



The UDI module of EUDAMED incl. 10 tips to meet the MDR requirements + EMDN overview

An important part of the MDR is the implementation of the Unique Device Identification (UDI). The mandatory regulation for the identification and registration of medical devices contains certain requirements for the different product classes and types. Special features apply here for implantable, reusable, or configurable products, e.g., software. Within the MDR, the UDI is an essential instrument in connection with the manufacture and distribution of medical devices: It is not only indispensable for the registration of products in EUDAMED, but also serves the traceability of individual batches, goods verification in quality management, and as an identifier for logistics, to track the whereabouts in the warehouse.

The UDI system is used to uniquely identify medical devices within the entire value chain. Manufacturers are therefore required to display the standardized UDI on the product and packaging label. (Read more: MDR (EU) 2017 / 745, Article

27 and Annex VI, Part C) In addition, the implementation of the UDI MDR is also part of various processes in the quality management of distributors and importers.

There are several challenges that medi-

cal device manufacturers face to comply with the MDR requirements on UDI. The new label design and comprehensive data entry into EUDAMED are just two of them. The same is true for in-vitro diagnostic manufacturers, who face much of the same UDI requirements.

Get started: How to use EUDAMED's UDI module

Before you can use the UDI module, you have to register as an Actor first. This applies in general to the use of EUDAMED. For this, you need an EU-Login (ECAS) account. After your registration, you will be assigned the Single Registration Number (SRN), which you have to enter in the UDI module. To be able to enter data in the UDI module, you must ensure that you have created the accounts required for this purpose.

You always need two accounts, regardless of whether you are responsible for the entries in EUDAMED as an individual or are working on them in a team. With the general account, the so-called Local Actor Administrator (LAA), you have to confirm all changes that have been made via a User Account. Then you need the User Account just mentioned. Ensure you are not logged in to the default role as a Viewer but as a Proposer or a Confirmer. As a Proposer, you create new data sets, in the Confirmer role you confirm the data. Only as a Confirmer, you do have the authorization to finally submit a product registration.

Which data belongs in the UDI module?*

More than 100 different data can be entered into the UDI module. Some are mandatory, others are optional, or depend on your specific product.

Basic UDI-DI

As part of a Basic UDI-DI registration, information is required from the following categories:

- information about the Actor/Economic Operator
- is it a legacy device?
- general information
- information about the currently valid certificate
- information about the identification, e.g., Issuing Entity and EMDN Code (European Medical Device Nomenclature)
- certain characteristics of the product
- market and sales information

There are special features for the registration of systems and treatment units (system or procedure packs). They have to be registered separately, otherwise, EUDAMED recognizes duplications. First, information such as the name or model designation of the product is recorded. Then it is queried whether it is an „active device“, e.g., whether it has a power supply or whether human or animal cells are used and whether it is implants, a measuring device, or a reusable product. In addition, there is the following information:

- GMN: Global Model Number = GS1 Company Prefix.
- Risk Class
- UDI reference source/issuing entity

* We always refer to the GS1 standards.

- type of product: Device, Procedure Pack, System

Depending on the product, however, there is a lot more information that can be stored for the Basic UDI-DI. (see MDR Annex XI Part A)

UDI-DI

For the UDI-DI, the same information requirements apply. But there are some additions.

- EMDN Code
- Number of pieces in which the medical device is usually delivered
- how often it can be reused
- reference - or catalogue number
- status: on the market, no longer on the market or not intended for EU market

Optional additional information, such as the website or online instructions for use, as well as information on available languages. (See MDR Annex XI Part B)

Additionaly

- information on critical warnings (to be updated accordingly)
- additional UDIs, e.g., Direct Marking or Unit of Use
- market information
- storage information
- substances contained
- information of different distribution names

Which data and attributes you specify depends on the one hand on the respective product and on the other hand on which optional information you would like to provide. EUDAMED serves as a basis to expand your product master data and to collect comprehensive detailed information about your products in one central place.

In our experience, it takes about 45 minutes to enter a Basic UDI-DI and a corresponding UDI-DI. To shorten the process for the respective products, you should have all the information together and close data gaps in advance.

Different deadlines for UDI carrier and UDI module

Under certain conditions (see MDR Article 120, paragraph 3), medical devices can still be handled according to MDD and until 2024 (respectively 2025, see paragraph 4). This exemption applies to the validity of the corresponding certificates, but not to all MDR obligations. Market surveillance, vigilance, and the registration of economic operators and products are excluded. Thus, all economic operators cannot avoid the UDI module. As long as the corresponding modules are not yet available or mandatory, the actors must nevertheless collect the data and keep it available for upload as soon as EUDAMED makes it mandatory.

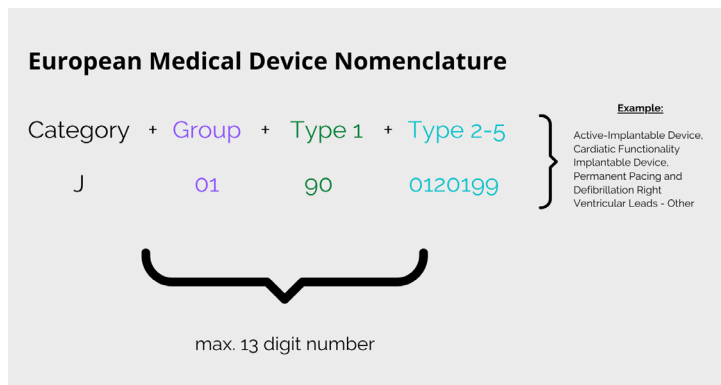
For the application of the UDI carrier to the medical devices, different deadlines apply per class. If the products are reusable and the UDI must be applied directly to the product, the respective transition period will be extended by another two years.

Class	Deadline
I	26.05.2025
II a	26.05.2023
II b	26.05.2023
III and Implants	26.05.2021

A brief introduction to the new EMDN

The European Medical Device Nomenclature, EMDN for short, was first introduced with the MDR. It enables a clear and systematic classification, labeling, and demarcation of product types. The market should thus become more transparent, and the database system (EUDAMED) is also supported in its handling. In EUDAMED, the EMDN of each product is linked to the corresponding UDI and serves to classify the various product types clearly and concisely. In addition to its function in EUDAMED, the EMDN is mainly used for device documentation (MDR and IVDR) and plays a crucial role in communication with Notified Bodies, post-market surveillance, data analysis of a product, and vigilance. The newly created nomenclature thus assumes a key function in connection with the implementation of the MDR and is therefore also mandatory to be entered in EUDAMED. At the same time, it is the key for patients to obtain comprehensive information about all devices of a functional type available on the market.

The EMDN is divided into three main levels: categories, groups, and types. A group can contain up to five types. The smallest possible classification type is always used, i.e., that of the smallest possible classification level available in the EMDN. The alphanumeric code is created by assigning the corresponding digits for the category, group, and types. It starts with the letter of the corresponding category, followed by two digits for the group and a sequence of digits for the type. The most specific classification level must always be selected for the type. This results in an EMDN code of a maximum of 13 characters. The exact number of characters depends on the granularity of the types for the respective group. In contrast to the GMDN codes, the EMDN codes are freely accessible and free of charge from the outset.



And afterward, everything directly in?

If the manufacturer has entered all information, such as legislation, Notified Body, certificate, Basic UDI-DI, UDI-DI, EMDN, packaging information, etc. in the UDI module, the product is finally registered, and all information is also publicly accessible. However, there are exceptions. Products of the high-risk classes, for which a type of examination or a certificate of technical documentation, or conformity assessment is available, the Notified Body must first confirm the product data. After a corresponding notification of the Notified Body in the system, the Notified Body deposits the respective product certificate and thus confirms the registration. Attention: For the products mentioned above, the manufacturer must apply for the Basic UDI-DI before the assessment can be applied for at the Notified Body.

10 tips for target-oriented handling of the UDI module

1. Where is your data located? Compile all the data you need to enter in the UDI module. Do you have an external service provider for your data management? Or do you want to enter or upload them directly in EUDAMED? Find out in advance which option works for you and fits your requirements.

2. Close data gaps. Surely there is information that you do not have directly at hand – obtain it.

3. Understand EMDN – not only essential for the UDI module. Especially important: always check here for changes, the EMDN is alive and currently still in a state of flux. Updates are not always announced.

4. Where do you get your Basic UDI-DI and UDI-DI? Who is your source of supply? Find out about the different standards. Note: Be aware of your class and the respective time requirements for Basic UDI-DI.

5. Research any special requirements documents for your class and product type mentioned in the MDR and the corresponding so that you can gather all data accordingly.

6. Evaluate the amount of work that will be required to transfer the data into EUDAMED. Do you have more than 20 different UDI-DI? From this volume on, it makes sense to find out about external service providers for data management.

7. Do you have questions about product registration? The EUDAMED Help Desk has already compiled some FAQs and can also be contacted – please be aware of possible waiting times for feedback from the support.

About mytracekey Med-Tech

There are different ways to enter the data into the UDI module. Manually directly in EUDAMED, in bulk upload of an XML file into EUDAMED or via the software of a service provider. With mytracekey MedTech, you have several options. The simplest way is the direct upload from the software into EUDAMED (M2M interface). This has several advantages:

- no problem with versioning in EUDAMED and the audit trail – both is covered by mytracekey MedTech
- you do not have to worry about the different roles
- you keep the data in one central place (SPOT)
- Excel upload into mytracekey MedTech of existing data possible, so you save a lot of time
- and much more

We are happy to support you on your way.

About the Author

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About tracekey solutions

Every product in the world has its unique story. We help to tell and trace this story. Therefore, we enable our customers to trace their products seamlessly from manufacture to customer. Furthermore, we help to systematically represent products with complex hierarchies as well as many properties, and to maintain this information to meet regulatory requirements on a global level.



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