MDR

Device

Basic UDI-DI & UDI-DI attributes

Basic UDI-DI set of data in UDI database

Principle: Each UDI-DI inherits the attributes of its linked Basic UDI-DI and devices DI

Basic UDI-DI

- Applicable legislation (MDR) (*)
- *2. Basic UDI-DI value (*)*
- *2b Basic UDI-DI Issuing entity (*);*
- *6. Manufacturer SRN (*)*
- *5. Name and address of manufacturer*
- *7. Name and address and SRN of AR*
- *9. Risk class (*)*
- *Implantable (Y/N) (*)*
- *For IIb implantable: Suture, staple, dental filling, dental brace, tooth crown, screw, wedge, plate, wire, pin, clip, connector (Y/N)*
- *Measuring function (Y/N) (*)*
- *Reusable surgical instrument (Y/N) (*)*
- *Active device (Y/N) (*)*
- *Intended to administer/remove a medicinal substance (Y/N) (*)*
- *11. A. Name and/or, if applicable, device model that identifies the device(s) with this BASIC UDI-DI in the technical documentation and/or certificate or declaration of conformity*

(Name and/or model shall be provided)

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UDI-DIs

- 0. UDI-DI value (*)
- 0b. UDI-DI Issuing Entity (*)
- Secondary DI (value and issuing entity)
- 11.B. Reference, Article or Catalogue number (*)
- Device with Direct marking (Y/N) (*)
- Direct marking UDI-DI value (*)
- Direct marking UDI-DI issuing entity (*)
- 1. Quantity of device(s) (*)
- 3. Type of UDI-PI (*)
- 4. Unit of use UDI-DI (*)
- 12. Clinical size (*)
- 14. Storage/handling conditions
- 10-15. Name(s)/Trade name(s) (including languages)
- 13. Additional product description
- 22. URL for additional information
- 16. Labelled as single use (Y/N) (*)
- 17. Maximum number of reuse (*)
- 18. Device labelled as sterile (Y/N) (*)
- 19. Need for sterilisation (Y/N) (*)
- 20. Containing latex (Y/N) (*)
- 21. CMR/Endocrine disruptor
- 23. Critical warnings or contra-indications
- 8. Medical device nomenclature (CND) code (1)
- 24. Status
- 25. (A.2.6) Reprocessed single-use (Y/N) (*)
- 26. (A.2.12) Annex XVI (*)
- 27. (A.2.13) In the case of devices designed and manufactured by another legal or natural person as referred in Article 10(15), the name, address and contact details of that Natural/legal person

UDI-DIs (container package DI)

- 0. UDI-DI value (*)
- 0b. Issuing entity (*)
- 1. Quantity per package (*)
- 24. Status

(1) Nomenclature decision: https://ec.europa.eu/docsroom/documents/34264

(*) may not be changed

- Mandatory
- Mandatory if applicable
- Optional

Other Device Data attributes

Basic UDI-DI

- *A.2.2 Certificate IDs (NB, type .. Link);*
- *A.2.14 SSCP;*
- *A.2.11 Clinical Investigations IDs (..link);*
- *A.2.9 Presence of Human tissues/Cells (Y/N) (*);*
- *A.2.10 Presence of Animal tissues/Cells (Y/N) (*);*
- *A.2.7 Presence of medicinal product substance (Y/N) (*);*
- *A.2.8 Presence of medicinal product substance derived from human blood or human plasma (Y/N) (*);*
- *Special device types: Software (Y/N), contact lenses (Y/N) … (max one choice) (*);*
- *System which is a device in itself (Y/N) (*);*
- *Procedure pack which is a device in itself (Y/N) (*);*

Provided by NB or for certificate ID under Art 29(3) provided by manufacturer and confirmed by NB

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UDI-DIs

- A.2.7 Medicinal product Substance(s);
- A.2.8 Medicinal product Substance(s) derived from human blood or human plasma;
- A.2.3 Member State of the Placing on the EU Market of the Device (*);
- A.2.4 Member State(s) were the Device is made available in the Country;

(*) may not be changed

Mandatory

Mandatory if applicable

Optional

Basic UDI-DI & UDI-DI attributes

Basic UDI-DI set of data in UDI database

Principle: Each UDI-DI inherits the attributes of its linked Basic UDI-DI and devices DI

Basic UDI-DI

Applicable legislation (MDR) (*)

- ***2.Basic UDI-DI value (*)***
- ***2b Basic UDI-DI issuing entity (*);***
- ***6. SPPP SRN (*)***
- ***5. Name and address of SPPP***
- ***9. Risk class (highest risk class of the device components) (*)***
- ***11. A. Name and/or, if applicable, system or procedure pack model that identifies the product with this BASIC UDI-DI in the statement drawn in accordance with Art 22.1***
- ***2.a. Indication of specific medical purpose of the System or Procedure pack;***
- ***System or Procedure pack (S/P)(*);***

UDI-DIs

- **0. UDI-DI value (*)**
- **UDI-DI issuing entity (*)**
- **Secondary DI (value and issuing entity)**
- **11.B. Reference, Article or Catalogue number (*)**
- **3. Type of UDI-PI (*)**
- **14. Storage/handling conditions**
- **10-15. Name(s)/Trade name(s) (including languages)**
- **13. Additional product description**
- **22. URL for additional information**
- **18. Labelled as sterile (Y/N) (*)**
- **19. Need for sterilisation (Y/N) (*)**
- **23. Critical warnings or contra-indications**
- **8. Medical device nomenclature (CND) code (1)**
- **24. Status**

UDI-DIs (container package DI)

- **Issuing entity (*)**
- **0. UDI-DI value (*)**
- **1. Quantity per package (*)**
- **24. Status**

(1) Nomenclature decision: https://ec.europa.eu/docsroom/documents/34264

(*) may not be changed

- **Mandatory**
- **Mandatory if applicable**
- **Optional**

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