

MDCG 2018-4

Annex: UDI database

Definitions/Descriptions and formats of the UDI core elements for systems or procedure packs

October 2018

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

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In accordance with Article 29(2) and Annex VI, Part B of the MDR, in the case of systems and procedure packs, the system or procedure pack producer shall provide to the UDI database the UDI-DI and all of the following information¹:

1. quantity per package configuration (meaning the quantity of systems or procedure packs in a package, whenever applicable)
2. the Basic UDI-DI as referred to in Article 29 (MDR) and any additional UDI-DIs,
 - 2a. Indication of specific medical purpose of the system or procedure pack
3. the manner in which the system or procedure pack is controlled (expiry date or manufacturing date, lot number, serial number),
5. name and address of the system or procedure pack producer (as indicated on the label),
6. the SRN of the system or procedure pack producer
8. The medical device nomenclature code as provided for in Article 26 (MDR)²
9. risk class (to be intended as the highest risk class of the device components of the system or procedure pack),
10. if applicable, name or trade name,
- 11.A. name or, if applicable, system or procedure pack model associated with the BASIC UDI-DI in the statement drawn in accordance with Article 22.1 of the MDR
- 11.B. reference or catalogue number, or product number found on the system or procedure pack label or accompanying packaging to identify a system or procedure pack
13. additional product description,
14. if applicable, storage and/or handling conditions of the system or procedure pack (as indicated on the label or in the instructions for use),
15. if applicable, additional trade names of the system/procedure pack,
18. labelled sterile (y/n) (meaning that the system or procedure pack in its entirety is labelled as sterile),
19. need for sterilisation before use (y/n)
22. URL for additional information, such as electronic instructions for use (optional),
23. if applicable, critical warnings or contra-indications

¹ Please note that format and definition of all UDI data elements are provided at <https://ec.europa.eu/docsroom/documents/28669>

² Applicability of this data element to systems and procedure packs is to be determined at the time of designation of the future EU nomenclature for medical devices (foreseen end of 2018/beginning 2019).

24. status of the system or procedure pack (on the market, no longer placed on the market, recalled, field safety corrective action initiated).

Whenever a label is referred to, the label of the entire system/procedure pack shall be meant, in accordance with Article 22(5) of Regulation 745/2017.

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