MedTech Europe
from diagnosis to cure

Practical guide to the use of the European Medical Device Nomenclature (EMDN)

27/05/2025

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Table of Contents

1. Introduction

This booklet provides a practical educational guide to the use of the European Medical Device Nomenclature (EMDN). It helps users such as manufacturers of medical devices and *in vitro* diagnostic medical devices (IVDs) in:

- the identification and assignment of the appropriate EMDN code to medical devices;
- the use of EMDN in regulatory documents and for sampling in accordance with MDCG 2019-13[1];
- registering devices and systems/procedure packs in the UDI/device module of EUDAMED;
- formulating proposals for new codes for the annual EMDN update.

Where possible, this is achieved using concrete examples.

The booklet should facilitate alignment in the identification of analogous or similar devices' (e.g. in the European database, on certificates, in sampling) and raise awareness among all EMDN users operating in the field of medical devices and *in vitro* diagnostic medical devices.

2. Brief history, use and general characteristics of the EMDN

2.1. Brief history of the EMDN

The EMDN is a tool to classify medical devices and *in vitro* diagnostic devices registered in the EUDAMED database as established by Article 26 of the Regulation 2017/745/EU (MDR) for medical devices and by Article 23 of Regulation 2017/746/EU for IVDs (IVDR).

The EMDN represents an evolution of the "Classificazione Nazionale dei Dispositivi Medici (CND)", the National Classification of Medical Devices system designed by the Italian Ministry of Health for its national MD/IVD database, which features all the fundamental requirements requested by the European Commission for application in EUDAMED. The CND had already been successfully used for years by three Member States in Europe (Italy, Greece and Portugal) for the registration of medical devices and *in vitro* diagnostic medical devices that are placed on the market, and for the notification of devices that are distributed in their respective territories.

The search for a nomenclature to be introduced to EUDAMED responded to the need to have a hierarchical classification system that groups together devices placed on the market by manufacturing companies. The nomenclature allows to compare products belonging to the same typology and with similar structural and functional characteristics.

Following an analysis and evaluation of the solutions available, based on the guidelines provided by MDCG 2018-2[2] and on the key principles set out by the European Commission and EU regulators[3], the Commission decided[4] to use the CND as the basis for the EMDN.

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[1] MDCG 2019-13 rev.1 Guidance on sampling of devices for the assessment of the technical documentation
[2] MDCG 2018-2 Future EU medical device nomenclature - Description of requirements
[3] Described here: https://webgate.ec.europa.eu/udi-helpdesk/en/other-relevant-information/emdn-codes.html
[4] The EMDN – The nomenclature of use in EUDAMED

The Italian Ministry of Health was requested to update the existing classification to meet the requirements of MDR and IVDR. A working group was established made up of all stakeholders operating in the medical devices sector and professional experts from the Italian national health service. This group updated the CND classification based on the types of devices used in the clinical field at the date of the project. For example:

- Registrations present in the Italian MD/IVD database
- The Global Medical Device Nomenclature (GMDN)
- The Global In Vitro Diagnostic Medical Devices (GIVD) classification

The revision led to the creation of a significant number of new codes, the deletion of obsolete levels, and the modification of the descriptions, which can be summarised in the following graph:

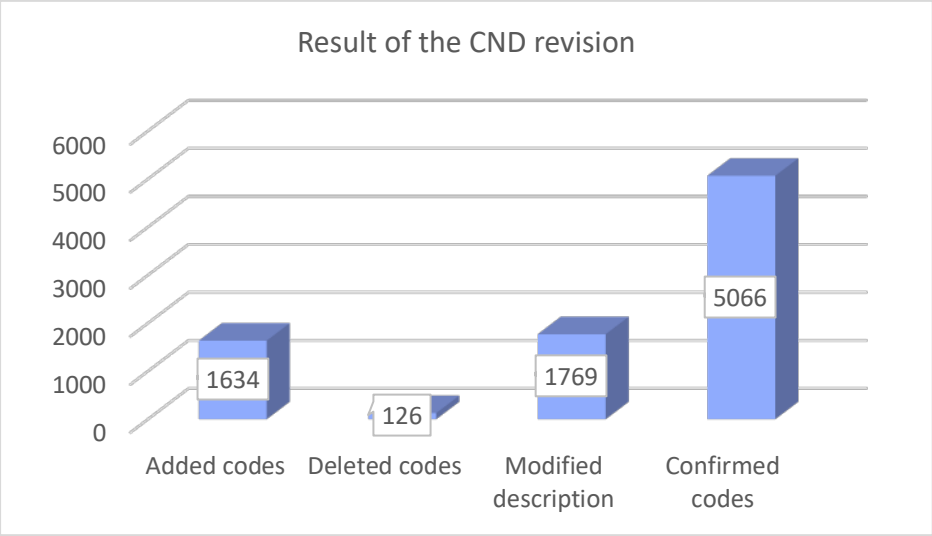


Figure 1 – Revision of CND to create EMDN in numbers

CATEGORY	CATEGORY DESCRIPTION	Added codes	Deleted codes	Modified description	Confirmed codes
A	DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION	79		94	184
B	HAEMATOLOGY AND HAEMOTRANSFUSION DEVICES	2		42	38
C	CARDIOCIRCULATORY SYSTEM DEVICES	38	2	21	234
D	DISINFECTANTS, ANTISEPTICS, STERILISING AGENTS AND DETERGENTS FOR MEDICAL DEVICES	4	11	58	12
F	DIALYSIS DEVICES	3	1	5	85
G	GASTROINTESTINAL DEVICES	20		9	139
H	SUTURE DEVICES	63	10	57	158
J	ACTIVE IMPLANTABLE DEVICES	49	13	52	65
K	ENDOTHERAPY AND ELECTROSURGICAL DEVICES	99	1	100	11
L	REUSABLE SURGICAL INSTRUMENTS	240	9	462	9
M	DEVICES FOR GENERAL AND SPECIALIST DRESSINGS	26		34	194
N	NERVOUS AND MEDULLARY SYSTEMS DEVICES	60		13	11
P	IMPLANTABLE PROSTHETIC AND OSTEOSYNTHESIS DEVICES	166	9	77	421
Q	DENTAL, OPHTHALMOLOGY AND ENT DEVICES	99		35	119

R	RESPIRATORY AND ANAESTHESIA DEVICES	76	1	41	112
S	STERILISATION DEVICES (EXCLUDING CAT. D - Z)	4		12	23
T	PATIENT PROTECTIVE EQUIPMENT AND INCONTINENCE AIDS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT (PPE))	10	2	21	60
U	DEVICES FOR UROGENITAL SYSTEM	66	2	26	126
V	VARIOUS MEDICAL DEVICES	117	2	43	28
W	IN VITRO DIAGNOSTIC MEDICAL DEVICES	159	15	169	1,894
Y	DEVICES FOR PERSONS WITH DISABILITIES NOT INCLUDED IN OTHER CATEGORIES	50	39	26	211
Z	MEDICAL EQUIPMENT AND RELATED ACCESSORIES, SOFTWARE AND CONSUMABLES	204	9	372	932
Total		**1,634**	**126**	**1,769**	**5,066**

Table 1: Result of CND revision[5]

At the end of the revision, the work carried out by the Italian Ministry of Health allowed the European Commission to launch a consultation among the Member States and the various stakeholders, followed by the subsequent publication of the first EMDN on 4 May 2021. The nomenclature was made publicly available online and free of charge for all operators, as required by the regulations.

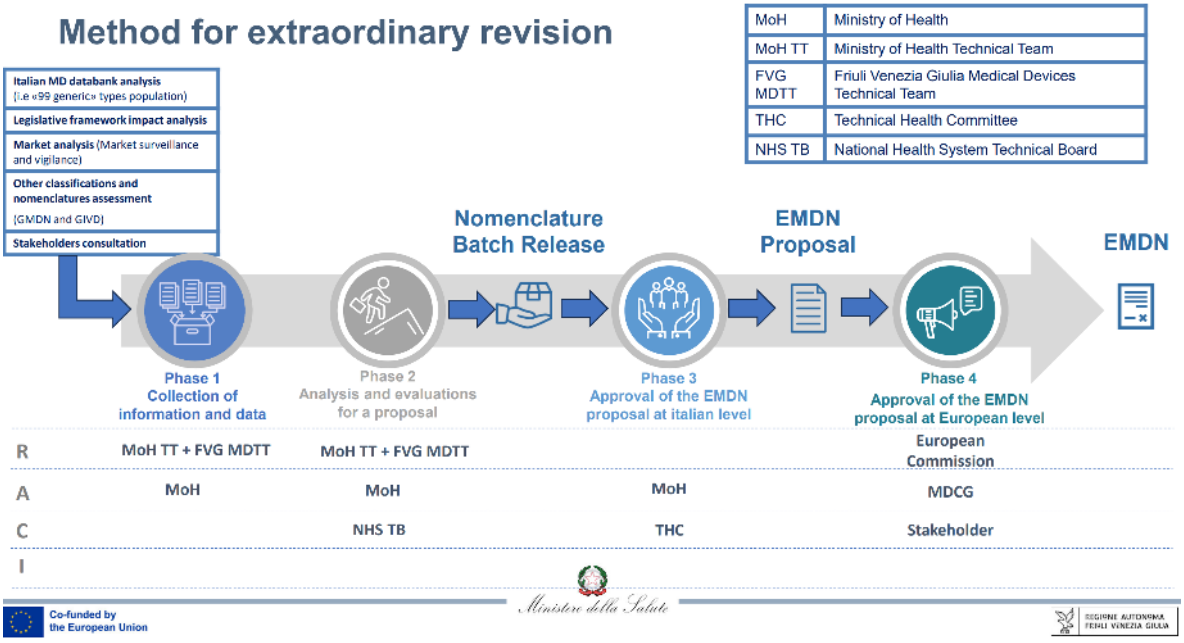


Figure 2 – Method of the extraordinary revision - *Source: EMDN training – 12 November 2024*[6]

[5] Source: EMDN training – 12 November 2024 Alessandra Basilisco, Elisabetta Stella: From the Italian CND classification to the EMDN

[6] Source: EMDN training – 12 November 2024 Alessandra Basilisco, Elisabetta Stella: From the Italian CND classification to the EMDN

Hint: The full list of EMDN codes and term are available for download in the following website: European Medical Devices Nomenclature (EMDN) - European Commission. The file behind the link 'Download EMDN' leads to the most up-to-date version of EMDN.

2.2. Use of the EMDN – including for legal compliance

The EMDN supports the functioning of the European database on medical devices (EUDAMED) as per Article 26 of MDR and Article 23 of IVDR. EMDN is one of the data elements as listed in Annex VI, Part B of MDR and IVDR to be provided for each device upon registration in EUDAMED where it will be associated to each Unique Device Identification – Device Identifier (UDI-DI). The most granular (lowest level) EMDN code should be assigned to each device (UDI-DI) and submitted to the database[7].

The assignment of the most appropriate EMDN code to each UDI-DI registered in EUDAMED is the sole responsibility of the manufacturer who, being aware of the structural and functional characteristics of their devices, is in the best position to carry out this task.

As indicated in the FAQ on the EMDN[8] published by the Medical Device Coordination Group (MDCG), the EMDN code plays a key role in the technical documentation of the related device. It is used for post-market surveillance, for vigilance and for any other data analysis activity relating to medical devices and *in vitro* diagnostic medical devices registered in EUDAMED.

Hint: In regulatory documents where the UDI-DI of the device is referenced, it is suggested to include the EMDN code that is consistent with the level of its registration in EUDAMED (i.e. the lowest level EMDN code/term assigned to the device).

Notified Bodies require EMDN codes for determining the generic device group and categories. For Class IIb (MDR) and Class C (IVDR), the technical documentation of at least one representative device per generic device group should be assessed. For Class IIa (MDR) and Class B (IVDR), the technical documentation of at least one representative device per category of devices is assessed.[9] The EMDN is used for the sampling activity conducted by Notified Bodies: the 4th level of the EMDN for MDR and 3rd level of the EMDN is used for IVDR for the sampling activity in accordance with MDCG 2019-13 – the level can be adapted based on the characteristics of the device.
The attribution of the appropriate EMDN code to each UDI-DI thus is essential to ensure that devices that have the same functional and structural characteristics to be evaluated in a homogeneous way. Furthermore, given that the EMDN primarily serves regulatory purposes in line with MDR and IVDR, it might also be a tool useful for stakeholders involved in the procurement of medical devices. However, the changes to the EMDN will be driven primarily by regulatory purposes, by innovation in the medical technology sector and not by any other use (e.g. purchasing).

2.3. General characteristics of the EMDN

The EMDN is a dynamic hierarchical classification system first published by the European Commission on 4 May 2021. It is subject to annual revisions as described in MDCG 2024-2[10] which results in the publication of updated versions.

A nomenclature is made up of a set of codes, assigned or not according to pre-established logical criteria. The EMDN is a hierarchical classification system organised on multiple levels,

[7] See Question 6 in MDCG 2021-12 rev.1 FAQ on the European Medical Device Nomenclature (EMDN)
[8] See Question 1 in MDCG 2021-12 rev.1 FAQ on the European Medical Device Nomenclature (EMDN)
[9] MDCG 2019-13 rev.1 Guidance on sampling of devices for the assessment of the technical documentation
[10] MDCG 2024-2 rev.1 Procedures for the updates of the EMDN

each identified by a sequence of letters and numbers that link one level to another. This allows a top-down analysis to go ever deeper into the details of the characteristics of a category of devices.

Hint: The term 'code' refers to the alphanumeric identifiers that classify and characterise each level of the EMDN.

2.3.1. Structure of the EMDN

The EMDN is presented as a multi-level tree, with these levels hierarchically linked to each other and groupable in the following way:

a) **Categories**: are represented by a letter of the alphabet that defines the first hierarchical level. Except for Category W (which represents *in vitro* diagnostic devices) and Category X (which represents products without an intended medical purpose), all other letters refer to medical devices.

b) **Groups**: are represented by a pair of numbers that define the second hierarchical level.

c) **Types**: are represented by a further series of pairs of numbers, in quantities varying from 1 to 5 depending on the devices considered, up to a maximum sequence of 13 digits.

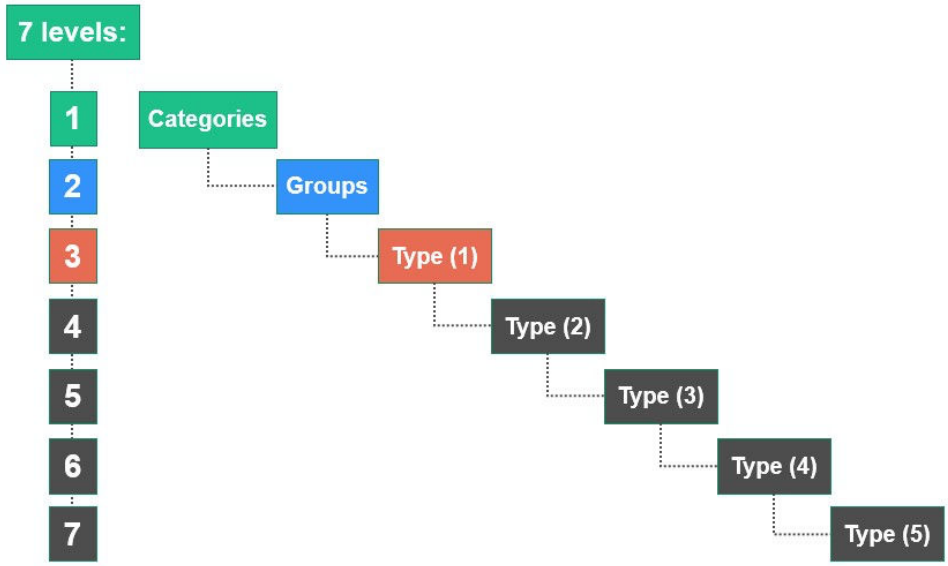


Figure 3 – The '7 levels hierarchical tree' of EMDN [11]

The terminal types to which the devices are paired can consist of the following numbers:

- 01 to 79: specific types of devices
- 80: accessories

[11] The CND nomenclature – Background and general principles, January 2020

- 82: specific software for equipment
- 85: specific materials for equipment
- 92: software medical devices
- 99: other devices

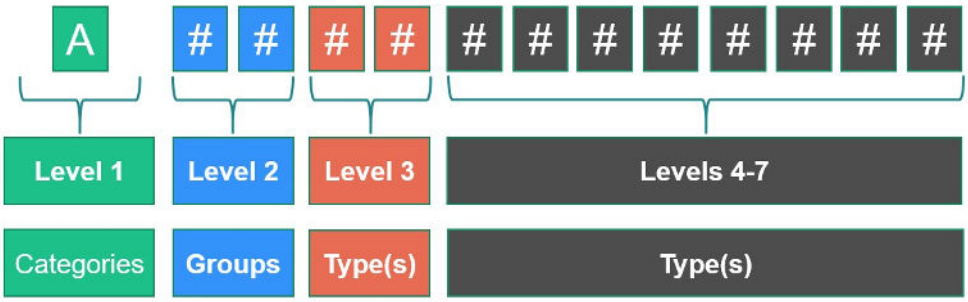


Figure 4 - The composition of an EMDN code

2.3.2. Description of EMDN categories for medical devices and products without an intended medical purpose (Annex XVI)

Medical devices are divided into 22 categories in the EMDN based on their anatomical or functional intended use, each of which is detailed in groups and typologies depending on the structural characteristics and/or the action exerted on the human organism. These can be divided into three types of categories:

ANATOMICAL categories

Devices used for the same specific apparatus, anatomical region or organ, or as a replacement for them:

Category B: Haematology and haemotransfusion devices

Category C: Cardiocirculatory system devices

Category F: Dialysis devices

Category G: Gastrointestinal devices

Category N: Nervous and medullary systems devices

Category Q: Dental, ophthalmologic and ENT devices

Category R: Respiratory and anaesthesia devices

Category U: Devices for the urogenital system

FUNCTIONAL categories

Devices characterised by similar use, intended use or clinical method:

Category A: Devices for administration, withdrawal and collection

Category D: Disinfectants, antiseptics, sterilising agents and detergents for medical devices

Category H: Suture devices

Category K: Endotherapy and electrosurgical devices

Category L: Reusable surgical instruments

Category M: Devices for general and specialist dressings

Category S: Sterilisation devices (excluding cat. D - Z)

Category T: Patient protective equipment and incontinence aids (excluding personal protective equipment (PPE))

Category V: Various medical devices

SPECIAL categories

Category J: Active implantable devices

Category P: Implantable prosthetic and osteosynthesis devices

Category Y: Devices for persons with disabilities not included in other categories

Category X: Products without an intended medical purpose (Annex XVI)

Category Z: Medical equipment and related accessories, software and consumables

The below listing includes most of the exceptions present within the Categories; it does not intend to cover all existing ones.

A.1 Category A – Devices for administration, withdrawal and collection

This category classifies the following types of devices:

a) NEEDLES – except (the asterisk placed as a suffix to an EMDN code means that all subsequent classification levels should be considered):

- peripheral I.V. catheters and cannulas, single use (C0101*)
- digestive endoscopy, needles, single use (G030201*)
- minimally invasive surgery needles, single use (K01020118)
- Veress needles (K0104)
- electrosurgery needles, single use (K02010108*)
- radiofrequency surgery needles, single use (K02030104)
- combined radiofrequency/ultrasonic surgery needles, single use (K02050104)
- needles, reusable (L*)
- needles and sets for oocite retrieval for assisted reproduction, single use (U080202*)
- urogenital thermoablation, needles and kits, single use (U090201)

b) SYRINGES – except for below examples from Category W which refer to IVDs:

- blood collection, closed syringes (W0501010101*)
- blood gas samples collection, syringes without needle (W0501010103)
- urine collection, syringes (W05010201*)

c) TUBULAR DEVICES

d) SOLUTIONS FILTERS

e) ELASTOMERIC AND NON-ELASTOMERIC INFUSION SYSTEMS

f) DRAINAGE AND FLUIDS COLLECTION DEVICES **– except**:

- clinical use containers (non-IVD) (V04*)
- urine collection, containers (W05010203)
- analysis containers (W050301*)

g) ADAPTERS, CONNECTORS, RAMPS, STOPCOCKS, CAPS **– except:**

- adapters and connectors for cardiovascular use (C*)
- reusable adapters and connectors (L*)
- adapters and connectors for intracranial use (N*)
- diffuser adaptors (S900103)

h) NUTRITION AND INFUSION BAGS AND CONTAINERS, SINGLE USE

i) ORGAN CONTAINERS – except:

- samples transport, containers (W050201*)

j) ABDOMINAL OSTOMY DEVICES

A.2 Category B – Haematology and haemotransfusion devices

Except:

- infusion controllers with filter (also transfusion controllers) (A03010102)
- self-transfusion equipment (Z120104)

- blood transfusion instruments (Z1217*)
- blood pumps (Z12099005)
- dialysis devices (F*)

A.3 Category C – Cardiocirculatory system devices

Except:

- cardiac functionality implantable devices (pacemaker, ICD, etc.) (J01*)
- vascular access devices (only for haemodialysis (F9002*)
- surgical scissors, reusable (L0104*)
- cardiovascular surgery instruments, reusable (L07*)
- vascular and cardiac prostheses (P07*)
- extra-vascular support prostheses (P10*)
- vascular procedures simulation devices (V0602)
- cardiology and cardio surgery instruments (Z1205*)

A.4 Category D – Disinfectants, antiseptics, sterilising agents and detergents for medical devices

No exceptions.

A.5 Category F – Dialysis devices

Except:

- peritoneal dialysis instruments (Z120901*)
- haemodialysis instruments (Z120902*)
- hospital beds or armchair scales for dialysis (Z12099003)
- liquid dialysis preparations (Z12099006)
- dialysis water treatment systems (Z12099007)

A.6 Category G – Gastrointestinal system devices

Except:

- gastric implantable neurostimulators (J0208*)
- gastroenterology scissors, reusable (L010408*)
- gastrointestinal system special forceps, reusable (L040802*)
- gastric dilators, reusable (L040903)
- gastroenterological instruments (Z1207*)

- Upper-gastrointestinal tract endoscopy instruments (Z120205*)

A.7 Category H – Suture devices

No exceptions.

A.8 Category J – Active implantable devices

No exceptions.

A.9 Category K - Endotherapy and electrosurgical devices

Except:

- surgical trocar, reusable (L0312*)
- laparoscopic and thoracoscopic surgery instruments, reusable (L12*)
- robotic surgery instruments, reusable (L13*)
- electrosurgery instruments, reusable (L18*)
- arthroscopic surgery instruments, reusable (L19*)

A.10 Category L – Reusable surgical instruments

No exceptions.

A.11 Category M – Devices for general and specialist dressings

No exceptions.

A.12 Category N – Nervous and medullary systems devices

Except:

- nervous system monitoring systems (Z121002)
- neurosurgery scissors, reusable (L010407*)
- neurosurgery and spinal surgery instruments, reusable (L11*)
- implantable neurostimulators and related electrocatheters (J02*)
- neuroendoscopy instruments (Z120209*)
- neuromuscular stimulation equipment (Z120628*)
- neurology and neurosurgery instruments (Z1210*)

A.13 Category P – Implantable prosthetic and osteosynthesis devices

No exceptions.

A.14 Category Q – Dental, ophthalmology and ENT devices

Except:

- dentistry needles and kits (A0106*)
- reusable surgical instruments (L*)
- odontological prostheses (P0102*)
- dental procedures simulation devices (V0603)
- instruments for orthopantomography and panoramic dental radiology (Z110303*)
- dental stomatology instruments (Z1211*)
- x-ray films (Z1301*)
- ophthalmology injection needles and kits (A0105*)
- ophthalmological use active implantable devices (J07*)
- reusable surgical instruments (L*)
- ophthalmology measurements devices not included in other classes (V030203)
- ophthalmological procedures simulation devices (V0605)
- ophthalmology instruments (Z1212*)
- ENT prostheses (P02*)
- ENT endoscopy instruments (Z120210*)
- ENT instruments (Z1214*)

A.15 Category R – Respiratory and anaesthesia devices

Except:

- pulmonary biopsy needles and kits (A010207)
- reusable surgical instruments (L*)
- respiratory prostheses (P04*)
- anaesthesia and pulmonary ventilation support instruments (Z120301*)
- pneumonology and respiratory physiopathology instruments (Z1215*)

A.16 Category S – Sterilisation devices (excluding categories D - Z)

A.17 Category T – Patient protective equipment and incontinence aids (excluding personal protective equipment - PPE)

No exceptions.

A.18 Category U – Devices for urogenital system

Except:

- urine collection systems and bags, single use (A060303*)
- urological irrigation controllers (A03010202)
- reusable surgical instruments (L*)
- urogenital prostheses (P08*)
- urine absorbing devices (T0401*)
- genitourinary endoscopy instruments (Z120207*)
- urology instruments (Z1216*)

A.19 Category V – Other devices

A.20 Category X – Products without an intended medical purpose (Annex XVI)

A.21 Category Y – Devices for persons with disabilities not included in other categories

Except:

- abdominal ostomy devices (A10*)
- incontinence devices (T04*)
- corrective optical devices (Q0210*)
- urethral, prostatic and bladder catheters (U01*)

A.22 Category Z – Medical equipment and related accessories, software and consumables

No exceptions.

2.3.2.1. Common types of codes used in multiple categories

There are some peculiarities that transversally concern all categories of the EMDN relating to medical devices.

a) Accessories for medical devices and IVDs

Accessories can be represented by the **suffixes 80** and **82**. Code 80 can be further detailed while code 82 cannot.

The presence of a generic code with the suffix "…8099" aims to allow an optimal degree of classification completeness and provide users with a terminal code in which the accessory can always be registered.

In category Z, however, accessories follow a different method. For each category of electromedical equipment, the following are classified:

1) **hardware accessories**, which is a term used to indicate accessories of an equipment, represented by codes characterised by the **suffix "80"**
2) **software accessories**, which is a term used to indicate software dedicated to a specific equipment or groups of equipment, whether pre-assembled or marketed separately. They are represented by codes characterised by the **suffix "82".**

In category J of medical devices and in group W02 of *in vitro* diagnostic medical devices, accessories are classified in the same way as in category Z.

b) Devices with multiple intended uses

If a device has multiple intended uses that allows the allocation of multiple EMDN terminal codes, the manufacturer may declare more than one code during the registration phase in EUDAMED, thus avoiding the need to resort to a "99" level.

For example, surgical scissors and forceps can be used for multiple purposes described in different types of the EMDN:

Adson forceps can be used as anatomical forceps (L031308), as intestinal tissue grasping forceps (L0408020301) and as surgical dissection forceps (L031310).

c) Consumable devices for specific use with electromedical equipment

Codes have been created in all levels of category Z dedicated to consumable devices for specific use with a given piece of equipment. These are devices that, due to structural or functional characteristics, can be used exclusively in combination with a type of instrumentation which is usually mentioned in the user manual and in the instructions for use.

These devices are assigned terminal codes with the suffix "85" of the EMDN, available exclusively in the categories J, W and Z, which are the only ones that contain references to electromedical equipment.

2.3.3. Description of EMDN categories for *in vitro* diagnostic medical devices (IVDs)

VDs are grouped in the EMDN in category W and subdivided as follows:

W01 **Reagents**

W0101 Clinical chemistry

W0102 Immunochemistry (Immunology)

W0103 Haematology / Haemostasis / Immunohaematology / Histology / Cytology

W0104 Microbiology (Culture)

W0105 Infectious diseases

W0106 Genetic testing

W02 **IVD Instruments**

W0201 Chemistry / Immunochemistry instruments

W0202 Haematology / Histology / Cytology instruments

W0203 Microbiology instruments (culture)

W0204 Infectious immunology instruments

W0205 Nucleic acid testing instruments

W0206 Sample processing systems

W0207 General purpose IVD instruments

W0299 IVD instruments – other

W05 IVD generic use consumables

W0501 Samples collection devices

W0502 Devices for samples transport (non-generic laboratory products)

W0503 Devices for samples analyses (no laboratory generic products)

W0580 IVD general use consumables devices – other accessories

W0599 IVD general use consumables devices – other

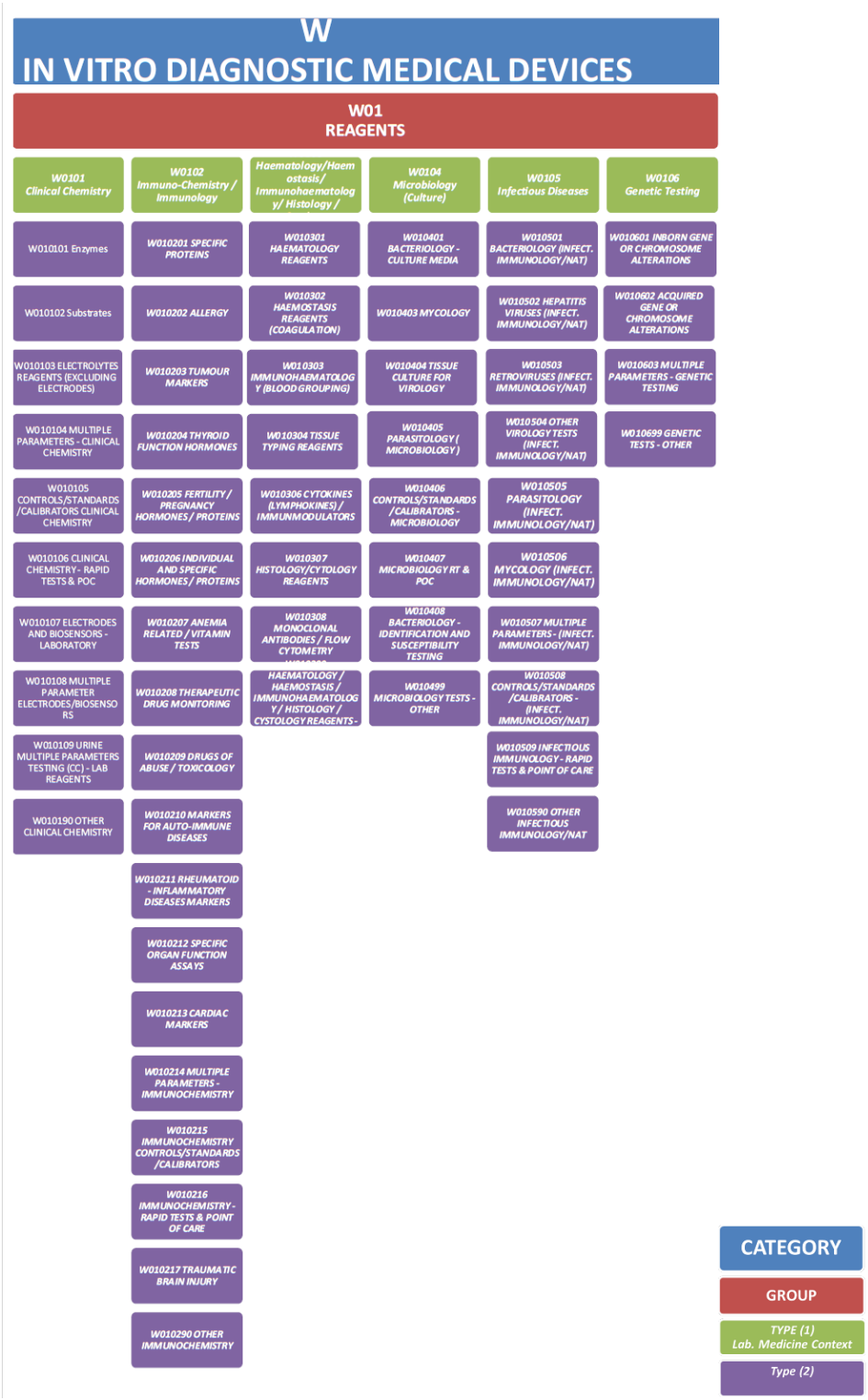

W
IN VITRO DIAGNOSTIC MEDICAL DEVICES
W01
REAGENTS
W0101 Clinical Chemistry
W0102 Immuno-Chemistry / Immunology
Haematology/Haemostasis/ Immunohaematology/ Histology /
W0104 Microbiology (Culture)
W0105 Infectious Diseases
W0106 Genetic Testing
W010101 Enzymes
W010102 Substrates
W010103 ELECTROLYTES REAGENTS (EXCLUDING ELECTRODES)
W010104 MULTIPLE PARAMETERS - CLINICAL CHEMISTRY
W010105 CONTROLS/STANDARDS /CALIBRATORS CLINICAL CHEMISTRY
W010106 CLINICAL CHEMISTRY - RAPID TESTS & POC
W010107 ELECTRODES AND BIOSENSORS - LABORATORY
W010108 MULTIPLE PARAMETER ELECTRODES/BIOSENSORS
W010109 URINE MULTIPLE PARAMETERS TESTING (CC) - LAB REAGENTS
W010190 OTHER CLINICAL CHEMISTRY
W010201 SPECIFIC PROTEINS
W010202 ALLERGY
W010203 TUMOUR MARKERS
W010204 THYROID FUNCTION HORMONES
W010205 FERTILITY / PREGNANCY HORMONES / PROTEINS
W010206 INDIVIDUAL AND SPECIFIC HORMONES / PROTEINS
W010207 ANEMIA RELATED / VITAMIN TESTS
W010208 THERAPEUTIC DRUG MONITORING
W010209 DRUGS OF ABUSE / TOXICOLOGY
W010210 MARKERS FOR AUTO-IMMUNE DISEASES
W010211 RHEUMATOID - INFLAMMATORY DISEASES MARKERS
W010212 SPECIFIC ORGAN FUNCTION ASSAYS
W010213 CARDIAC MARKERS
W010214 MULTIPLE PARAMETERS - IMMUNOCHEMISTRY
W010215 IMMUNOCHEMISTRY CONTROLS/STANDARDS /CALIBRATORS
W010216 IMMUNOCHEMISTRY - RAPID TESTS & POINT OF CARE
W010217 TRAUMATIC BRAIN INJURY
W010290 OTHER IMMUNOCHEMISTRY
W010301 HAEMATOLOGY REAGENTS
W010302 HAEMOSTASIS REAGENTS (COAGULATION)
W010303 IMMUNOHAEMATOLOGY (BLOOD GROUPING)
W010304 TISSUE TYPING REAGENTS
W010306 CYTOKINES (LYMPHOKINES) / IMMUNMODULATORS
W010307 HISTOLOGY/CYTOLOGY REAGENTS
W010308 MONOCLONAL ANTIBODIES / FLOW CYTOMETRY
HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYSTOLOGY REAGENTS -
W010401 BACTERIOLOGY - CULTURE MEDIA
W010403 MYCOLOGY
W010404 TISSUE CULTURE FOR VIROLOGY
W010405 PARASITOLOGY (MICROBIOLOGY)
W010406 CONTROLS/STANDARDS /CALIBRATORS - MICROBIOLOGY
W010407 MICROBIOLOGY RT & POC
W010408 BACTERIOLOGY - IDENTIFICATION AND SUSCEPTIBILITY TESTING
W010499 MICROBIOLOGY TESTS - OTHER
W010501 BACTERIOLOGY (INFECT. IMMUNOLOGY/NAT)
W010502 HEPATITIS VIRUSES (INFECT. IMMUNOLOGY/NAT)
W010503 RETROVIRUSES (INFECT. IMMUNOLOGY/NAT)
W010504 OTHER VIROLOGY TESTS (INFECT. IMMUNOLOGY/NAT)
W010505 PARASITOLOGY (INFECT. IMMUNOLOGY/NAT)
W010506 MYCOLOGY (INFECT. IMMUNOLOGY/NAT)
W010507 MULTIPLE PARAMETERS - (INFECT. IMMUNOLOGY/NAT)
W010508 CONTROLS/STANDARDS /CALIBRATORS - (INFECT. IMMUNOLOGY/NAT)
W010509 INFECTIOUS IMMUNOLOGY - RAPID TESTS & POINT OF CARE
W010590 OTHER INFECTIOUS IMMUNOLOGY/NAT
W010601 INBORN GENE OR CHROMOSOME ALTERATIONS
W010602 ACQUIRED GENE OR CHROMOSOME ALTERATIONS
W010603 MULTIPLE PARAMETERS - GENETIC TESTING
W010699 GENETIC TESTS - OTHER
CATEGORY
GROUP
TYPE (1)
Lab. Medicine Context
Type (2)

Figure 5 - EMDN categories for *in vitro* diagnostic medical devices: Reagents, IVD Instruments, IVD generic use consumables

3. How the EMDN relates to the GMDN and the GIVD

3.1. The GMDN

The Global Medical Device Nomenclature (GMDN) is a naming, classification and categorisation system for medical devices and IVDs. The GMDN Agency is a registered UK charity and non-profit organisation responsible for the ongoing maintenance of the GMDN Database. This nomenclature represents an important point of reference for manufacturers of medical devices and IVDs, allowing the use of a common language for the exchange of information relating to products belonging to the same typology in many countries around the world.

The GMDN consists of a numerical coding system with progressive assignment to the different types of devices. Each GMDN Term includes a unique five-digit code, a name, and a definition that allows the grouping of products with similar characteristics. It is dynamically updated while old codes are being removed.

3.2. Relation between the EMDN and the GMDN

The comparison of the EMDN and GMDN is complex, since GMDN has a multi-hierarchical classification system of categories (codes belong in categories of more than one branch of the hierarchy) while the EMDN has a two-dimensional hierarchical structure.

Given the different features of the two nomenclature systems, a mapping between the two systems is not always possible[12], because:

a) in a few cases, a GMDN code can only be matched to one EMDN code ("1 to 1 ratio");

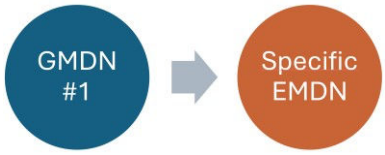


Figure 6 – GMDN code to EMDN code - 1:1

b) in several cases, a GMDN code can be matched to more than one EMDN code ("1 to many ratio");

[12] GMDN Agency: 'Feasibility of mapping the GMDN to the EMDN'. (Accessed May 2025) https://www.gmdnagency.org/wp-content/uploads/2023/09/Feasibility-of-mapping-GMDN-to-EMDN-article.pdf

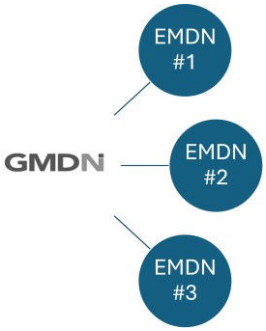


Figure 7 – GMDN code to many EMDN codes - 1 to many

c) in several cases, multiple GMDN codes can be matched to an EMDN code ("many to 1 ratio").

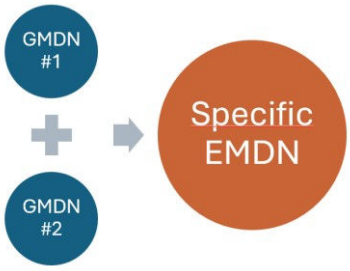


Figure 8 – several GMDN codes to one EMDN code – many to one

3.3. The GIVD

The Global In Vitro Diagnostic (GIVD) classification is a numerical coding system that allows users to group *in vitro* diagnostic products, with hierarchically related levels. It was created by MedTech Europe, replacing the previous EDMA classification with the aim of being used for market statistic surveys.

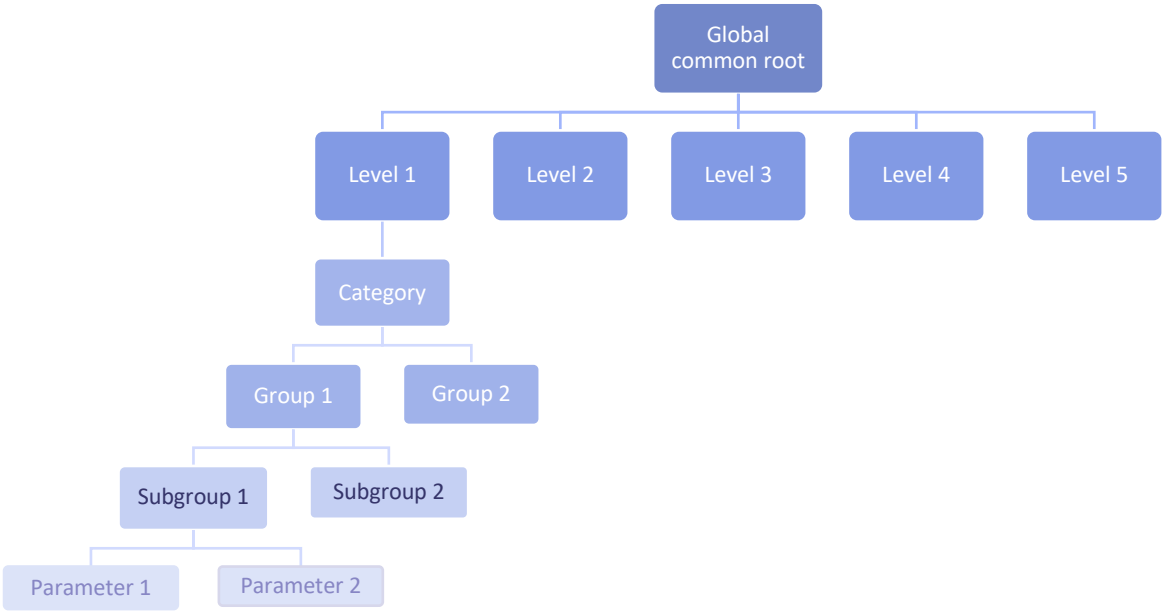


Figure 9 – Structure of GIVD

The GIVD uses six levels and up to eight digits, structured as follows:

- A unique root, representing the total market: code 6
- A first level, where each node is represented by a single digit: codes 1, 2, 3, 4, 5.
- The Category level – two digits: for instance, code 12 for "Immunochemistry Reagents"
- The Group level – four digits: for instance, code 12.03 for "Tumour markers"
- The Subgroup level – six digits: for instance, code 12.03.01 for "Cancer antigens"
- The Parameter level – eight digits: for instance, code 12.03.01.33 for "Free prostatic specific antigen (FPSA)".

The last four levels use a code (unique relative to their parent).

A Parameter is referenced by the codes of the last four levels, using the following convention:

<category>.<group>.<subgroup>.<parameter>

In addition to its code, each node has a specific name. The number of levels is not expected to change.

3.4. Relation between the EMDN and the GIVD

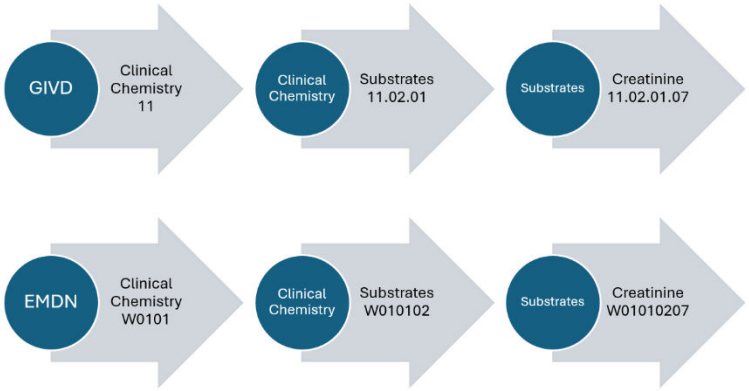
The characteristics of the EMDN, for the section dedicated to *in vitro* diagnostic medical devices, are very similar to those of the GIVD classification, as the working group established by the Italian Ministry of Health in 2020 took this classification system (2019 version of the GIVD) as a point of reference to create category W of the EMDN. In a similar way, the first EMDN annual revision performed in 2024 took account of the changes introduced in the GIVD (from 2020 to 2024) when updating the Group W01 – Reagents. This delivers consistency at terms level between the EMDN and the GIVD, but not always at a coding level. For companies assigning both EMDN and GIVD to their devices, this distinction is worth understanding.

However, EMDN groups W02 (IVD Instrumentation) and W05 (General purpose IVD consumables) under the W category do not have equivalent codes in the GIVD; in some of these (for example for IVD Instruments) the granularity and specificity achieved by the EMDN are greater than those achieved by the GIVD.

The main commonality between the two classification systems is their hierarchical structure, up to a maximum of 4 levels / 6 digits for GIVD and 7 levels / 13 digits for EMDN.

Below are some examples of this interrelationship between the two classification systems.

Example 1: Creatinine



As can be deduced from this comparison, the hierarchical structure in the two classification trees of the GIVD and the EMDN is equivalent for the substrate "**creatinine**".

Figure 10 – Example: Creatinine

Example 2: Instrumentation for clinical chemistry

In this case, the detail achieved by the EMDN allows users to distinguish all the main equipment used in the "clinical chemistry" sector, while the GIVD classification stops at a generic level. The GIVD includes accessories, consumables and software in the same group whereas the EMDN divides these into different classes.

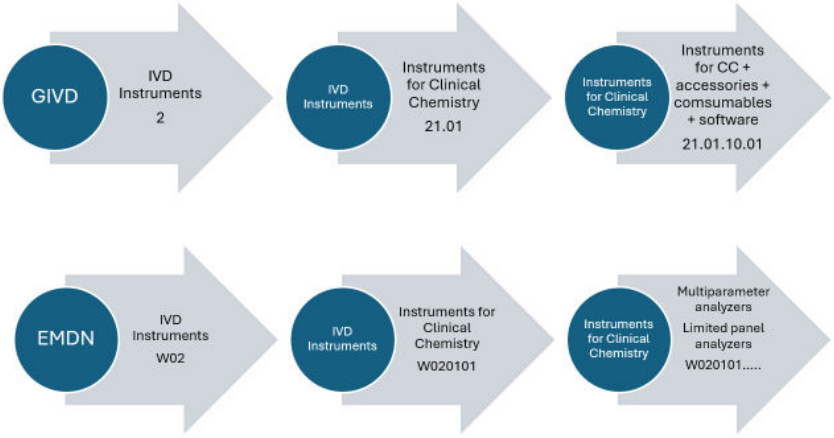


Figure 11 – Example: Instrumentation for clinical chemistry

4. Best practices for compliant use of the EMDN

The current structure of the EMDN provides specific detail, for each category, of the main types of medical devices present on the European market, allowing the identification of the most appropriate EMDN code for device registration in EUDAMED.

Hint: When registering a device in EUDAMED, it is important to follow the guidance established by the experts who developed the EMDN nomenclature – see MDCG guidance documents and EMDN training material listed in the List of References. This ensures that devices with similar structural and functional characteristics are assigned the same terminal EMDN code, avoiding inconsistencies that could hinder data analysis and the identification of comparable products.

4.1. Methods for identifying appropriate EMDN codes for devices

There are two paths that a manufacturer can follow to identify appropriate EMDN codes for devices, both of which can be achieved by using a query mask made available by the EUDAMED web registration platform[13] or the submission platform[14] for EMDN proposals:

a) The top-down approach involves scrolling through the hierarchical classification tree starting from the list of 22 categories and deepening the search by moving from one hierarchical level to another, until reaching the most appropriate terminal code. This method requires knowledge of the structural and functional characteristics of the device under examination, which will guide the search.

b) The keyword approach involves the identification of one or more keywords that characterise the device under examination and the search for their presence (individually or together) in the EMDN code descriptions. A complementary method is the **bottom-up approach**, which helps to determine the hierarchical context of the specific code under consideration.

Hint: When using the top-down approach, start from the main EMDN categories and navigate through the hierarchy using your knowledge of the device's structure and function to find the most accurate terminal code.

When applying the keyword approach, use relevant keywords to search EMDN code descriptions. Then, apply a bottom-up check to verify the code's position and context within the overall hierarchical classification system structure.

Manufacturers who have used the CND classification to register their devices in the databases of Italy, Portugal and Greece, may incorrectly assume that they can use the same device-CND combinations for the registration in EUDAMED. However, this path is risky.

In the table below you can see the impact that the publication of the EMDN had on the registrations present in the Italian database on 4 May 2021, for each individual category:

CATEGORY	CATEGORY DESCRIPTION	# OF REGISTRATIONS TO MODIFY IN THE ITALIAN DATABASE
A	DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION	20,619
B	HAEMATOLOGY AND HAEMOTRANSFUSION DEVICES	669
C	CARDIOCIRCULATORY SYSTEM DEVICES	11,262
D	DISINFECTANTS, ANTISEPTICS, STERILISING AGENTS AND DETERGENTS FOR MEDICAL DEVICES	1,525
F	DIALYSIS DEVICES	679
G	GASTROINTESTINAL DEVICES	3,54
H	SUTURE DEVICES	2,579
J	ACTIVE IMPLANTABLE DEVICES	1,253
K	ENDOTHERAPY AND ELECTROSURGICAL DEVICES	4,06
L	REUSABLE SURGICAL INSTRUMENTS	103,313

[13] EUDAMED https://ec.europa.eu/tools/EUDAMED/#/screen/search-device
[14] Submission platform for EMDN proposals https://webgate.ec.europa.eu/dyna2/emdn/

M	DEVICES FOR GENERAL AND SPECIALIST DRESSINGS	9,649
N	NERVOUS AND MEDULLARY SYSTEMS DEVICES	3,524
P	IMPLANTABLE PROSTHETIC AND OSTEOSYNTHESIS DEVICES	108,757
Q	DENTAL, OPHTHALMOLOGIC AND ENT DEVICES	64,948
R	RESPIRATORY AND ANAESTHESIA DEVICES	10,827
S	STERILISATION DEVICES (EXCLUDING CAT. D - Z)	9,259
T	PATIENT PROTECTIVE EQUIPMENT AND INCONTINENCE AIDS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE)	17,543
U	DEVICES FOR UROGENITAL SYSTEM	5,597
V	VARIOUS MEDICAL DEVICES	41,258
W	IN VITRO DIAGNOSTIC MEDICAL DEVICES	5,981
Y	DEVICES FOR PERSONS WITH DISABILITIES NOT INCLUDED IN OTHER CATEGORIES	70,582
Z	MEDICAL EQUIPMENT AND RELATED ACCESSORIES, SOFTWARE AND CONSUMABLES	14,731
Total		**512,155**

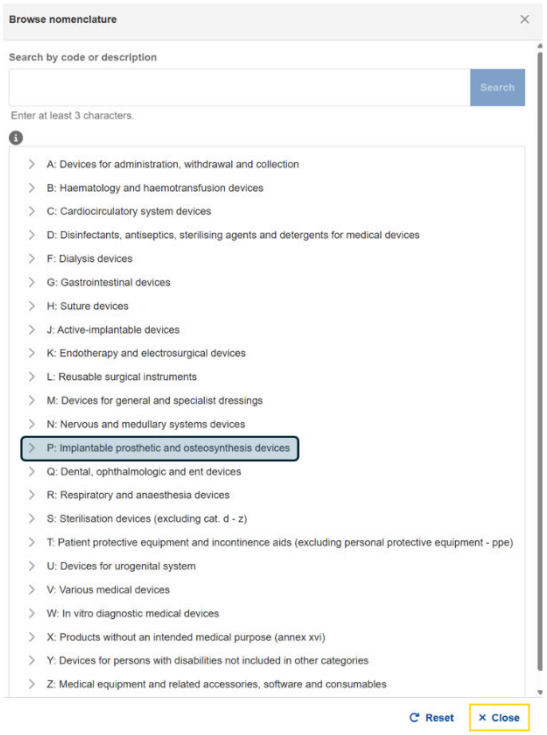
Table 2 – Revision of CND to existing registrations in the Italian national database

For more than one million devices present in the Italian national database, the CND code declared at national registration was no longer represented as a terminal level in the EMDN, either because it was deleted or because it was further split. Therefore, when registering devices in EUDAMED, it is essential to analyse the current EMDN codes to ensure accurate classification.

Hint: Avoid assuming that CND codes used in national databases apply directly to the same devices to register them in EUDAMED. The revision of CND to create EMDN may have introduced differences between CND and EMDN.

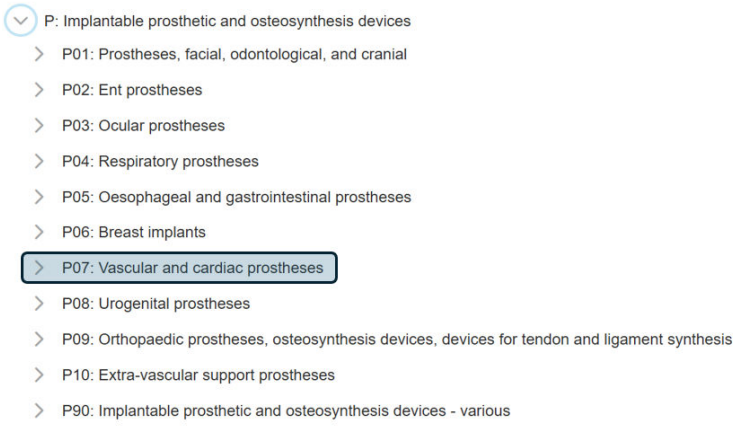
a) Top-down approach: searching through the hierarchical classification tree

The example of drug-eluting coronary stents with polymers illustrates the top-down and keyword approaches to searching for codes within the EMDN.



Coronary stents are implantable prosthetic devices, represented in the EMDN by category P "Implantable prosthetic devices and osteosynthesis devices". The operator's first selection should fall into this Category.

Figure 13 – Example: Top-down search for implantable prosthetic devices and osteosynthesis devices



Once the category is selected, the hierarchical classification tree proposes **11 groups**. The choice should fall into the group relating to "Vascular and cardiac prostheses".

At this point, the **typologies at various levels** detailing coronary drug-eluting stents are proposed in succession.

Figure 14 - Example: search for Vascular and cardiac prostheses

Scrolling through the nomenclature allows users to reach the **terminal level** relating to the class of devices being searched for:

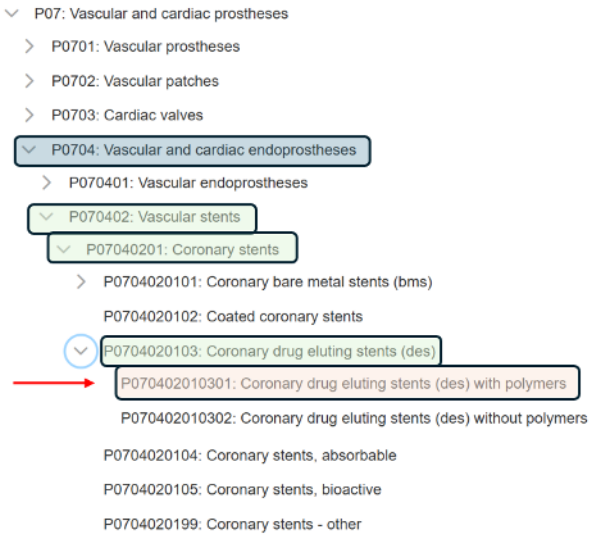


Figure 15 – Example: Top-down search for coronary drug-eluting stents with polymers

b) Keyword approach

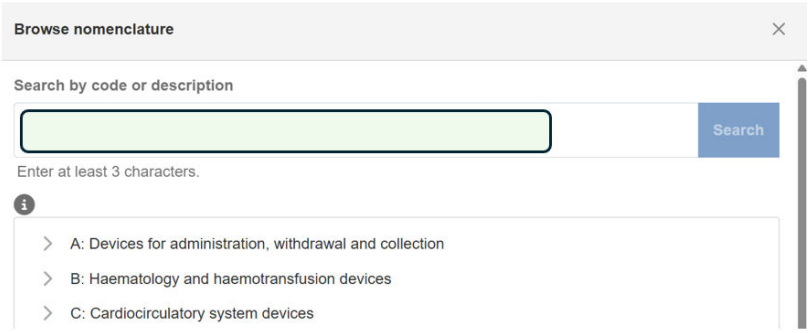


Figure 16 – Browser for keyword search

This type of search should be performed by indicating at least three characters of a text string that represents the description of an EMDN code. The search mode does NOT respond to any of these syntaxes:

b.1) **word #1 OR word #2**: e.g. “stent” OR “coronary”, in which case the result would match all descriptions containing the word “stent” and all those containing the word “coronary”

b.2) **word #1 AND word #2**: e.g. “stent” AND “coronary”, in which case the result would correspond to all descriptions containing the words “stent” and “coronary” at the same time, regardless of the sequence in which they are represented in the text strings

Instead, the word or words entered in the search field are selected in the EMDN code descriptions exclusively in sequence with each other, as a single text string. Consequently, if we search for the string “coronary stent” we would get the following result:

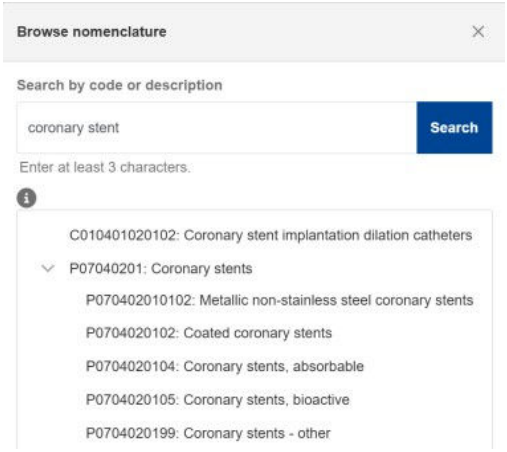


Figure 17 – Example: Keyword search for coronary stent

Continuing the example of the top-down scrolling of the hierarchical classification system, when looking for the code for coronary drug-eluting stents with polymers, the result obtained would not include this type of device, since the syntax with which these have been described in the EMDN includes the words “stent” and “coronary” not in strict sequence with each other:

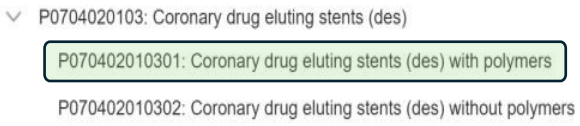


Figure 18 – Example: Search for coronary drug-eluting stents with polymers

To avoid making errors in the interpretation of the results obtained, it is therefore necessary to keep in mind the syntax with which the search mask made available in EUDAMED works. The code exists in the hierarchical classification tree but can only be identified if the words indicated are in immediate sequence with each other:

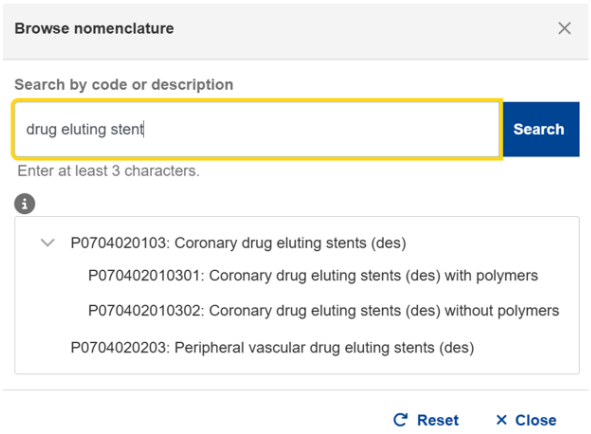


Figure 19 – Example: Keyword search for coronary drug-eluting stents with polymers

4.2. What to do when no appropriate code exists for a device

Not all types of medical devices and *in vitro* diagnostic medical devices have specific terminal levels created in the EMDN that allow manufacturers to match their products. In some cases, it is necessary to allocate the generic codes "99", created in all sectors of the hierarchical classification tree, which allow registration in EUDAMED.

If it is not possible to find a specific code for a product in the EMDN, it is necessary to consult the nomenclature tree in the generic code (with suffix "99"[15]) referring to the structural and functional characteristics of the device itself. This might be the case for orphan or niche devices.

For example, consider a **disposable cannula for intracranial parenchymal administration of substances**. Such a device should be placed in the typology:

N01 – Encephalic and peripheral nervous system devices

but none of the typologies in this group are appropriate for the device in question:

N0101 – Neurophysiology devices

N0102 – Neurologic physiotherapy devices

N0103 – Cranial drainage devices and kits

N0104 – Peripheral nervous system catheters

It is therefore necessary to match the device to the closest generic code with the suffix "99", i.e.

N0199 – Encephalic and peripheral nervous system devices – other

When there is no appropriate code to select, and the manufacturer assigns the code 'Other' (code extension 99) to their device, it is necessary to formulate a proposal for the creation of a new code – see next section. Manufacturers are also encouraged to notify the need for such potential new code early in the certification process. Once/if a new code is created, manufacturers must reflect this change and update their registration in EUDAMED and in all related regulatory documentation.[16]

Hint: Use the "Other" (99) code only when no suitable EMDN code exists and be sure to propose a new code via the EMDN submission platform[17].

The group of experts responsible for analysing proposals will periodically consider whether or not to insert new terminal codes into the EMDN specifically for devices with generic codes

[15] **Difference between codes 90 and 99**
- **Codes 99 'Others'** represent generic terminal levels for each type of device and can be used to classify those products that do not find a specific placement in other terminal levels.
- **Codes 90 'Various'** do NOT represent terminal levels, as they are hierarchically further detailed in EMDN. No device can therefore be classified with a code 90.

[16] See Question 24 in MDCG 2021-12 rev.1 FAQ on the European Medical Device Nomenclature (EMDN)

[17] Submission platform for EMDN proposals https://webgate.ec.europa.eu/dyna2/emdn/

"99", to adapt the nomenclature to the needs of the market and the characteristics of the devices.

4.3. Formulation of proposals for new EMDN codes

On an annual basis, stakeholders operating in the field of medical devices are called upon to submit to the European Commission their proposals for updating the structure of the EMDN nomenclature. This helps to optimise its usability for device registrations in EUDAMED. Periodic revisions must consider new technologies introduced on the market, the need for further in-depth classification in the nomenclature tree, as well as any regulatory and legislative updates.

Hint: It is recommended that stakeholders plan the submission of new code requests (e.g. for a new technology introduced on the market) well ahead of time: requests submitted by the end of January each year will be considered for technical evaluation within that calendar year and, if positively assessed, be published by the end of the same year.

Consider notifying early in the certification process and updating EUDAMED and related regulatory documents if a new code is later assigned.

The types of updates possible are as follows:

1. **Insert a new level (new code and new term)**: to include device types not currently present in the EMDN (new technologies, request for more detailed of EMDN code/term);
2. **Edit an existing term**: to make an existing term more comprehensive, clearer or to remove any errors. Each modification is aimed at improving usability;
3. **Delete an existing level (existing code and existing term)**: if an overlap in codes or critical issues in the structure is to be reported;
4. **Move an existing level (existing code and existing term) to another existing location (category, group or type) in the EMDN**: in case it is not properly placed in the existing hierarchical tree.

The following actors are represented in the updating process:

- Medical Devices Coordination Group (MDCG)
- Nomenclature Working Group (NOM-WG) – MDCG Subgroup
- European Medical Device Nomenclature Technical Team (EMDN-TT)
- Stakeholders (manufacturers, importers, distributors, Notified Bodies, Competent Authorities, healthcare professionals, etc.)

The EMDN-TT evaluates the submissions and produces a series of draft proposals of the EMDN structure to be sent to the NOM-WG. That working group must analyse the proposals and then share them with the MDCG for final approval and publication for the subsequent classification update.

Hint: Stakeholders can submit proposals for updates via the EMDN submission platform[18] by providing a thorough description of the device in question.

[18] Submission platform for EMDN proposals https://webgate.ec.europa.eu/dyna2/emdn/

4.4. Examples of combinations between medical devices and how these relate to EMDN codes

Example: The device reported in point 4.2 can serve as example to describe the steps that stakeholders must take to formulate their proposal. In this formulation it will be necessary to briefly describe the characteristics of the device:

> "Disposable cannula for intracranial parenchymal administration of drugs and other substances for therapeutic purposes, under the guidance of radiological procedures compatible with it (e.g.: MRI)"

suggesting the hierarchical structure that should integrate the current classification tree:

> N0105 – Devices for administration of substances into the CNS
>
> N010501 – Cannulas for administration of substances into the CNS
>
> N01050101 – Cannulas for administration of substances into the CNS under radiological guidance
>
> N01050102 – Cannulas for administration of substances into the CNS without radiological guidance
>
> N010599 – Devices for administration of substances into the CNS – others

Additional information may be provided in support of the proposal relating to:

- commercial name of the device
- manufacturers
- EMDN code used for possible registration in EUDAMED using the current EMDN structure
- CE risk class
- technical documentation

When formulating the proposal, it will be necessary to consider all the categories of the EMDN that could represent the type of device in question. In fact, category N may not be the most appropriate. It is advised to analyse the possible alternative categories and to evaluate their appropriateness:

- category A – Devices for administration, withdrawal and collection. Administration cannulas (whether disposable or reusable) do not fit into this category and are represented in other part of the EMDN nomenclature depending on the anatomical district of application.
- category C – Cardiocirculatory system devices. The cannula in question is not used for infusing substances into intracranial vessels, but into the brain parenchyma.
- category L – Reusable surgical instruments. The cannula is disposable and is not used for surgery.

Having eliminated all possible alternative placements, it can be concluded that category N is the only appropriate category for this device.

4.4. Examples of combinations between medical devices and how these relate to EMDN codes

4.4.1. Electrosurgery connecting cables

This definition includes the various types of electrosurgery techniques defined in detail in categories K and Z (mono- and bipolar devices, ultrasonic surgery devices, radiofrequency surgery devices, argon gas surgery devices, combined radiofrequency and ultrasound surgery devices).

The cables that connect an electrosurgery device to a handpiece, allowing the transmission of current and the operation of the device, can be of two types:

- for a **specific use on a single device** (in which case this characteristic is described in the user manual) or
- for **universal use on different types of devices** or even on all of them. Furthermore, these cables can be disposable or reusable.

These devices cannot be considered "accessories", as their absence prevents the functioning of the electrosurgery system to which they are connected: they therefore represent an integral part of the system itself.

The combination of these characteristics leads to a different EMDN code assignment for electrosurgery cables:

a) **cables for universal use, disposable**: K02010203 (Electrosurgery connection cables, single use)

b) **cables for universal use, reusable**: L181003 (Electrosurgery connection cables, reusable)

c) **specific cables for a single equipment, disposable**: Z12010985 (Electrosurgery instruments – consumables) for all types of electrosurgery except for ultrasound, for which the correct assignment is Z12010885 (Instruments for ultrasonic surgery – consumables)

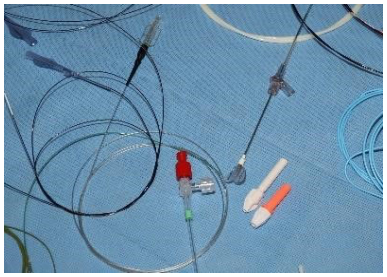
d) **specific cables for a single equipment, reusable**: since they are not accessories but components without which an electrosurgery system cannot function, they must be combined with the code in category Z of the specific equipment to which they are connected (Z12010801 Ultrasonic scalpels, Z12010901/02/03/04/05/99 for Electrosurgery instruments)

4.4.2. Abdominal ostomy plates

This type of medical device is characterised by the A100201 class and the levels below it. It is a "two-piece abdominal stoma device", consisting of an adhesive plate placed on the abdominal skin at the preternatural stoma and a bag secured to it through a locking system.

While abdominal stoma bags can have different structural characteristics depending on the type of surgery performed on the patient (colostomy, ileostomy, urostomy), there are plates that can be used for any type of stoma (even though each has a predominant use for one or the others). These plates do not have to be classified based on their predominant use but rather find an ideal location in one of the terminal levels of the A10020104 "parent" type ("Universal plates for abdominal stoma (colo-, ileo-, urostomy)"), depending on their flat shape (for non-retracted stoma) or convex shape (for retracted stoma).

4.4.3. Coronary artery guidewires for diagnostic and interventional use



For vascular guides introduced into the coronary arteries, the EMDN provides different codes depending on the intended use: for diagnostic procedures (e.g. for coronary angiography, which involves the administration of a contrast medium into the coronary tree) or for therapeutic procedures (e.g. for coronary angioplasty).

However, there are many coronary guides that can be used for both diagnostic and interventional procedures. For this type of device, the EMDN does not provide a specific code. Classifying these devices based on their predominant intended use does not appear to be the most appropriate approach, as it could lead to inconsistencies in EUDAMED. Depending on the choices made by each manufacturer, the same type of device may be registered under either the diagnostic or therapeutic EMDN code.

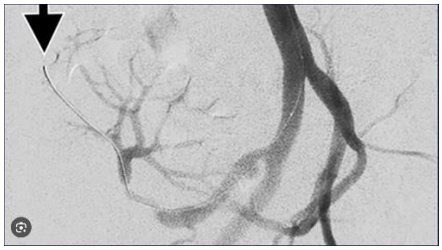
In similar cases relating to other EMDN categories, the devices are best suited to the terminal level "99" relating to the typology to which they belong: in this specific case, therefore, this placement should be sought in the level "99" corresponding to the coronary guides. However, in the EMDN nomenclature tree, a terminal code C040199 "Coronary arteries guidewires – other" has not been foreseen, so this option cannot be applied.

The only generic terminal level available is represented by C0499 "Cardiovascular guidewires – other", even though this does not represent the specific intended use (in the coronary arteries) of the devices in question. This assignment would allow the grouped recognition of these devices, providing an important element for evaluating the need to subsequently update the EMDN nomenclature with the creation of the terminal level C040199 "Coronary arteries guidewires – other".

Alternatively, since more than one EMDN code can be indicated in the EUDAMED registration, the user could classify such devices using the following codes (and related bottom levels) simultaneously:

- C040101 – Coronary artery diagnostic guidewires
- C040102 – Coronary artery therapeutic guidewires

4.4.4. Peripheral vascular guidewires for diagnostic and interventional use



s with coronary guides, the EMDN also provides for different codes of peripheral vascular guides depending on their intended use: for diagnostic procedures (e.g. for selective angiography, which involves the administration of a contrast medium into the peripheral vascular tree) or for therapeutic procedures (e.g. for peripheral angioplasty).

However, there is a considerable number of peripheral vascular guides that can be used for both diagnostic and interventional procedures: for this type of device, the EMDN does not provide a specific code and in this case the choice to classify them on the basis of the predominant intended use does not seem to be the most appropriate since, depending on the choices made by each manufacturer, EUDAMED would have the dispersion of the registrations in one (diagnostic) or the other (therapeutic) code made available by the EMDN nomenclature.

In similar cases relating to other EMDN categories, the devices find an optimal assignment in the terminal level "99" relating to the typology to which they belong: in this specific case, therefore, this assignment should be sought in the level "99" corresponding to the peripheral vascular guides. However, in the EMDN nomenclature tree a terminal code C040299 "Peripheral vascular guidewires - other" has not been foreseen, so this option cannot be applied.

The only generic terminal level available is represented by C0499 "Cardiovascular guidewires - other", even though this does not represent the specific intended use (in the coronary arteries) of the devices in question. However, this assignment would allow the grouped recognition of these devices, providing an important element for evaluating the need to subsequently update the EMDN nomenclature with the creation of the terminal level C040299 "Peripheral vascular guidewires - other".

Alternatively, since more than one EMDN code can be indicated in the EUDAMED registration, the user could classify such devices using the following codes (and related bottom levels) simultaneously:

- C040201 – Peripheral vascular diagnostic guidewires
- C040102 – Peripheral vascular therapeutic guidewires

4.4.5. Single-use surgery instruments

A significant portion of surgical instruments used in daily practice are devices that are placed on the market in non-sterile conditions and require sterilisation before use. These instruments are all classified in category L of the EMDN: "Reusable surgical instruments".

All disposable surgical instruments (which therefore do not require subsequent sterilisation once used and must be disposed of) are not placed in category L, but rather, depending on the type of device and its intended use, they have been classified in various other categories.

The following table lists the relevant codes of disposable instruments represented in the EMDN (the asterisk placed as a suffix to an EMDN code means that all subsequent classification levels should be considered):

C06*	Cardiovascular surgery instruments, single use
F9006	Dialytic treatment instruments, single use
G0308*	Gastrointestinal endoscopy and echoendoscopic, single-use instruments
H9008*	Single-use suture instruments
K010201*	Minimally invasive surgery surgical instruments, single use
K010202*	Robotic surgery instruments, single use
K010302	Minimally invasive spinal surgery instruments, single use
K020101*	Mono- and bipolar surgical instruments, single use
K020201*	Ultrasonic surgery instruments, single use
K020301*	Radiofrequency surgery instruments, single use
K020401*	Argon gas surgery instruments, single use
K020501*	Combined radiofrequency / ultrasound surgery instruments, single use
K0302*	Arthroscopy surgical instruments, single use
N018001*	Encephalic and peripheral nervous system surgical instruments, single use
N028002*	Spinal medullary system surgical instruments, single use
P0913*	Orthopaedic implant instruments, single use
Q0105*	Instruments for dentistry, single use
Q0211*	Ophthalmic surgery instruments, single use
Q0303*	ENT surgery instruments, single use
R0702*	Bronchoscopic surgery instruments, single use
R9003*	Respiratory system surgery instruments, single use
U0903*	Single-use instruments for urogenital endoscopy
U12*	Single-use instrumentation for urogenital system (non-endoscopic)
V9012	Non-specialist surgical instruments and kits, single use
V901601	Plastic surgery and non-aesthetic purposes generic use instruments and kits, single use

V901602	Dermosurgery instruments and kits, single use
V901603	Superficial treatments instruments and kits, single use

4.4.6. Hydrogen peroxide for disinfection of medical devices

Hydrogen peroxide is considered a medical device under the EU Medical Device Regulation (MDR) only when the manufacturer has explicitly declared its intended use for the disinfection of other medical devices. In such cases, the product must be classified under the terminal code D0502 of the European Medical Device Nomenclature (EMDN): "Hydrogen peroxide for disinfection of medical devices".

If the intended use is not clearly specified as disinfection of medical devices, the product cannot be registered in EUDAMED, as this intended use is a fundamental requirement for inclusion.

It is important to note that hydrogen peroxide intended for human use - such as disinfection of skin wounds or mucous membranes - does not fall within the scope of the MDR and is therefore not classified within the EMDN.

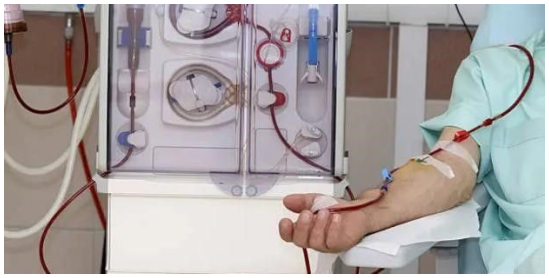
4.4.7. Ethanol for disinfection of medical devices

Ethanol (ethyl alcohol) qualifies as a medical device under the EU MDR only if the manufacturer declares its intended use as a disinfectant for medical devices. When this condition is met, the product is assigned to the EMDN terminal code D0701 "Ethanol for disinfection of medical devices."

The absence of this specific intended use excludes the product from registration in EUDAMED, as it is a necessary criterion under MDR.

Ethanol products intended for human use (e.g., skin antisepsis) or generic laboratory purposes are not regulated as medical devices and thus are not included in the EMDN nomenclature.

4.4.8. Dialysis filters



The filters used in extracorporeal haemodialysis procedures may be divided into two main types, for classification purposes:

a) filters through which the patient's blood flows, coming into contact with the so-called "dialysis bath" for the purification of toxic substances that the kidney is no longer able to process;

b) filters for purification and preparation of the water used for the "dialysis bath".

Type a) filters are classified in the EMDN in category F "Dialysis filters" and divided based on the structural characteristics and the dialysis technique of application.

Type b) filters, on the other hand, do not come into contact with the patient's blood and represent specific consumable devices for dialysis equipment. As such, they are assigned to the terminal code Z12099085 "Various nephrology and haemodialysis instruments – consumables". In fact, the systems for the treatment of water used in dialysis procedures are also classified in the same Z120990 category, of which the filters described represent a type of consumables.

4.4.9. Vascular prostheses, aortic arch

In relation to the prostheses used for the repair of lesions of the peripheral vascular system, the current structure of the nomenclature includes two distinct sections: a) prostheses used for replacement of portions of the peripheral vascular tree at the site of the lesion, and b) endoprostheses used for repair of the lesion with maintenance of the affected vascular tract. For vascular prostheses, the classification detail takes into consideration exclusively the shape and material from which these devices are made, regardless of the implant site. This peculiarity means that even those anatomical sectors that represent borderline areas between the heart and the peripheral vascular system must necessarily flow into the latter for classification purposes.

A special case is constituted by the prostheses for the aortic arch and the first section of thoracic aorta.

At present, these implantable devices must be classified as follows:

a) P070102010201 ("Dacron vascular prostheses, multifurcated") if in mesh dacron;

b) P07010299 ("Vascular prostheses, synthetic – other") if made of other materials.

4.4.10. Fixation screws for orthopaedic prostheses

Some components of major joint prostheses require fixation screws for anchoring to the bones. These screws must be classified as follows:

c) fixation screws for shoulder prosthesis: P09018001 ("Shoulder prostheses fixing screws")

d) fixation screws for ankle prosthesis: P09058099 ("Ankle prostheses – accessories – other")

e) fixation screws for hip prosthesis: P09088007 ("Hip prostheses fixing screws")

f) fixation screws for knee prosthesis: P09098099 ("Knee prostheses – accessories – other")

4.4.11. Locked intramedullary nails

In EMDN P09120201 typology ("Intramedullary nails") both solid and cannulated forms are classified, as well as forms blocked through the use of fixing screws.

The screws used for this purpose, however, should not be classified among cortical or cancellous screws, but in EMDN P09120604 typology ("Osteosynthesis nail-screw systems"). The current description of this code could be confusing during the research phase, leading to the idea that even locked intramedullary nails should be placed in it.

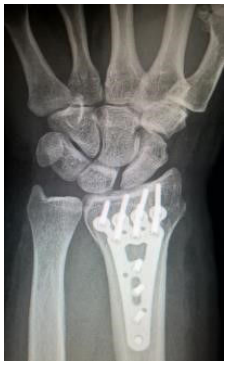
4.4.12. Locking screws for osteosynthesis plates

Locking screws for osteosynthesis plates can be of two types: a) screws used to lock plates that do not belong to specific screw-plate systems (in this case the plates do not require dedicated screws, the only ones for which the manufacturer has declared compatibility, so the same screws are used for fixing and locking different plates in different anatomical districts); b) screws dedicated to locking specific types of plates.

Screws belonging to the first type are classified as cortical screws (P09120601) or cancellous screws (P09120602) or cannulated screws (P09120603) depending on their structural and functional characteristics.

Those belonging to the second type, however, should be classified at the terminal level P09120503 (“Osteosynthesis screw-plate systems”).

4.4.13. Bone fixation plates



Without considering the structural and functional characteristics of this type of medical device, bone fixation plates can be divided into two blocks: a) plates not belonging to specific screw-plate systems (in this case they do not require dedicated screws); b) plates belonging to systems marketed with dedicated screws for locking (the only ones for which the manufacturer declares safe compatibility to safeguard the patient's health).

Plates belonging to the first type are divided based on the action performed on the skeletal district of application (P09120501 for compression plates, P09120502 for neutralisation and support plates).

Those belonging to the second type must be classified at the terminal level P09120503 ("Osteosynthesis screwplate systems").

4.4.14. Speaking valves

There are two types of speaking valves, both of which aim to allow the patient to express himself vocally despite the presence of a tracheostomy.

First type of speaking valve

It restores the ability to speak in laryngectomees by creating a fistula between the posterior wall of the trachea and the anterior wall of the oesophagus. A one-way valve is positioned in this fistula, allowing airflow to pass from the trachea to the oral cavity.

Valves of this type are considered to all intents and purposes implantable prosthetic devices and as such must be classified as follows:

P0205 – Phonation prostheses

Second type of speaking valve

It allows tracheostomy patients to speak, whether they are spontaneously ventilated or dependent on assisted ventilation.

Valves of this type should not be considered implantable prosthetic devices and should be classified as follows:

R900602 – Phonation valves for tracheostomy

4.5. Examples of combinations between IVDs and how these relate to EMDN codes

4.5. Examples of combinations between IVDs and how these relate to EMDN codes

Finding the correct matching codes for *in vitro* diagnostic medical devices is facilitated for those familiar with GIVD classification. In fact, during the design phase, the most faithful correspondence possible was maintained between the nascent EMDN and the GIVD classification. Within the latter, reagents, controls, calibrators, standards, point of care (POC) and rapid tests (RT) for a given sector cannot be displayed next to each other and must be searched by scrolling the tree down to the 4th and 5th levels. Therefore, the top-down approach described in 4.1 is the advisable search method.

Another useful approach may be to search for a given analyte or microbiological agent, so as not to make mistakes in attributing the code to which each device used for the analyte/agent determination (reagent, calibrators, controls etc,) belongs. Below are some examples.

Clinical chemistry

ENZYMES

Test	*EMDN*	*EMDN description*
Reagents	W010101*	Enzymes
Controls	W0101050201	Enzyme controls
Calibrators	W01010503*	Calibrators and standards (clinical chemistry)
Standards	W01010503*	Calibrators and standards (clinical chemistry)

For example, the **gamma-glutamyltransferase test** may be combined with the following EMDN codes:

Test	*EMDN*	*EMDN description*
Reagents	W01010116	Gamma glutamyltransferase
Controls	W0101050201	Enzyme controls
Calibrators	W0101050302	Calibrators single component (CC)
Standards	W0101050303	Aqueous standards (CC)

SUBSTRATES

Test	*EMDN*	*EMDN description*
Reagents	W010102*	Substrates
Controls	W01010502*	Specific controls (clinical chemistry)
Calibrators	W01010503*	Calibrators and standards (clinical chemistry)

Standards	W01010503*	Calibrators and standards (clinical chemistry)
Point of care	W010106*	Clinical chemistry – RT & POC
Rapid test	W010106*	Clinical chemistry – RT & POC

For example, the **bilirubin test** may be matched to the following EMDN codes:

Test	*EMDN*	*EMDN description*
Reagents	W01010203	Bilirubin
Controls	W0101050203	Bilirubin controls
Calibrators	W0101050302	Calibrators single component (CC)
Standards	W0101050303	Aqueous standards (CC)
Point of care	W0101060199	Blood test strips – other
Rapid test	W0101060199	Blood test strips (CC) – RT and POC – other

Immunochemistry

TUMOUR MARKERS

Test	*EMDN*	*EMDN description*
Reagents	W010203*	Tumour markers
Controls	W0102152005	Tumour marker controls
Calibrators	W0102152205	Tumour marker standard and calibrators
Standards	W0102152205	Tumour marker standard and calibrators
Point of care	W01021602*	Tumour markers RT & POC
Rapid test	W01021602*	Tumour markers RT & POC

For example, the test for the **Cyfra 21-1 marker** may be combined with the following EMDN codes:

Test	*EMDN*	*EMDN description*
Reagents	W0102030111	Cyfra 21-1
Controls	W0102152005	Tumour marker controls
Calibrators	W0102152205	Tumour marker standard and calibrators
Standards	W0102152205	Tumour marker standard and calibrators
Point of care	W0102160299	Tumour marker RT & POC – other
Rapid test	W0102160299	Tumour marker RT & POC – other

DRUG MONITORING

Test	*EMDN*	*EMDN description*
Reagents	W010208*	Therapeutic drug monitoring
Controls	W0102152001	TDM/drug controls
Calibrators	W0102152201	TDM/drug standard and calibrators
Standards	W0102152201	TDM/drug standard and calibrators
Point of care	W01021604*	Therapeutic drug monitoring (TDM) RT & POC
Rapid test	W01021604*	Therapeutic drug monitoring (TDM) RT & POC

For example, the **lidocaine dosage test** may be matched to the following EMDN codes:

Test	*EMDN*	*EMDN description*
Reagents	W0102080105	Lidocaine
Controls	W0102152001	TDM/drug controls
Calibrators	W0102152201	TDM/drug standard and calibrators
Standards	W0102152201	TDM/drug standard and calibrators
Point of care	W0102160499	TDM RT & POC – other
Rapid test	W0102160499	TDM RT & POC – other

CARDIAC MARKERS

Test	*EMDN*	*EMDN description*
Reagents	W010213*	Cardiac markers
Controls	W0102152004	Cardiac marker controls
Calibrators	W0102152204	Cardiac marker standard and calibrators
Standards	W0102152204	Cardiac marker standard and calibrators
Point of care	W01021607*	Cardiac markers – RT & POC
Rapid test	W01021607*	Cardiac markers – RT & POC

For example, the **troponin test** may be matched to the following EMDN codes:

Test	*EMDN*	*EMDN description*
Reagents	W01021306	Troponin I/T
Controls	W0102152004	Cardiac marker controls
Calibrators	W0102152204	Cardiac marker standard and calibrators

Standards	W0102152204	Cardiac marker standard and calibrators
Point of care	W0102160703	Troponin I/T – RT & POC
Rapid test	W0102160703	Troponin I/T – RT & POC

Microbiology

PARASITOLOGY

Test	*EMDN*	*EMDN description*
Reagents	W010405*	Parasitology (Microbiology)
Controls	W010406*	Controls/standards/calibrators – microbiology
Calibrators	W010406*	Controls/standards/calibrators – microbiology
Standards	W010406*	Controls/standards/calibrators – microbiology
Point of care	W010407	Microbiology RT & POC
Rapid test	W010407	Microbiology RT & POC

For example, the **test for cryptosporidium** may be matched to the following EMDN codes:

Test	*EMDN*	*EMDN description*
Reagents	W0104050203	Cryptosporidium
Controls	W01040699	Controls, standards, calibrators, microbiology – other
Calibrators	W01040699	Controls, standards, calibrators, microbiology – other
Standards	W01040699	Controls, standards, calibrators, microbiology – other
Point of care	W010407	Microbiology RT & POC
Rapid test	W010407	Microbiology RT & POC

Immunology of infectious diseases

BACTERIOLOGY

Test	*EMDN*	*EMDN description*
Reagents for antigen detection	W010501*	Bacteriology (infect. immunology/NAT)
Reagents for antibodies assay, total	W010501*	Bacteriology (infect. immunology/NAT)
Reagents for antibodies assay, IgA	W010501*	Bacteriology (infect. immunology/NAT)
Reagents for antibodies assay, IgG	W010501*	Bacteriology (infect. immunology/NAT)
Reagents for antibodies assay, IgM	W010501*	Bacteriology (infect. immunology/NAT)

Controls	W0105080801	Bacteriology controls – inf. imm.
Calibrators	W0105080901	Bacteriology standards and calibrators inf. Imm.
Point of care	W01050901*	Bacteriology – RT & POC
Rapid test	W01050901*	Bacteriology – RT & POC

As an example, the test for **Chlamydia trachomatis** may be combined with the following EMDN codes:

Test	*EMDN*	*EMDN description*
Reagents for antigen detection	W0105010107	Chlamydia trachomatis, antigen detection
Reagents for antibodies assay, total	W0105010108	Chlamydia trachomatis, antibody assays total
Reagents for antibodies assay, IgA	W0105010109	Chlamydia trachomatis, antibody IgA
Reagents for antibodies assay, IgG	W0105010110	Chlamydia trachomatis, antibody IgG
Reagents for antibodies assay, IgM	W0105010111	Chlamydia trachomatis, antibody IgM
Controls	W0105080801	Bacteriology controls - inf. imm.
Calibrators	W0105080901	Bacteriology standars and calibrators - inf. Imm.
Point of care	W0105090101	Chlamydia AG - RT & POC
Rapid test	W0105090101	Chlamydia AG - RT & POC

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