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FAQ on the European Medical Device Nomenclature (EMDN)

Revision 1 – January 2025

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	General	Restructuring of questions into clear categories
	New Questions	Addition of Questions 7 - 24

FAQ on the European Medical Device Nomenclature (EMDN)

Category 1: General questions

1. What is the European Medical Device Nomenclature (EMDN)?

Per 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), the European Medical Device Nomenclature (EMDN) aims at supporting the functioning of the European database on medical devices (EUDAMED). Among its various uses, it will be utilised by manufacturers for the registration of medical devices in EUDAMED, where it will be associated to each Unique Device Identifier – Device Identifier (UDI-DI[1]).

As the EMDN primarily serves regulatory purposes to support MDR and IVDR requirements, it also plays a key role in MDR/IVDR device documentation and technical documentation, sampling of technical documentation conducted by notified bodies, 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.

2. How was the EMDN created?

According to criteria and requirements set out by the European Commission and EU regulators in the Medical Device Coordination Group (MDCG) and based on orientations provided by the MDCG, the EMDN was founded following a European Commission notice indicating the utilisation of the Italian Ministry's 'Classificazione Nazionale Dispositivi medici (CND)' as the basis for the future EMDN.

[1] UDI-DI for legacy devices is the 'EUDAMED ID', see MDCG 2019-5 Registration of legacy devices in EUDAMED for further details.

At that time, the CND was already utilised in three Member States (Italy, Greece and Portugal) and supported the registrations of a variety of EU and international manufacturers within the EU.

During the course of 2019 and 2020, consultations and preparatory work on the CND took place with stakeholders and key experts. A first version of the EMDN was released on 4 May 2021.

3. What are the key principles of EMDN?

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 codes and terms could be meaningfully clustered into groups and types.
(c) Predictable: the structure and content remain sufficiently stable to allow various regulatory uses of the nomenclature, in a manner which still allows for the accommodation of technological innovation.
(d) Transparent: the policies for updates of the nomenclature codes and terms 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: codes and terms 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.

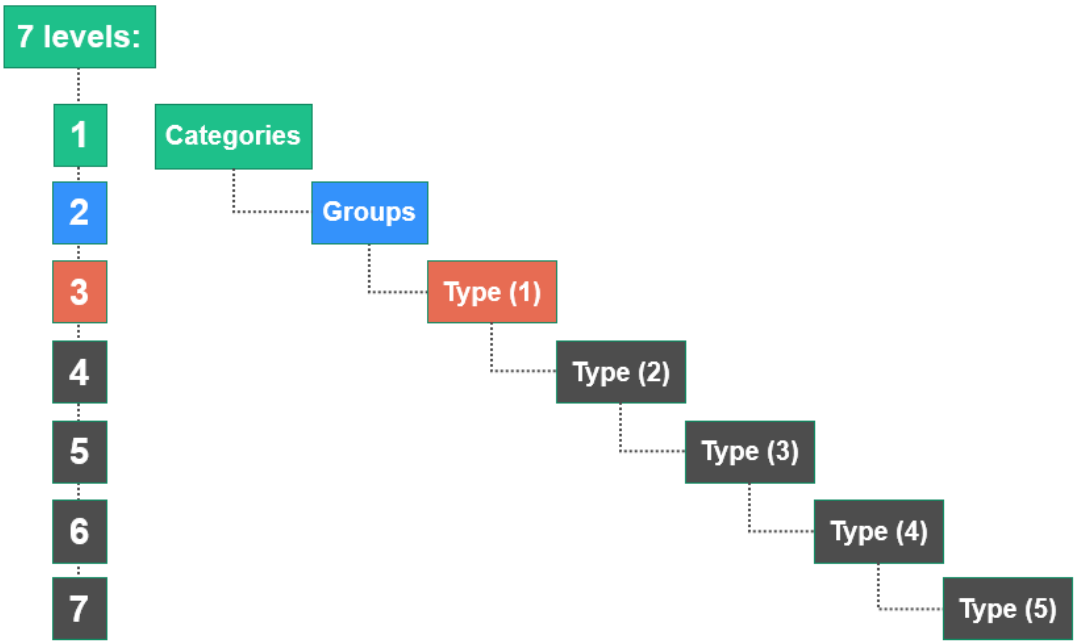
4. How do I gain access to the EMDN?

The entirety of the EMDN is accessible to all stakeholders, free of charge. It can hence be utilised by a non-exhaustive list of stakeholders such as manufacturers, patients, research organisations, practitioners, hospitals, pharmacies etc. The EMDN can be accessed and downloaded in excel format here and on the European Commission's MDCG endorsed documents and other guidance website page.

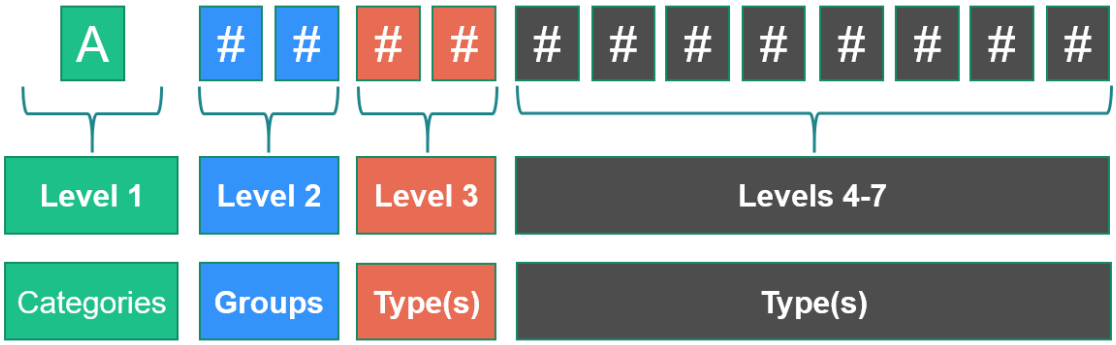
5. How is the EMDN structured?

The EMDN is characterised by its alphanumeric structure that is established in a seven-level hierarchical tree. It clusters medical devices into three main levels:

- Categories: the first hierarchical level,
- Groups: the second hierarchical level,
- Types: the third hierarchical level (which expands into several levels of detail (1°, 2°, 3°, 4° and 5°), where necessary.



Each alphanumeric code begins with a letter referring to the 'CATEGORY' for which the device falls under, followed by two numbers indicating the 'GROUP' and a series of numbers which refer to the 'TYPE'. The maximum number of digits is set at 13.



Each code is related to the term, which provides a concise and precise understanding of devices belonging to the same code, by outlining its characteristics or qualities. Each level includes both the code and the term.

Category 2: EMDN assignment

6. Which level of the EMDN should I use to assign to each UDI-DI[1] in EUDAMED?

Using the tree-like hierarchy of EMDN, manufacturers must always assign the most granular and terminal code and term available (lowest level in the tree) to their device (UDI-DI[1]).

7. How many EMDN codes can I assign to each UDI-DI[1] in EUDAMED?

As a general rule, manufacturers must always identify the singular most appropriate code to associate with the UDI-DI[1] of the device in question. An exemption to this rule is only foreseen for devices with multiple-intended purposes. In these cases, and especially when dealing with complex medical device systems which allow a large array of diagnostic and therapeutic functions, more than one code may be used.

8. Is there a priority for the assignment of multiple codes to a singular UDI-DI in EUDAMED?

In case multiple EMDN codes can be attributed to a singular UDI-DI, a hierarchy of significance between the chosen codes is not required.

9. What EMDN code should I assign to my device's UDI-DI if I can't find an appropriate EMDN term?

The user should always search the most granular (lowest) levels of the nomenclature for the most appropriate EMDN term for the device's UDI-DI[1] in question. It remains the sole responsibility of the manufacturer to review the entire nomenclature for the identification of the most appropriate term to report. Only if the most granular levels do not match the device's description, the manufacturer may assign the code extension '99' which refers to 'other' within that level type.

Note: UDI-DIs[1] associated with code extension '99' are subject to additionally scrutiny during the annual EMDN review procedure.

10. What should I do if there is no appropriate code to assign to my device's UDI-DI[1]?

a) assign the code extension 99 (term 'Other') to the device, as indicated in Question 9,
b) make a proposal in the EMDN submission platform or through the MDCG Nomenclature WG for the creation of a new level (code and term), providing a thorough description of the device in question[2]. Manufacturers are also encouraged to notify of such potential new code needs early in the certification process.
c) once/if a new code is created, manufacturers must reflect this change and update their registration in EUDAMED and in all related regulatory documentation (see Question 23)

[2]Refer to MDCG 2024-2 Procedures for the update of EMDN (europa.eu)

Category 3: Questions related to the annual review procedure

11. What should I do if I want to submit a proposal for the EMDN update?

Please refer to the annual EMDN update procedure.

12. How are users informed about changes to the EMDN that have been implemented?

Documentation on changes made (in comparison with the previous EMDN version) will be made available every year in December/January alongside the annual update publication on the European Commission's MDCG endorsed documents and other guidance website page.

13. Will there be a notification to impacted users of the changed codes?

Notifications to users is not currently possible. Publications of the final annual revisions will be available on the European Commission's MDCG endorsed documents and other guidance website page.

14. Will there be a consultation process for changes that will be impacting codes that are already in use by other actors?

Contacting individual actors of existing codes is not foreseen.

15. Is there a consultation mechanism during the technical evaluation for requesters to provide additional information, justification or answers to questions before rejection of the request?

Submitters may be contacted if the information submitted should be considered insufficient. To ensure a fair and comprehensive assessment, submitters are invited to provide comprehensive information at the time of submission to avoid unnecessary delays.

16. Will there be a set timeframe where feedback / questions will need to be addressed by the requester / submitter in order to meet the same calendar year processing time?

The timeframe is 15 working days for clarification after the request from EMDN-Technical Team mailbox, if the clarification arrives after the deadline date, the proposal may not be processed in the same calendar year.

17. Will devices associated with more than one EMDN code be reviewed on a periodic basis to see if there is a synergy that should be captured in a new code?

UDI-DIs[1] associated with multiple EMDN codes will be subject to additionally scrutiny during the annual EMDN update procedure.

Example: If a manufacturer assigns both the code relevant for CT systems and a second code for PET systems, this may be reviewed to include a new code for a combined PET/CT. Note: this example is for descriptive purposes only. An EMDN code already exists for such combined systems.

18. For requests that are accepted or rejected, how and when will the requester be informed?

Publications of the final annual revisions will be available on the European Commission's MDCG endorsed documents and other guidance website page. In addition, documentation on changes made (in comparison with the previous EMDN version) as well as a summary of all received submissions will be published in the same manner. For submissions received, the assessments (Accepted / Not Accepted) and a short description will be provided.

19. Is there a mechanism for requesting re-consideration of a submission or a re-assessment?

This is not currently foreseen. Although it is possible to submit the same request in the following annual procedure, the user is recommended to consult the rationale of rejection and the endorsed new version of EMDN.

20. Is there a prioritisation process on multiple requests that will be received on the same code via the annual collection?

The prioritisation criteria could be based on the order of arrival and their role according to the scheme below:

- Priority 1: Member States, NBs, WHO
- Priority 2: Economic operators and trade associations
- Priority 3: Health professionals, hospitals, laboratories, other users

21. Will there be an impact assessment before a change to existing codes is decided upon?

All potential changes will be assessed by the EMDN-Technical Team. The proposed changes are intended to improve the EMDN structure for the intended MDR/IVDR purposes by ensuring the least impact to keep the structure stable but also appropriately represent the information needs to be fulfilled by the nomenclature.

22. Will any criteria be established to determine which proposals are accepted and which are rejected?

Each change is aimed to improve the use of the EMDN. The criteria used for the evaluation of requests is related to the types of upgrades planned:

1) the inclusion of new levels is planned to include types of devices not present in the current version of the EMDN (new technologies, need for greater detail of a level).

For this purpose, informative elements characterizing the products that will populate the new level are evaluated (intended use, structural characteristics, functionality, constituent materials, sterility, reusability).

2) changing existing terms is planned to make the existing terms more understandable or to correct errors.
3) deletion of existing levels is provided to eliminate non-functional codes.
4) moving levels is provided in the case of levels improperly placed in the existing hierarchical tree (category, group, or type).

Proposals that imply non-compliance with the principles of the EMDN by affecting the stability of its structure will be rejected.

23. What happens in EUDAMED in case of changes to EMDN related to codes rendered obsolete or split?

Codes which are rendered 'obsolete' will not be immediately deleted from EUDAMED and will remain visible for at least 5 years from the date of their obsolescence. While the codes will still be displayed in during that a 5-year cycle (maximum certificate lifespan), manufacturers will no longer be able to use obsolete codes for device registration or updates to existing registrations. An archive with obsolete codes and related information such as date and reason for obsolescence will be maintained and kept publicly available to all.

Codes which are split will remain visible but, since they are no longer terminal codes, they will not be available for device registration or updates to existing registrations. An archive with split codes and related information such as date and justification for splitting, will be maintained and kept publicly available to all.

24. In case of changes in EMDN (new codes, split codes, obsolete codes), when do manufacturers need to update the relevant code(s)?

Manufacturers and notified bodies, as appropriate, are expected to reflect such updates, as relevant, within different documentations (e.g. certificates, declaration of

conformity) and in EUDAMED in a timely manner and reasonable manner[3], and at the latest prior to the next annual surveillance audit following the finalisation of the annual EMDN update cycle. Since individual contact is not foreseen, it is therefore recommended that manufacturers make a standard practice to assess each annual publication of EMDN for any changes which may impact devices in their product portfolio, in order to notify their notified bodies ahead/during their annual surveillance audit.

[3] As the annual release of EMDN takes place in January of every year, it would not be reasonable to expect manufacturers to implement all relevant changes ahead of an audit which takes place in the very first months of the year.