MedTech Europe
from diagnosis to cure

# Explaining Medical Devices Regulation (EU) 2017/745 transition period to health institutions

## MedTech Europe information leaflet on UDI and implant card availability

### Purpose

The aim of this information leaflet is to explain the transition timeline for when the Unique Device Identifier (UDI) information and the implant cards can be expected to be supplied with medical devices under the Medical Devices Regulation (EU) 2017/745 (MDR), to help health institutions navigate in the new legislative environment and comply with any arising legal requirements.

### Background

The MDR has applied since the 26 May 2021. To avoid market disruption and to allow a smooth transition from the Medical Device Directives (AIMDD - 90/385/EEC and MDD – 93/42/EEC) to the MDR, several transitional provisions are in place, including allowing devices CE marked under the Medical Device Directives to continue to be received by the health institutions until **26 May 2025 and used beyond that time**.

**This means that during this transition phase, devices certified under the AIMDD/MDD and under the MDR may coexist on the market**. Both will have equal status under the legislation, and no discrimination in public tenders may take place. See reference 2.

They bear the CE marking to indicate conformance with the respective applicable legislation (either the MDR or the national transpositions of the AIMDD/MDD) and are safe to be used any time; while noting that devices including those for single use only, must be used before any labelled expiry date.

## Q&A on UDI and implant card availability

### Legal obligations

**1. Which legal obligations arise from the new MDR for health institutions?**

A new legal requirement for health institutions arising from the MDR Article 27(9) is that they shall store and keep, – preferably by electronic means – the Unique Device Identifiers (UDIs) of the Class III implantable devices they have supplied, or with which they have been supplied.

**2. Which legal obligations may arise due to the MDR from the national legislation for health institutions?**

The following requirements may arise according to MDR Article 18(2) and 27(9) from the national legislation: for devices other than class III implantable devices, according to MDR Article 27(9) Member States shall encourage, and may require, health institutions to store and keep, preferably by electronic means, the UDI of the devices with which they have been supplied. In other words, the UDI for other classes of devices may also need to be retained by the health institutions.

In addition, according to MDR Article 18(2) health institutions are required via national legislation to supply to any patients who have been implanted with a device with an implant card and the related patient information (or its electronic access). Note: Some implants are exempt from needing an implant card. See reference 1.

## Implant card:

**3. Why are health institutions receiving implant cards?**

This is a requirement for certain implantable devices that are certified according to the MDR. Please also consult Questions 4, 5 and 6. See references 1, 2 and 3.

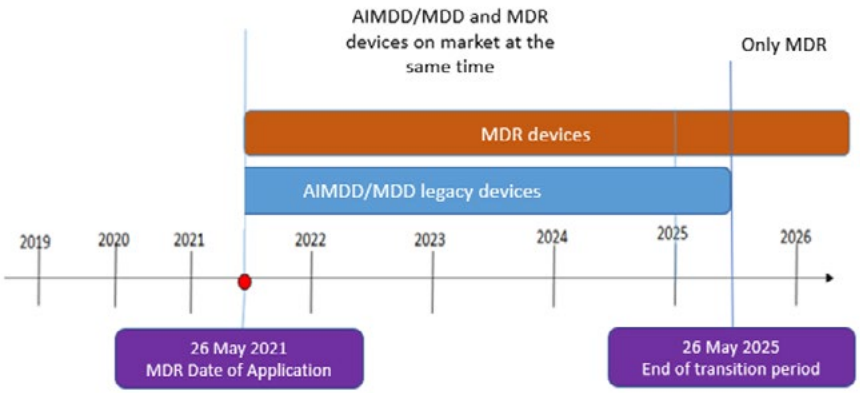
**4. What shall health institutions do with the implant card?**

Health institutions must deliver the implant card to the patient who received an implant. The health institution is expected to fill in the patients' name, date of implantation and contact of the health institution and if applicable, apply stickers to the implant cards with implant information. See references 1 and 3.

**5. Why don't health institutions get an implant card with every implantable medical device?**

a. Devices certified under the AIMDD/MDD are not required to have an implant card. The implant card must be delivered with an implantable device that is certified under the MDR, unless that device falls into one of the exempted categories. Therefore both, AIMDD/MDD (without an implant card) and MDR (with an implant card) certified devices can continue to be received by health institutions until 26 May 2025. Please also consult Question 9. See Q1 in reference 1

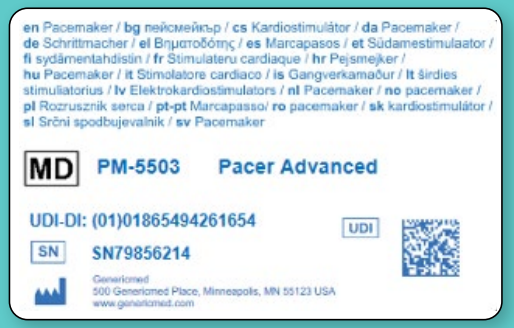
b. Also, in the MDR certain types of implantable devices are exempted from this obligation. See reference 1.




## An example of an implant card for MDR compliant implants:

**Front – Not to scale** (handwritten text on pre-printed content)


**Back – Not to scale** (blank – serial printed content in production)



**6. Do implant cards need to be provided retrospectively for devices already placed on the market under the AIMDD/MDD?**

No. The relevant requirement (MDR Article 18) applies only to devices certified under the MDR. See Q1 in reference 1

## Unique Device Identifiers (UDIs)

**7. What are Unique Device Identifiers (UDIs)?**

As described in MDR (MDR Article 27), Unique Device Identifiers (UDIs) are numeric or alphanumeric codes that shall be used to uniquely and unambiguously identify individual devices and enhance their traceability.

Note that many devices marketed in the EU and around the globe may already be labelled with a UDI-carrier due to other non-EU jurisdictions' UDI requirements. See reference 4.

**8. Why do health institutions not receive the UDI-carrier (scannable barcode (AIDC) and its human readable interpretation (HRI) on every product?**

a. Devices certified under the AIMDD/MDD may have but are not required to have a UDI-carrier on the label. Because a transition period is in place to include UDI on the labels of MDR devices (see table below), you may continue seeing devices being received by your health institutions without the UDI-carrier on the label until 26 May 2025.

b. If not already present, UDI-carriers will be added to labels in phases up to 26 May 2025 depending on the risk class of devices transitioning to MDR. See reference 4. Some exemptions may apply.

| Device as per Regulation (EU) 2017/745 (MDR) | Implantable devices and Class III devices | Class IIa and Class IIb devices | Class I devices |
|---|---|---|---|
| Placing UDI-carriers on the labels of devices<br>MDR Article 123(3)(f), Article 27(4) | 26 May 2021 | 26 May 2023 | 26 May 2025 |
| Direct marking of the reusable devices<br>MDR Article 123(3)(g), Article 27(4) | 26 May 2023 | 26 May 2025 | 26 May 2027 |

## Other considerations:

**9. If the device does not have a UDI-carrier or implant card, does it mean that it is non-compliant or less safe than an MDR certified device?**

No. The device safety and performance is indicated by the affixed CE marking which shows that it satisfies the applicable legal requirements at the time when the individual product is placed on the market. That means the device fulfils its intended purpose and it is safe to use.

### Examples of UDI-carrier formats put on the label (scannable barcode (AIDC) and its human readable interpretation (HRI))

**Automatic identification and data capture (AIDC):**
Technology used to automatically capture data. AIDC technologies include bar codes, smart cards, biometrics and RFID.


**Human Readable Interpretation (HRI)**
HRI is a legible interpretation of the data characters encoded in the UDI-carrier.

**10. Until when can health institutions use devices certified under the AIMDD/MDD: do health institutions need to dispose of AIMDD/MDD devices after 26 May 2025 or can they still use them until their expiry date (if there is any)?**

AIMDD/MDD devices can continue to be received by the health institutions until 26 May 2025 and can still be used after that date and within the expiry date (if any), and if stored according to the label and Instruction for Use.

**11. Should health institutions return (e.g. for rework to MDR compliance), dispose of, or not use AIMDD/MDD-certified devices that do not have a UDI or implant card after the MDR Date of Application (26 May 2021)?**

No. The device should be used as normal; consult the label and the Instructions for Use. If the individual product is certified under the applicable Directive, the requirements of the MDR will not apply. Please also consult Question 9.

**12. Could a pre-MDR certified device have UDI-carrier or an implant card?**

Yes.

- UDI-carrier on the package label, UDI permanently marked on the reusable device: yes, either on a voluntary basis or because the same device may be sold in another geography that already requires a UDI-carrier (e.g. US, China, South Korea).
- Implant card: yes, because the manufacturer may provide a (kind of) implant card on a voluntary basis with a pre-MDR-certified implantable device.

## References:


1. European Commission Factsheet for Manufacturers of Implantable Medical Devices
2. European Commission Factsheet for healthcare professionals and health institutions
3. MDCG 2019-8 v2 Guidance on Implant Card relating to the application of MDR Article 18
4. European Commission's UDI system - frequently asked questions and answers


## About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.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