THE MDR JOURNEY

«Let's make transparency a standard requirement»

NEWSLETTER N. 35 –June 2023

Subject: European Medical Device Nomenclature (EMDN)

What is EMDN?

The European Medical Device Nomenclature (EMDN) is a nomenclature system for medical devices that has been developed by the European Commission to comply with the provisions of article 26 of Regulation (EU) 2017/745 on medical devices (MDR).

The basis for the EMDN is the "Classificazione Nazionale Dispositivi medici" (CND).

EMDN terms are available to all stakeholders free of charge on a dedicated European Commission webpage.

This nomenclature system has the following main uses:

- Used by manufacturers when registering their medical devices in the EUDAMED database, where it will be associated to each Unique Device Identifier - Device Identifier (UDI-DI);
- Used by manufacturers in the MDR Technical Documentation;
- Used by the Notified Bodies in the sampling of Technical Documentation submitted by the manufacturers;
- Used in post-market surveillance, vigilance and post-market data analysis.

The EMDN is intended to support all MDR actors in their activities and provides key device descriptions to patients as regards their own devices and all other devices available on the market and registered in EUDAMED

How is the EMDN structured?

The EMDN has an alphanumeric structure with seven-level hierarchical tree. It clusters medical devices into three main levels:

- Categories: the first hierarchical level with a letter
- Groups: the second hierarchical level with two numbers
- Types: the third hierarchical level which expands into several levels of detail where necessary, with two to ten numbers.

EMDN codes therefore consist of five to a maximum of thirteen digits. Each EMDN term has a defined EMDN code and description.

The EMDN term must be assigned to a specific device using the most granular and terminal term available (lowest level in the tree).

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The following anatomic, functional and special categories have been defined:

Anatomic Categories – by anatomical area of use:

B – haematology and haemotransfusion devices
C – cardiocirculatory devices
F – dialysis devices
G – gastrointestinal devices
N – nervous and medullary systems devices
Q – dental, ophthalmologic and ear, nose, and throat (ENT) devices
R – respiratory and anaesthesia devices
U –devices for urogenital system

Functional categories – by intended use or clinical method:

A – devices for administration, withdrawal, and collection
D – disinfectants, antiseptics, sterilizing agents, and detergents for medical Devices
H – suture devices
K – endotherapy and electrosurgical devices
L – reusable surgical instruments
M – devices for general and specialist dressings
S – sterilization devices (excluding cat. D-Z)
T – patient protective equipment and incontinence aids (excluding personal protective equipment (PPE))
V – various medical devices

Special categories – by other criteria:

J – active-implantable devices
P – implantable prosthetic devices and osteosynthesis devices
W – in vitro diagnostic medical devices
Y – devices for persons with disabilities not included in other categories
Z – medical equipment and related accessories, software and consumables

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When will be EMDN terms for specific devices available in EUDAMED?

EMDN terms are being assigned by manufacturers and verified by the Notified Bodies according to MDR certification scope.

EMDN terms must be registered in EUDAMED by the manufacturers, according to the timeline established by the European Commission. The current timeline establishes optional UDI/device registration that in practice will become mandatory by Q4 2024 considering that there may be reporting obligations for vigilance, clinical investigation and performance studies or market surveillance. In any case, it will become ultimately mandatory by Q2 2026.

What is the use of EMDN terms for the distributors?

Once registered in EUDAMED, the EMDN term assigned to a specific device will be publicly available for consultation.

This newsletter is part of our campaign to increase the sensitivity and the awareness of all our business partners, to bring more clarity around the MDR journey and challenges and opportunities around the MDR Art.22 "Systems and Procedure Packs".

We are already today all dependent on efficient cooperation. For the MDR implementation, we require even closer collaboration to ensure we all can deliver safe supplies to hospitals and patients in the future.

We are confident we will continue to supply health care competently on customized surgical procedure sets and small kits.

Do you wish to know more about specific MDR topics? Do you have any questions or comments about STS newsletter? Write us at MDR2020@stsmedicalgroup.com.

The next MDR newsletter will be issued in July. We wish everyone productive and pleasant days.

Augusto Orsini
CEO
STS Medical Group

Meritxell Laguna
Group Manager Regulatory Affairs
STS Medical Group