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UDIWG 2018-1

UDI Database, Definitions/Descriptions and formats of the UDI core elements

1) Introduction: List of data to be provided to the UDI database

Annex VI - Part B of the two Regulations lays down that the manufacturer shall provide to the UDI database the UDI-DI and all of the following information relating to the manufacturer and the device:

1. quantity per package configuration,

2. the Basic UDI-DI as referred to in Article 29 (MDR) and Article 26 (IVDR) and any additional UDI-DIs,

3. the manner in which production of the device is controlled (expiry date or manufacturing date, lot number, serial number),

4. if applicable, the unit of use UDI-DI (where a UDI is not labelled on the device at the level of its unit of use, a 'unit of use' DI shall be assigned so as to associate the use of a device with a patient),

5. name and address of the manufacturer (as indicated on the label),

6. the SRN issued in accordance with Article 31(2) (MDR) and Article 28(2) (IVDR),

7. if applicable, name and address of the authorised representative (as indicated on the label),

8. the medical device nomenclature code as provided for in Article 26 (MDR) and Article 23 (IVDR),

9. risk class of the device,

10. if applicable, name or trade name,

11. if applicable, device model, reference, or catalogue number,

12 (MD only). if applicable, clinical size (including volume, length, gauge, diameter),

13. additional product description (optional),

14. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use),

15. if applicable, additional trade names of the device,

16. labelled as a single-use device (y/n),

17. if applicable, the maximum number of reuses,

18. device labelled sterile (y/n),

19. need for sterilisation before use (y/n),

20 (MD only). containing latex (y/n),

21 (MD only). where applicable, information labelled in accordance with Section 10.4.5 of Annex I,

22. URL for additional information, such as electronic instructions for use (optional),

23. if applicable, critical warnings or contra-indications,

24. status of the device (on the market, no longer placed on the market, recalled, field safety corrective action initiated).

Additional elements to be provided by the manufacturer, resulting from Part A of Annex VI, are

25. (MD only) reprocessed single-use device (y/n),

26. (MD only) in the case of devices listed in Annex XVI, specification as to whether the intended purpose of the device is other than a medical purpose,

27. in the case of devices designed and manufactured by another legal or natural person as referred in Article 10(15) (MDR) and Article 10(14) (IVDR), the name, address and contact details of that legal or natural person,

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2) Table of definitions/descriptions and formats of the core data elements to be provided to the UDI database

Data element	Description/Definition	Data format
0 – UDI-DI	The UDI-DI is a unique numeric or alphanumeric code specific to a model of device and that is also used by the manufacturer as the first key element to be provided to the UDI database in the context of the registration process. The UDI-DI allows for the unequivocal identification if the device. It is assigned by the manufacturer in compliance with the rules of the issuing entity designated by the Commission and is attached to the packaging/labelling/marking of the device. The designated issuing entity providing the manufacturer with the UDI-DI shall be indicated.	String (format check from issuing entity rules)
1 - Quantity per package configuration	The number of items (packages or devices) within a package identified by a UDI-DI	Number (Integer)
2 - Basic UDI-DI and any additional UDI-DIs	For the Basic UDI-DI, see dedicated guidance. Additional UDI-DIs are all those UDI-DIs associated with the same database entry.	String (format check from issuing entity rules)

	The designated issuing entity providing the manufacturer with the Basic UDI-DI and any additional UDI-DIs shall be indicated.	
3 - Manner in which production of the device is controlled (expiry date or manufacturing date, lot number, serial number, software identification,) - Type of UDI-PI	Manner in which the manufacturer controls its own production. Options are as follows: - Expiry date is the upper limit of the time interval during which the performance characteristics of a product stored under specified conditions can be assured - Manufacturing date is the date on which a device is manufactured. - Lot number is the number assigned with the defined amount of material that is uniform in its properties and has been produced in one process or series of processes - Serial number is the number that allows for the identification of an individual device, indicating its position within a series. For IVD, a unique serial number shall be given for IVD instruments. - software identification is a means that allows for the identification of software which is commercially available on its own and of software which constitutes a device in itself. NB: According to point 3.5 of Part C of Annex VI of the two Regulations if a lot number, serial number, software identification or expiry date appears on the label, it shall be part of the UDI-PI. If there is also a manufacturing date on the label, it does not need to be included in the UDI-PI. If there is only a manufacturing date on the label, this shall be used as the UDI-PI.	drop down list of manners with multiple choice
4- Unit of use UDI-DI	An unmarked identifier assigned to an	String (format check

(where a UDI is not labelled on the device at the level of its unit of use, a 'unit of use' DI shall be assigned so as to associate the use of a device with a patient)	individual medical device when a UDI-DI is not labelled on the individual device at the level of its unit of use (for example in the event of several units of the same device being packaged together). Its purpose is to associate the use of a device to/on a patient.	from issuing entity rules)
5 - Name and address of the manufacturer (as indicated on the label)	Name and address of the natural or legal person acting as the legal manufacturer and associated with the Single Registration Number.	Read only information provided by the system from SRN
6 - SRN issued in accordance with Article 31(2) of the MDR / 28(2) of the IVDR	The number which identifies the relevant economic operator and which has been issued to the operator by the relevant Competent Authority in accordance with the procedure set in Article 31(2) of the MDR and in Article 28(2) of the IVDR .	String
7- Name and address of the authorised representative (as indicated on the label) (if applicable)	If the manufacturer has its registered place of business outside the Union, the name of the authorised representative and address of the registered place of business of the authorised representative associated with its Single Registration Number.	Read only information provided by the system from SRN
8 - Medical device nomenclature code as provided for in Article 26 of the MDR / 23 of the IVDR	Code associated with the nomenclature term that describes the device. To this purpose, the Commission ensures that a medical device nomenclature is available to all concerned operators/stakeholders in accordance with the requirements of the Regulations. See our webpage for any information related to nomenclature under the new Regulations.	String (autocomplete or pick-up from reference list)
9 - Risk class of the device	The risk class assigned to the device resulting from the classification rules	Drop down list of classes

	contained in Annex VIII of the two medical device Regulations and provisions related to conformity assessments contained in Article 52 of the MDR and Article 48 of the IVDR.	
10 - Name or trade name	The Proprietary/Trade/Brand name of the medical device model/version as used on the label. The EUDAMED system requires the language associated with that proprietary/brand/trade name if applicable.	Input text
11 (A) Name or, if applicable, device model that identifies the BASIC UDI-DI Group in the technical documentation and/or certificate and declaration of conformity	Indication of the name or, if applicable, of the device model that identifies the BASIC UDI-DI Group in the technical documentation and/or certificate and declaration of conformity. For clarifications related to the Basic UDI-DI, see dedicated guidance.	String
11 (B) Reference or catalogue number	- The catalogue, reference, or product number found on the device label or accompanying packaging to identify a particular product.	String
12 - Clinical size (including volume, length, gauge, diameter) (Not applicable for IVD) (if applicable)	Numeric value for the clinically relevant size measurement of the medical device as indicated on the label. Where applicable, the manufacturer will associate a clinical size range with a Basic UDI-DI and a specific clinical size for each relevant UDI-DI.	Complex
13 - Additional product description (optional)	Text providing further explanation about specific features of the device. It should possibly contain elements other than those described in the corresponding nomenclature term/description. (optional)	Free text/Text area
14 - Storage and/or handling conditions (as indicated on the label or in the instructions for	Indicates storage and handling requirements that are required for the device in accordance with Annex I, 23.2 (k) of the MDR and Annex I, 20.2 (k) of the IVDR.	Free text/Text area

use) (if applicable)		
15 - Additional trade names of the device (if applicable)	Any additional trade name to the one already indicated in relation to point 10. Any additional trade names used in the EU (including those resulting by simple translation in the language of those EU countries where the product is made available) shall be indicated. Any change in trade names resulting from translation in the language of those EU countries where the product is made available triggers a new UDI-DI. The EUDAMED system will require the language associated with each additional proprietary/brand/trade name.	Free text/Text area
16 - Labelled as a single-use device ((y/n)	indicates whether the device is labelled as labelled as "single –use"	Radio button (Yes/No)
17 - Maximum number of reuses (if applicable)	If the device is reusable, an indication of how many times the device may be re-used according to its label and instructions of use.	Number (Integer)
18 - Device labelled sterile	Indicates whether the medical device is labelled as sterile meaning it is sterile and in a sterilised packaging.	Radio button (Yes/No)
19 – Need sterilisation before use (y/n)	Indicates whether the device requires sterilization prior to use.	Radio button (Yes/No)
20 - Containing latex (y/n) (Not applicable for IVD)	An indication of whether the device or packaging is labelled as containing natural rubber that comes in contact with humans.	Radio button (Yes/No)
21 - Information labelled in accordance with Section 10.4.5 of Annex I	Indicates whether a device is labelled with an Indication of (a) substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of	Indication if CMR or endocrine disruptor + Free text/text area for details

(Not applicable for IVD)	category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council, or (b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council, in accordance with the criteria that are relevant to human health amongst the criteria established therein. which are contained in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2 of Annex I of the Regulation. NB: This applies to devices, or those parts thereof or those materials used therein that: – are invasive and come into direct contact with the human body, – (re)administer medicines, body liquids or other substances, including gases, to/from the body, or - transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body	
22 - URL for additional information, such as electronic instructions for use (optional)	A web address (URL) where additional official information on the device can be found on the Internet.	String
23 - Critical warnings or contra-indications	Warnings, contraindications, precautions (such as MRI safety status) that need to be	Free text/Text area

(if applicable)	brought to the immediate attention of the user of the device, and to any other person, as they are indicated on the label in accordance with Annex I, 23.2 (m) of the MDR and Annex I, 20.2 (m) of the IVDR.	
24 - Status of the device (on the market, no longer placed on the market, recalled, field safety corrective action initiated)	Indication of the device status on the market, including whether it is subject to recall or field safety corrective action.	Drop down list of statuses
25. reprocessed single-use device (y/n), (if applicable) (Not applicable for IVD)	Indication as to whether the device is a reprocessed single-use device. Please refer to Article 2 and Article 17 of the Medical Device Regulation for the relevant definitions and requirements related to reprocessed single-use devices.	Radio button (Yes/No)
26. Indication on whether the intended purpose of the device is other than a medical purpose (y/n) (if applicable) (Not applicable for IVD)	In the case of devices listed in Annex XVI of the Medical Device Regulation, specification as to whether the intended purpose of the device is other than a medical purpose	Radio button (Yes/No) + reference list
27. Name, address and contact details of the legal or natural person (other than the manufacturer) that has designed or manufactured the device (if applicable)	In the case of devices designed and manufactured by another legal or natural person as referred in Article 10(15) of the MDR and Article 10(14) of the IVDR, the name, address and contact details of that legal or natural person. In case that natural or legal person is already registered in EUDAMED, its SRN shall be provided.	Complex