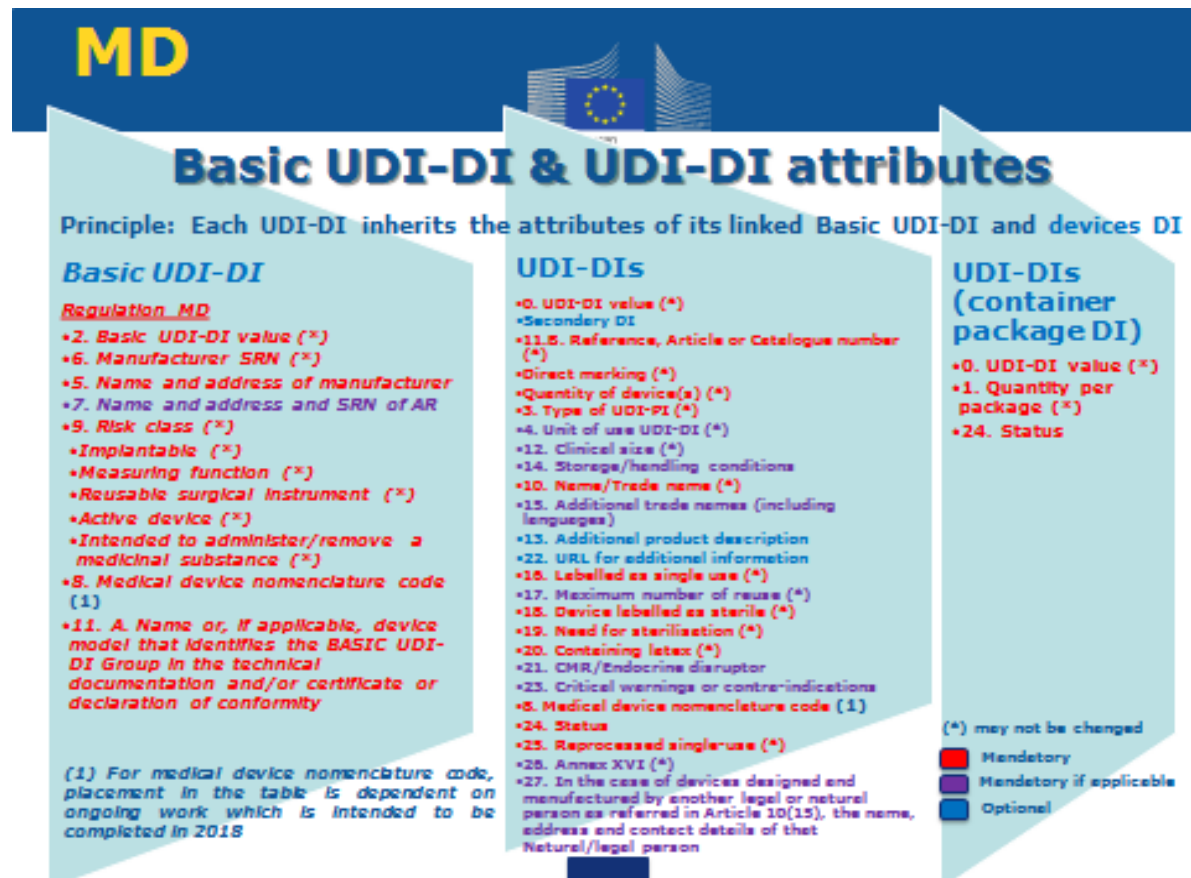


This document has been endorsed by the EU UDI Work Group and was positively received by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. It reflects the latest state-of-art of the thinking on this matter and might be subject to further changes prior to final MDCG endorsement.

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UDIWG 2018-2

The architecture of the UDI database - Basic UDI-DI and UDI-DI attributes for Medical devices and In-vitro diagnostic medical devices



Please refer to the document UDIWG/2018/1 for definitions/descriptions and formats of the data elements contained in the two slides

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IVD

Basic UDI-DI & UDI-DI attributes

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

Basic UDI-DI

Regulation IVD

- 2. Basic UDI-DI value (*)
- 6. Manufacturer SRN (*)
- 5. Name and address of manufacturer
- 7. Name and address and SRN of AR
- 9. Risk class (*)
 - Intended for self-testing (*)
 - Intended for near-patient-testing (*)
 - Companion diagnostics (*)
- 8. Medical device nomenclature code (1)
- 11. A. Name or, if applicable, device model that identifies the BASIC UDI-DI Group in the technical documentation and/or certificate or declaration of conformity

(1) For medical device nomenclature code, placement in the table is dependent on ongoing work which is intended to be completed in 2018

UDI-DIs

- 0. UDI-DI value (*)
- Secondary DI
- 11.B. Reference, Article or Catalogue number (*)
- Direct marking (*)
- Quantity of device(s) (*)
- 3. Type of UDI-PI (*)
- 4. Unit of use UDI-DI (*)
- 14. Storage/handling conditions
- 10. Name/Trade name (*)
- 15. Additional trade names (Including languages)
- 13. Additional product description
- 22. URL for additional information
- 16. Labelled as single use (*)
- 17. Maximum number of reuse (*)
- 18. Device labelled as sterile (*)
- 19. Need for sterilisation (*)
- 23. Critical warnings or contra-Indications
- 8. Medical device nomenclature code (1)
- 24. Status
- 27. 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 (*)
- 1. Quantity per package (*)
- 24. Status

(*) may not be changed

- Mandatory
- Mandatory if applicable
- Optional

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