REA

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# Implementation of the UDI Directive

## Marking and code verification devices for medical products from a single source

# The UDI is coming soon - act now!

In accordance with the EU Ordinance on Medicinal Products entitled the "Medical Device Regulation" (MDR) 2017/745, producers, handlers, importers and EU representatives will be required to clearly mark their products starting on May 26, 2021. The goal is to increase patient safety by making medical products traceable from the manufacturer to the user.

## Who issues the UDI?

Standards and regulations must be complied with to ensure the traceability of medical products. Product identification is assigned using systems from one of four ISO Issuing Agencies: These are the GS1, HIBCC, ICCBBA and the Informationsstelle für Arzneispezialitäten (IFA GmbH – English: Information Center for Medicinal Products). The GS1 or HIBCC are used most frequently.

The manufacturers are required to maintain a list of all assigned UDIs as part of the technical documentation for each medical product.

In accordance with the Medical Device Regulation (MDR), all medical products along with their master data and the Unique Device Identification (UDI) will be stored bit by bit in the EU-wide EUDAMED database starting in Q4/2024; this is comparable to the American UDI marking of the FDA and the GUDID database.

## Marking deadlines

Medical products are categorized. There are products for single use, reusable products, implants and others such as software and devices as well as sets.

The products are divided into risk classes on which the implementation deadlines in the legislation are based. The category of a product can differ in the EU and the US.

Attention:
The countdown for classes IIa and IIb is running. These must be marked as of May 2023.

Manufacturers of in vitro diagnostic devices (IVDR 2017/746) are also affected. The transition period ends on May 26, 2022.

## Marking requirement from:

**MAY 2021**
**CLASS III – high risk**
e.g. cardiac catheters, artificial joints, heart valves, active implants, breast implants
realized

**MAY 2023**
**CLASS IIa – medium risk**
e.g. contact lenses, dental materials, syringes, nasal sprays containing salt
realized

**CLASS IIb – increased risk**
e.g. blood bags, condoms, dental implants, contact lens cleaners

**Reusable medical devices CLASS III – high risk**

**MAY 2025**
**KLASSE I – low risk**
e.g. bandages, dental floss, surgical textiles

**Reusable medical devices CLASS II – medium risk**
e.g. diagnostic ultrasound-, dialysis equipment

**MAY 2027**
**Reusable medical devices CLASS I – low risk**
e.g. walking aids, wheelchairs, care beds, surgical instruments (scissors, tweezers...)

**UDI**

## Structure of the UDI

Product identification consists of two components:

- Device identifier (DI): A static code with about 20 characters for manufacturer and product identification
- Production identifier (PI): Variable data used for traceability purposes, such as the batch number, expiry date or serial number (e.g. for implants)

## Special role of Basic UDI-DI

The Basic UDI-DI is the number of a product category or variant. Identical products, which, for example, vary due to a different connector standard, are grouped together.

It is used as a key for the UDI database and certification documents. The Basic UDI does not appear on the product or its packaging.

## UDI example

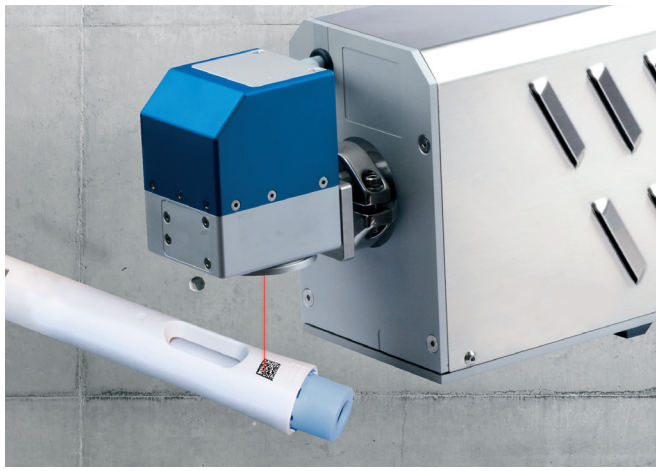

## Where does the UDI marking have to be located?

The UDI must be attached directly to the product, on primary packaging as well as all higher packaging levels in accordance with UDI regulations by means of direct marking with ink, lasers or labels.

The code should be positioned so that it is easily accessible and legible both in the warehouse and when the product is in use.

It is essential that is remains legible throughout its entire life cycle. For instance, this is particularly important for reusable surgical instructions that have to survive numerous cleaning cycles.

Marking packaging material with ink


UDI marking with laser systems

## UDI coding and marking systems

Depending on the product and its properties, there is a very wide variety of possible markings. These can be high-resolution inkjet printers (direct printing on the product or packaging), laser marking or labels.

**REA JET HR systems:** With the High Resolution (HR) product family, marking can be done directly on the product or its packaging at high speed and with a high level of quality. Printing on paper, plastic or metal is possible with selection of the right ink.

**REA JET laser systems:** The laser marking systems mark directly on paper, plastic, ceramic or metallic surfaces such as aluminum without using consumables. We are happy to consult you on suitable laser processes for stainless steel products.

The selection of the laser light source and the laser optics depends on the respective medical product.

**REA LABEL systems:** Labeling solutions are the best choice wherever direct marking with inkjet printers or laser marking systems cannot be used.

REA LABEL offers the right solution for this purpose, ranging from simple label printers to complex labeling systems for all applications.

Creation of UDI labels


Pacemaker with UDI code

## Consultation and training

- REA offers consultation and training on UDI topics
- Contact to capable partners for data management
- Qualification and use of marking technologies
- Qualification and use of verification devices for compliance with code quality specifications

GS1 Germany | Solution Partner REA Elektronik GmbH

# Everything from a single source: REA offers the complete solution

## Printing and marking UDI codes

Only a uniform code shape and reliably legible markings ensure dependable traceability.

Marking is done in plain text and as a machine-readable code. Depending on the space requirements, 1D barcodes or 2D matrix codes can be used on medical products.

Innovative REA systems are the first choice for medical product marking and are capable of handling challenging coding and serialization tasks.

They can be integrated seamlessly into production processes and ensure reliable, high-resolution and razor-sharp markings.

Our customers profit from decisive advantages:

- Flexible generation of the printing contents
- Contact-free marking
- Absolutely no maintenance needed
- Very high speeds
- High first-pass reading rates
- Simple operation via the REA JET TITAN Platform

## Checking UDI code quality

Ensuring high first-pass reading rates in automated UDI processes requires compliance with applicable standards and high code quality.

REA VERIFIER code verification devices are used to ensure that markings and codes are free of errors and that the Medical Device Regulation Standard is upheld. Each marking receives an acceptance test report in this way.

**REA VeriCube:**

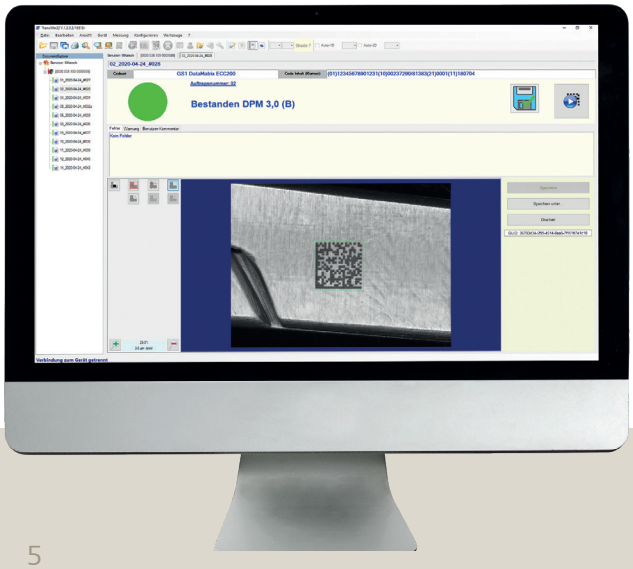
In the standard version, the test device can measure all printed codes with a maximum measurement width of up to 11.5 cm, for example on Tyvek material, labels, plastic, etc.

**REA VeriCube DPM (Direct Part Marking):**

This variant offers extremely diffuse illumination and a very high resolution. This makes it possible to measure directly marked codes from a matrix cell size of 50 µm on very glossy and rounded surfaces, such as on surgical instruments.

If the code is positioned on a uneven device surface, the REA VeriCube stand is indispensable for verification with the REA VeriCube models.

With the optional REA ScanLink software, a more accurate UDI check (in terms of the UDI data structure in the code) can be performed. It is possible to query the UDI-DI in the American UDI database GUDID online. If the item exists, the REA ScanLink result is passed. If not, it has failed.





REA VeriCube DPM:
UDI code verification on surgical instruments

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made in Germany

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