

WHO Webinar: Nomenclature of medical devices EMDN and GMDN

Questions and answers

Disclaimer: The following document contains answers to questions submitted during the Webinar: [“Nomenclature of Medical Devices: EMDN & GMDN,” which took place on 8 July 2024 from 14:00 to 15:00 CET.](#) All speakers in the webinar contributed to answering these questions to the best of their knowledge. However, please note that the responses are not exhaustive. For further information, kindly contact the relevant institutions using the following details:

EMDN - For more information on EMDN visit <https://webgate.ec.europa.eu/dyna2/emdn/> or send an email to sante-med-dev@ec.europa.eu and sante-emdn@ec.europa.eu

GMDN - For more information on GMDN visit <https://www.gmdnagency.org/> or send an email to admin@gmdnagency.org

WHO Medical devices - For more information on medical devices <https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/nomenclature> or send an email to medicaldevices@who.int

1. Question by Yves Rausch

This is all wonderful, but I am missing the reference to UDI (FDA or EUDAMED), is something planned or already implemented?

EMDN: The European Medical Device Nomenclature (EMDN) plays a crucial role in the functioning of EUDAMED. In EUDAMED, EMDN is associated with each Unique Device Identifier - Device Identifier (UDI-DI) during device registration. EMDN provides essential device descriptions, supporting all actors under the Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR).

Find here link to EUDAMED: [EUDAMED database - EUDAMED \(europa.eu\)](#)

GMDN: GMDN has collaborated with the FDA since they launched AccessGUDID and the GMDN Terms, Codes and Definitions are on the AccessGUDID Database. GMDN is also working with the MHRA, TGA, Health Canada, ANVISA and INVIMA on their UDI programs. Additionally, countries working on their UDI implementation, that have access to the GMDN Database include Japan, Türkiye, Saudi Arabia, Singapore, South Korea, Switzerland, and others. The GMDN Agency is willing to collaborate with all National Medical Device Regulators who wish to utilize the GMDN Database.

WHO: Currently there are no plans to link MeDevIS directly to EUDAMED or AccessGUDID, however the inclusion of both EMDN and GMDN in MeDevIS will simplify the identification of items in both databases.

2. *Question by Ian Green (SNOMED)*

As regulators move towards electronic reporting, what are the plans to provide integration with clinical terminologies within EHRs ?

EMDN: Outside the scope of medical device regulations. Note, the new regulation on the European Health Data Space intends to regulate Electronic Health Record Systems.

GMDN: The GMDN Agency is willing to collaborate with relevant stakeholders who wish to utilize the GMDN Database within EHRs. GMDN has collaborated with SNOMED CT, for further information regarding SNOMED CT – GMDN Linkage Tables please contact the GMDN Agency by e-mailing admin@gmdnagency.org.

3. *Question by Nkwanyana, Sabelo*

Are the plans to also harmonize with Universal Medical Device Nomenclature System (UMDNS)?

WHO: The WHO feasibility study in 2022, included four nomenclatures: EMDN (European Medical Device Nomenclature) overseen by the Medical Device Coordination Group of the European Commission, GMDN (Global Medical Device Nomenclature) managed by the GMDN Agency, UMDNS (Universal Medical Device Nomenclature System) developed by the Emergency Care Research Institute (ECRI), and UNSPSC (United Nations Standard Products and Services Code) administered by GS1 US for the UN Development Programme. However, since 2023, WHO has concentrated its standardization efforts primarily on EMDN and GMDN, which are for medical devices only.

The UNSPSC is for products and services and go beyond medical devices, therefore the relation with UNSPSC could be done in the future, depending on resources available and licence agreements, but is not a priority for 2024.

ECRI was also invited initially to collaborate with the standardization process, but no further advances took place, therefore no harmonization with UMDNS is planned.

Reference: World Health Organization (2024). *Medical Devices Nomenclature*. Available at: <https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/nomenclature>. (Accessed: 16 July 2024).

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4. *Question by Farah, Riad*

What is the relation between nomenclature used in America and what is discussed here? Is EMDN/GMDN going to be used all over the world?

EMDN: EMDN is utilised currently in 30 countries (EU Member States (27), Liechtenstein, Norway and Turkey (3)). In addition, the 9 accession candidate countries to the EU will be expected to align their regulations to the EU MDR and IVDR and hence utilise the EMDN.

GMDN: The US FDA uses GMDN Terms, Codes and Definitions on the AccessGUDID Database for UDI implementation. TGA, ANVISA, MHRA and INVIMA utilise GMDN for UDI implementation. GMDN is also used in some regulatory capacity by more than 70 Regulators globally and has members in 145 countries.

WHO: Countries can select which system to use, preferably EMDN or GMDN And preferably a country national approach using the same system in the ministry of health, regulatory agency, supply and procurement and in health care facilities. WHO recommends having a national committee on nomenclature to decide accordingly.

Reference: World Health Organization. (2023). *WHO Expert Committee on Biological Standardization: seventy-sixth report. Annex 3. Section 6.3.1.4.* World Health Organization. <https://iris.who.int/handle/10665/368140>. License: CC BY-NC-SA 3.0 IGO

5. *Question by Diego Alvarez*

I have a question related to the medical devices categories (first level), e.g. Active-implantable-devices. If I'm correct, there are 22 categories (A-Z) in EMDN nomenclature?

EMDN: There are currently 23 categories of the EMDN. For more information see the categories and directly downloadable EMDN here:
<https://webgate.ec.europa.eu/dyna2/emdn/o>

How many categories in the first level are include in GMDN nomenclature? are the categories (first level) in both nomenclatures related?

GMDN: GMDN and EMDN are different nomenclatures, having different structures and granularity. GMDN is the nomenclature in multi-hierarchical classification system. The GMDN consists of 25,000 Nomenclature Terms, these are grouped by 2600 Categories arranged in a multi-hierarchical structure. The Categories are grouped under different headers (e.g., Device Function, Anatomical Specialty, Use Frequency). Under Device Function for example there are 22 first level Categories. This multi-hierarchical structure of higher-level Categories that can group devices based on a range of device attributes (e.g., implantable vs. non-implantable, active vs. non-active) is a powerful tool for device analysis.

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6. Question by Tashi Penjore

Where should the nomenclature system start? From the country's HTM Agency or Regulatory agency or Policy maker?

EMDN: depends on its intended purpose. For the sake of association with the Unique Device Identification for compliance with the EU MDR/IVDR, the EMDN was mandated by the Medical Device Coordination Group established under the EU MDR/IVDR which consists of the medical device regulatory authorities of each EU Member State.

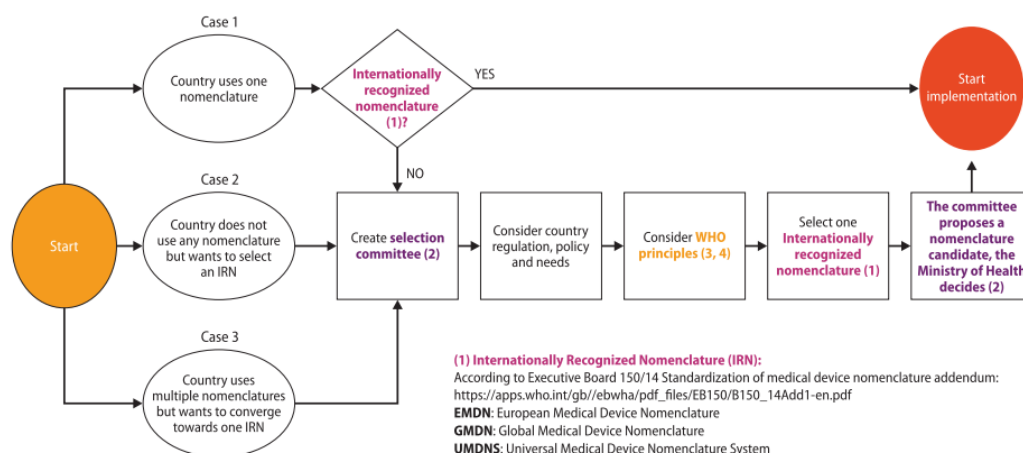
GMDN: It is up to each country to decide the best approach to using a nomenclature for themselves. In the GMDN Agency's 25 years' experience we would suggest that the national regulatory agency should focus on embedding a nomenclature into their systems, by creating a medical device master database with the GMDN embedded within it.

WHO: WHO recommends having a national committee on nomenclature to decide accordingly. And preferably a country national approach using the same system in the Ministry of health, regulatory agency, supply and procurement and in health care facilities, and manufacturers to harmonize nationally. Suggest using EMDN or GMDN to facilitate harmonization globally.

Note: when the diagram below was published, UMDNS was also considered, but due to the copyright restrictions, suggest limiting to EMDN and GMDN which are also used in regulatory agencies and now approved to be used by WHO in databases and publications.

Fig. 6.1

Selection of an internationally recognized nomenclature (IRN)



(1) Internationally Recognized Nomenclature (IRN):

According to Executive Board 150/14 Standardization of medical device nomenclature addendum:
https://apps.who.int/gb/ebwha/pdf_files/EB150/B150_14Add1-en.pdf

EMDN: European Medical Device Nomenclature

GMDN: Global Medical Device Nomenclature

UMDNS: Universal Medical Device Nomenclature System

For more information visit the WHO nomenclature website: <https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/nomenclature>

(2) Selection Committee to include stakeholders, i.e. members from Health Council, Ministry of Health, NRA, Health Service providers, Insurance, Med tech industry and patients organizations.

(3) WHO Principles

According to Executive Board 150/14 - Standardization of Medical Device Nomenclature:
https://apps.who.int/gb/ebwha/pdf_files/EB150/B150_14-en.pdf

(4) Internationally Recognized Nomenclatures compared against WHO principles and other characteristics (as of June 2022)

WHO Expert Committee on Biological Standardization
 Seventy-sixth report

Reference: World Health Organization. (2023). *WHO Expert Committee on Biological Standardization: seventy-sixth report. Annex 3. Section 6.3.1.4.* World Health Organization. <https://iris.who.int/handle/10665/368140>. License: CC BY-NC-SA 3.0 IGO

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7. *Question by Elizabeth Abraham*

How does MEDEVIS account for the fact that a particular medical device (e.g., an auto-disable syringe) could be used for different intended purposes, resulting in different EMDN codes? For instance, an auto-disable syringe used for insulin injection would receive a different EMDN code.

EMDN: The EMDN implementation in the EU permits the allocation of more than one code and term for devices with multiple intended purposes.

8. *Question by Ian Green (SNOMED)*

How is the alignment managed between EMDN and GMDN on an ongoing basis?

GMDN: The two nomenclatures EMDN and GMDN are not aligned. They are both managed by different organizations. The EMDN is managed by the European Commission. The GMDN is managed by the GMDN Agency. Please contact either the EMDN or GMDN Agency for information relating to each nomenclature. You can contact the GMDN Agency by e-mailing admin@gmdnagency.org.

9. *Question by Anis Ben Brahim UGPO-MOH TUNISIA*

What about to use nomenclature of WHO in the MDR745/2017

EMDN: MDR 2017/745 and 2017/746 utilise the European Medical Device Nomenclature [European Medical Device Nomenclature \(EMDN\) \(europa.eu\)](http://europa.eu)

WHO: just to clarify, there is no “WHO international nomenclature”, WHO publications and electronic database will be referencing to EMDN and GMDN only.

10. *Question by Ian Green (SNOMED)*

For GMDN, the 3,000 codes you are making available, are these at a category level, or detailed level?

GMDN: GMDN Codes for List of Priority Medical Devices is at lowest level Term; for ELD both GMDN Categories and Terms are available.

11. *Question by Dube, Sithobile*

Which specific journal are you referring to, when you mentioned that we can send articles to WHO for publication?

WHO: We are unsure on how to address this question, there are numerous papers published in various journals on the subject of nomenclature of medical devices. The WHO Medical devices and in vitro diagnostics team recently submitted a paper on this topic to the WHO bulletin which is a peer review journal.

Reference: World Health Organization. (n.d.). Bulletin of the World Health Organization. Available at: <https://www.who.int/publications/journals/bulletin> (Accessed: 16 July 2024).

12. *Question by Joseph Habiyaremye*

As a regulator, how to manage a medical device that is found to not meet labelling requirements such Brand mark/trademark, model, serial number... this is actually identified during importation process.

WHO: Please refer to the WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices.

Reference: World Health Organization. (2023). *WHO Expert Committee on Biological Standardization: seventy-sixth report. Annex 3. Section 6.3.1.4.* World Health Organization. <https://iris.who.int/handle/10665/368140>. License: CC BY-NC-SA 3.0 IGO

13. *Question by Ehab Mohammedy*

when the EUDAMED to be fully implemented?

EMDN: When it will be declared fully functional. With the recent amendment of the MDR and IVDR, it is now possible to render each EUDAMED module declared fully functional independently of the entire system completion.

14. *Question by Claudio Meirovich*

is anybody developing any open public API for them for developers to be able to use them?

EMDN: EMDN is completely accessible and downloadable by all users from our website. See here for more information on EMDN visit <https://webgate.ec.europa.eu/dyna2/emdn/>

GMDN: GMDN Regulatory members can download the full GMDN dataset via API/FTP access from the membership website. www.gmdnagency.org or alternatively e-mail the GMDN Agency at admin@gmdnagency.org to request further information.admin@gmdnagency.org to request further information.

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15. *Question by Emmanuel Kouemo*

Is there an initiative related to hospital "non-medical" equipment nomenclature? as EMDN and GMDN for medical devices?

WHO: MeDevIS lists some non-medical devices, and some of them have a code in EMDN or GMDN. And if unavailable it indicates: N/A.

For other products, non-medical devices, you can review the UNSPSC, which include extensive list of products and services, being medical devices just a section of them.

Reference: United Nations Standard Products and Services Code (UNSPSC). (n.d.). *UNSPSC*. Available at: <https://www.unspsc.org/> (Accessed: 16 July 2024).

16. *Question by Qian Dong NMPA*

EMDN has different categories, from A to Z, which principle to distinguish and select the right category.

EMDN: Please feel free to contact us at sante-emdn@Ec.europa.eu

17. *Question by Jagadesh Kumar Dhayalan*

We've been exploring GMDN, EMDN, MeDevIS, and other nomenclature systems for potential integration into our CMMS. One of the challenges we encounter is identifying the correct name/code in these systems, as it demands significant effort and expertise to match them with the colloquial names we use. The ability to search using our colloquial names would be highly beneficial. Are there any plans to incorporate this feature in the future?

EMDN: The EU is currently working on the development of a glossary to assist users.

WHO: in MeDevIS we have included "alternative names" or synonyms to help this search, you can use the search filters and then export the excel table with the results.

18. *Question by Federico Pasqualini*

I have two questions: 1) Is available a tool (excel o similar) that automatically "translates" the different nomenclatures used? 2) as today, if preparing a medical list for a procurement Agency, which nomenclature WHO suggest to use? Thanks Federico

WHO: in MeDevIS, you can search the medical devices you need, then export the table and then you will have a "related" term, which you will have to double check to ensure this is the devices you need. Remember GMDN and EMDN have different structure and granularity.

19. *Question by Mihaela Idu*

Do you plan to extend the list of medical devices on MeDevIS? For example, proton therapy systems are not yet included.

WHO: yes, it is intended that every 6 months WHO can expand MeDevIS with new devices in alignment with WHO guidelines, recommendations or publications.

20. *Question by Mitsuo Fukuda*

We are concerned that medical equipment waste around the world is not aligned with the SDGs.

WHO: WHO has been addressing healthcare waste management, including efforts to reduce waste and promote environmentally sound practices. Some important aspects include the following:

- WHO recommends using eco-friendly packaging and shipping methods.
- Investing in technologies like autoclaves for waste treatment reduces reliance on incineration.
- Autoclaves sterilize waste without harmful emissions.
- This approach aligns with sustainable waste management practices.
- Implementing reverse logistics ensures efficient waste collection and transportation.
- Centralized treatment facilities improve waste management systems.
- Supporting the recycling sector ensures that materials like plastics have a second life.
- WHO emphasizes responsible disposal and recycling practices.

These steps enhance overall waste reduction and safety. For more detailed information, you can refer to the WHO's report on "[Global analysis of health care waste in the context of COVID-19](#)". This report highlights the urgent need for better waste management practices.

Reference: World Health Organization. (2022). *Global analysis of healthcare waste in the context of COVID-19: status, impacts and recommendations*. World Health Organization. <https://iris.who.int/handle/10665/351189>. License: CC BY-NC-SA 3.0 IGO

In addition, WHO works to eliminate mercury from healthcare facilities aiming to phase out mercury-containing medical devices like thermometers and sphygmomanometers (devices that measure blood pressure). However further efforts are needed to reduce medical equipment waste management.

Reference: World Health Organization (2024) *Nations unite to eliminate mercury-containing medical devices*. Available at: <https://www.who.int/news/item/15-05-2024-nations-unite-to-eliminate-mercury-containing-medical-devices> (Accessed: 16 July 2024).

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For guidance on disposal and reuse of medical devices WHO also has published [Decommissioning of medical devices](https://iris.who.int/handle/10665/330095) to manage them.

Reference: World Health Organization. (2019). *Decommissioning medical devices*. World Health Organization. <https://iris.who.int/handle/10665/330095>. License: CC BY-NC-SA 3.0 IGO