European Medical Device Nomenclature

SANTE B6 Medical Devices and HTA -
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Background

European Commission

The road towards the EMDN

The two new regulations published in May

2017

2018-2019

MDCG deliberation on choice of Nomenclature and Commission notice on choosing CND as basis for future EMDN

Extra-ordinary revision of the CND

2019

2020

COVID-19

A one year postponement of the MDR was announced in April

Publication of IT and EN EMDN and DOA of MDR in May

2021

2021

September UDI module go-live

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Key EMDN principles

- The EMDN is based on fundamental key principles jointly set out by the European Commission and EU regulators. These principles include but are not limited to:
- **(a) Regulators-led**: regulators play a key role in managing, validating, updating and advising on the nomenclature.
- **(b) Structured:** the nomenclature has transparent hierarchies by which terms and codes could be meaningfully clustered into groups and types.
- **(c) Predictable:** the structure and content remains sufficiently stable to allow various regulatory uses of the nomenclature, in a manner which still allows for the accommodation of technological innovation.

EMDN key principles continued.

- **d) Transparent:** the policies for updates of the nomenclature terms and descriptions are sound and reflect the needs of regulators and the wider healthcare community.
- **(e) Inclusive:** the periodic reviews are open to all, based on real-world use and demonstrable needs.
- **(f) Available:** the terms, descriptions and codes are available, in full, to all users.
- **(g) Accessible:** no manufacturer or natural/legal person should be subject to fee or suffer from any discrimination, compared to other operators, in relation to the use of the nomenclature.
- **(h) International:** internationally recognised at the time of the date of application of the MDR/IVDR.

European Medical Device Nomenclature

- Serves as terms associated to the UDI-DI
- Supports work related to market surveillance and vigilance.
- Used for sampling basis for Class II A & B as well as Class B & C.
- Used in the implant card*
- Used on certificates*
- Used in the clinical investigation application form
- Used in the SAE reporting form

Beyond the medical device regulation (non-exhaustive):

- Can be used by hospitals and clinics internally in their systems
- Empowers the patient in gaining more information regarding their device, and other devices falling within the same code.
- Can play a role in other healthcare related frameworks
- Data analysis and research

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Categories

- A - DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION
- B - HAEMATOLOGY AND HAEMOTRANSFUSION DEVICES
- C - CARDIOCIRCULATORY SYSTEM DEVICES
- D - DISINFECTANTS, ANTISEPTICS, STERILISING
- F - DIALYSIS DEVICES
- G - GASTROINTESTINAL DEVICES
- H - SUTURE DEVICES
- J - ACTIVE-IMPLANTABLE DEVICES
- K - ENDOTHERAPY AND ELECTROSURGICAL DEVICES
- L - REUSABLE SURGICAL INSTRUMENTS
- M - DEVICES FOR GENERAL AND SPECIALIST DRESSINGS
- N - NERVOUS AND MEDULLARY SYSTEMS DEVICES
- P - IMPLANTABLE PROSTHETIC AND OSTEOSYNTHESIS DEVICES
- Q - DENTAL, OPHTHALMOLOGIC AND ENT DEVICES
- R - RESPIRATORY AND ANAESTHESIA DEVICES
- S - STERILISATION DEVICES (EXCLUDING CAT. D - Z)
- T - PATIENT PROTECTIVE EQUIPMENT AND INCONTINENCE AIDS
- U - DEVICES FOR UROGENITAL SYSTEM
- V - VARIOUS MEDICAL DEVICES
- W - IN VITRO DIAGNOSTIC MEDICAL DEVICES
- Y - DEVICES FOR PERSONS WITH DISABILITIES NOT INCLUDED IN OTHER CATEGORIES
- Z - MEDICAL EQUIPMENTS AND RELATED ACCESSORIES, SOFTWARE AND CONSUMABLES

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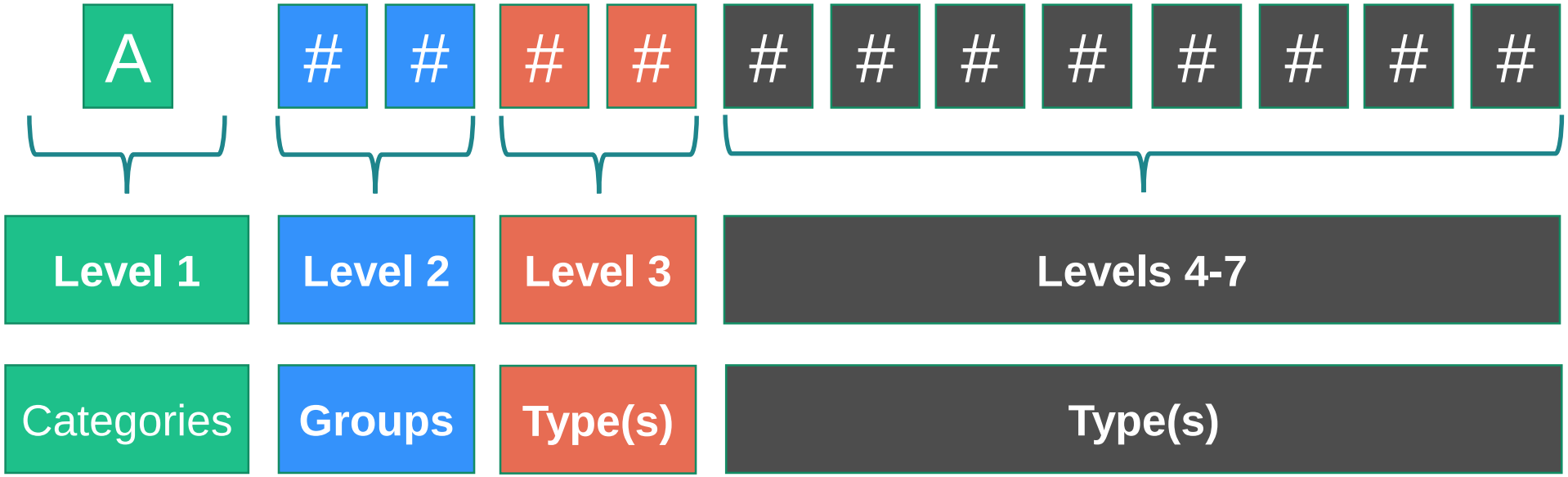
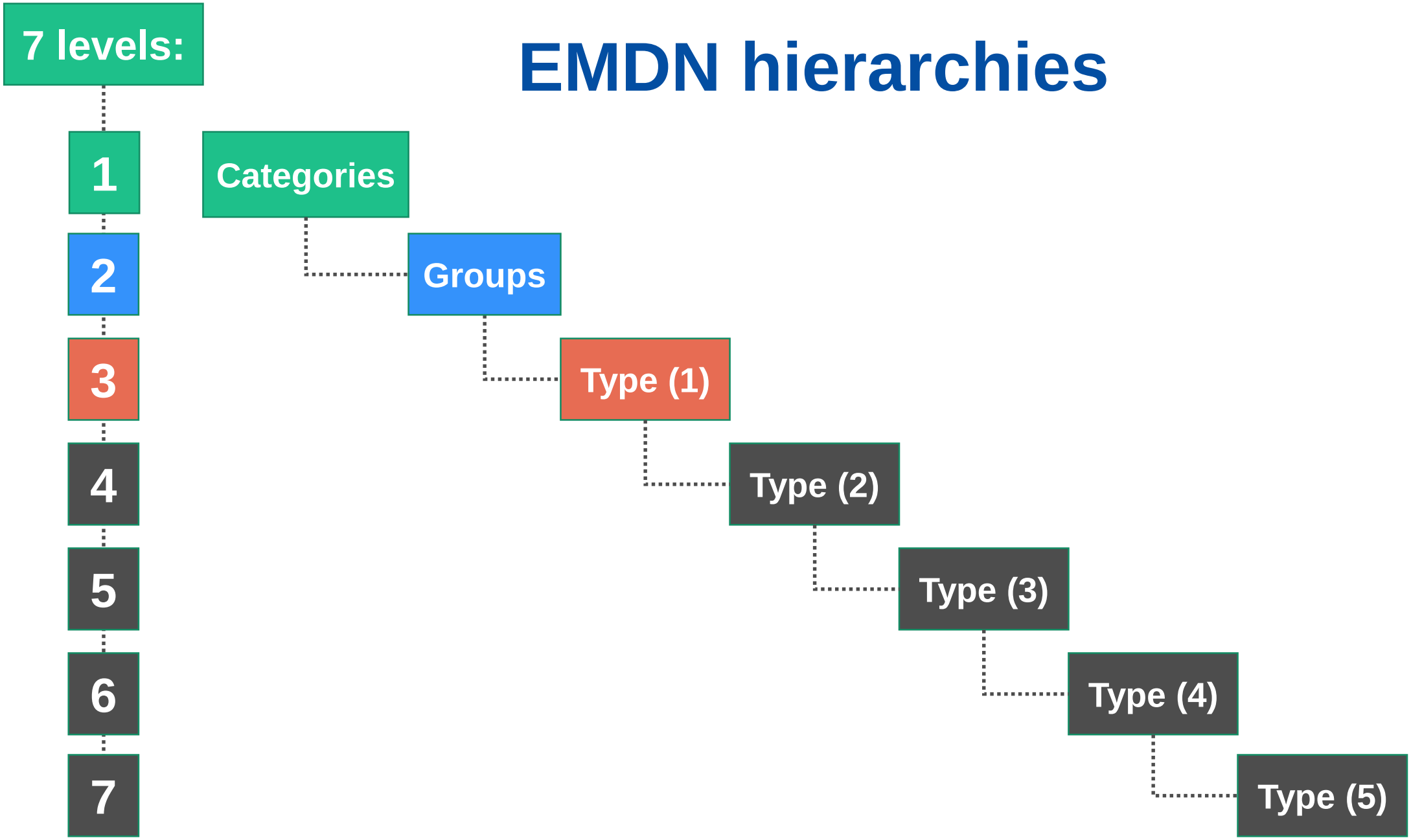
EMDN structure

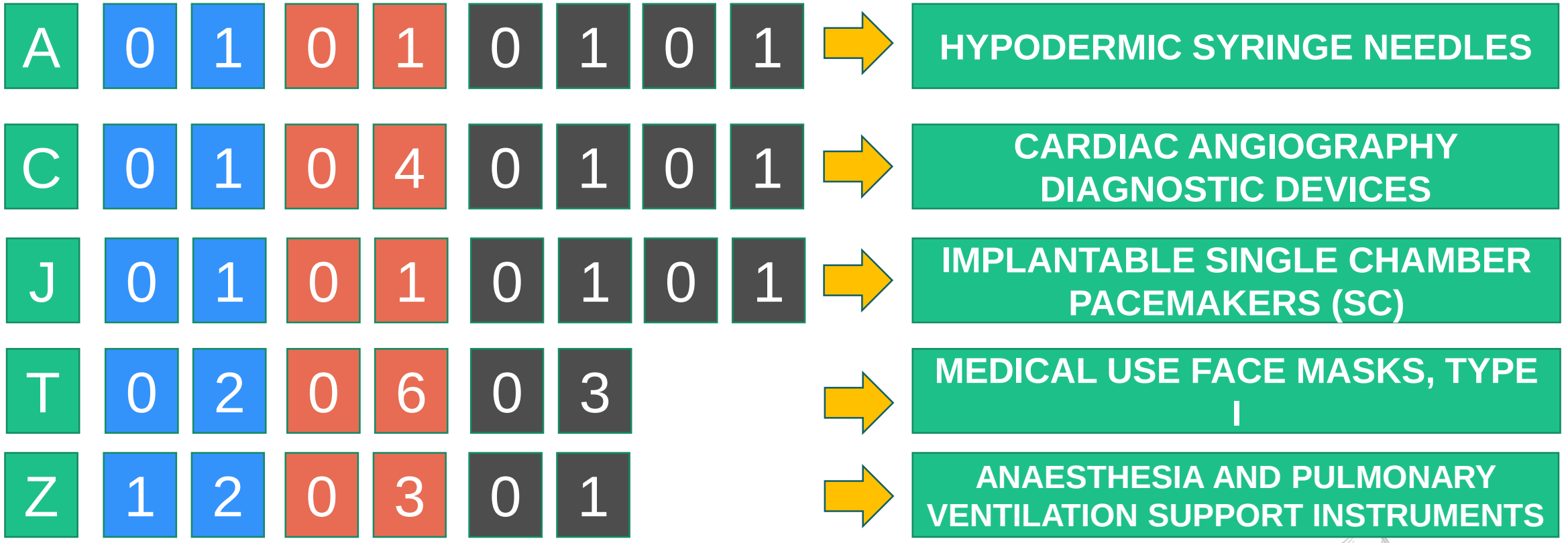


EMDN hierarchies



EMDN structure in practice

- Alphanumeric structure → Device description



EMDN public access portal

English Search

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European Medical Device Nomenclature (EMDN)

According to Article 26 of Regulation (EU) 2017/745 on medical devices (MDR) and Article 23 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), and following discussions with the Medical Device Coordination Group, the European Commission announced in 2019 that the European Medical Device Nomenclature (EMDN) would be created and based upon the Italian Ministry's 'Classificazione Nazionale dei Dispositivi medici'.

The EMDN is the nomenclature of use in the European database on medical devices (EUDAMED). Among its various uses, it will be utilised by manufacturers for the registration of medical devices, where it will be associated to each Unique Device Identifier – Device Identifier (UDI-DI).

The EMDN is multi-purposed and plays a key role in device registration, device documentation and technical documentation, notified bodies' sampling of technical documentation, post-market surveillance, vigilance and post-market data analysis, etc. It is intended to support all actors in their activities under the MDR/IVDR and provides key device descriptions to patients as regards their own devices and all other devices available on the market and registered in EUDAMED.

The entirety of the EMDN is fully accessible to all stakeholders, free of charge. It can hence be utilised by a non-exhaustive list of stakeholders such as manufacturers, research organisations, practitioners, hospitals, pharmacies etc. The EMDN can be accessed and downloaded in excel format below.

Currently, the European Commission is holding a public consultation on the draft EN version of the EMDN with the aim of collecting feedback from users and the wider healthcare community as regards the EN translation of the EMDN. Any errors and or syntax suggestions can be flagged through a submission on this page.

Propose a new translation for an EMDN term description

Select the EMDN term description (download full list)

Search

The EMDN browser

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Search

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- B - HAEMATOLOGY AND HAEMOTRANSFUSION DEVICES
- C - CARDIOCIRCULATORY SYSTEM DEVICES
- D - DISINFECTANTS, ANTISEPTICS, STERILISING AGENTS AND DETERGENTS FOR MEDICAL DEVICES
- F - DIALYSIS DEVICES
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- A - DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION
  - A01 - NEEDLES
  - A02 - SYRINGES
  - A03 - TUBULAR DEVICES
  - A04 - SOLUTION FILTERS
  - A05 - MECHANICAL INFUSION SYSTEMS, SINGLE-USE
  - A06 - DRAINAGE AND FLUID COLLECTION DEVICES
  - A07 - ADAPTERS, CONNECTORS, RAMPS, STOPCOCKS, CAPS
  - A08 - NUTRITION AND INFUSION BAGS AND CONTAINERS, SINGLE-USE
  - A09 - ORGAN CONTAINERS
  - A10 - ABDOMINAL OSTOMY DEVICES
  - A11 - SAMPLE COLLECTION SWABS
  - A12 - SAMPLE COLLECTION SPATULAS
  - A99 - DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION - OTHER

- A - DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION
  - A01 - NEEDLES
  - A02 - SYRINGES
    - A0201 - SINGLE-USE SYRINGES
    - A0202 - REUSABLE SYRINGES
      - A020201 - REUSABLE INFUSION SYRINGES
      - A020202 - REUSABLE IRRIGATION SYRINGES
      - A020203 - CARTRIDGE SYRINGES
      - A020299 - REUSABLE SYRINGES - OTHER

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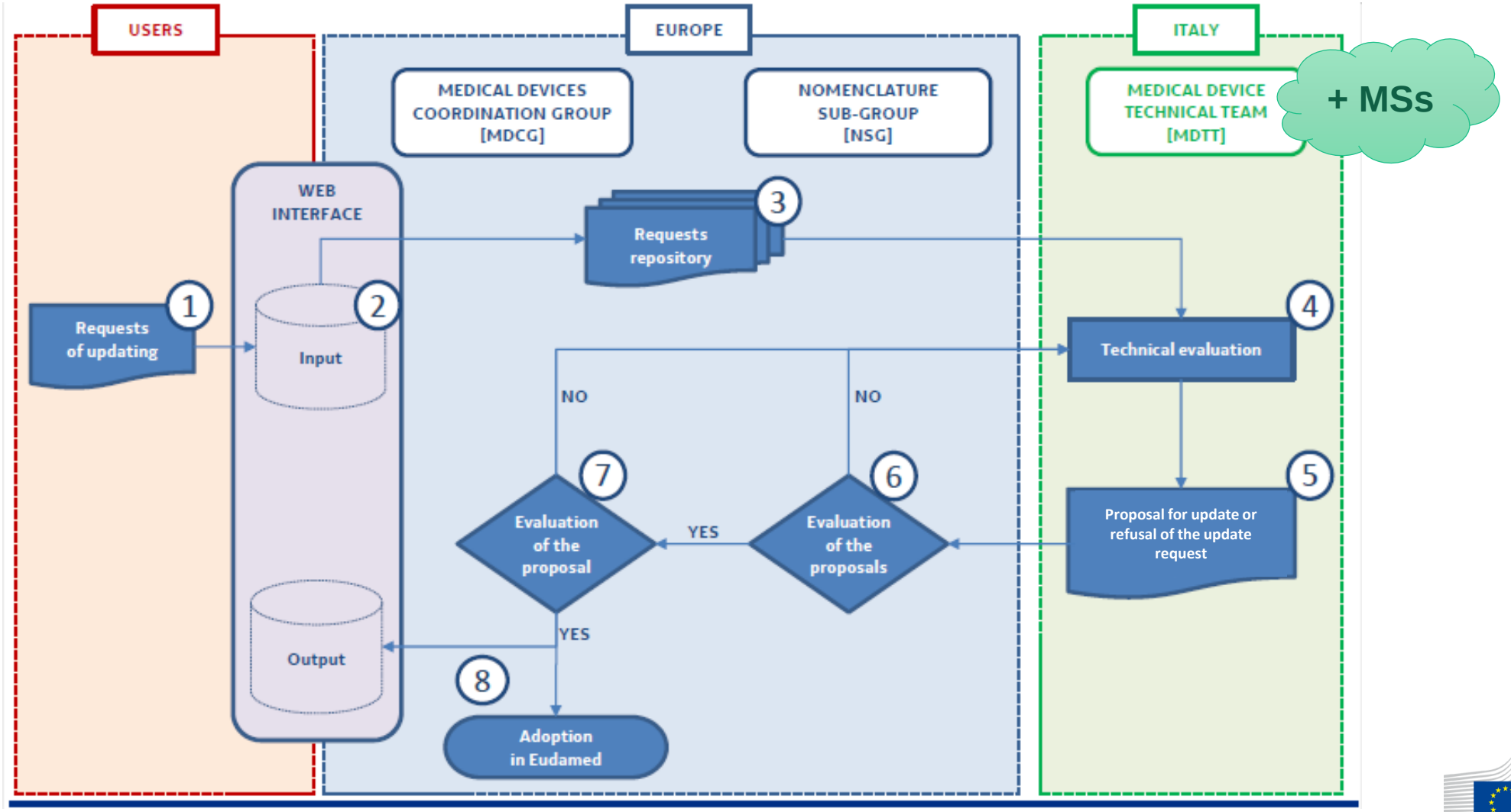
Open update procedures for EMDN accessible to all



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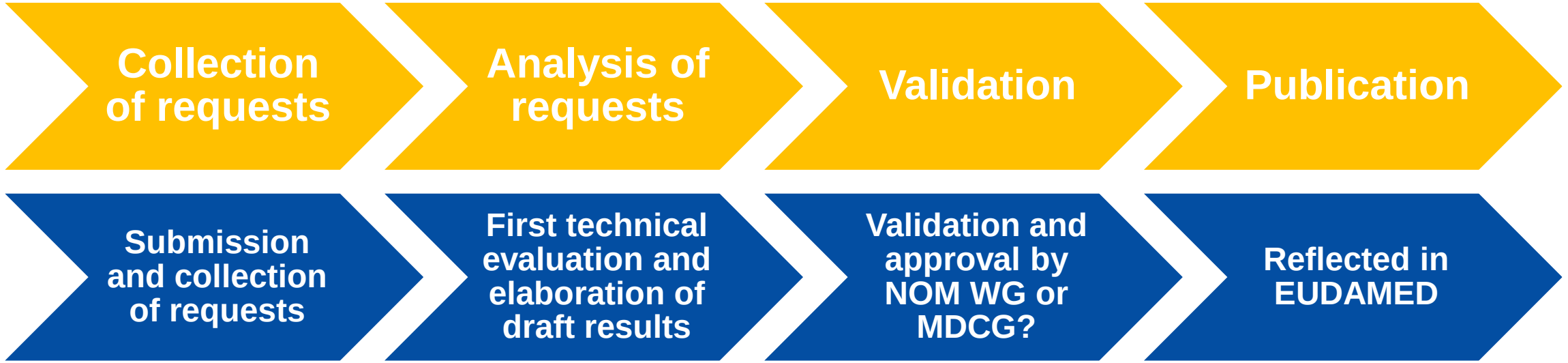
Annual EMDN updates procedures



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Ad-hoc EMDN updates procedures

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Thank you

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