UDI in the EU MDR – How Different is it from the US FDA?

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Learning Objectives

- ✓ **Overview** of fundamental UDI concepts
- ✓ **Review** the requirements of UDI in the EU MDR
- ✓ **Highlight** the key differences between the EU & US systems
- ✓ **Review** the timelines for implementation

The Basics

Unique Device Identification – the Process

General term for a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard

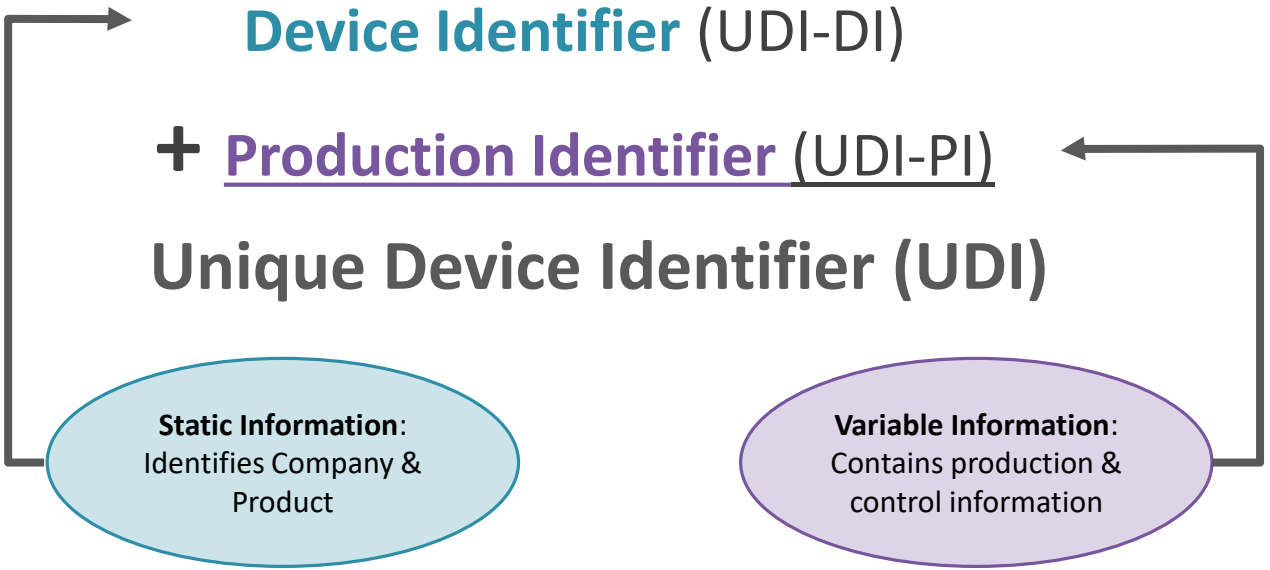
- i.e. GS1, HIBCC, ICCBBA

Allows the unambiguous identification of a specific device on the market

“Unique" does not imply serialization of individual production units

Unique Device Identifier – the Tool

Unique numeric or alpha-numeric code that includes:



UDI – Why Do We Need It?

Provide more efficiency, accuracy and automation of capturing device information through automation

- Supply chain
- Electronic health records
- Global device registries

Better visibility of device supply & movement through the supply & distribution chain to the patient

Improved visibility & management of adverse events, recalls and post-market surveillance

Definitions

ANNEX VI, PART C

Basic UDI-DI

Main key for records in the UDI database & relevant documents

- i.e. certificates, declarations of conformity, technical documentation

Associates devices with same intended purpose, risk class, and essential design & manufacturing characteristics

- Unique to each organization

Independent/separate from the packaging & labeling

- Does **not** appear on trade item

Each certificate identifies & covers all devices associated with the same Basic UDI-DI (B-UDI)

Device Identifier (UDI-DI)

Static portion of the UDI

Unique numeric/alphanumeric code specific to a model of device

Used as the '**access key**' to information stored in a UDI database

Contains company & device Information:

- Company
  - Name & Address
- Product
  - Product Name
  - GMDN Code & Term

Critical for IDENTIFICATION of DEVICE and the DEVICE MANUFACTURER

Production Identifier (UDI-PI)

Dynamic/Variable portion of the UDI

Not included in the UDI database

Contains dynamic information specific to **production controls**

- Lot/Batch/Serial Data
- Expiration Date
- Manufactured Date

Critical for TRACEABILITY of DEVICE and the PATIENT LEVEL

UDI Database

Eudamed = the European database for medical devices

Integrate electronic systems to collate and process information regarding devices on the market

Objectives of the database:

- **Enhance** overall **transparency & coordination** between Member States
- Allow better **access to information** for the public and healthcare professionals
- Avoid multiple **reporting** requirements
- Streamline & facilitate the **flow of information** between EO, NB, sponsors and Member States

Automatic Identification & Data Capture - AIDC

Technology used to **automatically capture data**

AIDC technologies include **bar codes**, smart cards, biometrics and RFID

Human Readable Interpretation - HRI

Legible interpretation of the data characters encoded in the UDI carrier

UDI Carrier

Method used to **present the AIDC** and HRI information

UDI Carrier Types:

- Linear
- 2D Matrix
- RFID

UDI Carrier | Barcode Format
GS1

(AI) codes = **Application Identifiers**

Used to **identify pieces of data**

- (01) = GTIN (Global Trade Identification Number)
- (10) = Lot/Batch Number
- (17) = Expiration Date

http://www.idautomation.com/barcode-properties/definitions/gs1-application-identifiers.html

http://www.gs1.org/healthcare/udi

UDI Carrier | Barcode Format HIBCC

"**+**" indicates HIBC barcode structure

Primary Data Structure includes:

- LIC = Labeler Identification Code (4 characters)
- PCN = Product/Catalog Number (1-13 characters)
- U/M = Unit of Measure Identifier (1 digit)

Secondary Data Structure may include:

- Quantity/Date Fields
- Lot/Batch/Serial Number fields
- Link Character

http://www.neodynamic.com/Products/Help/BarcodeWPF4.0/barcodes/HibcLic128.htm

http://www.hibcc.org/udi-resources/

EU MDR Requirements - UDI

ANNEX VI, PARTS A, B, C

Article 27 – Unique Device Identification System

(1) States the **requirement for implementing** a UDI system

(2) Specifies need to designate one or multiple '**issuing entities**' to assign UDI

(3) Manufacturer must **assign a UDI** to the device and all higher levels of packaging **before placing the device on the market**

(4) UDI carriers shall be placed on the **label of the device** and on all **higher levels of packaging**

Article 27 – Unique Device Identification System

5) UDI must be used for **reporting serious incidents and field safety corrective actions**

6) **Basic UDI-DI** must appear on the **EU declaration of conformity**

7) Manufacturer must keep a **current list of all assigned UDIs** in the technical documentation

Articles Related to UDI

ARTICLE #	TITLE
27	UDI System
28	UDI Database
29	Registration of Devices
31	Registration of manufacturers, authorized representatives and importers (issuing of SRN)
32	Summary of safety and clinical performance
60	Certificate of free sale

Annexes Related to UDI

ANNEX #	TITLE
II	Technical documentation
IV	EU declaration of conformity
VI, part A	Information to be submitted upon the registration of devices and economic operators
VI, part B	Core data elements to be provided to the udi database together with the UDI-DI
XII	Certificates issues by a notified body

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Separate UDIs Required…

System

- products combined to achieve a medical purpose

Configurable device

- device consisting of several components

Procedural pack

- products packaged for a medical purpose

UDI must also be on the individual devices/packages or components of a system, configurable device, or procedural pack

UDIs are NOT Required…

SUDs not intended for use outside of the system/pack

Devices that are already exempt

Configurable Device vs System

Configurable device:

consists of several components that can be assembled by the manufacturer in multiple configurations

System:

combination of products, either packaged together or separately, that are intended to be inter-connected or combined to achieve a specific medical purpose

UDI for Implantable Devices

UDI placed on **lowest level of packaging**

Active implantable devices must have a **serial number** as part of the UDI-PI

The device UDI must be **identifiable prior to implantation**

Implant card with the UDI on it must be provided with the device

UDI for SaMD

Software that is a **device and separately distributed** must have its own UDI

UDI assigned at the **system level**

UDI on the label (with AIDC & HRI) and software must be **identical**

HRI must be on **readily accessible screen** (i.e. About)

Direct Marking

Reusable devices must have UDI carrier (**AIDC and HRI**) on the device itself

UDI on reusable devices requiring processing between uses must be **permanent** & **readable throughout the intended lifetime** of the device

UDI on the label (with AIDC & HRI) and software must be **identical**

DM **not required** if it **interferes with safety and performance** or is not **technologically feasible**

Exceptions…

Custom & Investigational Devices

Devices for retail/POS do not need the UDI-PI in AIDC on the POS UDI label

Individually packaged and sold Class I and IIa SUDs

- bulk packaged SUDs can have UDI on higher level packaging

Significant space constraints on the Unit of Use packaging

- place UDI on the next higher level of packaging

If limited space for both AIDC and HRI on label, only AIDC required

- unless intended for home care – then HRI on label and no AIDC

Key Differences

EU MDR UDI VS US FDA UDI

Differences in Requirements

EU MDR UDI	US FDA UDI
Class I devices – must have both DI & PI	Class I devices – only required to have DI
SUD packaging exception – limited to Class I/IIa devices	SUDs of all classes (except implants) sold individually do not need UDI (UDI must be on the bulk packaging)
UDI on label & software must be identical	Software distributed in both packaged & unpackaged form **may** be identified with the same device identifier
Cleaning is considered processing for reusable devices; No DM exemption allowed	FDA mentions sterilization and disinfection but not cleaning
Manufacturers are responsible for UDI	Labelers are responsible for UDI

Database Elements - Eudamed

1. Quantity per package configuration
2. **Basic UDI-DI**
3. UDI-PI Controls
4. Unit of use UDI-DI
5. Manufacturer name and address
6. **Single Registration Number (SRN)**
7. **Authorized representative name and address**
8. Medical device nomenclature code (GMDN)
9. **Risk class of device**
10. Name or trade name
11. Device model, reference, or catalog number
12. Clinical size

Database Elements - Eudamed

13. Product description *(optional)*
14. Storage and/or handling conditions
15. Additional trade names
16. Labeled as single use
17. **Max number of reuses**
18. Device labeled sterile
19. Sterilization needed before use
20. Contains latex
21. Labeled carcinogenic, mutagenic, or toxic to reproduction
22. **URL for additional information**
23. Critical warnings or contra-indications
24. Status of the device in the market

Database Elements – Additional Fields in GUDID

- Issuing agency
- Device count
- Labeler DUNS number
- Version or model
- DI record publish date
- Commercial distribution end date
- DM exempt
- DM DI different from primary DI
- DM DI number
- Secondary DI information
- Previous DI information
- Package DI number
- Contains DI number
- Package type
- Package discontinue date
- Package status

Database Elements – Additional Fields in GUDID

- Customer contact phone
- Customer contact email
- Human cell, tissue or cellular based
- Kit
- Combination product
- Device exempt from premarket submission
- FDA premarket number
- Supplement number
- FDA product code
- FDA listing number
- Donation identification number
- Rx
- OTC
- MRI safety information
- Sterilization method

Database Translations

Data fields common to both GUDID and Eudamed

Will likely need to be **translated into the 24 official languages** of the EU

- Name or trade name
- Additional product description
- Additional trade name
- Clinical size (volume, length, gauge, diameter)
- Storage and/or handling conditions
- Critical warnings or contra-indications
- Name & address of AR
- CMR and/or endocrine-disrupting substances

Implementation Dates – MDR UDI

Device Class	Labels & Packaging	Direct Marking (reusable devices)	Eudamed Database
Implantable & Class III	26 May 2021	26 May 2023	26 May 2020
Class IIa and Class IIb	26 May 2023	26 May 2025	26 May 2020
Class I	26 May 2025	26 May 2027	26 May 2020

BEFORE placing a device on the market:
Assign the Basic UDI-DI & submit to Eudamed along with the core data elements

Implementation Dates – MDR UDI

Type of Device	FDA does not intend to enforce UDI labeling, GUDID Data Submission, and Standard Date Format requirements before:	FDA does not intend to enforce Direct Mark requirements before:
Class 1 and unclassified devices manufactured and labeled on or after September 24, 2018	24 Sept 2020	24 Sept 2022
Finished class 1 and unclassified devices manufactured and labeled before September 24, 2018	24 Sept 2021	24 Sept 2022

Have Questions? Need Help?

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