MDCG 2024-2 Rev.1

Procedures for the updates of the European Medical Device Nomenclature

Revision 1 – January 2025

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

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	General	Inserting table for ad hoc procedure aligning with newly published template form for submissions

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The European Medical Device Nomenclature (EMDN), as established by Article 26 of Regulation (EU) 2017/745 – Medical Device Regulation (MDR) and Article 23 of Regulation (EU) 2017/746 - *In Vitro* Diagnostic medical devices Regulation (IVDR), will be annually reviewed and updated based on the practical use of the EMDN and feedback from its users.

This document lays out the procedures for the annual revision as well as the procedure for ad-hoc requests requiring an expedited review.

A) Actors involved

MDCG Nomenclature working group

The Nomenclature working group ("NOM WG") is an expert group established under the Medical Device Coordination Group ("MDCG") per Article 103(7) of the MDR responsible for managing, maintaining and monitoring the use of the EMDN.

The NOM WG provides assistance and advice to the Medical Device Coordination Group (MDCG) on all implementation issues related to the EMDN with the aim of supporting the functioning of the future European database on medical devices (EUDAMED).

In particular, the NOM WG provides relevant advice in matters related to the update and maintenance of the EU nomenclature, which is made available by the Commission, in accordance with Article 26 of Regulation (EU) 2017/745 and Article 23 of Regulation (EU) 2017/746.

The NOM WG is composed of representatives of Member States' competent authorities who are experts in the particular policy area. The group also includes economic operators, healthcare professionals, notified bodies, hospitals, laboratories, patients and consumers at Union level which are appointed as observers to the working group, as a result of a public call for applications.

EMDN-TT

The European Medical Device Nomenclature Technical Team (EMDN-TT) is a smaller technical group established under the Nomenclature WG which is composed of technical experts appointed by the Italian Consortium[1] instituted for the implementation of project "Supporting the Maintenance of the European Medical Device Nomenclature" with the purpose to assess and review proposals, or to provide draft amendments, which include the definition of new and revisions of existing codes of the EMDN for the MDCG Nomenclature WG's consideration.

[1] Italian Consortium set up for the implementation of SMEMDN project, (HS – g- 22 – 19.02) is composed of the Ministry of Health (MOH) and by Friuli Venezia – Giulia Region (FVG – REG)

Users

Users of the EMDN include but are not limited to competent authorities, notified bodies, manufacturers, authorised representatives, importers, distributors, and persons referred to in Art. 22(1,3), trade associations, professional bodies, healthcare professionals, hospitals, laboratories, patients, consumers and the World Health Organization (WHO).

B) Procedure for the annual revision of the EMDN

The annual revisions of the EMDN will proceed by means of four phases. During each phase, different tasks and objectives are undertaken by different actors.

Phase I – Collection of requests (January)

Phase I of the procedure involves the collection of requests from users through the platform for EMDN requests[2]. The platform for requests will be available year-long. However, the deadline for submitting requests for processing in that same calendar year is 31 January 20XX.

Phase II – Evaluation of the requests and analysis of the practical use (February – July)

Phase II of the procedure involves a technical evaluation by the EMDN-TT of the:

- requests submitted during Phase I,
- requests by the NOM WG,
- EMDN usage in EUDAMED (e.g. review of devices registered with multiple codes, review of devices registered with code extension “99”).

Following the technical evaluation, a first draft proposal for the update of the EMDN is prepared. This proposal and the list of rejected requests are submitted to the NOM WG for review.

Phase III – Validation and endorsement (August – October)

Under Phase III of the procedure, the NOM WG reviews the proposal submitted at the end of Phase II and provides feedback on the proposed changes to the EMDN-TT, as necessary. Following the processing of feedback, a final draft is then endorsed by the NOM WG.

Phase IV – MDCG endorsement and publication (November – December)

Phase IV of the procedure is the final part of the annual cycle and involves the endorsement of the final draft by the MDCG and publication of the officially endorsed update in EUDAMED and the EMDN browser. After MDCG endorsement, translations are elaborated in all EU languages and are validated by the NOM WG.

[2] https://webgate.ec.europa.eu/dyna2/emdn/

Note: the above-described timetable for annual updates may be subject to revision depending on the number of requests received.

C) Pilot procedure for the ad-hoc updates of the EMDN requiring an expedited review

The general rule remains that all requests must proceed through the annual procedure. For reasons related to established need, only requests submitted by competent authorities and notified bodies qualify under the ad-hoc procedure.

Under the ad-hoc update procedure, only new code requests may be submitted. If the new code request results in the need to render obsolete or split other codes, then the request will be redirected to the annual procedure pathway.

Information to be submitted by applicants

A form must be filled out by the applicant which can be found on the Commission's website under 'Guidance - MDCG endorsed documents and other guidance'. This form will require the following non-exhaustive information:

1	Name of NCA[1] / NB [2]	
2	Indication if the request is needed for the registration in the UDI-DI module of EUDAMED	
3	Established need demonstration, justification as to why the request should be assessed under the ad-hoc procedure	
4	Justification as to why currently existing codes cannot be utilized	
5	Manufacturer's name and authorised representative (where applicable)	
6	Device name or technology name under question	
7	Detailed description of the device or technology under question, including its intended purpose;	
8	Indication if this is considered a novel device [3]	
9	Indication if the device has or will undergo an	

	expert panel assessment	
10	EMDN Category, Group, and Type where the code could be added	
11	Draft term description for the new code	
12	Reference to other devices on the market with similar technology, potentially also requiring the use of this new code (where applicable)	
13	Additional information (e.g. reference to other nomenclature, if any)	

Processing of the ad-hoc requests

Requests should be submitted to SANTE-EMDN@ec.europa.eu . Following receipt of the completed form, the Commission will circulate the information provided by the applicant to the EMDN-TT for a written consultation. Following assessment of the request, the EMDN-TT will provide feedback to the Commission who in turn will inform the applicant whether the application is eligible for the ad-hoc procedure.

If the request is considered ineligible, the user will be informed and their submission will be deferred for an assessment under the annual update procedure.

If the request is considered eligible for the ad-hoc procedure, it is further analysed by EMDN-TT and a technical proposal is elaborated and circulated with the NOM-WG for review and endorsement. Following the NOM-WG's endorsement, the MDCG endorses the final version of the technical proposal.

During the annual review procedure, ad-hoc updates will be reflected in the annual EMDN updated version.