MedTech Europe guidance for assigning Basic UDI-DI

2 June 2020

v1.1

Aim of the document

The MedTech Europe Basic UDI-DI guidance document aims to provide a framework for companies to help their Basic UDI-DI assignment. The document describes the legal and other connected rules - mainly arising from the EUDAMED[1] database design - that are essential to understand before making decision on the Basic UDI-DI grouping.

Introduction

Within the EU, the manufacturer[2] is legally responsible to assign both Basic UDI-DI and UDI-DI[3] to their medical devices. The assignment of a Basic UDI-DI is not required by other jurisdictions. The manufacturer and the system or procedure pack producer are responsible for complying with UDI related requirements which includes the assignment of the UDI-DI and Basic UDI-DI and their registration in the EUDAMED database.

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[1] The European database on medical devices to be set up under Regulation (EU) 2017/745 and Regulation (EU) 2017/746
[2] Note: mind the difference between the responsibility of the 'labeller' in the US
[3] The UDI stands for Unique Device Identification. The DI is the Device Identifier.

What is the Basic UDI-DI?

Basic UDI-DI legal requirements

1. **As per [Regulation (EU) 2017/745](#) (MDR) and [Regulation (EU) 2017/746](#) (IVDR) Annex VI Part C definition:**

   "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 is referenced in relevant certificates and EU declarations of conformity."

   Note: *As per the* related [MDCG 2018-1 v3](#) *guidance document, which provides more clarification to this definition, the Basic UDI-DI is not assigned at the level of unit of use.*

2. **As per [MDCG 2018-1 v3](#) guidance:**[4]

   "The Basic UDI-DI is the main access key in the database and relevant documentation (e.g. certificates, declaration of conformity, technical documentation and summary of safety and clinical performance) to **connect devices with same intended purpose, risk class and essential design and manufacturing characteristics**. It is independent/separate from the packaging/labelling of the device and it does not appear on any trade item."

   Any Basic UDI-DI shall identify the devices (group) covered by that Basic UDI-DI in a unique manner.

3. **As per the current EUDAMED database design** (**The current EUDAMED database design is not final yet**. *See Annex III of this document for more information.)*

   The Basic UDI-DI is the access key for device-related information entered in the EUDAMED database.

   The EUDAMED [UDI device data dictionary](#) defines all data elements that are associated with a Basic UDI-DI.

   Any change in the following data elements indicated with asterisk (*) requires the assignment and registration of a new Basic UDI-DI (Reference: *April 2019 version of* [MDR – UDI and device data sets to provide in EUDAMED](#) and [IVDR UDI and device data sets to provide in EUDAMED](#)):

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[4] MDCG 2018-1 v3: *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. The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.*

Common data elements of a BUDI-DI

MD

Basic UDI-DI

- Applicable legislation (MDR) (*)
- 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 (*)
  - Implantable (Y/N) (*)
  - For IIb implantable: Suture, staple, dental filling, dental brace, tooth crown, screw, wedge, plate, wire, pin, clip, connector (Y/N)
  - Measuring function (Y/N) (*)
  - Reusable surgical instrument (Y/N) (*)
  - Active device (Y/N) (*)
  - Intended to administer/remove a medicinal substance (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)

- A.2.2 Certificate IDs (NB, type .. Link);
- A.2.14 SSCP;
- A.2.11 Clinical Investigations IDs (..link);
- A.2.9 Presence of Human tissues/Cells (Y/N) (*);
- A.2.10 Presence of Animal tissues/Cells (Y/N) (*);
- A.2.7 Presence of medicinal product substance (Y/N) (*);
- A.2.8 Presence of medicinal product substance derived from human blood or human plasma (Y/N) (*);
- Special device types: Software (Y/N), contact lenses (Y/N) … (max one choice) (*);
- System which is a device in itself (Y/N) (*);
- Procedure pack which is a device in itself (Y/N) (*);

IVD

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)

- 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) (*);

Version April 2019

Colour coding:

Mandatory information needed to be completed when submitting a BUDI

Mandatory if applicable

Provided by NB or for certificate ID under MDR Art 29(3)/IVDR Art 26(3) provided by manufacturer and confirmed by NB

* Data element that may not be changed = triggers a new BUDI when changes

Common data elements of a BUDI-DI – System and Procedure Pack

Basic UDI-DI

Applicable legislation (MDR) (*)
- 2.Basic UDI-DI value (*)
- 2b Basic UDI-DI issuing entity (*);
- 6. SPPP SRN (*)
- 5. Name and address of SPPP
- 9. Risk class (highest risk class of the device components) (*)
- 11. A. Name and/or, if applicable, system or procedure pack model that identifies the product with this BASIC UDI-DI in the statement drawn in accordance with Art 22.1
- 2.a. Indication of specific medical purpose of the System or Procedure pack;
- System or Procedure pack (S/P)(*);

- **Mandatory information needed to be completed when submitting a BUDI**
- **Mandatory if applicable**
* Data element that may not be changed = triggers a new BUDI when changes

Note: SPPP stands for System / Procedure Pack Producer, Reference: Section 3.1 in MDCG 2018-3 Guidance on UDI for systems and procedure packs

Prior to making Basic UDI-DI grouping decisions, cross-functional collaboration is needed to consider the impact on:

Documents where Basic UDI-DI is referenced:	Others:
- Technical Documentation (provided to Notified Body in conformity assessment application) - EU Declaration of Conformity - Product Certificate - EU Technical Documentation assessment certificate - EU type examination certificate - EU product verification certificate - Certificate of Free Sale - Summary of Safety and Clinical Performance (SSCP) for Medical Devices/ Summary of Safety and Performance (SSP) for IVDs - Vigilance and Post-Market Surveillance Reports (auto-populated in EUDAMED if form is completed online): - Manufacturer Incident Reporting form (MIR) - Periodic Summary Update Report (PSUR) - Field Safety Corrective Action Reporting form (FSCAR form) - Periodic Summary Report form (PSR) - Trend Reporting form - Clinical investigation forms for post-market studies	- Audits[5] - Instruction for Use[6]

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[5] The European Medical Device Nomenclature codes will be linked to NBOG codes – more specifically to MDA / MDN - which is the basis for sampling by Notified Bodies as per Regulation (EU) 2017/2185
[6] The MDR requires (IVDR does not require) to include a link to the SSCP in the IFU. One option as per the MDCG 2019-9 guidance on SSCP is to state the value of the Basic UDI-DI in the IFU. Alternatively, another metadata can be stated provided it can be used to unambiguously search and find the intended SSCP in EUDAMED. See: MedTech Europe position paper on Provision of the Summary of Safety and Clinical Performance (SSCP) & link in the Instructions for Use (IFU) – Feb 2020

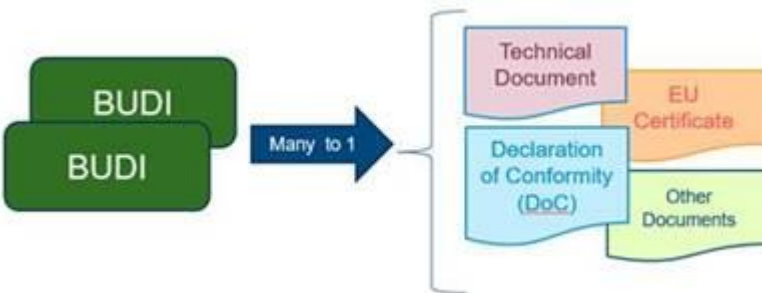## Basic UDI-DI Decision Tree

(Please use the flow chart in conjunction with the explanations on the following page)

This decision tree takes into account those considerations that are arising from the EUDAMED database design (indicated with blue) and those that are arising from the MDCG Basic UDI-DI guidance (indicated with orange).

Introduce new or existing Basic UDI-DI

Rules arising from the EUDAMED database design are indicated with blue and considerations arising from the MDCG Basic UDI-DI guidance are indicated with orange.

Does the device have the same **Manufacturer SRN** as a currently existing Basic UDI-DI?

No

Yes

Does the device have the same MDR/IVDR **risk class and Basic UDI-DI data elements** as a currently existing Basic UDI-DI?

No

Yes

Does the device have the same **intended purpose** as a currently existing Basic UDI-DI?

No

Yes

Will the device be included on the same product certificate, SSCP (for MDs)/SPP (for IVDs), DoC and/or Tech.Doc. as other devices assigned to the same existing Basic UDI-DI?

No

Yes

Does the device ONLY differ in minor characteristics* from other devices assigned to the same Basic UDI-DI?

No

Does the device have the same essential design and manufacturing characteristics as other devices assigned to the same Basic UDI-DI?

No

Allocate new Basic UDI-DI

Yes

Yes

Use the same Basic UDI-DI

Consider using the same Basic UDI-DI

* Minor characteristics = Differences are only in Non-Essential Characteristics

Explanation for the Basic UDI-DI Decision Tree

Question #	Explanation
1	**Does the device have the same Manufacturer SRN?** Refer to the "Manufacturer" information on the product labelling who is legally responsible for the product and to whom the SRN is assigned.

2	**Does the device have the same EU MDR/IVDR risk class and Basic UDI-DI data elements?**
	
	a. For the applicable regulation MDR:
	to answer "Yes", identify the risk class with applicable Basic UDI-DI data elements. The device must have the same following data elements:
	    i. Implantable;
	    ii. Active;
	    iii. Reusable surgical instrument;
	    iv. Measuring function;
	    v. Presence of medicinal product substances;
	    vi. Presence of medicinal product substance derived from human blood or human plasma;
	    vii. Device intended to administer and/or remove medicinal product;
	    viii. presence of human tissues or cells, or their derivates;
	    ix. presence of animal tissues or cells, or their derivates;
	    x. Special device types: software / orthopaedic / standard soft contact lenses / rigid gas permeable (RPG) & made-to-order soft contact lenses;
	b. For the applicable regulation IVDR:
	to answer "Yes", identify the risk class with applicable Basic UDI-DI data elements. The device must have the same following data elements:
	    i. Intended for Near-patient-testing;
	    ii. Intended for Self-testing;
	    iii. Companion diagnostics;
	    iv. Reagent;
	    v. Instrument;
	    vi. Professional testing;
	    vii. Presence of human tissues or cells, or their derivates;
	    viii. Presence of animal tissues or cells, or their derivates
	    ix. Presence of substances / cells of microbial origin;
	    x. Special device types: software

	Note: Ensure all UDI-DIs under a Basic UDI-DI are the same risk class and have the same Basic UDI-DI data elements as listed above.
3	**Does the device have the same intended purpose?** Definition of intended purpose: means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation (MDR Article 2.12). Note: The intended purpose does not necessarily align 1:1 with its indication. It typically represents the function that the device is used for (what does the device do to the patient or target organ, etc.). Devices may have the same intended purpose (same function) but could be used in a different patient population.
4	**Will the device be included on the same product certificate[7], same Declaration of Conformity, same SSCP/SSP, and/or same Technical Documentation as other devices assigned to the same Basic UDI-DI?** All devices covered by a given Basic UDI-DI should be on the same product certificate, SSCP/SSP, and/or Technical Documentation. Example*: * The example represents higher class devices and a best practice as understood based on the MDR and IVDR requirements by the industry experts who developed this external guidance document. This interpretation could evolve overtime as EUDAMED specifications are being developed and finalised.

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[7] Type of product certificates:
- EU Technical Documentation assessment certificate
- EU type examination certificate
- EU product verification certificate

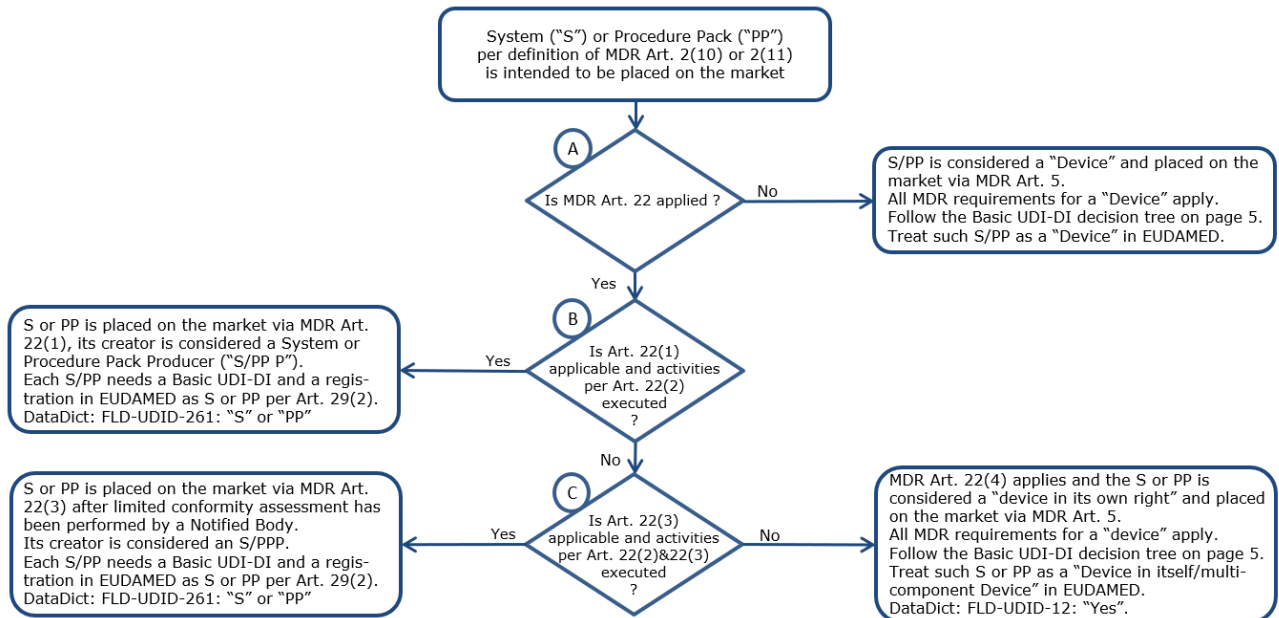|	
	Product certificates, Declaration of conformities, and Technical Documentation may refer to multiple Basic UDI-DIs. *(For relationship between Summary of safety and clinical performance (SSCP) and Basic UDI-DI see Annex III of this document.)* The association between different Basic UDI-DIs, where applicable, shall be identified through the technical dossiers. (Reference: **MDCG 2018-1 v3** guidance, **Link between Basic UDI-DIs and certificates or declaration of conformity**)
5	**Does the device ONLY differ in minor characteristics?** For devices that only differ in minor characteristics, consider assigning the same Basic UDI-DI.
6	**Does the device have the same essential design and manufacturing characteristics?** If the device differs in essential design and manufacturing characteristics, consider assigning a new Basic UDI-DI.

General rules to comply with:

1. Before placing a device [other than a custom-made device, clinical investigational devices (MDR) or device for performance evaluation (IVDR)], on the market, the manufacturer shall, in accordance with the rules of the issuing entity referred to in Article 27(2) of MDR / Article 24(2) of IVDR, assign a Basic UDI-DI as defined in Part C of Annex VI to the device and shall provide it to the UDI database[8] together with the other core data elements referred to in Part B of Annex VI related to that device. [Reference: Regulation EU 2017/745 (MDR) Article 29(1)/ Regulation EU 2017/746 (IVDR) Article 26(1)]

2. A UDI-DI shall be associated with one and only one Basic UDI-DI. (Reference: MDCG 2018-1 v3)
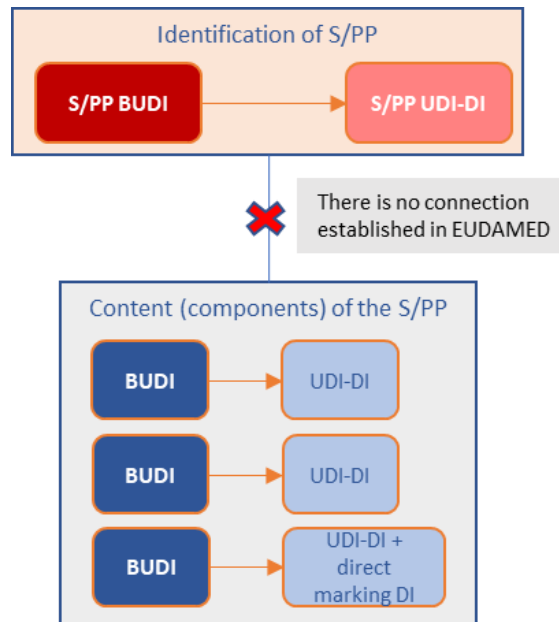
Rules specific for systems or procedure packs:

1. "Before placing on the market a system or procedure pack pursuant to MDR Article 22(1) and (3), that is not a custom-made device, the natural or legal person responsible shall assign to the system or procedure pack, in compliance with the rules of the issuing entity, a Basic UDI-DI and shall provide it to the UDI database[7] together with the other core data elements referred to in Part B of Annex VI related to that system or procedure pack." [Reference: MDR Article 29(2)]

2. "The Basic UDI-DI shall identify systems or procedure packs having the same group of components and the same intended purpose, regardless of the original components' manufacturers. *(Footnote from MDCG 2018-3: this is to prevent that two systems or procedure packs with the same intended purpose, but having one or more components coming from different manufacturers, would need to be assigned two different Basic UDI-DIs.)* System and procedure packs shall be assigned and bear their own UDI […], in accordance with Annex VI, Part C, points 3.7 and 6.3.1. of the MDR" (Reference: MDCG 2018-3 *5. Specific UDI rules for systems and procedure packs* - page 4)

3. The relationship between the UDI-DI and Basic UDI-DI of a system or a procedure pack (S/PP) can be many to one. (At an earlier stage of the EUDAMED development this relationship was defined as 1:1 which is now removed to allow multiple UDI-DIs created under a Basic UDI-DI of a system or procedure pack.)

4. For Systems or Procedure Packs, the risk class is the highest risk class of the device components of the system or procedure pack. (Reference: MDCG 2018-4)

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[8] Until May 2022 earliest, it will not be possible, to upload this information to EUDAMED before the placing the devices on the market. If EUDAMED is deployed in May 2022, this requirement will apply 24 months (18+6) after the publication of the notice in the EU Official Journal confirming EUDAMED's full functionality – see *MDCG 2019-4* for the registration timelines.

Decision tree for systems or procedure packs:

Decision tree flowchart:

System ("S") or Procedure Pack ("PP") per definition of MDR Art. 2(10) or 2(11) is intended to be placed on the market

A — Is MDR Art. 22 applied?

No → S/PP is considered a "Device" and placed on the market via MDR Art. 5.
All MDR requirements for a "Device" apply.
Follow the Basic UDI-DI decision tree on page 5.
Treat such S/PP as a "Device" in EUDAMED.

Yes ↓

B — Is Art. 22(1) applicable and activities per Art. 22(2) executed?

Yes → S or PP is placed on the market via MDR Art. 22(1), its creator is considered a System or Procedure Pack Producer ("S/PP P").
Each S/PP needs a Basic UDI-DI and a registration in EUDAMED as S or PP per Art. 29(2).
DataDict: FLD-UDID-261: "S" or "PP"

No ↓

C — Is Art. 22(3) applicable and activities per Art. 22(2)&22(3) executed?

Yes → S or PP is placed on the market via MDR Art. 22(3) after limited conformity assessment has been performed by a Notified Body.
Its creator is considered an S/PPP.
Each S/PP needs a Basic UDI-DI and a registration in EUDAMED as S or PP per Art. 29(2).
DataDict: FLD-UDID-261: "S" or "PP"

No → MDR Art. 22(4) applies and the S or PP is considered a "device in its own right" and placed on the market via MDR Art. 5.
All MDR requirements for a "device" apply.
Follow the Basic UDI-DI decision tree on page 5.
Treat such S or PP as a "Device in itself/multi-component Device" in EUDAMED.
DataDict: FLD-UDID-12: "Yes".

General assumptions:

1. One Product Certificate allows reference to multiple Basic UDI-DIs; however, one Basic UDI-DI cannot be referenced in multiple Product Certificates.

2. Clinical investigation records allow to reference multiple Basic UDI-DIs.

3. Vigilance reporting (MIR, PSR, FSCAR, FSN form) allow to reference only one Basic UDI-DI

4. Post-Market Surveillance report allow a reference to multiple Basic UDI-DIs (PSUR – Periodic Safety Update Report) (On the relationship between Periodic Safety Update Report (PSUR) and Basic UDI-DI *see Annex III of this document*). Technical Documentation allows to reference multiple Basic UDI-DIs

5. EU Declaration of Conformity documents allow to reference multiple Basic UDI-DIs

6. "If the device is a system of several components/devices, each device in the system should have a Basic UDI-DI but also one Basic UDI-DI for the system. It is the Basic UDI-DI for the system that is intended to be provided in section 1.4 in the template, and that will be associated with the SSCP in EUDAMED. The device system, and any Basic UDI-DIs of included devices, should be described in section 3.1." (Reference: Section 3.1 on page 12 of MDCG 2019-9 Summary of safety and clinical performance A guide for manufacturers and notified bodies)
   The above scenario is <u>only</u> applicable if the system is considered to be a device on its own right as per MDR Article 22(4).

7. Premarket clinical investigational devices [MDR Article 27(1)]/devices for performance evaluation [IVDR Article 27(1)]are generally out of scope for Basic UDI-DI; however, some exceptions may apply [MDR Article 74(2)/ IVDR Article 70(2)]

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information, visit www.medtecheurope.org.

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The **Regulation (EU) 2017/745** (MDR) and **Regulation (EU) 2017/746** (IVDR) contain several provisions that are capable of being given more than one interpretation. In the preparation of this Guidance, MedTech Europe has used its best efforts to ensure that the opinions and advice expressed are sound. However, the Association makes no assertion that those opinions and advice are correct, and it accepts no legal responsibility for them. Specific legal advice should be sought before acting on any of the topics covered. MedTech Europe reserves the right to change or amend this document at any time without notice in order to keep the information up to date.

Members are reminded that, while competent authorities and notified bodies may be helpful in providing views as to the meaning of the IVDR and MDR Regulations, it is ultimately for the courts to interpret legislation.

References

1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

2. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

3. MDCG 2018-1 v3 Guidance on Basic UDI-DI and changes to UDI-DI

4. EUDAMED database final data elements under the Basic UDI-DI:
   https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/EUDAMED_en
   • MDR UDI and device data sets and IVDR UDI and device data sets
   • EUDAMED UDI device data dictionary

5. MDCG 2018-3 Guidance on UDI for systems and procedure packs

6. MDCG 2018-4 Definitions/descriptions and formats of the UDI core elements for systems or procedure packs

7. MDCG 2019-1 MDCG guiding principles for issuing entities rules on Basic UDI-DI

8. MDCG 2019-4 Timelines for registration of device data elements in EUDAMED

9. MDCG 2019-9 Summary of safety and clinical performance A guide for manufacturers and notified bodies

10. European Commission: UDI system frequently asked questions and answers

11. Regulation (EU) 2017/2185 Commission Implementing Regulation (EU) 2017/2185 of 23 November 2017 on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices

Annex I

List of UDI issuing agencies with a link to their rules how to construct a Basic UDI-DI

The [Commission Implementing Decision (EU) 2019/939 of 6 June 2019 on the issuing entities designated to operate a system for the assignment of Unique Device Identifiers (UDIs) to comply with the MDR and IVDR](#) designated the following UDI issuing entities:

- GS1
- Health Industry Business Communications Council (HIBCC)
- International Council for Commonality in Blood Banking Automation (ICCBBA)
- Informationsstelle für Arzneispezialitäten (IFA)

Please find below the Basic UDI-DI specification of the various UDI issuing entities following the Commission's MDCG guiding principles for issuing entities rules on Basic UDI-DI [MDCG 2019-1](#):

- GS1 Basic UDI-DI Specification:
  https://www.gs1.org/docs/barcodes/GSCN_19-012_GlobalModelNumberUpdate_v3.pdf

- GS1 Basic UDI-DI Global Model Number calculator:
  https://www.gs1.org/services/gmn-generator

- IFA Basic UDI-DI Specification (instructions for Basic UDI-DI from page 5):
  https://www.ifaffm.de/mandanten/1/documents/04_ifa_coding_system/IFA-Info_Spec_UDI_Code_EN.pdf

- IFA Basic UDI-DI check digit calculation guidance:
  https://www.ifaffm.de/mandanten/1/documents/04_ifa_coding_system/IFA-Info_Check_Digit_Calculations_PZN_PPN_UDI_EN.pdf

- HIBC Basic UDI-DI summary:
  https://www.hibcc.org/wp-content/uploads/HIBCC-Basic-UDI-DI.pdf

- HIBC Basic UDI-DI generator:
  https://www.hibcc.org/basic-udi-di-generator/

- ICCBBA Basic UDI-DI specifications and checksum calculation (on pages 45-49):
  https://www.iccbba.org/uploads/d9/8c/d98cb402cf283141375400c68a2e1449/ST-017-ISBT-128-Standard-Coding-and-Labeling-of-Medical-Devices-Containing-MPHO-v1.0.0.pdf

Annex II

Example of Basic UDI-DI assignment (MD and IVD examples)

Example for MDR Basic UDI-DI assignment

120-010 IV Cannula are disposable peripheral venous catheters/cannulas.

They are manufactured in different clinical sizes:

· Gauge Options: 1.02 mm/18 Gauge, 0.81 mm/20 Gauge, 0.64 mm/22 Gauge, 0.51mm/24 Gauge.

· Catheter Length Options: 19.05mm/0.75 Inch, 25.4mm/1 Inch, 31.75mm/1.25 Inch, 44.45mm/1.75 Inch.

· Flow Rate Options (mL per minute): 22, 35, 60, 65, 100, 105.

Quantity per package (1st level): 25, 50, 100, 200

Quantity per package (2nd level): 200, 1000

All REF numbers associated to the device model (that identifies the devices with this BASIC UDI-DI) share the same intended purpose, risk class and essential design and manufacturing characteristics

All REF numbers associated to the device model (that identifies the devices with this BASIC UDI-DI) are covered by the same technical documentation

All REF numbers associated o the device model (that identifies the devices with this BASIC UDI-DI) are covered in the same registration documents (declaration of conformity, certificates, summary of safety and clinical performance, etc.)
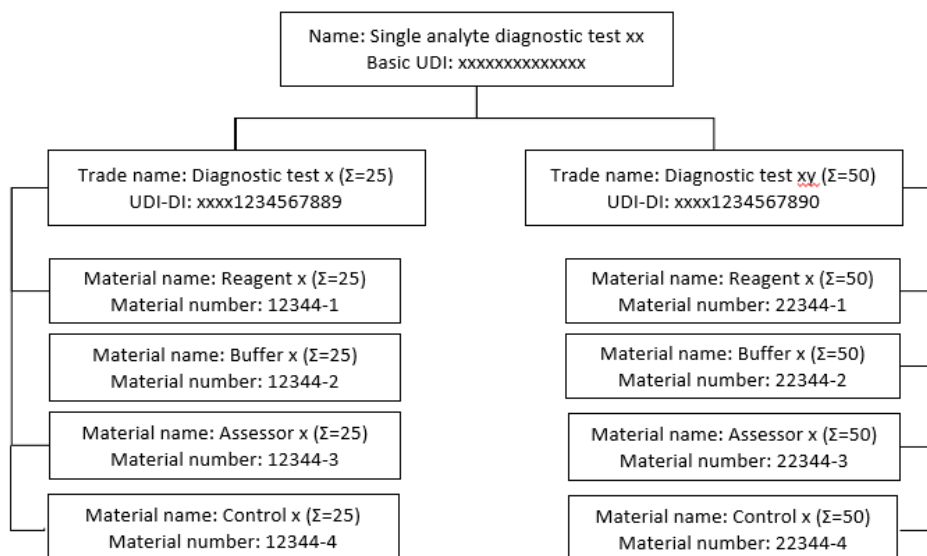
The device model (that identifies the devices with this BASIC UDI-DI) is the level / grouping used for post-market surveillance, vigilance, etc.
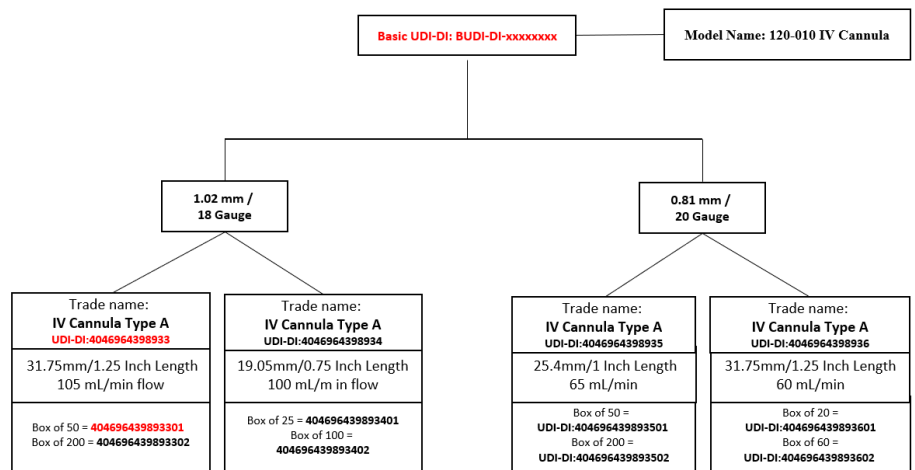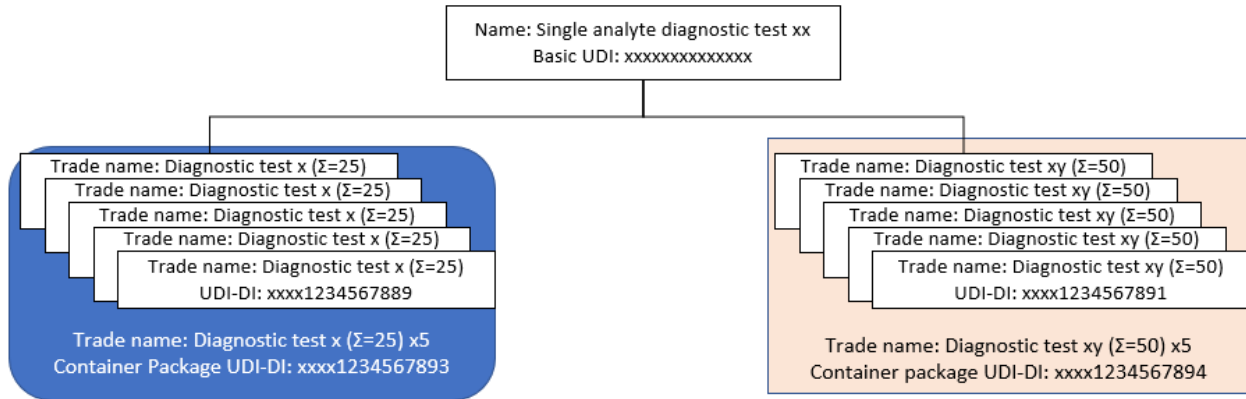
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Example for IVD Basic UDI-DI assignment

IVD example – different package size

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[9] Name and/or device model identifies the device(s) with this BASIC UDI-DI in the technical documentation and/or certificate or declaration of conformity

IVD example – different package level

Name: Single analyte diagnostic test xx
Basic UDI: xxxxxxxxxxxxxx

Trade name: Diagnostic test x (Σ=25)
Trade name: Diagnostic test x (Σ=25)
Trade name: Diagnostic test x (Σ=25)
Trade name: Diagnostic test x (Σ=25)
Trade name: Diagnostic test x (Σ=25)
UDI-DI: xxxx1234567889

Trade name: Diagnostic test x (Σ=25) x5
Container Package UDI-DI: xxxx1234567893

Trade name: Diagnostic test xy (Σ=50)
Trade name: Diagnostic test xy (Σ=50)
Trade name: Diagnostic test xy (Σ=50)
Trade name: Diagnostic test xy (Σ=50)
Trade name: Diagnostic test xy (Σ=50)
UDI-DI: xxxx1234567891

Trade name: Diagnostic test xy (Σ=50) x5
Container package UDI-DI: xxxx1234567894

Annex III

Please note that some of the concepts of this guidance document listed in this Annex are not final yet and will be updated upon receiving confirmation from the European Commission's EUDAMED developers.

1. **The current EUDAMED database design is not final yet.** See disclaimer at the official EUDAMED information page of the European Commission's website:
   "We update the documents below under 'functional specifications', 'MDR/IVDR UDI and device', and 'data exchange' as new information becomes available. Please check back regularly for the latest versions as they are subject to adjustments and fine-tuning."

2. **Relationship between Summary of safety and clinical performance (SSCP – MD only) and Basic UDI-DI:**

   The **MDCG 2019-9** Summary of safety and clinical performance A guide for manufacturers and notified bodies states that "In EUDAMED, the SSCP is associated to one unique Basic UDI-DI."

   Therefore, the current database design seems to limit the scope of a Summary of Safety and Clinical Performance (SSCP) to one Basic UDI-DI.

   This technical constraint causes an unproportionate burden for individually CE marked medical devices which intend to work together (compatible) as the SSCP needs to be created at individual device level and not at 'system' level. These devices are not systems as per the MDR Article 2(11) definition, neither are 'systems which are a device in themselves' as per MDR Article 22(4). Therefore, individual Basic UDI-DIs are assigned to each of them. (e.g. when implantable components of the compatible devices "system" intended to work together to deliver a certain therapy but the selection of specific devices is left to the surgeon to suit a particular patient), The evidence and data is collected at 'system' level and not for the individual device which makes the limitation of the required data to one individual device for the purpose of drawing up an SSCP impossible.

   Linking the SSCP to one Basic UDI-DI only increases the workload of Notified Bodies (i.e. uploading identical SSCPs multiple times multiplied by the number of translated versions).

   To be able to link the SSCP to multiple Basic UDI-DI provide a value to patients as they will be able to see how whole compatible devices "system" works together.

   Depending whether this constraint is removed from EUDAMED, the Summary of Safety and Clinical Performance (SSCP) may refer to multiple Basic UDI-DIs.

3. **Relationship between Periodic Safety Update Report (PSUR) and Basic UDI-DI**

   There are ongoing discussions about the scope of a PSUR: to be clarified in a future MDCG guidance document on PSUR. e.g. if a PSUR can cover multiple certifications thus multiple Basic UDI-DIs (as

long as all devices are covered by the same notified body) or only multiple Basic UDI-DIs provided that they are on the same certificate.

The latest agreement is that one Basic UDI-DI should belong to one PSUR only (but one PSUR can cover several Basic UDI-DIs) and that grouping of devices would be possible provided the devices have in common the same intended medical purpose and therefore the same technical file / clinical evaluation report / risk management file / PMS plan. (Applicable to class IIa, class IIb and class III Medical Devices and to class C and class D IVDs for each device and where relevant for each category or group of devices.)   [Reference: MDR Article 86 / IVDR Article 81 on Periodic safety update report]