Core Data Elements to Be Provided To the UDI Database

Medical Device Regulation	In Vitro Diagnostic Device Regulation
Annex V Information To Be Submitted With The Registration Of Devices And Economic Operators In Accordance With Article 25a and Core Data Elements To Be Provided To The UDI Data Base Together With The Device Identifier In Accordance With Article 24a and The European Unique Device Identification System	**Annex V Information To Be Submitted With The Registration Of Devices And Economic Operators In Accordance With Article 23a and Core Data Elements To Be Provided To The UDI Data Base Together With The Device Identifier In Accordance With Article 22a and The European Unique Device Identification System**
Part B Core Data Elements To Be Provided To The UDI Database Together With The UDI Device Identifier In Accordance With Article 24a	**Part B Core Data Elements To Be Provided To The UDI Database Together With The UDI Device Identifier In Accordance With Article 22a**
1. quantity per package configuration	1. quantity per package configuration
2. if applicable, the Basic UDI-DI according to article 24(4b) and additional identifier(s)	2. if applicable, the Basic UDI-DI according to Article 22(4b) and additional identifier(s)
3. the way how the device production is controlled (expiration date or manufacturing date, lot or batch number, serialization number)	3. the way how the device production is controlled (expiration date or manufacturing date, lot or batch number, serialization number)
4. if applicable, the unit of use device identifier (when a UDI is not assigned to the device at the level of its unit of use, a 'unit of use' device identifier shall be assigned to associate the use of a device with a patient)	4. if applicable, the 'unit of use' device identifier (when a UDI is not assigned to the device at the level of its 'unit of use', a 'unit of use' device identifier shall be assigned to associate the use of a device with a patient)
5. name and address of the manufacturer (as indicated on the label)	5. name and address of the manufacturer (as indicated on the label)
5a. the single registration number according to article 25a(2)	5a. the single registration number according to Article 23a(2)
6. if applicable, name and address of the authorized representative (as indicated on the label)	6. if applicable, name and address of the authorized representative (as indicated on the label)
7. Medical Device Nomenclature code according to article 23a	7. Medical Device Nomenclature code according to Article 21a
7a. risk class of the device	7a. risk class of the device
8. if applicable, trade/brand name	8. if applicable, trade/brand name
9. if applicable, device model, reference, or catalogue number	9. if applicable, device model, reference, or catalogue number
***	10. additional product description (optional)
10. if applicable, clinical size (including volume, length, gauge, diameter)	***
12. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use)	11. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use)
13. if applicable, additional trade names of the device	12. if applicable, additional trade names of the device
14. labelled as single use device (y/n)	13. labelled as single use device (y/n)
15. if applicable, restricted number of reuses	14. if applicable, restricted number of reuses
16. device packaged sterile (y/n)	15. device packaged sterile (y/n)
17. need for sterilization before use (y/n)	16. need for sterilization before use (y/n)
18. labelled as containing latex (y/n)	***
19. labelled in accordance with Annex I, section 7.4.5	***

Medical Device Regulation	In Vitro Diagnostic Device Regulation
20. URL for additional information, *e.g.*, electronic instructions for use (optional)	17. URL for additional information, e.g. electronic instructions for use (optional)
21. if applicable, critical warnings or contraindications	18. if applicable, critical warnings or contraindications
22. status of the device on the market (choice box, no longer placed on the market, recalled, Field Safety Corrective Action initiated)	19. status of the device on the market (choice box, no longer placed on the market, recalled, Field Safety Action initiated)

References from the Core Data Elements

Basic UDI-DI

MDR: Article 24(4b)

> 4b. The Basic UDI device identifier ('Basic UDI-DI' as defined in Annex V Part C) of the device shall appear on the EU declaration of conformity referred to in Article 17.
>
> > Basic UDI-DI – The Basic UDI-DI is the primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and shall be referenced in relevant certificates and declarations of conformity.

IVDR: Article 22(4b)

Single Registration Number

MDR: Article 25a(2)

> After having verified the data entered pursuant to paragraph 1, the competent authority shall procure from the electronic system referred to in Article 25 a single registration number ('SRN') and issue it to the manufacturer, the authorised representative or the importer.

IVDR: Article 23a(2)

Medical Device Nomenclature

MDR: Article 23a

> To facilitate the functioning of the European Databank on medical devices ('Eudamed') established pursuant to Article 27 the Commission shall ensure that an internationally recognised medical devices nomenclature shall be available free of charge to manufacturers and other natural or legal persons required to use nomenclature for the purpose of this regulation. The Commission shall also endeavour to ensure that that nomenclature is available to other stakeholders free of charge, where reasonably practicable.

IVDR: Article 21a

Label

MDR: Annex I, section 7.4.5

7.4.5 Labelling

If devices, parts thereof or materials used therein as referred to in Section 7.4.1 contain substances referred to in points (a) or (b) of Section 7.4.1 in a concentration above 0.1% weight by weight (w/w), these devices shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for use.

Section 7.4.1 (a) substances which are carcinogenic, mutagenic or toxic to reproduction of 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 of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Section 7.4.1 (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 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) or in accordance with those criteria that are relevant to human health of the criteria established in the delegated act adopted by the Commission pursuant article 5(3), first paragraph, of Regulation (EU) No 528/2012 of the European Parliament and the Council of 22 May 2012 concerning the making available on the market of and use of biocidal products