# IVDR

# 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 (IVDR) (*)**

- **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 (*)**
- **A.2.14 Intended for self-testing (Y/N) (*)**
- **A.2.14 Intended for near-patient-testing (Y/N) (*)**
- **Companion diagnostics (Y/N) (*)**
- **Intrument(Y/N) (*)**
- **Reagent(Y/N) (*)**
- **Professional testing (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 (*)**
- **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 (*)**
- **13. Storage/handling conditions**
- **10-14. Name(s)/Trade name(s) (including languages)**
- **12. Additional product description**
- **19. URL for additional information**
- **15. Labelled as single use (YN) (*)**
- **16. Maximum number of reuse (*)**
- **17. Device labelled sterile (Y/N) (*)**
- **18. Need for sterilisation (Y/N) (*)**
- **20. Critical warnings or contra-indications**
- **8. Medical device nomenclature (CND) code(s) (1)**
- **21. Status**
- **27 (A.2.10). In the case of devices designed and manufactured by another legal or natural person as referred in Article 10(14), 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 (*)**
**21. Status**

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

**(*) may not be changed**

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

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# Other Device Data attributes

## *Basic UDI-DI*

- *A.2.2 Certificate IDs (with NB, type .. Link);*
- *A.2.11 SSP;*
- *A.2.9 Performance study IDs (..link);*
- *A.2.5 Presence of Human tissues/Cells (Y/N) (*);*
- *A.2.6 Presence of Animal tissues/Cells (Y/N) (*)*
- *A.2.7 Presence of Substances/cells of microbial origin (Y/N) (*);*
- *Kit (Y/N) (*);*

## UDI-DIs

- A.2.13 New Device (Y/N) (*);
- 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;

Provided by NB or for certificate ID under Art 26(2) provided by manufacturer and confirmed by NB

(*) may not be changed

Mandatory

Mandatory if applicable

Optional

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