Basic UDI-DI & UDI-DIs 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) (*)
• Instrument(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

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

IVDR

Basic UDI-DI

- Version July 2019
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;

(*) may not be changed

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

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