Unique Device Identification system
Art. 27

Guiding you through the MDR, one article at a time.

To **trace** back your **products**, it is important to be able to **identify** them. To make this possible, the MDR has set up requirements for a **unique device identification system (UDI system)**.
In this fast fact, we will help you understand the requirements of the EU concerning the UDI system.

If you need help or guidance regarding the UDI system, contact us!

Unique Device Identification system [Requirements to the UDI system]

1. The **Unique Device Identification system** ('UDI system') described in Part C of Annex VI shall allow the identification and facilitate the **traceability of devices**, other than custom-made and investigational devices, and shall consist of the following:

(a) production of a UDI that comprises the following:

(i) a **UDI device identifier** ('UDI-DI') specific to a manufacturer and a device, providing access to the information laid down in Part B of Annex VI;

(ii) a **UDI production identifier** ('UDI-PI') that identifies the unit of device production and if applicable the packaged devices, as specified in Part C of Annex VI;

(b) placing of the UDI **on the label** of the device or on its packaging;

(c) **storage** of the UDI by **economic operators, health institutions** and **healthcare professionals**, in accordance with the conditions laid down in paragraphs 8 and 9 of this Article respectively;

(d) establishment of an **electronic system** for Unique Device Identification ('UDI database') in accordance with Article 28.

Unique Device Identification system [Requirements for the Commission]

2 **The Commission** shall, by means of implementing acts, designate one or several entities to operate a system for assignment of UDIs pursuant to this Regulation ('issuing entity'). That entity or those entities shall satisfy all of the following criteria:

(a) the entity is an **organisation** with **legal personality**;

(b) its system for the **assignment** of UDIs is adequate to **identify** a device throughout its distribution and use in accordance with the requirements of this Regulation;

(c) its system for the assignment of UDIs **conforms to the relevant international standards**;

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Unique Device Identification system [Requirements for the Commission]

2 (continued)

(d) the entity gives **access to its** system for the assignment of UDIs to all interested users in accordance with a set of predetermined and transparent terms and conditions;

(e) the entity undertakes to do the following:

(i) **operate** its system for the assignment of UDIs for **at least 10 years** after its designation;

(ii) **make available** to the Commission and to the Member States, upon request, information concerning its system for the assignment of UDIs;

(iii) remain in compliance with the criteria for designation and the terms of designation.

When designating issuing entities, the Commission shall endeavour to ensure that UDI carriers, as defined in Part C of Annex VI, are **universally readable** regardless of the system used by the issuing entity, with a view to minimising financial and administrative burdens for economic operators and health institutions.

For more information, please review:

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Unique Device Identification system [Requirements for the manufacturer]

3. Before placing a device, other than a custom-made device, on the market, the manufacturer shall assign to the device and, if applicable, to all higher levels of packaging, a **UDI** created in compliance with the rules of the issuing entity designated by the Commission in accordance with paragraph 2.
Before a device, other than a custom-made or investigational device, is placed on the market the manufacturer shall ensure that the information referred to in Part B of Annex VI of the device in question are **correctly submitted and transferred to the UDI database** referred to in Article 28.

For more information, please review:

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Unique Device Identification system [General Requirements]

4. UDI carriers shall be placed on **the label** of the device and on **all higher levels of packaging**. Higher levels of packaging shall **not** be understood to include **shipping containers**.
5. The UDI shall be used for reporting **serious-incidents** and **field safety corrective actions** in accordance with Article 87.
6. The **Basic UDI-DI**, as defined in Part C of Annex VI, of the device shall appear on the **EU declaration of conformity** referred to in Article 19.
7. As part of the **technical documentation** referred to in Annex II, the manufacturer shall keep up-to-date a **list of all UDIs** that it has assigned.

For more information, please review:

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Unique Device Identification system [Requirements of Economic Operators]

8. **Economic operators** shall **store** and **keep**, preferably by electronic means, the **UDI** of the devices which they have supplied or with which they have been supplied, if those devices belong to:

— **class III implantable** devices;

— the devices, categories or groups of devices determined by a measure referred to in **point (a) of paragraph 11**.

For more information, please review:

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Unique Device Identification system [Requirements for Health institutions]

9. **Health institutions** shall store and keep preferably by electronic means the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to **class III implantable** devices.

For devices other than class III implantable devices, 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.

Member States shall encourage, and may require, healthcare professionals to store and keep preferably by electronic means, the UDI of the devices with which they have been supplied with.

For more information, please review:

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Unique Device Identification system [Requirements of the Commission]

10. The Commission is empowered to adopt delegated acts in accordance with Article 115:
(a) **amending** the list of information set out in Part B of Annex VI in the light of technical progress; and
(b) **amending** Annex VI in the light of international developments and technical progress in the field of Unique Device Identification.
11. The Commission may, by means of implementing acts, **specify** the detailed arrangements and the procedural aspects for the UDI system with a view to ensuring its harmonised application in relation to any of the following:
(a) determining the devices, categories or groups of devices to which the obligation laid down in paragraph 8 is to apply;
(b) specifying the data to be included in the UDI-PI of specific devices or device groups;
The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 114(3).

For more information, please review:

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Unique Device Identification system [Requirements of the Commission]

12. When adopting the measures referred to in paragraph 11, the Commission shall take into account all of the following:
(a) **confidentiality** and **data protection** as referred to in Articles 109 and 110 respectively;
(b) the r**isk-based** approach;
(c) the c**ost-effectiveness** of the measures;
(d) the **convergence** of UDI systems developed at **international** level;
(e) the need to **avoid duplications** in the UDI system;
(f) the needs of the **healthcare systems of the Member States**, and where possible, compatibility with other medical device identification systems that are used by stakeholders.

For more information, please review:

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Takeaway

In Article 27, requirements not only for the manufacturers are mentioned.
The following entities are mentioned:

- European Commission
- The entity responsible for drawing up the UDI system
- Healthcare Providers
- Other Economic Operators

Another important note is, that the UDI doesn't just need to be placed on the device itself but on EVERY higher level of packaging other that shipping containers.

For more information, please review:

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