### Basic UDI-DI & UDI-DI attributes

#### 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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**Version July 2019**

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#### UDI-DIs

- 0. UDI-DI value (*)
- 0b. Issuing entity (*)
- Secondary DI (value and issuing entity)
- 11.B. Reference, Article or Catalogue number (*)
- Is device directly marked (Y/N) (* if Y)
- Direct marking UDI-DI value (* if not null)
- Direct marking UDI-DI issuing entity (* if not null)
- 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) (*)
- 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

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**UDI-DIs (container package DI)**

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


(*) may not be changed

- **Mandatory**
- **Mandatory if applicable**
- **Optional**
**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) (*);

**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

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

**Version April 2019**
Basic UDI-DI & UDI-DI attributes

Basic UDI-DI

Applicable legislation (MDR) (*)
1. 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
2a. 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(s) (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

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

Version April 2019