



# 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)**

### 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/docroom/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) where the Device is made available in the Country;**

(\*) may not be changed

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



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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/docroom/documents/34264>

- (\*) may not be changed
- **Mandatory**
- **Mandatory if applicable**
- **Optional**



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