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) (*)**
- **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 (*)**
- **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 (1)**
- **21. Status**
  - 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**


(*) 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

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(*) may not be changed

- Mandatory
- Mandatory if applicable
- Optional