# 7 steps towards a successful UDI project

## Understanding MDR-UDI and adapting processes

**Unique Device Identification (UDI) is a system for unique and harmonized identification of medical devices throughout their life cycle. There are currently three regulations in use worldwide: in the USA, in China, and the EU.**

The legal regulation on Unique Device Identification (UDI) under the EU MDR, Directive (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR) obliges manufacturers to label their medical devices uniquely and in a machine-readable manner. In addition, the corresponding product data must be made available in a UDI database. In the EU, this is the EUDAMED. One aim of the legal obligation for UDI labeling is increased patient safety, for example, through easier traceability of individual products. The clear labeling and the publicly accessible data in the EUDAMED lead to more transparency, both for hospitals and doctors, and the patients themselves. Questions about the product can be clarified even faster if, for example, a problem arises during usage.

# The basis: Understanding UDI

Depending on the UDI regulation, different versions of the UDI are mandatory. In the EU, in addition to the usual UDI-DI (Device Identifier), the Basic UDI-DI was also introduced. It has a different function in device identification.
The Basic UDI-DI represents the highest level of the product hierarchy. It identifies either a product family or a product model. It thus forms the level above the individual products, whose different variants are combined in a product family and thus under a Basic UDI-DI. The products each have their identification number, the UDI-DI. This means, that many individual UDI-DIs are combined under one Basic UDI-DI. A UDI-DI though may be linked to only one Basic UDI-DI. A single product can therefore only be assigned to one product family.
The Basic UDI-DI is not only the parent key to a product family or a product model in the EUDAMED database but must also be listed in many other documents. For example, in certificates, EU declarations of conformity, or within the technical documentation. The Basic UDI-DI has a special position, as it only exists in the EU so far and has been introduced with the MDR.
The Basic UDI-DI can be formed according to different standards. According to GS1 standards, it is formed as follows: Its GS1 equivalent is the Global Model Number (GMN). The first part of the Basic UDI-DI/GMN is the so-called GS1 base number. This is followed by the model reference, which is determined by the manufacturer, and then a checkmark pair, which can also be calculated via GS1. The Basic UDI-DI can consist of maximum 25 characters. Unlike the UDI-DI, the Basic UDI-DI is never applied in plain text or as a code on the packaging or on the medical device itself. It only appears in the EUDAMED database and the corresponding documentation. It is also important that only one Basic UDI-DI may be listed in a Technical Documentation document. The assignment of the different products (UDI-DI) must therefore be designed accordingly.

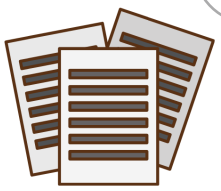
**Basic UDI-DI/GMN**

1446753AJK345h7daz14VL

GS1 Basisnummer

Model Referenz

Check Character



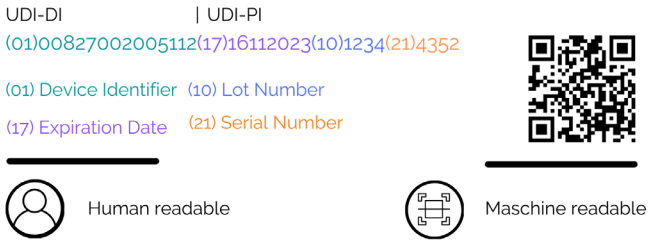
The UDI-DI (UDI Device Identifier) is a unique numeric or alphanumeric code that belongs to an individual product and acts as an access key for EUDAMED. The GS1 equivalent is the GTIN, the Global Trade Item Number.
Medical devices are often produced for more than one market. Accordingly, packaging and package inserts are provided in different languages. A major change to the product, including language, leads to the assignment of a new UDI-DI. Only in the case of multimarket packs only one UDI-DI is assigned.

The UDI-PI (UDI Production Identifier) is also a numeric or alphanumeric code, that identifies the production unit of the product and contains corresponding production data. There are different types of UDI-PI. These include a serial number, lot number, software identification, manufacturing date and/or expiry date. If these data are provided, they are auto-

| | EUDAMED | Product | Packaging | Documentation | Hierarchy level |
|---|---|---|---|---|---|
| Basic UDI-DI | x | | | x | Parent: Indicates product family or product model |
| UDI-DI | x | x | x | | Child: Indicates single product (variant) |
| UDI-PI | | x | x | | Child: Product-related, enables traceability |

matically part of the UDI-PI. So-called application identifiers (AI) are used for the correct assignment of the individual details. These can vary depending on the standard issuing organization but are assigned accordingly by the scanners.
The UDI-DI and UDI-PI together form the UDI barcode, which must be included on the label of the product packaging, and applied to the product itself and all higher packaging units. This information must be present on the label both as human-readable text and as a barcode. Exactly one code shall be applied per pack. Multiple codes may not be assigned to one package or sales unit.

**Unique Device Identifier (Label)**




Also, for legacy devices, there is the EUDAMED DI/EUDAMED ID, as an equivalent to the Basic UDI-DI/UDI-DI. The EUDAMED DI/EUDAMED ID enables the manufacturer/importer to store the information in EUDAMED according to the same structure.[1]

1 https://ec.europa.eu/health/sites/default/files/md_eudamed/docs/legacy_dvc_management_en.pdf

## The UDI project: 7 steps to a correctly labeled product

A systematic approach and an early start with the Unique Device Identification project are essential for the project's success. Contrary to what it may seem at first glance, numerous aspects must be taken into account, otherwise, problems may arise at the latest when the code is scanned by the end customer, for example in the hospital. Unlike medicine, which sometimes maybe cannot be verified when scanned in the pharmacy, the use of a medical device in a hospital may be time-critical, and there are no alternative products available. Therefore, it is important to approach the UDI project with attention to detail.
Some problems can arise, for example, if the quality of the printed codes is inadequate or the labels do not contain the required symbols and information. The materials must also be coordinated. For example, the packaging material must work together with the applied ink, because if the print quality is inferior, the code will not be readable. In the area of quality management, it is therefore not only important to formally fulfill all specifications and produce a high-quality pro-

duct, but also to include the packaging, labeling, hardware, data management, and, if necessary, suppliers. The latter is particularly important, as the label content must exactly match the data in EUDAMED.

**1. Determine the starting position**

As in any process, the starting position must first be determined for the UDI under the MDR. Companies that do not yet have a code standardization organization must choose one. There are four that work according to the ISO standard and issue codes accordingly within the framework of the UDI MDR:GS1, HIBCC, ICCBBA, IFA GmbH. Another important question to be considered, is whether a company already applies barcodes to its product packaging. This is because the use of standards and the technical requirements for applying codes are basic prerequisites for complying with the UDI Regulation. In addition, it must be clarified whether the products in question are already equipped with identification numbers that match the UDI.

**2. Identify company divisions**

Different company divisions are involved in the UDI process. These typically include regulatory affairs, production, quality, and product management. Responsibilities and general organization within the company should be clarified in time and communicated transparently.

**3. Identify processes**

Many processes are affected: Which processes along the supply chain, such as labeling, master data maintenance, or the exchange with your contract manufacturers or distribution partners, need to be reorganized?

**4. Enable synchronization**

The data stored in EUDAMED must exactly match the data on the respective labels. To ensure this, new coordination and synchronization processes with suppliers, manufacturers, etc., may have to be worked out.

5. Determine deadlines Depending on the product classes of the manufactured products, different deadlines must be met. Which ones are binding for your products?

**6. Analyze infrastructure**

Following you should clarify whether the IT infrastructure, i.e., hardware and software, need to be adapted to the new processes. In the case of hardware, for example, you need to clarify: Can the printer print the barcode in such a way that it has the quality it needs to be read by all scanners? Do the paper, ink, background colour, and space on the packaging/products match? Do I need additional software, e.g., for master data and document management or the connection to EUDAMED?

**7. Preparation and planning**

Prepare labeling and identification. You can obtain the Basic UDI-DI and the UDI-DI from one of the above-mentioned code allocation bodies; you have to determine the UDI-PI yourself. Employees, production, suppliers, and all parties involved that you have previously identified must be brought on board at this point at the latest. The new processes and requirements should be communicated transparently and across departments so that even if an important role is lost, everything continues to run smoothly.

## The central database: EUDAMED

The EU's UDI database, EUDAMED, is an important tool. It is intended to provide transparency and quickly access data, enable easy traceability of medical devices, and thus also increase patient safety.
UDIs play a central role in the use of EUDAMED. However, data is alive, and just as the product data itself can change, the UDIs change in response. In the case of the UDI-PI, it is obvious because they contain dynamic data such as manufacturing and expiry dates. However, if the central product information is changed, a new UDI-DI must also be assigned. The central properties include, for example, the form, the mode of operation, or also the area of application of a medical device. The assignment of new UDI-DIs is important because otherwise, problems can arise in tracing a product. Should this be necessary, a medical device is traceable from the patient via the hospital and the specialized trade back to the manufacturer. All important key data can be viewed centrally via the publicly accessible EUDAMED.

## How does your data get into EUDAMED?

Although the product master data can be entered manually into EUDMAED via a mask, this can only be done for a small number of products. For the Basic UDI-DI alone, up to 52 properties are stored in EUDAMED, and for the UDI-DI even 78. Many of the properties are interdependent so that not all properties have to be stored for every product. Here, the EUDAMED mask allows „try-and-error." Therefore, you can also enter incorrect data or parameters and correct them again and again until everything fits. However, if you supply international markets, such as the USA, this is not possible. Only pre-validated data sets can be entered into the FDA's UDI database. Since more and more countries will gradually require UDI, it is most sustainable to prepare the data directly in a form that allows it to be adapted for all regulations. This also facilitates the synchronization of the database and label content for the different regions or requirements.

## Seeking support: UDI and mytracekey MedTech

Master data management, UDI, product hierarchies - buzzwords that don't sound like much at first, but which are all important in connection with the MDR/IVDR and EUDAMED.
The legal requirements are unequivocal. Unique numbers for product identification must be stored as keys to numerous product data in the European database. They guarantee a problem-free and fast possibility for information or traceability of the product, should errors or problems occur.
A large amount of data is associated with the individual UDIs, which must be organized, kept up to date in the correct structure, and stored in the database. Even with a small number of products, this can quickly become confusing and time-consuming. With mytracekey MedTech, all cross-connections and dependencies can be easily mapped. At the same time, the data are pre-validated by being automatically checked against the valid structure. Explanations of the respective data fields also facilitate the handling of the numerous data.

The delay in activating the individual EUDAMED modules shows: It can get bumpy on the way to the UDI MDR. MedTech companies, therefore, need a partner at their side who is already familiar with such processes and can react flexibly to new and changed requirements. That is why we haven't developed mytracekey MedTech as a pure software tool but are also available to support our SME customers in word and deed.

## Outlook: Supply Chain Management and UDI

The UDI project is extensive. Numerous data has to be managed, many processes are affected, some even outsourced, and depending on the international orientation, various UDI regulations have to be fulfilled now or in the future. Initially, of course, all of this serves primarily to meet regulatory requirements. However, there is also a lot of potentials to directly connect further change processes. For example, integrate your supply chain partners and use the codes that already exist to synchronize and simplify logistics processes. Instead of exchanging data and documents along the supply chain in paper form, digitize your processes. Due to the far-reaching upheavals caused by the MDR, the medical technology sector has great potential to renew itself as a whole and to shape its work in a future-oriented way.

We support you on your journey.

## The author

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### tracekey solutions

Every product in the world has its own 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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