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# ***Informative support to the EMDN***

*web access, FAQ and Helpdesk platform*

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*November 12, 2024  
Brussels*



# Goals

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1. **ACCESS TO EMDN.** Provide users with information on **how to access** the updated version of the EMDN, **general information**, and **supporting documents**.
  
2. **FAQ ON EMDN.** Inform them about the **periodic updates** of the FAQs and the methods by which they are developed.
  
3. **HELP DESK PLATFORM**
  - I. Provide the basic concepts for accessing and using the **Helpdesk platform**
  - II. Detail **good and bad practices** in platform usage: indicating which requests are eligible for support
  - III. Explain **how user requests are handled**, and support materials are developed.





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## Where to consult the nomenclature

The entirety of the EMDN is accessible to all stakeholders, free of charge. It can hence be utilised by a non-exhaustive list of stakeholders such as manufacturers, patients, research organisations, practitioners, hospitals, pharmacies etc.

The EMDN can be accessed and downloaded here:

<https://webgate.ec.europa.eu/dyna2/emdn/>



The screenshot shows the top part of the EMDN website. At the top, there is a navigation bar with the European Union flag and the text 'An official website of the European Union' and 'How do you know?'. Below this is the European Commission logo and a search bar with 'log in' and 'English' options. The main content area has a blue header with the text 'Home > Live, work, travel in the EU > Public Health' and a large blue box with the title 'European Medical Device Nomenclature (EMDN)'. Below the title, there are sections for 'Submission platform for EMDN proposals', 'What is the purpose of this webpage?', 'Who can participate?', 'Timeline', 'How to submit a proposal?', and 'Mode of operation'. The 'Mode of operation' section contains a numbered list of four steps: 1. Enter proposer identification fields (name, surname, contact details, organization/company, type of proposer); 2. Select the specific level of the EMDN structure (i.e. select the most granular level, as relevant); 3. Select the type of update\*; 4. Provide details to support the proposal.



## Where to consult the nomenclature

The EMDN can be downloaded as an Excel file from the link present above the box containing the EMDN available for consultation:

- errors. Each modification is aimed at improving usability;
- 3. **Delete an existing level (existing code and existing term):** in the event that 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.

Download EMDN (download full list)

Select the EMDN term description

Search

- ⊕ A - DEVICES FOR ADMINISTRATION,  
WITHDRAWAL AND COLLECTION
- ⊕ B - HAEMATOLOGY AND  
HAEMOTRANSFUSION DEVICES
- ⊕ C - CARDIOCIRCULATORY SYSTEM DEVICES
- ⊕ D - DISINFECTANTS, ANTISEPTICS,

<https://webgate.ec.europa.eu/dyna2/emdn/>

## Where to consult the nomenclature

	A	B	C	E	F	I	J	K	L
1	ID	CATEGORY	EMDN CODE	LEVEL	BOTTOM LEVEL YES/NO	CATEGORY DESCRIPTION ITALIAN_29092021	EMDN IT DESCRIPTION_29092021	CATEGORY DESCRIPTION_29092021	EMDN EN DESCRIPTION_29092021
2	1	A	A	1	NO	DISPOSITIVI PER SOMMINISTRAZIONE, PRELIEVO E RACCOLTA	DISPOSITIVI PER SOMMINISTRAZIONE, PRELIEVO E RACCOLTA	DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION	DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION
3	2	A	A01	2	NO	DISPOSITIVI PER SOMMINISTRAZIONE, PRELIEVO E RACCOLTA	AGHI	DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION	NEEDLES
4	3	A	A0101	3	NO	DISPOSITIVI PER SOMMINISTRAZIONE, PRELIEVO E RACCOLTA	AGHI PER INFUSIONE E PRELIEVO	DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION	NEEDLES FOR INFUSION AND SAMPLING

The spreadsheet contains a column for the **category**, a column for the **EMDN code**, a column indicating **if it's a bottom level or not**, a column with the **description of the category**, and one for the **description** of that **specific level** (EMDN code) in Italian and in English, along with the related dates of the last update.

<https://webgate.ec.europa.eu/dyna2/emdn/>

## Where to consult the nomenclature

The EMDN is also available for consultation from the Devices/SPPs section in the EUDAMED Database at the following link:

[EUDAMED database - EUDAMED](#)

And on this page, by changing the language in the top section, the EMDN will be available in the selected language, if available.

The screenshot shows the EUDAMED website interface. At the top, there is a search bar with a language selection dropdown set to 'EN English'. Below the search bar is a blue navigation bar with the following menu items: Home, Actors, Devices/SPPs, Certificates, and News. The 'Devices/SPPs' menu is expanded, showing a sub-menu with the following options: Home, Devices/SPPs, European Medical Device Nomenclature (EMDN), and EUDAMED d. A red arrow points to the 'EN English' dropdown, and another red arrow points to the 'European Medical Device Nomenclature (EMDN)' option in the sub-menu. Below the navigation bar, there is a paragraph of text: 'The creation of a European database on medical devices (EUDAMED) is one of the key aspects of the new rules on medical devices (Regulation (EU) 2017/745) and in vitro diagnostic medical devices (Regulation (EU) 2017/746). EUDAMED will provide a living picture of the lifecycle of medical devices that are made available in the European Union (EU). It will integrate different electronic systems to collate and process information about medical devices and related companies (e.g. manufacturers). In doing so, EUDAMED aims to enhance overall transparency, including through better access to information for the public and healthcare professionals, and to enhance coordination between the different Member States in the EU. EUDAMED will be composed of six modules related to: actor registration, unique device identification (UDI) and device registration, notified bodies and certificates, clinical investigations and performance studies, vigilance and market surveillance.'

# Where to consult the nomenclature

European Commission

EN English Search Search

## EUDAMED - European Database on Medical Devices

Home > European Medical Device Nomenclature (EMDN)

### European Medical Device Nomenclature (EMDN)

Search by code or description

Enter at least 3 characters.

[Browse nomenclature](#)

[EMDN information](#)

[EUDAMED database - EUDAMED](#)

### Browse nomenclature

Search by code or description

Enter at least 3 characters.

- > 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

Reset Close





## How to navigate the nomenclature

On the homepage there is a diagram illustrating the hierarchical structure of the EMDN. The diagram is organized into levels, each representing a different category of medical devices.

The diagram helps users employ a **top-down** approach for effective consultation of the nomenclature to identify the EMDN levels for specific medical devices.

Alternatively, the user can use the **keyword** search tool.

### Select the EMDN term description

Search





## Consulting the nomenclature: alternative approaches

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An example on how to use the two approaches:

### IDENTIKIT

*Description:* Disinfectant for medical devices- Ethanol based.

*Intended use:* "Disinfection of invasive and non-invasive medical devices and in particular of surfaces of medical equipment, thermometers and other instruments used in the oral cavity for diagnosis and therapy»



# Consulting the nomenclature: alternative approaches

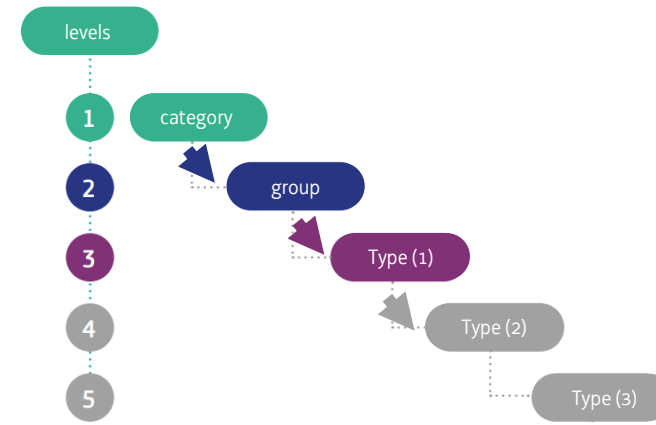
## Top-Down example

### IDENTIKIT

*Description:* Disinfectant for medical devices- Ethanol based.

*Intended use:* “Disinfection of invasive and non-invasive medical devices and in particular of surfaces of medical equipment, thermometers and other instruments used in the oral cavity for diagnosis and therapy»

*In the top – down method we start from the top (the first level) choosing a fitting category proceeding to the following sub-levels (groups, types and so on)*



# Consulting the nomenclature: alternative approaches

## Top-Down example

### IDENTIKIT

*Description:* Disinfectant for medical devices- Ethanol based.

*Intended use:* "Disinfection of invasive and non-invasive medical devices and in particular of surfaces of medical equipment, thermometers and other instruments used in the oral cavity for diagnosis and therapy»

- ∨ D: Disinfectants, antiseptics, sterilising agents and detergents for medical devices
  - > D01: Aldehydes for the disinfection of medical devices
  - > D02: Biguanides for the disinfection of medical devices
  - > D03: Chlorine derivatives for the disinfection of medical devices
  - > D05: Oxygen producers for disinfection of medical devices
  - > D06: Phenols for disinfection of medical devices
  - ∨ D07: Alcohols for the disinfection of medical devices
    - D0701: Ethanol for the disinfection of medical devices
    - D0702: Isopropyl alcohol for the disinfection of medical devices
    - D0799: Alcohols for the disinfection of medical devices - other
  - > D08: Detergents for medical devices
  - > D09: Ammonium salts and associates for the disinfection of medical devices
  - D99: Disinfectants, antiseptics, sterilising agents and detergents for medical devices - other

## Consulting the nomenclature: alternative approaches

### Keyword example

#### IDENTIKIT

Description: Disinfectant for medical devices - Ethanol based.

Intended use: Disinfection of invasive and non-invasive medical devices and in particular of surfaces of medical equipment, thermometers and other instruments used in the oral cavity for diagnosis and therapy»

Browse nomenclature ×

Search by code or description

Search

Enter at least 3 characters.

i

- D0701: Ethanol for the disinfection of medical devices
- W0102090207: Ethanol (alcohol)

We are presented with 2 suggestions. In this case it's a simple decision: the specification «for medical devices» excludes the other option located in the W category dedicated to IVDs

## Consulting the nomenclature: alternative approaches

### TOP-DOWN

- Comprehensive view and navigation of the classification
- visual identification of the list of available detail levels
- familiarization with the structure



- Consultation not immediate

### KEYWORD

- No identification of the context (group, type)
- potential difficulties with synonymous
- no familiarization with the structure



- Immediate view of the levels

...to be continued in *How to choose the EMDN code: examples of real usage of the nomenclature*



## Supporting documents on EMDN

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The European Commission provides a series of supporting documents in order to help users understand and correctly use the EMDN.

These documents include:

FAQ

Provides answers to frequently asked questions about the EMDN, assisting in clarifying uncertainties and addressing practical issues.

Technical  
documents

Provides detailed technical information on the requirements and specifications of the EMDN.



# Supporting documents on EMDN

## FAQ

The document with frequently asked questions from users and their answers is available at the link:

[https://health.ec.europa.eu/document/download/d90b3f63-1d62-43e6-bf5f-fb32ea7c47a2\\_en](https://health.ec.europa.eu/document/download/d90b3f63-1d62-43e6-bf5f-fb32ea7c47a2_en)

And on the homepage of the EMDN:

- ⊕ D010102 - GLUTARALDEHYDE AND POLYPHENOLS FOR THE DISINFECTION OF MEDICAL DEVICES
- ⊕ D010103 - ORTHOPHTHALALDEHYDE FOR THE DISINFECTION OF MEDICAL DEVICES
- ⊕ D010199 - ASSOCIATED GLUTARALDEHYDE FOR THE DISINFECTION OF MEDICAL DEVICES - OTHER
- ⊕ D0199 - ALDEHYDES FOR THE DISINFECTION OF MEDICAL DEVICES - OTHER
- ⊕ D02 - BIGUANIDES FOR THE DISINFECTION OF MEDICAL DEVICES

Frequently Asked Questions

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

Per Article 26 of Regulation (EU) 2017/745 on medical devices (MDR) and Article 23 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), the European Medical Device Nomenclature (EMDN) aims at supporting the functioning of the European database on medical devices (EUDAMED). Among its various uses, it will be utilized by manufacturers for the registration of medical devices in EUDAMED, where it will be associated to

## Medical Devices

Medical Device Coordination Group Document

MDCG 2021-12

## MDCG 2021-12

## FAQ on the European Medical Device Nomenclature (EMDN)

May 2021



# Supporting documents on EMDN

**FAQ** Inside, you can find answers to questions such as:

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

2. How was the EMDN created?

3. What are the key principles of EMDN? ?

4. How do I gain access to the EMDN?

5. How is the EMDN structured?

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

# Supporting documents on EMDN



**FAQ** In the near future, they will also be updated to include the following topics:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



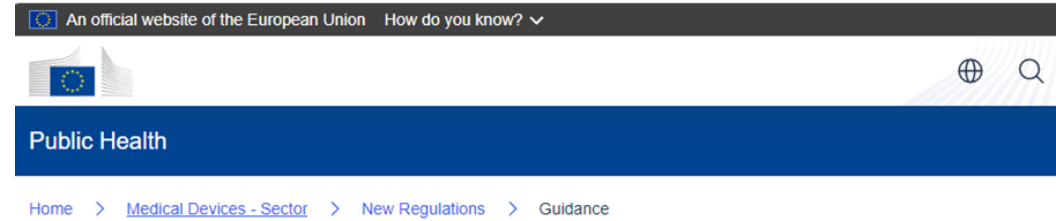
# Consulting the nomenclature

## Technical documents

The European Commission provides supporting documents for the use of the EMDN, available on the page for MDCG approved documents.






[Guidance - MDCG endorsed documents and other guidance - European Commission \(europa.eu\)](#)

*Informative support to the EMDN  
November 12, 2024, Brussels*



## Guidance - MDCG endorsed documents and other guidance

### European Medical Device Nomenclature (EMDN)

Reference	Title	Publication
<a href="#">MDCG 2024-2</a> 	Procedures for the <b>updates</b> of the EMDN	February 2024
<a href="#">MDCG 2021-12</a> 	<b>FAQ</b> on the European Medical Device Nomenclature ( <b>EMDN</b> )	June 2021
<a href="#">The EMDN – The nomenclature of use in EUDAMED</a> 		January 2020
<a href="#">The CND nomenclature – Background and general principles</a> 		January 2020
<a href="#">MDCG 2018-2</a> 	Future EU medical device nomenclature - Description of requirements	March 2018



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2. **FAQ ON EMDN.** Inform them about the **periodic updates** of the FAQs and the methods by which they are developed.

### 3. HELP DESK PLATFORM

- I. Provide the basic concepts for accessing and using the **Helpdesk platform**
- II. Detail **good and bad practices** in platform usage: indicating which requests are eligible for support
- III. Explain **how user requests are handled**, and support materials are developed.



## Help Desk for EMDN stakeholders

The Helpdesk activity is managed by the EMDN technical team (EMDN-TT) and aims to provide support by responding to **requests for information** and **clarifications on the nomenclature**. The dedicated digital platform will be activated and launched in the Q4 of 2024.

The link to access the digital platform and the user guide will be published on:

[Guidance - MDCCG endorsed documents and other guidance - European Commission \(europa.eu\)](#)

[European Medical Device Nomenclature \(EMDN\) \(europa.eu\)](#)

Through the platform:

- user can **submit questions about the structure of the EMDN** (Categories, Groups and Types)
- manufacturer is provided with all relevant information that will help him to choose the appropriate EMDN code for the DM/IVDR



**The Helpdesk service is solely intended to assist in selecting the code to assign to your device; the final decision and responsibility for assigning the correct code remain with the user.**



## Help Desk for EMDN stakeholders

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Users include:

- competent authorities,
- notified bodies,
- manufacturers,
- authorised representatives,
- importers,
- distributors,
- persons referred to in Art. 22(1,3)
- trade associations,
- professional bodies,
- healthcare professionals,
- hospitals,
- laboratories,
- patients,
- consumers and the World Health Organization (WHO).

In accordance with [https://health.ec.europa.eu/document/download/de470384-e8be-45e7-a334-226757f8816d\\_en?filename=mdcg\\_2024-2\\_en.pdf](https://health.ec.europa.eu/document/download/de470384-e8be-45e7-a334-226757f8816d_en?filename=mdcg_2024-2_en.pdf)



# Help Desk for EMDN stakeholders: user interface




# Login and registration



Sign in to your account

Email

Password  

[Forgot Password?](#)

Login →

← First – time registration

To access the service it is necessary to log in with an email and password through the login screen or, for first-time users, proceed with registration.





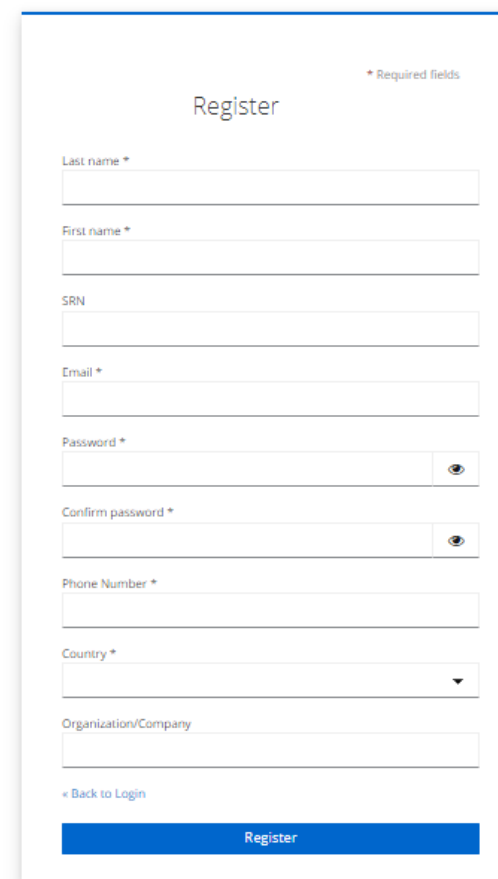
## Login and registration

When the user clicks on «Register», this form will open.

The data to be filled out are:

- Last name\*
- First name\*
- SRN (if available)
- Email\*
- Password\*
- Phone number\*
- Country\*
- Organization/Company

The fields marked with «\*» are mandatory.



The screenshot shows a registration form titled "Register" with a "Required fields" indicator. The form contains the following fields: Last name \* (text input), First name \* (text input), SRN (text input), Email \* (text input), Password \* (password input with visibility toggle), Confirm password \* (password input with visibility toggle), Phone Number \* (text input), Country \* (dropdown menu), and Organization/Company (text input). At the bottom, there is a "Back to Login" link and a blue "Register" button.


# Homepage: new request

## Welcome to the EMDN CustomerPortal

This service is part of the SMEMDN (Supporting the Maintenance of the European Medical Device Nomenclature) project co-funded by the European Commission under the EU4Health 2022 programme. The platform provides users with information on the nomenclature structure (category/groups/types) as well as any useful information to enable the manufacturers to choose the appropriate EMDN code(s) for their MD/IVD. Before submitting a request, please **consult the FAQ section** and the **KNOWLEDGE BASE section**.

If you want to propose an **EMDN update**, you can find [HERE](#) the instructions and the submission platform.

SERVICE CATALOG



**NEW REQUEST**  
Please click here to send a new support request →

## Support requests

Refresh Find by ID...

From date  To date

Status  Subject

ID	DATE	SUBJECT	STATUS
55C	6/20/2024 11:09 am	Request for information of... Translator Translator Perchè ne...	Solved



## Homepage: new request

After the user clicks on «**New Request**», a form will open, with the following fields:

- EMDN code
- Request Type (with a drop-down menu)\*
- Detailed request\*
- Role of the user\*
- Attachments

The fields marked with «\*» are mandatory.

By clicking on «**Submit Request**», the user can send a request to the EMDN technical team (EMDN-TT).

The screenshot shows the 'NEW REQUEST' form interface. At the top, there are navigation tabs: 'SUPPORT REQUESTS', 'KNOWLEDGE BASE', and 'FAQ'. Below the tabs, there is a breadcrumb trail: '← SERVICE CATALOG > NEW REQUEST'. The form itself is titled 'NEW REQUEST' and contains the following fields:

- EMDN Code**: A text input field.
- Request Type \***: A dropdown menu.
- Detailed request \***: A rich text editor with a toolbar containing various formatting options (bold, italic, underline, strikethrough, text color, background color, bulleted list, numbered list, link, unlink, insert image, insert video, insert table, insert code block).
- Role \***: A dropdown menu.
- Attachments**: A dashed box containing the text 'Drop files here' and a 'Browse' button with a folder icon.

At the bottom of the form, there are two buttons: 'SUBMIT REQUEST' and 'CANCEL'.

# Homepage: how to see my submitted requests?

Co-funded by the European Union | Ministero della Salute | REGIONE AUTONOMA FRIULI VENEZIA GIULIA

1 | User (Name Surname)

SUPPORT REQUESTS | KNOWLEDGE BASE | FAQ

### Welcome to the EMDN CustomerPortal

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HOME SERVICE CATALOG

**NEW REQUEST**  
Please click here to send a new support request →

### Support requests

Refresh Find by ID...

From date To date

Status Subject

ID	DATE	SUBJECT	STATUS
55C	6/20/2024 11:09 am	Request for information of... Translator Translator Perché ne...	Solved

Page 1 of 1 Page size 20 Displaying 1 - 1 of 1

View of requests history



# Homepage: Knowledge base and FAQ


SUPPORT REQUESTS **KNOWLEDGE BASE** FAQ

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If you want to propose an **EMDN update**, you can find [HERE](#) the instructions and the submission platform.

🏠 SERVICE CATALOG

 **NEW REQUEST**  
Please click here to send a new support request →

## Support requests

⌵ ✕ Refresh Find by ID...

From date  To date

Status  Subject

⏪ < Page 1 of 1 > ⏩ Page size 20 Displaying 1 - 1 of 1





## Homepage: Knowledge base and FAQ

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In these sections, users will find:

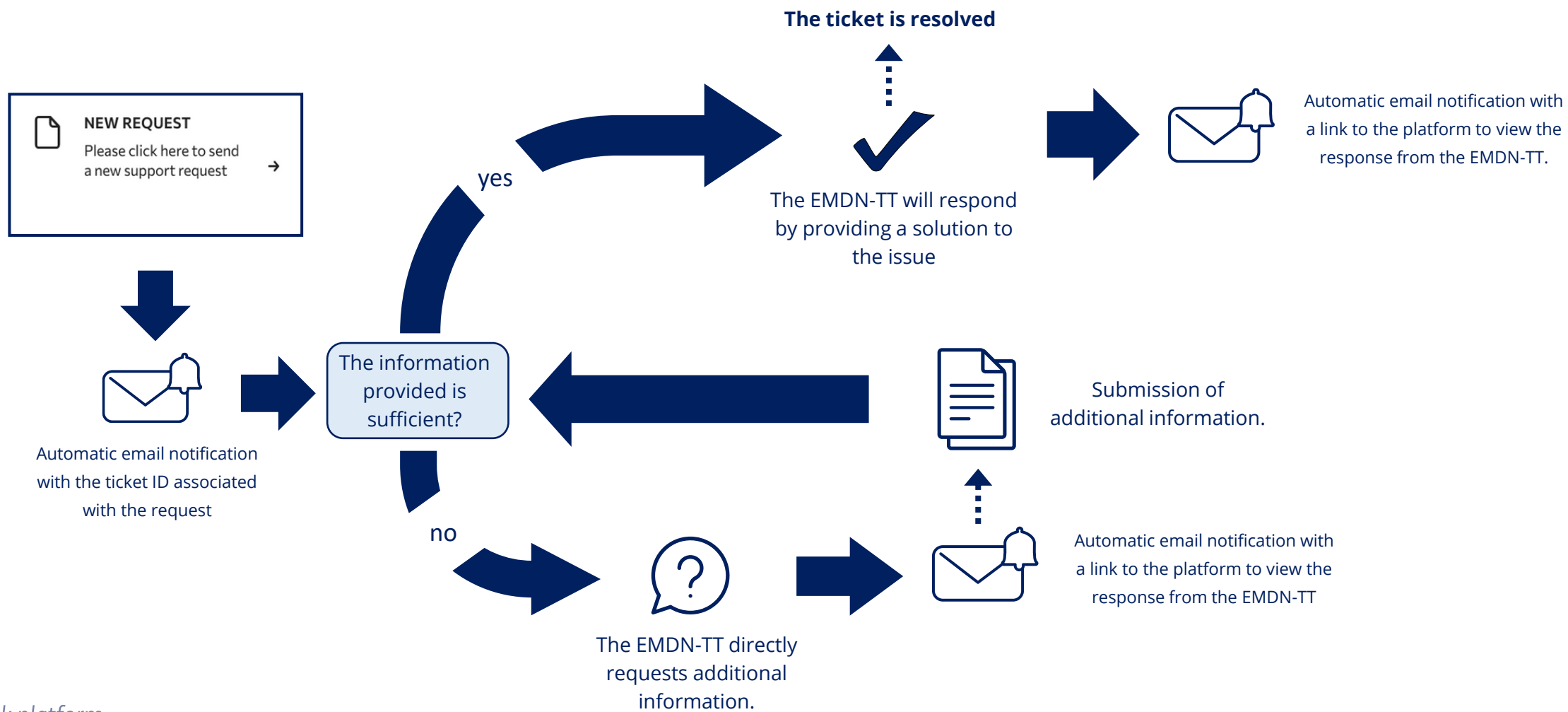
- Useful information about EMDN structure
- Some tips for the EMDN code association with their MDs o IVDs (example: EMDN code for IVDs always start with W)
- A document containing frequently asked questions (FAQ) from users.



By consulting these sections, you can find a lot of useful information. A solution for the request you are about to send might already be available!



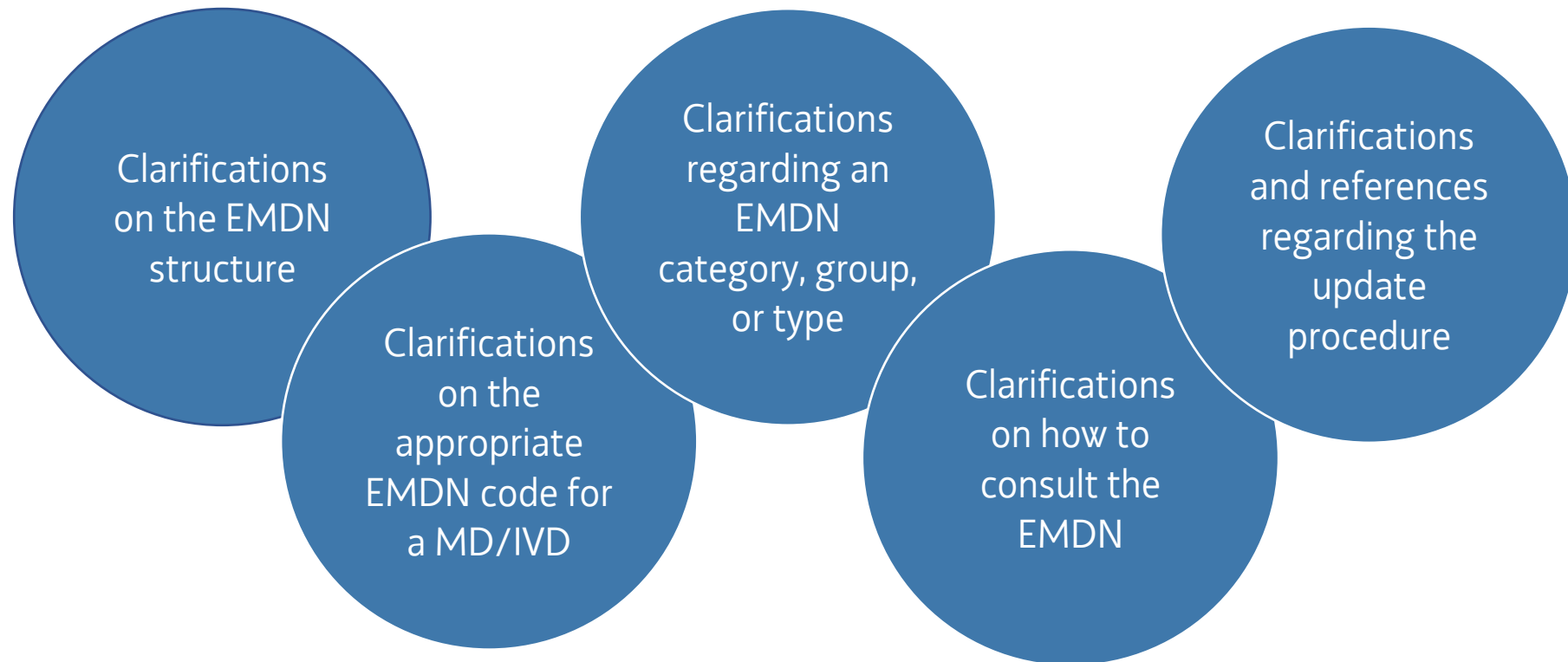
# What happens after submitting a request?





## Good practices: What types of requests can be addressed?

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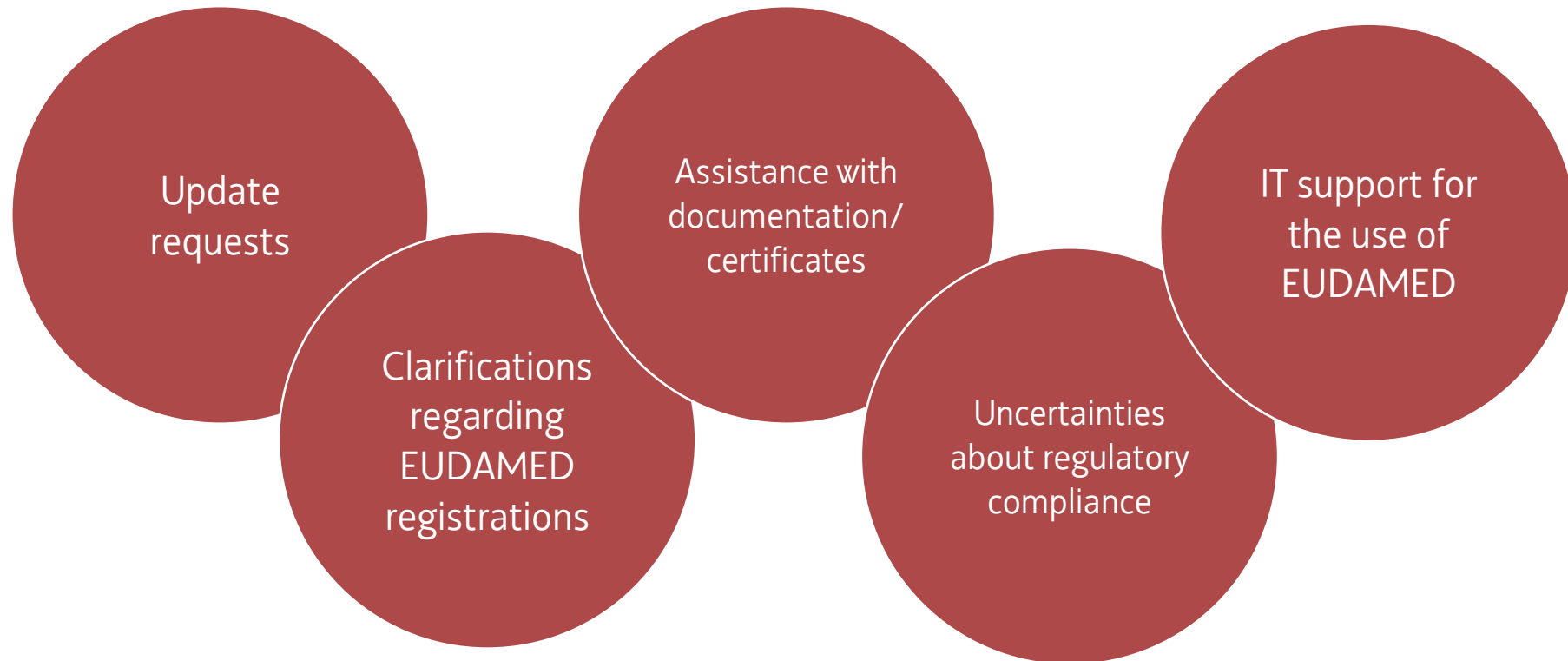




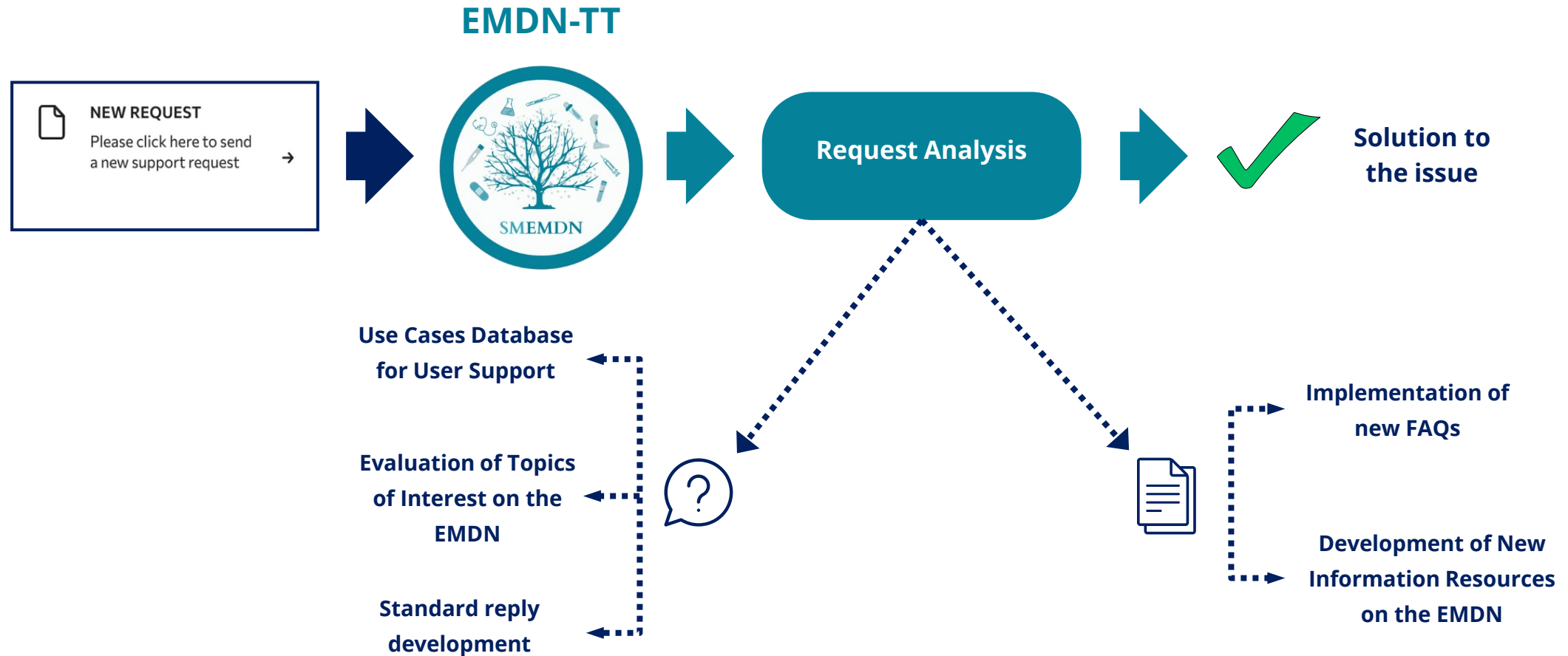


## Bad practices: what types of requests cannot be addressed?

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# What happens after a request is submitted?





## Take – home messages

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- Don't forget to consult the existing information sources before choosing the EMDN codes for your device. These sources will also be available and summarized in the Knowledge Base section on the Helpdesk platform
- The Helpdesk is a support service for understanding the nomenclature and is intended to assist in selecting the code to assign to your device; the final decision and responsibility for assigning the correct code remain with the user
- Indirectly, the Helpdesk enables us to improve the information sources



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# *Thank you for your attention*

*For more information, you can contact us at: [EMDN-TT@regione.fvg.it](mailto:EMDN-TT@regione.fvg.it)*