The new UDI-System

a straightforward overview with a practical example

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CONTENT

THE NEW UDI REQUIREMENT OF THE MDR

The new EU-Regulation (EU) 2017/745 (MDR) requires an unique product identification and the adherence to registration regulation. This requirement applies to medical devices including medical software, but not for custom-made and investigational devices.

The establishment of a new system for „Unique Device Identification (UDI)" shall significantly facilitate safety relevant activities and traceability for products after placing them on the market. The UDI code shall be publicly available through registration in a central database.

The requirement for UDI is new and the central database, Eudamed (https://eudamed.eu/), is not yet accessible for it. Therefore, no practical examples and experiences are available. However, medical device manufacturers must find a way to prepare for the implementation of the UDI system.

This white paper shall provide a straightforward illustration and description of the UDI System, based on a practical example.

THE UDI SYSTEM – EXPLAINED USING A PRACTICAL EXAMPLE

OVERVIEW OF THE UDI SYSTEM

Several codes and involved parties play a role within the UDI system. In a nutshell, the system works as follows:

In order to make the UDI system work, not only the products, but also the manufacturers must register in the central database. The manufacturer requests a so-called **SRN**, the single registration number, at the central database Eudamed. The SRN will be submitted by the competent authority, e.g. by Swissmedic in Switzerland or BfArM in Germany, to the manufacturer. The SRN will appear on each declaration of conformity and some more documents of the respective manufacturer.

The **Basic-UDI-DI** is the primary identifier of a device model, e.g. all sizes of a hip stem. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity, but it won't appear on the product label. A notified issuing agency provides the manufacturer with the requirements for the Basic-UDI-DI.

The same issuing agency provides the requirements as well for the **UDI**, which is the unique device identifier on product level and appears on the product label. Economic actors and some health care providers, which get in contact with the product throughout the supply chain, register the UDI number.

Furthermore, a **nomenclature code** is needed for the products. The nomenclature code is provided through Eudamed by a nomenclature provider.

All these codes and numbers will be filed in the Eudamed database, together with further information of the product and the legal manufacturer, prior to market release.

The following graphic illustrates the UDI system:

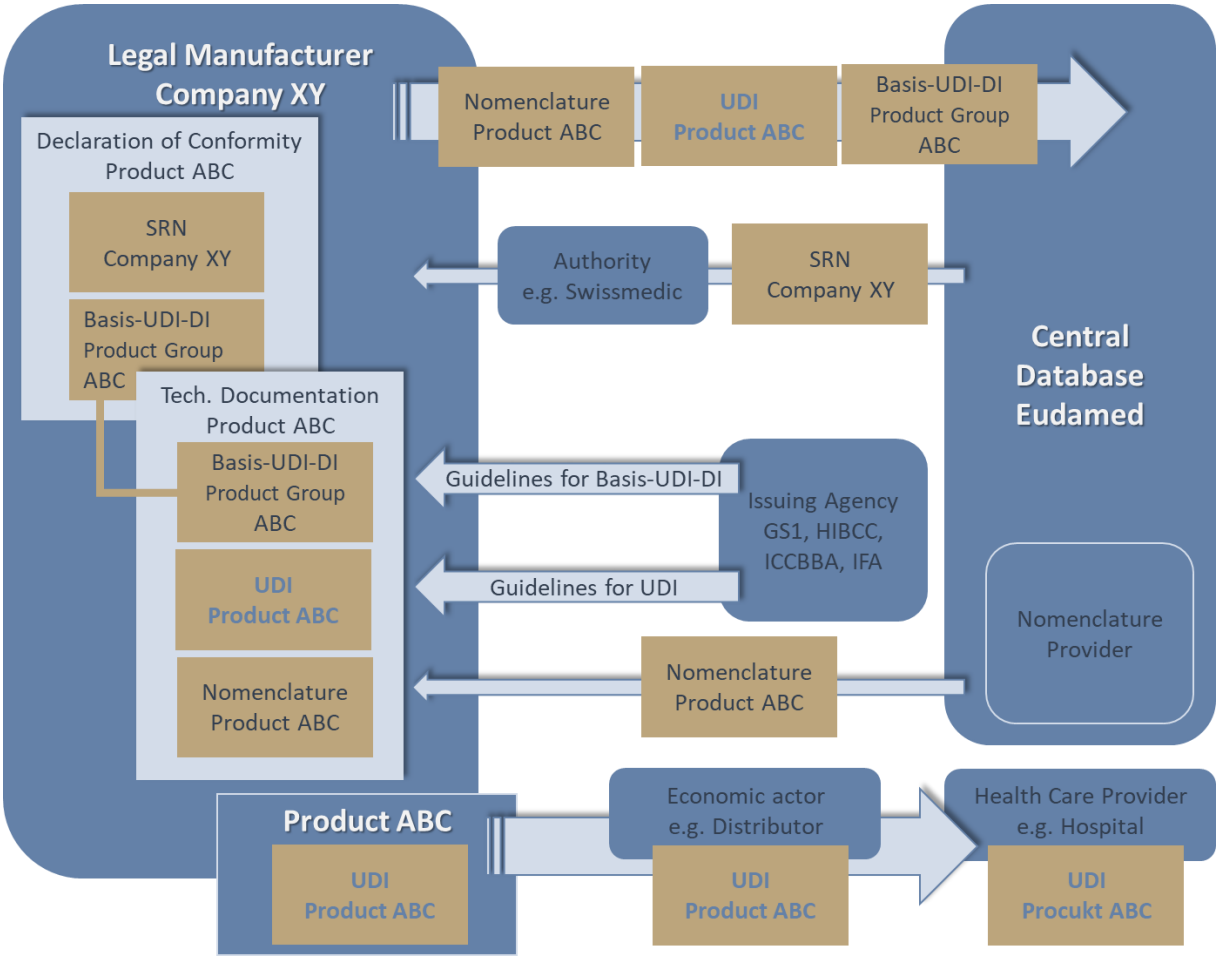


Illustration of the UDI System. © EFFECTUM MEDICAL AG 2019

THE PRACTICAL EXAMPLE

The practical example to describe the UDI system, is an instrument set for an orthopaedic surgery. Let's call it "OrthoSurgery" instrument set. It contains a case with reusable instruments and a set of single use instruments, which are sterile packed in a blister. Although the example doesn't cover implants, information for the UDI of implants has been added to the description of the example, where necessary.

SRN – SINGLE REGISTRATION NUMBER

Manufacturers, authorised representatives and importers who plan to place a medical device on the market, need to be registered in Eudamed. This means for the manufacturer of our "OrthoSurgery" instrument set, he first must register in the Eudamed database and receives his SRN by the local competent authority, who verifies the submitted data. The information required for the submission are listed in chapter "Information relating to Codes" of this white paper. Obtaining an SRN is a onetime task. No later than one year after the registration and thereafter every second year, the accuracy of the data shall be confirmed by the manufacturer.

MDR [1] Article 31

NOMENCLATURE

To facilitate the functioning of Eudamed, an internationally recognised medical device nomenclature shall be available free of charge through Eudamed. The nomenclature has a hierarchical structure and translations into all EU languages. A nomenclature provider keeps the database up to date.

The manufacturer of the example instrument set obtains nomenclature codes for all products of the instrument set.

MDR [1] Article 26, MDCG 2018-2 [5], MDCG 2018-7 [7]

BASIC-UDI-DI

The Basic-UDI-DI is the primary identifier of a device model. In case of an implant set, like for example all sizes of a particular hip stem, the set receives a Basic-UDI-DI.

In our case of the “OrthoSurgery” instrument set, the manufacturer will release a system which contains re-usable instruments and a procedure pack of sterile packed single-use instruments. Systems and procedure packs are both identified by a Basic-UDI-DI. This means, the “OrthoSurgery” instrument set receives a Basic-UDI-DI for the system and another Basic-UDI-DI for the procedure pack. Each individual article of the “OrthoSurgery” instrument set shall be allocated to the respective Basic-UDI-DI.

In order to obtain the Basic-UDI-DI, the manufacturer shall decide for one of the notified issuing agencies, which are Gs1, ICCBBA, HIBCC or IFA. The issuing agency sets the structure of the Basic-UDI-DI.

The Basic-UDI-DI and all related products must be referenced unambiguously in the EU declaration of conformity, in the product description and specification of the technical documentation. The technical documentation specifies the relation between various Basic-UDI-DI’s.

The manufacturer shall provide the Basic-UDI-DI to the Eudamed UDI data base, together with all relating information, which can be found in chapter “Information relating to Codes”. The notified body shall include a reference to the Basic-UDI-DI on the issued certificate and confirmed in Eudamed the correctness of the information. Afterwards, the manufacturer reviews all further information in Eudamed.

MDR [1] Article 29, MDR [1] Annex VI Part A and B, MDCG 2018-1 v2 [3], MDCG 2018-3 [9], MDCG 2018-4 [6], MDCG 2019-1 [10]

UDI – UNIQUE DEVICE IDENTIFICATION

The UDI is the unique device identifier on product level and consists of an UDI-DI and an UDI-PI → **UDI = UDI-DI + UDI-PI.** Broadly speaking, it is a "part number (UDI-DI) + lot number (UDI-PI)", accommodating much more information.

- → The UDI-DI is the "Device Identification" and allows access to various information about the product like e.g. part number, product size, single-use or re-usable, etc. The UDI-DI shall be assigned to a Basic-UDI-DI and must not be allocated to more than one Basic-UDI-DI*.
- → The UDI-PI is the "Production Identifier" and contains the expiry date (or manufacturing date, if there is no expiry date declared) and the lot number.

Higher levels of packaging receive an UDI as well.

Details for information allocated to UDI-DI and UDI-PI can be found in chapter "Information relating to Codes". *MDR [1] Artikel 27, MDR [1] Anhang VI, Teil C, Artikel 1 und 3*

This means for the "OrthoSurgery" instrument set; the manufacturer generates the UDI with guidelines of the issuing agency. Like for the Basic-UDI-DI. Each individual article of the "OrthoSurgery" instrument set receives an UDI. The System itself and the procedure pack need an UDI as well, despite both have a Basic-UDI-DI likewise. Remember, the UDI serves for labelling, the Basic-UDI-DI for administration.

**The allocation of an UDI-DI to only one Basic-UDI-DI seems in many cases as practically not feasible.*

MDR [1] Annex VI, Part C, Article 3.7 and 6.3.1, MDCG 2018-3 [9]

The following graphic illustrates the "OrthoSurgery" instrument set and its components:

Illustration of the example instrument set. © EFFECTUM MEDICAL AG 2019

The now specified UDI-DI will be submitted to Eudamed by the manufacturer, including all data according to chapter "Information relating to Codes" and registered in the technical documentation. The correctness of the data behind the UDI must be reviewed regularly. Changes on the product or relating data might require a new UDI. Changes of data which require no new UDI, shall be updated within 30 days. The UDI-PI will not be submitted to the Eudamed database.

MDR [1] Article 28, MDR [1] Annex VI Part B, MDR [1] Annex VI, Part C, Chapter 3.9.

«OrthoSurgery» Instrument Set

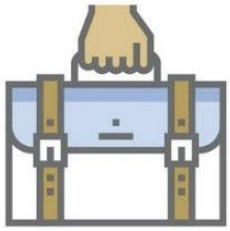
Case with re-usable instruments
Basic-UDI-DI and UDI for the System

- **UDI Instrument 1** - Class IIa Re-usable, nonsterile
- **UDI Instrument 2** - Class IIa Re-usable, nonsterile
- **UDI Instrument 3** - Class IIa Re-usable, nonsterile
- **UDI Instrument 4** - Class Ir Re-usable, nonsterile
- **UDI Instrument 5** - Class Ir Re-usable, nonsterile
- **UDI Instrument 6** - Class Ir Re-usable, nonsterile

Blister with sterile single-use instruments
Basic-UDI-DI and UDI for the Procedure Pack

- **UDI Instrument 7** - Class IIa Single use, sterile
- **UDI Instrument 8** - Class IIa Single use, sterile
- **UDI Instrument 9** - Class IIa Single use, sterile
- **UDI Instrument 10** - Class IIa Single use, sterile
- **UDI Instrument 11** - Class IIa Single use, sterile
- **UDI Instrument 12** - Class IIa Single use, sterile

UDI CARRIER



The UDI carrier is the marking to convey the UDI. It is part of the labelling and it shall be electronically readable (AICD) and readable by humans (HRI). AICD includes linear bar-code, QR-code and RFID (Radio Frequency Identification), whereas when using RFID, a linear bar-code or QR-code is still required. The application of the UDI is an addition and doesn't replace any other labelling requirements.

MDR [1] Annex VI, Part C

The following example illustrates an UDI carrier using a linear barcode:

AICD →

HRI → (01)1 654 64010 (17)20191012 (10)19000123

(01)Device Identifier	(17)Manufacturing-Date (10)Lot-Number
UDI-DI	**UDI-PI**

“OrthoSurgery” instruments 1 to 6 are **re-usable instruments** and therefore, the UDI carrier shall bear an UDI carrier on the device itself. It shall be permanent and remain readable during the entire lifetime of the device. It must be electronically and human readable. If the application of the carrier is technically not possible, or if it would interfere with the safety or performance of the device, it can be omitted. In case of narrow space for marking, the AICD part is to be preferred. The UDI shall be applied as well to the labels of the packaging, which are used for distribution packaging of the instruments. The UDI for the system shall be added to the label of the outer packaging for the complete system. The instrument case is no medical product and doesn’t need an UDI.

MDR [1] Annex VI, Part C, Article 4

The sterile packed **single-use instruments** 7 to 12 don’t require an UDI carrier on the instrument itself, nevertheless, it shall be applied to the outer packaging. In this case, the packaging of the instruments is equivalent with the packaging of the procedure pack. Thus, the packaging of the sterile instruments bears the UDI of the procedure pack plus the UDI’s for instruments 7 to 12. The shipping container doesn’t need an UDI.

MDR [1] Annex VI, Part C, Article 4.3 and 6.3

The following chapter provides an overview on data relating to the codes.

INFORMATION RELATING TO CODES

SRN	1) Type of economic operator (manufacturer, authorised representative, or importer) 2) Company name, address and contact details 3) Name address and contact details of the person responsible for regulatory compliance
Basic-UDI-DI	1) Name or identification number of the notified body 2) Type, number and expiry date of the certificate issued by the notified body[e)] 3) SRN 4) Name /address of manufacturer 5) Devices manufactured by another legal or natural person: name, address and contact details of that manufacturer 6) Member State in which the device is to or has been placed on the market in the Union 7) Class IIa, class IIb or class III devices: Member States where the device is or is to be made available 8) Risk class of the device 9) Measuring function (y/n) 10) Implantable (y/n) 11) Reprocessed single-use device (j/n) 12) Active device (y/n) 13) Intended to administer / remove medicinal substance (y/n) 14) Presence of a medicinal product (y/n) and name of that substance 15) Presence of a medicinal product derived from human blood or human plasma (y/n) and name of this substance 16) Presence of tissues or cells of human origin, or their derivatives (y/n) 17) Presence of tissues or cells of animal origin, or their derivatives (y/n) 18) * Identification number or link to electronic system of clinical investigations 19) * Specification as to whether the intended purpose of the device is other than a medical purpose 20) Class III products /implants: summary of safety and clinical performance 21) Status of the device[c)]
UDI-DI[d)]	1) UDI-DI value 2) Quantity per package 3) Basic-UDI-DI 4) Additional UDI-DI 5) * Reference /catalogue number 6) * Device model 7) Direct marking (y/n) 8) * Unit of use UDI-PI 9) Type of UDI-PI[a)] 10) Name and address of the manufacturer 11) SRN 12) * Name and address of the authorised representative 13) Nomenclature Code 14) Risk class[b)] 15) * Name/trade name 16) * Additional product description 17) * Clinical size 18) * Storage /handling conditions 19) Single use (y/n) 20) * Maximum number of reuses

	21) Sterile (y/n) 22) Need for sterilisation before use (y/n) 23) Containing latex (y/n) 24) * Information labelled in accordance with Section 10.4.5 of Annex I 25) * URL for additional information (eIFU, etc.) 26) * Critical warnings /contra-indications 27) Status of the device [c)] 28) Systems /procedure pack: UDI-PI 29) Systems /procedure pack: Indikation
UDI-PI[e)]	1) Serial number /lot number 2) Expiry date 3) Manufacturing date, if expiry date is not applicable

* if applicable
a) Type of UDI-PI: Expiry or manufacturing date, lot number, serial number
b) For systems and procedure packs: highest risk class of included products
c) Status of the device: on the market, no longer placed on the market, recalled, field safety corrective action initiated
d) UDI-DI for systems and procedure packs require only the information marked in blue
UDI-DI for packaging require only: quantity, name/address of manufacturer and status of the device [c)]
e) No registry in the Eudamed database

MDR [1] Annex VI, Part A and B, UDIWG 2018-2 [4], MDCG 2018-4 [6], UDIWG 2018-1 [8].

OVERVIEW ON DOCUMENTS AND INCLUSION OF CODES

The following table provides an overview on the documents on which the new codes like SRN, Basic-UDI-DI and UDI will be included:

Document	SRN	Basic-UDI-DI	UDI
EU declaration of conformity	X	X	
Conformity assessment	X	X	
Certificate of free sale		X	
Tech. doc. Product describtion and specification		X	
Tech. doc. Information to be supplied by the manufacturer, up-to-date List			X
Reporting of serious incidents and field safety corrective actions	X		X
EU technical documentation assessment certificate		X	
EU type-examination certificate.		X	
EU product verification certificates		X	
Summary of safety and clinical performance (Class III)	X	X	
Implant card for Patients			X

LEGACY DEVICES

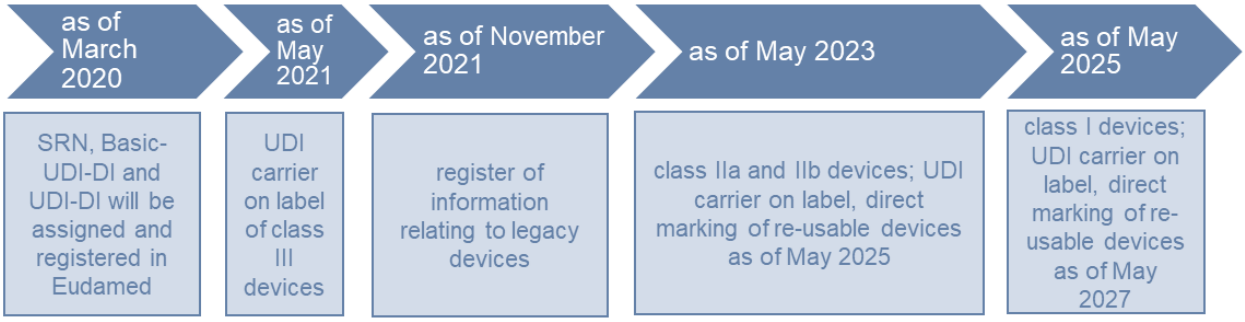
Devices released according to MDD which can continue to be placed on the market after the relevant MDR application date, should be registered in Eudamed without a Basic-UDI-DI and UDI-DI. In order to allow the system to work and to be as close as possible to the new system, an Eudamed-DI will be assigned to the device instead of a Basic-UDI-DI and an Eudamed-ID will be assigned by Eudamed instead of the UDI-DI. *MDR [1] Article 120-3, MDCG 2019-5 [12]*

THE UDI SYSTEM IN THE USA

The US-system already uses an UDI system for medical devices. However, the US-System doesn't use a Basic-UDI-DI and the US system uses a different database; the GUDID database. UDI codes guarantee a worldwide unambiguous identification of a device, the big difference between the EU-UDI system and the US-UDI system are the registration and the required data relating to codes.

IMPLEMENTATION

The roadmap for the implementation of the UDI according to MDR [1] is as follows:



MDR [1] Article 123, MDCG 2019-4 [11]

It has been announced, that the release of Eudamend will be delayed for 2 years. As a consequence, transitional measures for the MDR implementation will be further defined.

CONCLUSIONS

Since the UDI system is new and no experiences are available, possible obstacles which can't be anticipated could occur for all involved parties. In any case it may be wise, to observe all activities around the UDI system, to be prepared without acting overhasty. Identify possible hurdles as early as possible and find a way to handle them. Independently from possible obstacles, patience for the implementation might be valuable in any case.

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ABBREVIATIONS

AIDC	Automatic Identification and Data Capture
EAN	European Article Numbering
GMDN	Global Medical Devices Nomenclature
Gs1	Issuing Agency for UDI
GTIN	Global Trade Item Number of GS1 (former EAN-System)
HIBCC	Issuing Agency for UDI (Health Industry Business Communication Council)
HRI	Human Readable Interpretation
ICCBBA	Issuing Agency for UDI (International Council for Commonality in Blood Banking Automation)
IFA	Issuing Agency for UDI (Informationsstelle für Arzneispezialitäten GmbH)
IMDRF	International Medical Device Regulator Forum
MDCG	Medical Device Coordination Group of the European Commission
MDR	Medical Device Regulation
RFID	Radio Frequency Identifacation
SRN	Single Registration Number
UDI	Unique Device Identification
UDI-DI	UDI-Device Identification
UDI-PI	UDI-Production Identifier
UMDNS	Universal Medical Device Nomenclature System

REFERENCES

[1] EU-Regulation (EU) 2017/745 (MDR)

[2] MDCT Guidance - https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en

[3] MDCG 2018-1 v2 – Guidance on BASIC UDI-DI and changes to UDI-DI

[4] UDIWG 2018-2 – The architecture of the UDI database

[5] MDCG 2018-2 – Future EU medical device nomenclature

[6] MDCG 2018-4 – Definitions/Descriptions and formats for the UDI core elements for systems and procedure packs

[7] MDCG 2018-7 – Provisional considerations regarding language issues associated with the UDI database

[8] UDIWG 2018-1 – UDI Database, Definitions/Descriptions and formats of the UDI core elements

[9] MDCG 2018-3 – Guidance on UDI for systems and procedure packs

[10] MDCG 2019-1 – MDCG guiding principles for issuing entities rules on Basic UDI-DI

[11] MDCG 2019-4 – Timelines for registration of device data elements in EUDAMED

[12] MDCG 2019-5 – Registration of legacy devices in EUDAMED