

Alessandra Basilisco
Elisabetta Stella



Supporting the
Maintenance of the
European
Medical
Device
Nomenclature



Ministero della Salute

**From the Italian CND
classification to the EMDN:**

Principles and Features



Ministero della Salute



Co-funded by
the European Union



REGIONE AUTONOMA
FRIULI VENEZIA GIULIA

Regulatory Framework

The same for IVDR



1

WHEREAS 44 MDR

One key aspect in fulfilling the objectives of this Regulation is the creation of a European database on medical devices (Eudamed)

2

WHEREAS 45 MDR

To facilitate the functioning of Eudamed, an internationally recognised medical device nomenclature should be available free of charge to manufacturers and other natural or legal persons required by this Regulation to use that nomenclature. Furthermore, that nomenclature should be available, where reasonably practicable, free of charge also to other stakeholders.

3

ARTICLE 26 MDR

Medical devices nomenclature

To facilitate the functioning of the European database on medical devices ('Eudamed') as referred to in Article 33, the Commission shall ensure that an internationally recognised medical devices nomenclature is available free of charge to manufacturers and other natural or legal persons required by this Regulation to use that nomenclature. The Commission shall also endeavour to ensure that that nomenclature is available to other stakeholders free of charge, where reasonably practicable.



Co-funded by
the European Union



https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2018_2_nomenclature_en.pdf



REGIONE AUTONOMA
FRIULI VENEZIA GIULIA

The choice of CND

MDCG meeting
14 February 2019 - Brussels, Belgium



EUROPEAN COMMISSION

European Commission > DocsRoom > Document detail

Medical Devices Nomenclature

Document date: 03/03/2019 - Created by GROW.DDG1.D.4 - Publication date: 04/03/2019

Download links:

[Medical Devices Nomenclature](#)  (12 KB)

Medical Devices Nomenclature

According to Article 26 of Regulation (EU) 2017/745 on medical devices and Article 23 of Regulation (EU) 2017/746 on in-vitro diagnostic medical devices, the Commission is required to make available a common nomenclature to support the functioning of the future EUDAMED.

The relevant Commission services, in order to exert its faculty with the maximum possible level of information and having due regard to the role held by the Medical Device Coordination Group (MDCG) under the new Regulations on medical devices, have initiated, in cooperation with the MDCG, a process which included:

1. A task-force of Member States, operating under the UDI Work Group, to coordinate Commission services in the information gathering process of possible options;
2. Endorsement by the MDCG of a document (MDCG 2018-2), providing a description of the requirements and criteria for the new nomenclature arising from the new Regulations on medical devices;
3. Evaluation by the relevant Commission services, in cooperation with the task-force, of possible options;
4. Production by the task-force of a report for consideration and discussion by the MDCG;

This process has come to completion and relevant discussions took place at the MDCG meetings of 30 November 2018 and 14-15 February 2019.

In accordance with Articles 23 IVDR and 26 MDR, having due regard to the views provided by the MDCG, the CND nomenclature, to be mapped to the GMDN nomenclature, will be made available in the future Eudamed.

The correspondence between the nomenclatures will be visible to operators and incorporated in the future database. This will allow all operators registering their device to find CND nomenclature equivalent to a GMDN code. To the purpose of providing better regulatory oversight over the EU nomenclature system, a sub-group of the Medical Device Coordination Group (MDCG) will be soon established.

Ways will also be explored to support the work that the World Health Organisation (WHO) is carrying out in the field.

Any additional informational on the details related to the governance and operational functioning of the system will be provided in the course of the next few months.



Ministero della Salute



<https://ec.europa.eu/docsroom/documents/34264>



Co-funded by
the European Union



REGIONE AUTONOMA
FRIULI VENEZIA GIULIA

CND as European Medical Device Nomenclature

Medical Devices

DG Health and Food Safety
Directorate Health systems, medical products and innovation
Unit Medical Devices

January 2020

The European Medical Device Nomenclature (EMDN)

The European Medical Device Nomenclature (EMDN) will be the nomenclature of use by manufacturers when registering their medical devices in the EUDAMED database.

Founded on pre-established criteria and requirements¹ and based on orientations provided by the Medical Device Coordination Group (MDCG), the European Commission decided in favour of the use of the '*Classificazione Nazionale Dispositivi medici (CND)*'² as the basis for the EMDN.

Currently, an extraordinary revision of the CND is ongoing so that to release the first version of the EMDN, which will be integrated in EUDAMED for use by operators. The EMDN will be fully available and accessible to any operators and will be copyright free.

https://health.ec.europa.eu/document/download/95d6ae6c-6a1e-4b76-ac8d-46475f8c5f1a_en?filename=md_emdn_eudamed_nomenclature_en.pdf



Ministero della Salute



Co-funded by
the European Union



REGIONE AUTONOMA
FRIULI VENEZIA GIULIA

The Italian CND

Medical Devices

DG Health and Food Safety
Directorate Health systems, medical products and innovation
Unit Medical Devices

January 2020

The CND Nomenclature

‘Classificazione Nazionale Dispositivi medici’

Table of Contents

1. Background and General Principles.....	2
2. The CND structure	4
Anatomic Categories – by anatomical area of use:	6
Functional Categories – by intended use or clinical method:	6
Special Categories – by other criteria:	6
Groups: the second hierarchical level.....	7
Type: the third hierarchical level (expands into several levels of detail (1°, 2°, 3°, 4° and 5°))	7
3. External links	8



Classificazione nazionale
dei dispositivi medici

Classificazione Nazionale Dispositivi medici (CND)



https://health.ec.europa.eu/document/download/69373ce1-3248-4431-be50-b2d430e61951_en?filename=md_cnd_general_principles_en.pdf



Ministero della Salute



Co-funded by
the European Union



REGIONE AUTONOMA
FRIULI VENEZIA GIULIA

The construction of the CND

Medical Devices

DG Health and Food Safety
Directorate Health systems, medical products and innovation
Unit Medical Devices

January 2020

Its subsequent updates and maintenance have been based on three fundamental principles:



Participative approach



Qualified validation of proposals



Formal adoption and free public availability

The Participative approach



Participative approach

For the update and maintenance of a qualitative nomenclature, highly differentiated and qualified expertise is required. As the medical device sector is acknowledged for its heterogeneity and complexity, a broad participation of all stakeholders is essential

- Economic operators
- Healthcare professional from National Health System - at all levels of organization;



Ministero della Salute



Co-funded by
the European Union



REGIONE AUTONOMA
FRIULI VENEZIA GIULIA

Qualified validation of proposals



Qualified validation of proposals

Proposals are technically validated based on assessments of actual need. Elements taken into consideration are:

- other existing nomenclature and classification systems available at international level
- consumption and spending information
- assessment by experts from different clinical area



Ministero della Salute



Co-funded by
the European Union



REGIONE AUTONOMA
FRIULI VENEZIA GIULIA

Qualified validation of proposals Healthcare system expenditure monitoring:



2nd hierarchical level

Code	Description CND	Aggregated Data
W01	REAGENTI DIAGNOSTICI	23,91%
P09	PROTESI ORTOPEDICHE E MEZZI PER OSTEOSINTESI E SINTESI TENDINEO-LEGAMENTOSA	29,48%
P07	PROTESI VASCOLARI E CARDIACHE	34,99%
C01	DISPOSITIVI PER SISTEMA ARTERO-VENOSO	40,21%
Z12	STRUMENTAZIONE PER ESPLORAZIONI FUNZIONALI ED INTERVENTI TERAPEUTICI	45,43%
J01	DISPOSITIVI IMPIANTABILI PER FUNZIONALITA' CARDIACA	50,63%
T01	GUANTI (ESCLUSI I DISPOSITIVI DI PROTEZIONE INDIVIDUALE DPI)	56,15%
K02	DISPOSITIVI PER ELETTROCHIRURGIA, MONOUSO	58,12%
H02	SUTURATRICI MECCANICHE	60,01%
C02	DISPOSITIVI PER ARITMOLOGIA	61,90%
M04	MEDICAZIONI SPECIALI	63,73%
...%
Totale:		100,00%

Qualified
validation of
proposals

1st hierarchical level

Code	Description CND	Aggregated Data
W0101010101	REAGENTI PER VIROLOGIA - REAGENTI NAS - ALTRI	5,26%
P0701010101	ENDOPROTESI VASCOLARI - ALTRE	6,80%
Z1204011585	SENSORI MONOUSO PER SISTEMI DI MONITORAGGIO INVASIVO DELLA GLICEMIA	8,23%
J01010302	PACE MAKER IMPIANTABILI BICAMERALI CON SENSORE (DR)	9,55%
W0101060101	STRISCE PER ANALISI DEL GLUCOSIO	10,80%
J01050301	DEFIBRILLATORI IMPIANTABILI TRICAMERALI CON SENSORE	12,03%
P0703010302	VALVOLE CARDIACHE BIOLOGICHE DA TESSUTO DI ORIGINE ANIMALE CON SUPPORTO PER IMPIANTO PERCUTANEO	13,14%
...%
Totale:		100,00%

Last hierarchical level

Code	Description CND	Aggregated Data
W	DISPOSITIVI MEDICO-DIAGNOSTICI IN VITRO (D. LGS. 332/2000)	26,40%
P	DISPOSITIVI PROTESICI IMPIANTABILI E MEZZI PER OSTEOSINTESI	39,65%
C	DISPOSITIVI PER APPARATO CARDIOCIRCOLATORIO	50,52%
A	DISPOSITIVI PER SOMMINISTRAZIONE, PRELIEVO E RACCOLTA	56,78%
J	DISPOSITIVI IMPIANTABILI ATTIVI	62,87%
Z	APPARECCHIATURE SANITARIE E RELATIVI ACCESSORI, SOFTWARE E MATERIALI SPECIFICI	68,42%
T	DISPOSITIVI DI PROTEZIONE DEL PAZIENTE E AUSILI PER INCONTINENZA (ESCLUSI I DISPOSITIVI DI PROTEZIONE INDIVIDUALE DPI)	72,70%
H	DISPOSITIVI DA SUTURA	76,39%
K	DISPOSITIVI PER CHIRURGIA MINI-INVASIVA ED ELETTROCHIRURGIA	79,85%
*	SISTEMI O KIT ASSEMBLATI	83,25%
M	DISPOSITIVI PER MEDICAZIONI GENERALI E SPECIALISTICHE	86,33%
Q	DISPOSITIVI PER ODONTOIATRIA, OTALMOLOGIA E OTORINOLARINGOIATRIA	88,43%
F	DISPOSITIVI PER DIALISI	90,31%
L	STRUMENTARIO CHIRURGICO RIUTILIZZABILE	92,18%
U	DISPOSITIVI PER APPARATO UROGENITALE	93,79%
R	DISPOSITIVI PER APPARATO RESPIRATORIO E ANESTESIA	95,23%
G	DISPOSITIVI PER APPARATO GASTRO-INTESTINALE	96,48%
V	DISPOSITIVI VARI	97,49%
B	DISPOSITIVI PER EMOTRASFUSIONE ED EMATOLOGIA	98,43%
D	DISINFETTANTI, ANTISEPTICI, AGENTI STERILIZZANTI E DETERGENTI DI DISPOSITIVI MEDICI	99,23%
N	DISPOSITIVI PER SISTEMA NERVOSO E MIDOLLARE	99,56%
Y	DISPOSITIVI PER PERSONE CON DISABILITA' NON COMPRESI IN ALTRE CATEGORIE	99,89%
S	DISPOSITIVI PER STERILIZZAZIONE (ESCLUSI DM CAT. D - Z)	100,00%
Totale:		100,00%

Formal adoption and free public availability

The CND system, which represents the basis of the whole information system on medical devices is formally approved and thus constitutes an official reference, freely available to all stakeholders.

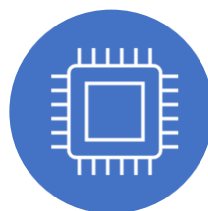


**Formal adoption
and free public
availability**

National Health System
Regions Technical board

Technical health committee
Section F – Medical devices
Universities, resource centers

Technical Team
Ministry of Health TT
and Region Friuli Venezia
Giulia (FVG) MDTT



Economic Operators
Manufacturers,
importers, distributors.



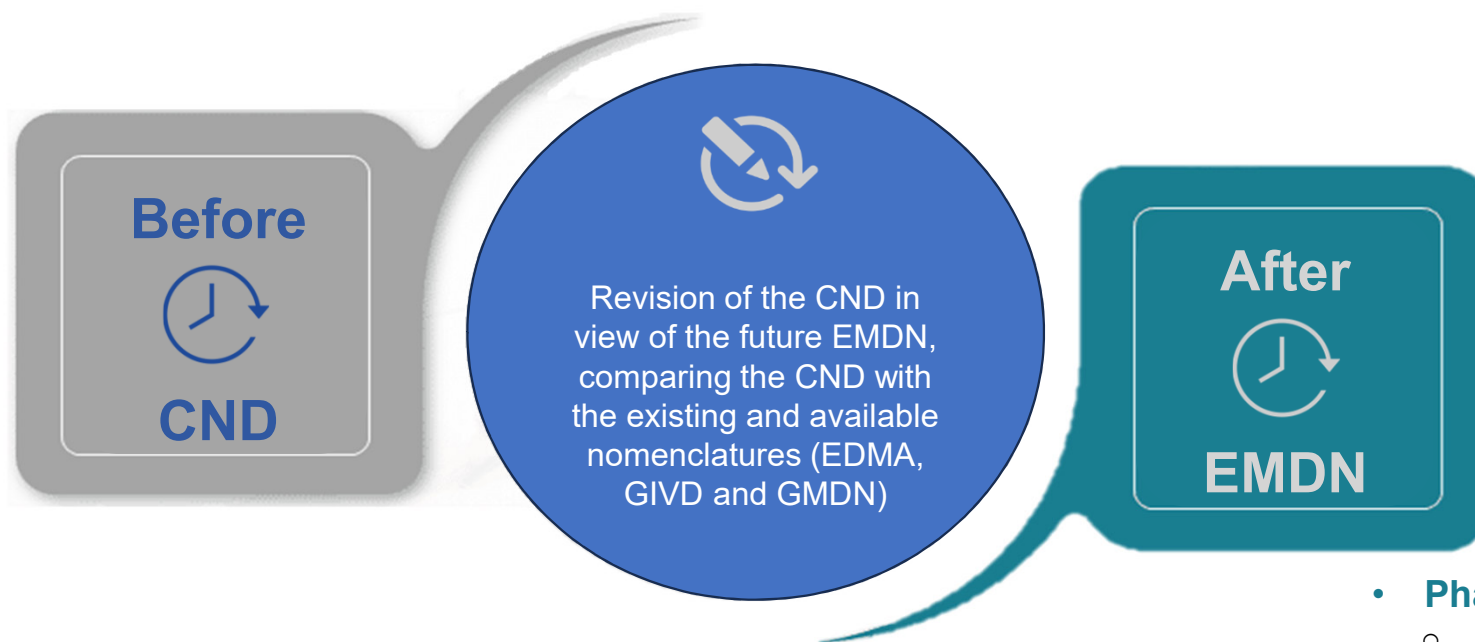

Ministero della Salute

From the Italian CND classification to the EMDN v. 0

The EMDN implementation plan consist in two main phasis:

- **Phase 1 (Extraordinary):**

- Extraordinary revision of CND
- Establishment of the working group and the definition of the procedures necessary for the management of the EMDN in EUDAMED



- **Phase 2 (Ordinary):**

- Updating and maintaining EMDN;

CND revision for EMDN criteria - extraordinary phase



- **Analysis of Italian databank of MD:**

- The **analysis of the 99 general levels of the CND was performed in order to proceed with the extraordinary revision of the CND** . The presence of medical devices not yet identified by a specific codes has been verified.



- **GMDN mapping**

- the correspondence or collocability of the GMDN terms in the terminal classification level of the CND was verified and, if necessary, new terminal «Types» were introduced in the CND;
- In the cases of GMDN terms not corresponding to specific terminal "types" of the CND, the location of these terms at the highest levels of the classification tree has been defined.



- **GIVD mapping**

- **The mapping of the W category with the last version available of GIVD was performed**, in analogy to what has been done in the previous updates of the CND.



- **Results of EU Consultation**

- **A consultation was addressed to member states and stakeholders for collecting comments on CND update**. The suggestions coming from the stakeholders have been considered maintaining the conservative approach of the extraordinary revision



Ministero della Salute



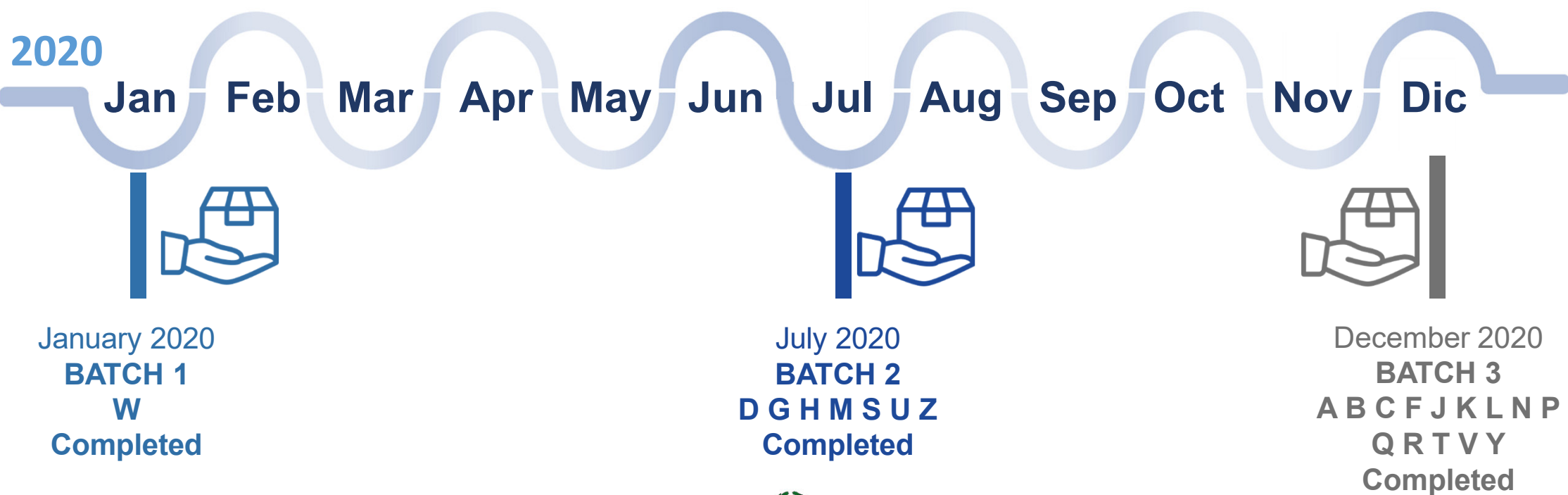
Co-funded by
the European Union



REGIONE AUTONOMA
FRIULI VENEZIA GIULIA

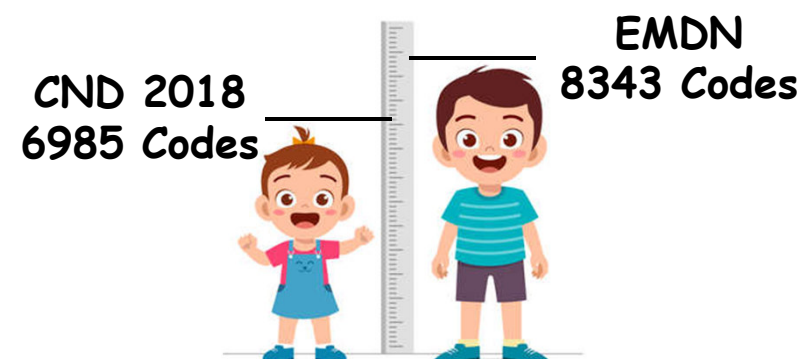
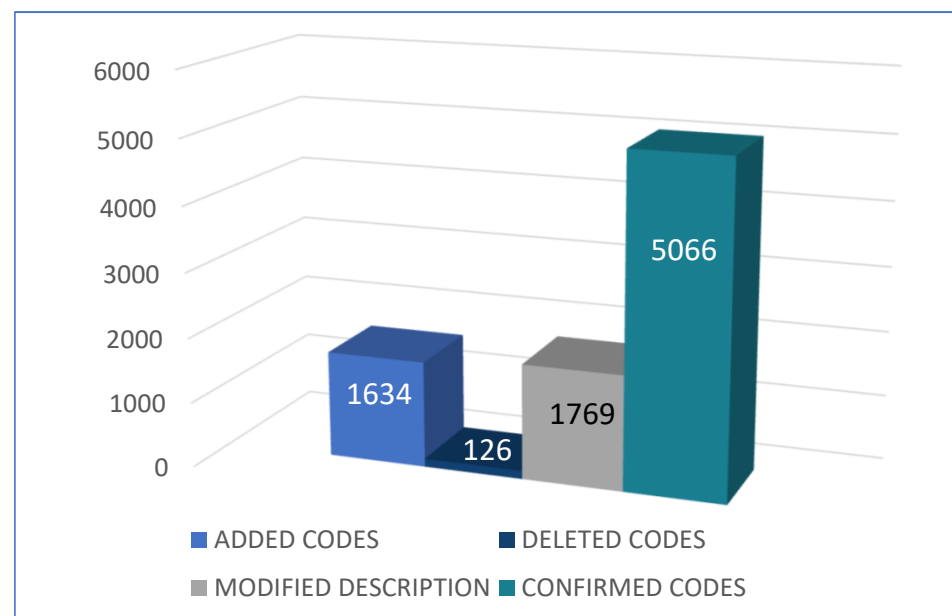
Extraordinary revision of the CND

EMDN Nomenclature TIMELINE



Result of the extraordinary revision

CAT.	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	DISPOSITIVI PER SISTEMA NERVOSO E MIDOLLARE	60		13	11
P	IMPLANTABLE PROSTHETIC AND OSTEOSYNTHESIS DEVICES	166	9	77	421
Q	DENTAL, OPHTHALMOLOGIC AND ENT DEVICES	99		35	119
R	RESPIRATORY AND ANAESTHESIA DEVICES	76	1		112
S	STERILISATION DEVICES (EXCLUDING CAT. D - Z)	4			23
T	PATIENT PROTECTIVE EQUIPMENT AND INCONTINENCE AIDS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE)	10			60
U	DEVICES FOR UROGENITAL SYSTEM	66		26	126
V	DISPOSITIVI VARI	117		43	28
W	IN VITRO DIAGNOSTIC MEDICAL DEVICES	159		169	1894
Y	DEVICES FOR PERSONS WITH DISABILITIES NOT INCLUDED IN OTHER CATEGORIES	50		26	211
Z	MEDICAL EQUIPMENT AND RELATED ACCESSORIES, SOFTWARE AND CONSUMABLES		9	372	932
Total		1634	126	1769	5066



Co-funded by
the European Union

Ministero della Salute

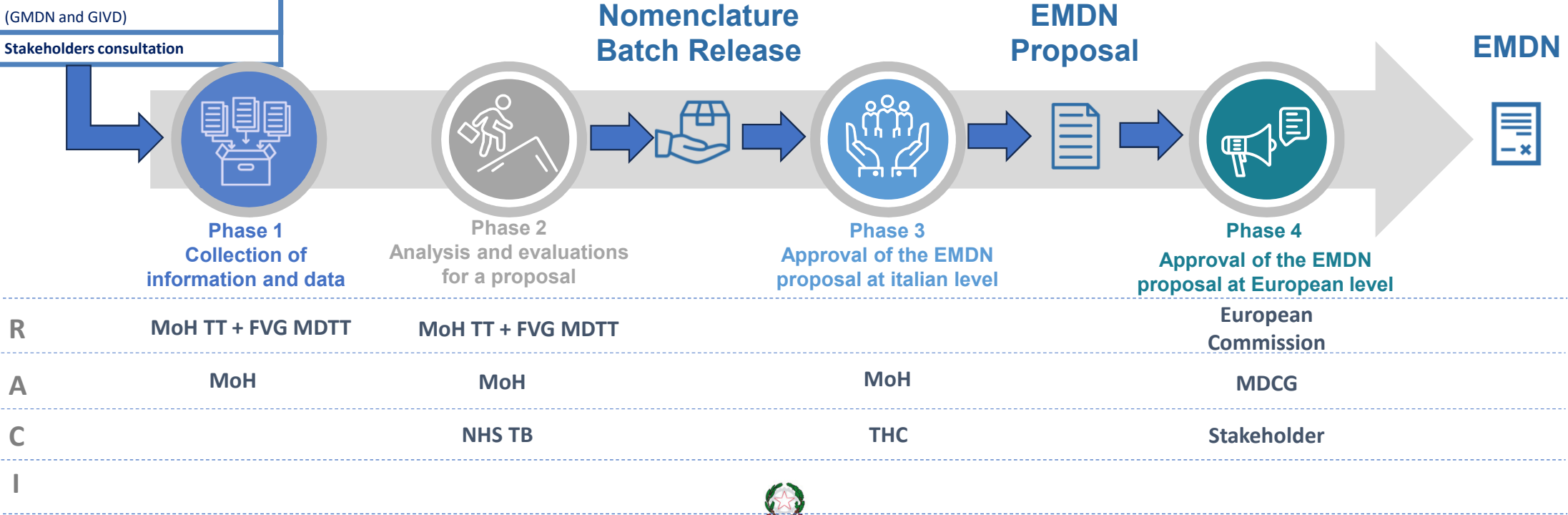


REGIONE AUTONOMA
FRIULI VENEZIA GIULIA

Method for extraordinary revision

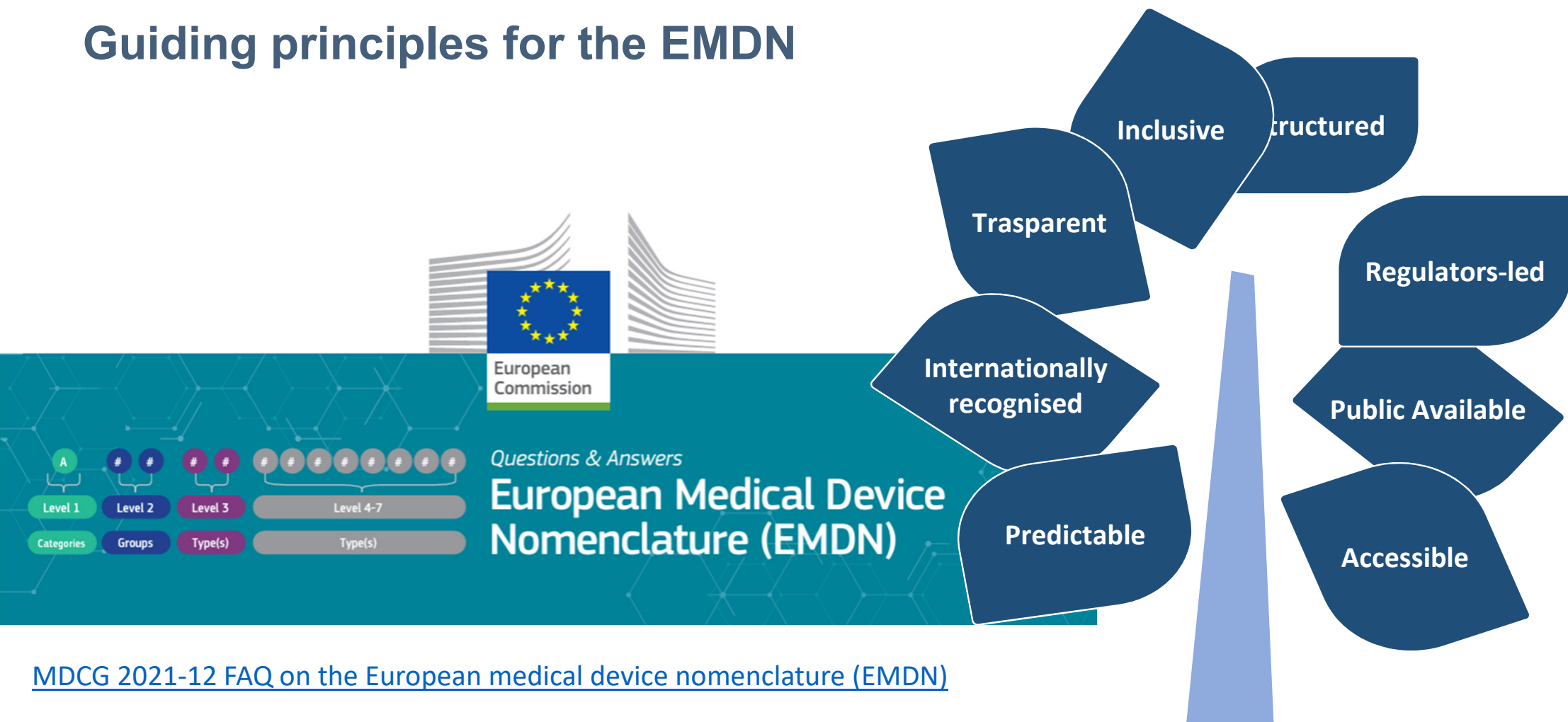
MoH	Ministry of Health
MoH TT	Ministry of Health Technical Team
FVG MDTT	Friuli Venezia Giulia Medical Devices Technical Team
THC	Technical Health Committee
NHS TB	National Health System Technical Board

Italian MD databank analysis (i.e «99 generic» types population)
Legislative framework impact analysis
Market analysis (Market surveillance and vigilance)
Other classifications and nomenclatures assessment (GMDN and GIVD)
Stakeholders consultation





Guiding principles for the EMDN



[MDCG 2021-12 FAQ on the European medical device nomenclature \(EMDN\)](#)

EMDN structure

The CND has an alpha-numeric structure which is developed in a multi-level hierarchical tree and it clusters medical devices in three main levels:



Category: the first hierarchical level

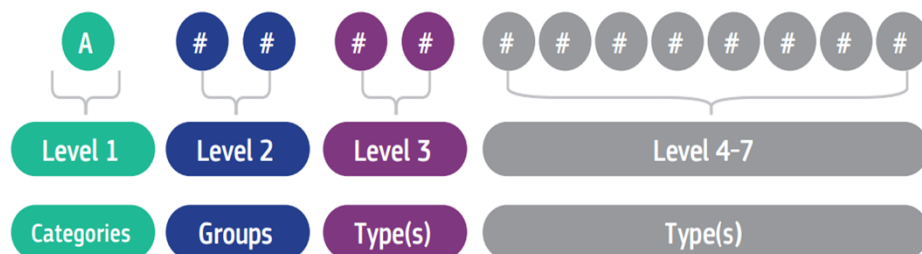
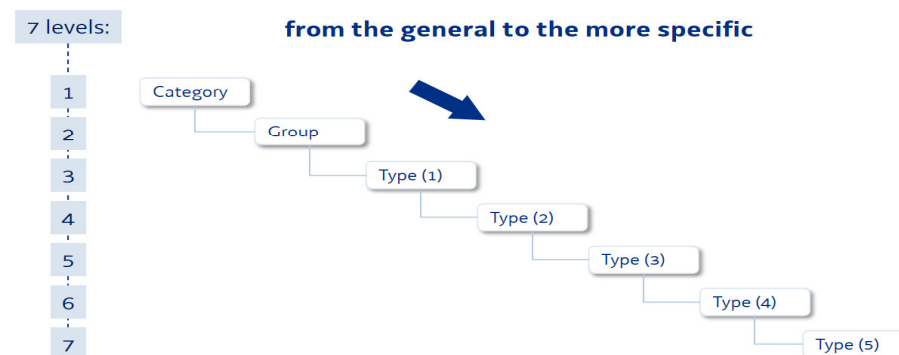


Group: the second hierarchical level



Type: the third hierarchical level which if necessary, expands into several levels of detail (1°, 2°, 3°, 4° e 5°).

The classification structure is a "7 levels hierarchical tree"



An alphanumeric code (max 13 digits)



Ministero della Salute



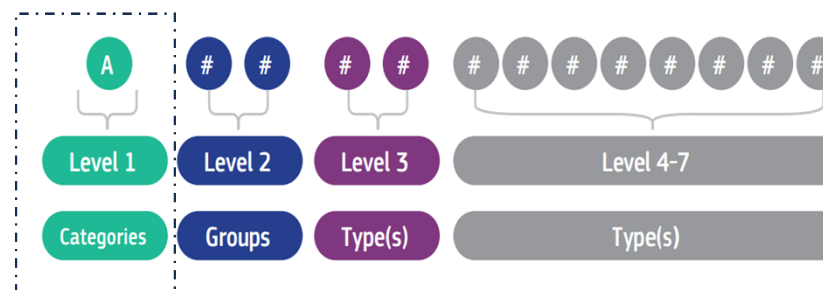
Co-funded by
the European Union



REGIONE AUTONOMA
FRIULI VENEZIA GIULIA

Category: the first hierarchical level

A	DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION
B	HAEMATOLOGY AND HAEMOTRANSFUSION DEVICES
C	CARDIOCIRCULATORY SYSTEM DEVICES
D	DISINFECTANTS, ANTISEPTICS, STERILISING AGENTS AND DETERGENTS FOR MEDICAL DEVICES
F	DIALYSIS DEVICES
G	GASTROINTESTINAL DEVICES
H	SUTURE DEVICES
J	ACTIVE-IMPLANTABLE DEVICES
K	ENDOTHERAPY AND ELECTROSURGICAL DEVICES
L	REUSABLE SURGICAL INSTRUMENTS
M	DEVICES FOR GENERAL AND SPECIALIST DRESSINGS
N	NERVOUS AND MEDULLARY SYSTEMS DEVICES
P	IMPLANTABLE PROSTHETIC AND OSTEOSYNTHESIS DEVICES
Q	DENTAL, OPHTHALMOLOGIC AND ENT DEVICES
R	RESPIRATORY AND ANAESTHESIA DEVICES
S	STERILISATION DEVICES (EXCLUDING CAT. D - Z)
T	PATIENT PROTECTIVE EQUIPMENT AND INCONTINENCE AIDS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE)
U	DEVICES FOR UROGENITAL SYSTEM
V	VARIOUS MEDICAL 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



The first hierarchical level of the EMDN is defined as a **“Category”**

There are 22 Categories, each identified by an alphabet letter

Each Category includes

- devices used for the same specific apparatus, anatomical district or organ or as a replacement of them (**anatomical categories**), or
- devices characterized by similar use, intended use or clinical method (**functional categories**).
- In addition, there are 5 special categories

Considering these criteria and the ramified tree structure with different detail level, the following Categories have been defined:

Anatomic (8), **Functional (9)** and **Special (5)**



Ministero della Salute



Co-funded by
the European Union



REGIONE AUTONOMA
FRIULI VENEZIA GIULIA

Group: the second hierarchical level

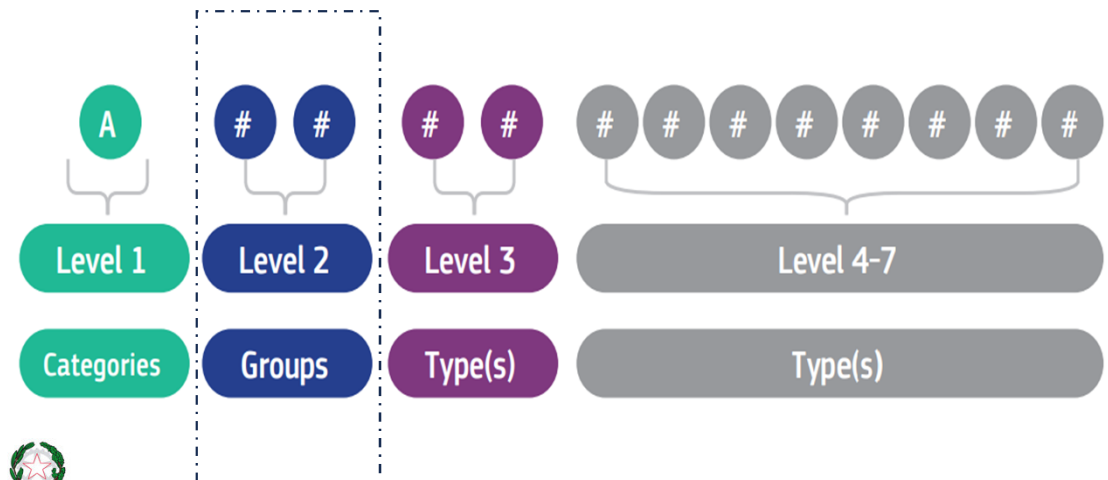


The second hierarchical levels are called “Groups” which represent the various differentiations that distinguish devices contained in the Categories

The “**Group**” is the 2nd hierarchical level. There are **146 anatomical/functional Medical Devices Groups** that represent the various differentiations in which are distinguished the devices contained in the Categories.

They are identified by a **two-digit numbers from 01 to 99 for each Category**. Number “90” identifies the groups containing devices having various characteristics, not related to existing groups.

Number “99” “**Others**” is dedicated to medical devices that are not included in already existing Groups and will be grouped in later updates.



Type: the third hierarchical level

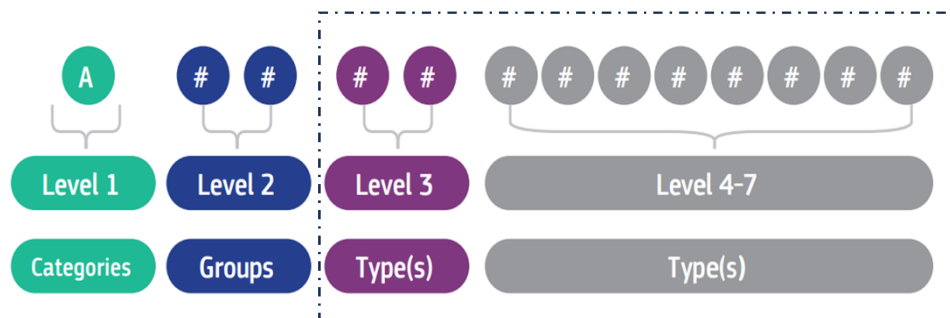
The third hierarchical level (**TYPES**) expands into five further levels of detail (4°, 5°, 6°, 7°).
"TYPES" represent the various differentiations that distinguish the devices contained in the Groups.
The type includes medical devices characterized by a **high affinity of use, intended use** or **similar clinical method**.



✓ Z: Medical equipment and related accessories, software and consumables **1° level**

- > Z11: Bioimaging and radiotherapy instruments
- > Z12: Instruments for functional explorations and therapeutic interventions **2° level**
- > Z13: Non-specific consumables for diagnostic instruments

- ✓ Z1203: Instruments to support and monitor vital signs **3° level**
 - > Z120301: Anaesthesia and pulmonary ventilation support instruments
 - > Z120302: Vital signs monitoring instruments
 - > Z120303: Infusion instruments
 - > Z120304: Cardiac compressors
 - > Z120305: Defibrillators**4° level**



Ministero della Salute

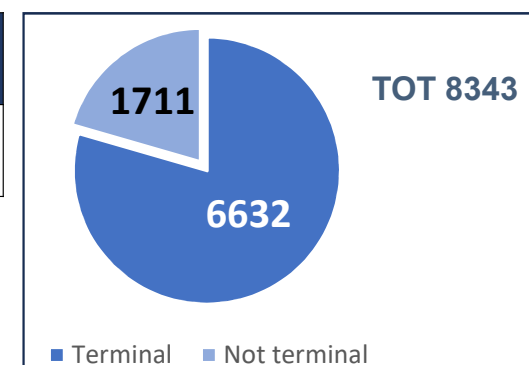
Terminal levels

Number of terminal levels for each categories

Categories	A	B	C	D	F	G	H	J	K	L	M	N	P	Q	R	S	T	U	V	W	Y	Z
Number of terminal levels	259	60	222	43	66	121	182	115	158	557	176	65	469	199	166	25	67	159	145	1875	194	1309

Number of specific codes at the 5th and 6th levels

Terminal Levels	1°	2°	3°	4°	5°	6°	7°
Number of terminal levels	0	23	468	1450	2345	1975	371



Code extensions

8x

Code 8x

- Accessories except the cases where the accessories can be identified by a specific code

All categories except J, W, Z:

- Code 80 accessories

In case of categories J, W, Z:

- Code 80 accessory hardware
- Code 82 accessories software
- Code 85 consumables

90

Code 90 “Various”

- medical devices that cannot be allocated in existing non-terminal types

92

Code 92 “Medical device software”

- MDSW (stand alone)

99

Code 99 “Others”:

- medical devices that are not included in already existing codes and will be categorized in later updates.



Ministero della Salute



Co-funded by
the European Union



REGIONE AUTONOMA
FRIULI VENEZIA GIULIA

EMDN V.0: number of terminal levels 80, 82, 85, 90, 92

1/2

Terminal codes 80, 82, 85, 90, 92

	80	82	85	90	92
CND 2018	324	169	169	73	0
EMDN	455	171	175	71	172

Number of terminal levels 80 per each categories

	A	B	C	D	F	G	H	J	K	L	M	N	P	Q	R	S	T	U	V	W	Y	Z
CND 2018	19	4	14	0	3	3	3	16	7	2	0	2	29	2	10	1	0	7	11	49	0	142
EMDN	27	4	31	0	3	3	7	20	7	12	0	33	45	2	29	1	0	9	15	52	8	147

Number of terminal levels 82 per each categories

	A	B	C	D	F	G	H	J	K	L	M	N	P	Q	R	S	T	U	V	W	Y	Z
CND 2018	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	31	0	135
EMDN	0	0	0	0	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	34	0	133

Number of terminal levels 85 per each categories

	A	B	C	D	F	G	H	J	K	L	M	N	P	Q	R	S	T	U	V	W	Y	Z
CND 2018	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	31	0	135
EMDN	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	34	0	138



Ministero della Salute



Co-funded by
the European Union



REGIONE AUTONOMA
FRIULI VENEZIA GIULIA

EMDN V.0: number of terminal levels 80, 82, 85, 90, 92

2/2

Terminal codes 80, 82, 85, 90, 92

	80	82	85	90	92
CND 2018	324	169	169	73	0
EMDN	455	171	175	71	172

Number of terminal levels 90 per each categories

	A	B	C	D	F	G	H	J	K	L	M	N	P	Q	R	S	T	U	V	W	Y	Z
CND 2018	1	1	3	0	1	0	1	1	1	4	1	0	4	2	2	1	0	3	1	22	0	24
EMDN	1	1	3	0	1	0	1	1	0	5	1	0	3	2	2	1	0	1	1	23	0	24

Number of terminal levels 92 per each categories

	A	B	C	D	F	G	H	J	K	L	M	N	P	Q	R	S	T	U	V	W	Y	Z
CND 2018	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EMDN	0	0	0	0	0	0	0	4	0	0	0	0	0	0	0	0	0	0	1	34	0	133

Code 99 “others”

1090

Total number of codes 99

Number of terminal levels 99 for each single Category

Category	A	B	C	D	F	G	H	J	K	L	M	N	P	Q	R	S	T	U	V	W	Y	Z
Number of codes 99	60	17	50	17	16	32	42	18	16	111	30	19	104	43	38	7	19	41	29	246	46	92

It should be attributed exclusively to devices for which suitable and representative code is not available within the existing EMDN structure.

The code “99” will include innovative devices

The 99 codes is analyzed to develop update proposals



Ministero della Salute



Co-funded by
the European Union



REGIONE AUTONOMA
FRIULI VENEZIA GIULIA

The role of the EMDN



Technical support in clinical and management activities for healthcare institutions and professionals



Technical support in the implementation of the regulatory framework of MDR and IVDR for economic operators

- registration of devices in Eudamed
- sampling for the conformity assessment by the NB
- post-market surveillance
- market surveillance
- vigilance



Support in managing shortages, useful to identify valid alternatives of devices on the market



Ministero della Salute



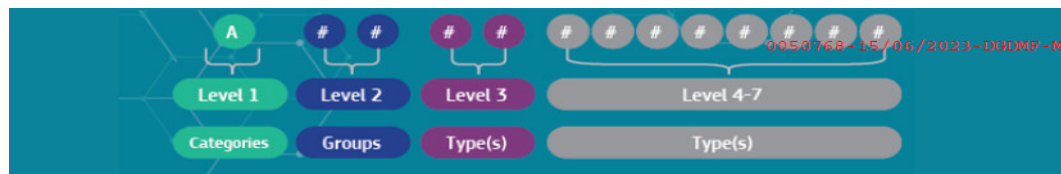
Co-funded by
the European Union

https://health.ec.europa.eu/document/download/2b2bb9d2-0f21-4cad-8bb0-08919329c49a_en?filename=wp2022_en.pdf



REGIONE AUTONOMA
FRIULI VENEZIA GIULIA

SMEMDN Project: Supporting maintenance of the EMDN



© European Union, 2023
reuse is authorised, provided the source is acknowledged. The reuse policy of the European Commission is implemented by a Decision of 12 December 2011.

BACKGROUND

The project stems from the need to support the maintenance of the European Medical Device Nomenclature (EMDN), established by article 26 of Regulations (EU) 2017/745 and article 23 of Regulations (EU) 2017/746 and made available free of charge by the European Commission in order to facilitate the operation of the European medical device database, "EUDAMED".

OBJECTIVES AND EXPECTED RESULTS

The project aims to achieve a high quality, clear and accurate EMDN that is regularly maintained through the following support activities to the European Commission:

- periodic update of the EMDN
- communicate information and provide clarifications on the nomenclature to Member States' authorities and stakeholders
- make available tools to support the use of the EMDN
- collaborate with World Health Organization

SMEMDN PROJECT

SUPPORTING THE MAINTENANCE OF THE EUROPEAN MEDICAL DEVICE NOMENCLATURE



Supporting the Maintenance of the European Medical Device Nomenclature



Method for ordinary revision

MoH	Ministry of Health
MoH TT	Ministry of Health Technical Team
FVG MDTT	Friuli Venezia Giulia Medical Devices Technical Team
THC	Technical Health Committee
NHS TB	National Health System Technical Board

B) Procedure for the annual revision of the EMDN4

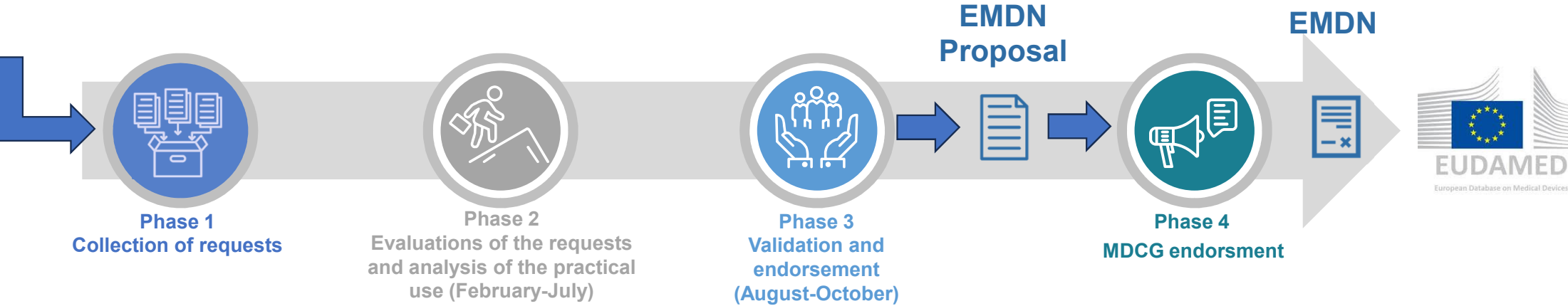
Phase I – Collection of requests (January).....4

Phase II – Evaluation of the requests and analysis of the practical use (February – July)4

Phase III – Validation and endorsement (August – October)4

Phase IV – MDCG endorsement and publication (November – December).....4

Submission platform for EMDN proposals



R	EMDN TT (MoH TT + FVG MDTT)	EMDN TT (MoH TT + FVG MDTT)		European Commission
A	MoH	MoH	MoH	MDCG
C		NHS TB	THC	Stakeholder
I				



CREDITS

Alessandra Basilisco

Unit 3 – Directorate general medical devices and pharmaceuticals services

Elisabetta Stella

Unit 3 – Directorate general medical devices and pharmaceuticals services

Thanks for your attention!