant Collective Terms and published.

A Product Variant

Company B has updated its design of a product. The product has a new feature. Company B reviews the GMDN Term it previously used for this product, but the new feature does not seem to be included. There is no other GMDN Term that is suitable either. They submit an Enquiry and usefully refer to the existing Term and identify where the variation in the Definition could be made, in their opinion. The GMDN Term Developer reviews the product information and the similar GMDN Terms and decides if an amendment to the existing Term will be the best solution. Amendments are not always made if the new product feature is minor or cosmetic. A Term amendment is drafted and provided to Company B to review. There is no consultation period with Term amendments because the change should not affect the suitability of the Term for any existing users. When published the Term amendment notification is provided to members who opt for this service. All members who subscribe to Alerts also receive a monthly newsletter which list all the amendments that are relevant to the Terms they use. Amendments can be seen in the Details page for each GMDN Term with a summary note of the changes made.

A major review of Terms

Company C has developed a new product that is functionally like other products on the market, but it includes a novel electronic control system that improves patient care. There are now similar devices that have electronic control and those that do not. Company C submits an Enquiry and the GMDN Term Developer decides, in consultation with the manufacturers of similar devices, to make two new GMDN Terms to distinguish between the two variants of product type, 'manual' and 'electronic control'. The existing GMDN Term is made obsolete because it no longer represents a single product group. As with Term amendments, users of the existing Term are notified by email that it has been made obsolete and are directed to use one of the two new Terms.

We can see from these case studies that decisions about Term changes are made in consultation with the manufacturers and if necessary, a consensus is reached after wider consultation, sometimes with regulators input. The timespan necessary from the Enquiry being submitted to us to the publication of any change is dependent on the complexity of the product, the responsiveness of the applicant to any question we have and the impact of any changes on the GMDN database. We aim to complete the processes as soon as possible, because we know regulators and manufacturers are waiting to use the GMDN Terms to register their products and make them available to patients.

Term Development Process
The GMDN Agency uses a bespoke application on its website to manage the change request process, called an Enquiry. The process called Term Development is controlled by the application and it manages communication with the Enquirer and records any correspondence. The process is regularly audited under our Quality Management System (ISO9001:2015). All registered users can submit an Enquiry for consideration. The Enquiry form requested information about the medical device and its use. After considering the information provided there will be one of three outcomes:
- Guidance to use and existing GMDN Term
- Creation of a new GMDN Term
- Modification of an existing GMDN Term to encompass a new product. But we only increase the scope of a GMDN Term, so that it still meets the needs of all existing users of it.

New and modified GMDN Terms are published daily on our website.

A set of GMDN Terms are available for download by governments and healthcare providers to integrate into their own systems. Sets of update files are available as daily and monthly versions.

Translations of GMDN Terms are available in monthly updates.

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2. Please describe in detail the structure of your nomenclature - hierarchy, levels, etc.

The GMDN system is in two parts:

The nomenclature
A nomenclature is a naming system. It should provide a specific name (GMDN Term) for each medical device. Devices that share a GMDN Term are known as a Generic Device Group. (See ISO 15225:2016)

Each GMDN Term has a 5-digit numeric GMDN Code and is cross-referenced to a precisely defined Term Name and Definition, as seen in this example:

GMDN Term Name: 'Scalpel, single-use'
GMDN Code: 47569
GMDN Definition: 'A sterile, hand-held, manual surgical instrument constructed as a one-piece handle and scalpel blade (not an exchangeable component) used by the operator to manually cut or dissect tissue. The blade is typically made of high-grade stainless steel alloy or carbon steel and the handle is often made of plastic. This is a single-use device.'

The Term Name provides a convenient short name for the Generic Device Group. The Definition provides information to limit the scope of the Generic Device Group. The GMDN Code is a convenient record number for the GMDN Term. The GMDN Code is non-hierarchical and has no inherent meaning.

The GMDN Term Names are specific and exclusive and avoid the use of 'Not Elsewhere Classified' or 'Other' concepts as these cause problems when analysing historic data (see J J Cimino, 1998 'Desiderata for Controlled Medical Vocabularies in the Twenty-First Century' https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3415631/)

The hierarchy

The GMDN system uses a polyhierarchical structure of GMDN Collective Terms to provide better navigation of the GMDN Terms and to help aggregate data into larger groups of devices. For example, this would be useful if you needed to find out how many 'Endoscopes' your organisation used or the total number of implanted 'Knee Joint Prostheses' were made in the last year.

Fig 1. The Explorer showing an example of a Collective Term hierarchy and the five GMDN Terms in its group.

The Collective Terms have three components:

GMDN CT Name: 'Finger joint prosthesis'
GMDN CT Code: CT1413
GMDN CT Definition: 'Devices designed as implantable artificial substitutes to replace an injured or diseased metacarpophalangeal (MCP) or interphalangeal (IP) joint.'

Over 2000 GMDN Collective Terms are available to group the GMDN Terms and because it is a poly-hierarchical structure, the system is very flexible and can be adapted and amended quickly without affecting the status of any specific GMDN Term.

Therefore, each GMDN Term is linked to many Collective Terms. These can be seen in the Details page of each GMDN Term.

Fig 2. The Collective Terms associated with GMDN Term 'Metacarpophalangeal joint prosthesis, modular'.

The maximum number of levels available in the Explorer is not limited. Currently the largest number of related CTs in an Explorer group is eight.

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3. Please provide a copy of your license agreement including any subscription or other costs associated with the use of your nomenclature.

Standard License
Our licence agreement for website users is updated regularly and can be found at the following location https://www.gmdnagency.org/Legal/License and subscription costs are found here https://www.gmdnagency.org/Services/Prices . These meet the requirements of most website users, who all need to renew their subscriptions annually. While access to the GMDN Term Names, Definitions and Codes are free for all registered users, we provide some additional navigation and Term management tools to some manufacturers who opt for it, on a paid-subscription basis.

All Governments, Healthcare Providers and Conformity Assessment Bodies have full access to the GMDN and our navigation hierarchy (Collective Terms) and can also request access to our data files free of any charge.

Special License
Some government users have special requirements, and these are negotiated bilaterally. For example, they may request an integration of the GMDN within an internal or publicly available national product registration system, such has been previously agreed with US FDA, Health Canada, TGA Australia, MHRA UK, Roszdravnadzor Russia, ANVISA Brazil, SFDA Saudi Arabia and European Commission (EUDAMED II).

There is no cost for any user requesting a new GMDN Term for their product.

There is no cost for any user for requesting help, training, guidance, or other user support function.

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4. Please describe how codes, names and descriptions are accessed by user groups.

4.1 Is a login/ registration/ subscription required?

Access to the GMDN Terms is primarily made via an annual subscription for membership to the GMDN website. Subscription plans are available by user type and approriate access is provided to meet the specific needs for that user type, as described here
https://www.gmdnagency.org/Services/Plans

Alternatively by agreement with a national regulator of medical devices, GMDN Terms may be available within a national product registration system (see section 3).

4.2 Are their APIs available ?

The GMDN Agency provides all its data files (GMDN Terms and GMDN Collective Terms) on a Secure FTP platform. Data files can be downloaded manually or using a script (this is effectively an API).

4.3 Is the full dataset (codes, names, descriptions, hierarchies) downloadable?

4.3.1. No, explain:

4.3.2. yes, only partial, explain conditions:
4.3.3 Yes, only with previous registration or login, explain.
The GMDN Agency provides all its data files (GMDN Terms and GMDN Collective Terms) on a Secure FTP platform. The SFTP is password protected. Access is given to qualifying organisations, such as governments and healthcare providers.
4.3.4. Yes, can be open and downloaded by anyone, anywhere.

4.4 Is the information freely available?
Yes. Access to the GMDN Term Names, Definitions and Codes are free for all registered users.
If not, please specify which are the costs associated with the access of your nomenclature?
4.5 Which electronic platform are you using?
The GMDN is published on the GMDN Website https://www.gmdnagency.org/.

II. Work for convergence/ standardisation /access

1. Please describe the ways your organization currently supports WHO in the work for convergence and standardisation of medical device nomenclature by completing the following.
Please select the applicable options you make available (open access) and describe any conditions tied to that option.
  b) ____ the codes
  c) ____ the terms
  d) ____ the definitions
  e) ____ the hierarchy

2. For each item not checked above, please describe how you will be willing to make each item available to support convergence and meet WHO Member States requirements.

3. Does your Agency map to other existing Nomenclatures? (Please select the applicable option(s), when applicable).

Nomenclature	Yes	No	N.A.
EMDN		✓	
GMDN			✓
UMDNS	✓		
UNSPSC		✓	

4. If you answered "yes" to the question 3 of section II, please indicate the periodicity of mapping updates. Please provide your answer in the table below, when applicable:					
	Periodicity of mapping updates				
Mapping with the following nomenclature	**Once a year**	**Twice a year**	**Quarterly**	**Other**	**Comments**
EMDN					
GMDN					
UMDNS				✓	The GMDN was partially based (Codes below 20000) on the UMDNS and has a common numbering structure. Over time a lot of the concepts have been modified, but some partially match.
UNSPSC					

5. If you answered "yes" to the question 3 of section II, please indicate if you fully or partially mapped nomenclature(s). If it is a partial mapping, please be so kind to indicate which section(s) were mapped.			
	Extent of mapping		
Mapping with the following nomenclature	**Full mapping**	**Partial mapping**	**Sections mapped (if partial mapping)**
EMDN			
GMDN			
UMDNS		✓	Codes below 20000
UNSPSC			

6. Please describe the challenges you face for mapping
Mapping or Semantic Mapping should provide an exact match between concepts in each data set. This would infer concepts could be interchangeable. The EMDN and UNSPSC are product classification systems. Their structures are unsuitable for mapping to GMDN. Mapping between GMDN and UMDNS may be possible. Discussions between the GMDN Agency and ECRI are ongoing on future collaboration. It may be possible to provide some guidance to GMDN members that need to submit an EMDN Code to meet the requirements of EUDAMED. This is because the EMDN is generally a low resolution. A data transformation tool could provide a EMDN Codes for each known GMDN Code. The EMDN provides no accurate Definitions for their concepts and therefore it is difficult to determine their exact meaning. The use of 'Other' groups in EMDN provides further complexity for effective mapping.

7. Has your agency calculated the costs of mapping to other existing nomenclatures? Please present your estimates.

Nomenclature to be mapped against your nomenclature	Estimate cost of mapping (in dollars)
EMDN	
GMDN	
UMDNS	
UNSPSC	

III.   Translations to other the official Languages of the UN

1.   In which languages is your nomenclature available?
The GMDN Terms and Collective Terms are published in English. The GMDN Terms and Collective Terms are already translated into the following UN languages: Spanish French Russian Chinese (Simplified) Discussions are ongoing about translating the GMDN into Arabic.

2.   Is your agency willing to work on translations?
Translation of medical device nomenclature is very complicated and costly. The GMDN Agency has procedures in place for managing translations and checking their quality. The Russian translation of GMDN Terms is provided to the GMDN Agency by the government of the Russian Federation.

3. Has your agency calculated the cost of translating your nomenclature into the six UN official languages (English, Spanish, French, Russian, Chinese, and Arabic)? If yes, please provide the estimates in the table below.	
Six UN official languages	**Estimate cost of nomenclature translation (in dollars)**
English	
Spanish	
French	
Russian	
Chinese	
Arabic	

4. Is your Agency willing to work on mapping to other existing nomenclatures? (Please select the adequate option(s), when applicable).			
Nomenclature	**Yes**	**No**	**N.A.**
EMDN			
GMDN			
UMDNS			
UNSPSC			

IV.   Unique Device Identification

1. Have your nomenclature terms been assigned UDI-DIs (device identifiers of UDIs)? (Please select below the applicable answer)	
Yes	Within the US FDA GUDID system
No	

2. If yes, please indicate if the following sentences are true or false (Yes or No) and provide the solicited elements, if applicable:	
a. *Our nomenclature is required in UDI regulatory requirements.* Please provide a link to the regulation
FDA 21 CFR Parts 16, 801, 803, et al. Unique Device Identification System; Final Rule https://www.govinfo.gov/content/pkg/FR-2013-09-24/pdf/2013-23059.pdf
b. *Our nomenclature is not required in UDI regulatory requirements. However, we have assigned some or all of our nomenclature terms to UDI-DIs.* Please provide a file with this assignment.

3. If not, are you willing to work to assign UDI-DIs to your Nomenclature terms? (Please select below the applicable answer)	
Yes	
No	GMDN Terms are assigned to their UDI-DI by manufacturers as required by device regulators. The knowledge and resources needed to assign UDI-DIs to GMDN Terms is unlikely to be available elsewhere.

V. Financial information

1. How is the development, maintenance and updating your nomenclature funded (please describe what are the sources and mechanisms of funding)?
The GMDN Agency is a registered charity (nonprofit) regulated by the UK government. All funding for the GMDN Agency is only used to maintain the GMDN and promote its use.   All income is from GMDN users that have opted to purchase our additional services to help manage GMDN Terms. These additional services are described on our website https://www.gmdnagency.org/Services/Benefits   The total number of members (July 2021) is 15,458   The total number of paid subscribers (July 2021) is 1,592   The large number of separate paid subscribers is sufficiently large to maintain the independence of the GMDN Agency from undue commercial or political influence.   The Annual Report with audited financial accounts is publicly available from the UK Charities Commission. https://register-of-charities.charitycommission.gov.uk/charity-search/-/charity-details/5032026

2. What is the cost of development, maintenance and updating your nomenclature per year? (please select the adequate statement).	
Less than 100.000 dollars	
Between 100.000 and 250.000 dollars	
Between 250.000 and 500.000 dollars	
Between 500.000 and 1.000.000 dollars	
Between 1.000.000 and 2.000.000 dollars	1.486.432 USD
More than 2.000.000 dollars	
Comment:	The cost is taken from the published GMDN Annual Report 2020 converted to USD at 1.38.

3. How many FTE annually do you need for the development, maintenance and updating your nomenclature?
7 FTE are involved in developing the GMDN. 4 FTE are support staff.

3.1 Is the electronic platform used for (please select the applicable options)?	
a) only nomenclature of medical devices	Yes
b) other products related to medical devices	No
c) other products besides medical devices	No
d) comments:	

3.2 When was the latest update on your electronic platform?
Today.

3.3 How often do you update the data?
Daily.

VI.   Nomenclature use to promote public health/patient safety/device evaluation

1. Has your agency developed initiatives with governments/regulatory agencies to promote public health/patient safety/device evaluation
The main purpose of the GMDN is to provide health authorities and regulators, health care providers, manufacturers and others with a naming system that can be used to exchange medical device information and support patient safety.

The GMDN is used for:

Data exchange between manufacturers, regulators and healthcare authorities
Exchange of post-market vigilance information
Supporting inventory control in hospitals
Purchasing and supply chain management |

VII.   Nomenclature to be used in WHO document and electronic platforms

2.	Are you willing to provide access to code, name, definition or hierarchy to WHO so that it can be used in:
	WHO publications?
	The GMDN Agency have previously agreed the GMDN Term Names and Codes are available to be provided in WHO publications. See example https://www.who.int/publications/m/item/who-technical-specifications-for-13-medical-devices-on-un-life-saving-commodities
	WHO electronic platforms?
	To be discussed and agreed.

VIII. Final comments, if any

The GMDN Agency is a not-for-profit organisation established by the world's leading regulators with the purpose of enhancing patient safety and public health outcomes by providing a basis for unambiguous data collection and exchange about medical device performance. As an agency we are driven by the dynamic innovation in this sector and the demands of a rapidly increasing number of the world's regulators who are actively using the Global Medical Device Nomenclature.

The Agency is open to stakeholder input on the need to evolve and has recently undertaken an extensive consultation on strategic drivers as a basis for a soon to be launched strategy. We remain firm believers in the need for a single, unambiguous nomenclature which requires the active engagement of all stakeholders to maintain and develop.