MEDICAL DEVICE REGULATION (MDR) 
EUROPE

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AGENDA

I. MDR overview
II. UDI requirements
III. EUDAMED
IV. Conclusion
EU Regulation MDR 2017 / 745

KEY DATES
MDR Publication → 05 May 2017
Entry into force → 26 May 2017
Date of Appl. → 26 May 2020
Transition Period → 26 May 2024

10 chapters - 123 articles - 17 annexes
175 pages - replaces the MDD 93/42/EC

Scope / Definitions
Making available + putting into service, obligations economic operators, reprocessing, CE marking, …
Identification, traceability, registration of economic operators + devices, EUDAMED, …
Notified Bodies
Classification / conformity assessment
Clinical evaluation / investigation
Post-market surveillance, vigilance, market surveillance
Cooperation between MS, Med Dev Coord. Group, expert panels, …
Confidentiality, data protection, funding, penalties
Final provisions

Anx | Subject
---|---
I | General safety + performance requirements
II | Technical documentation
---|---
VII | Registration + UDI
---|---

SCOPE
all Medical Devices
Except:
Custom-made dev
Perform.study/investig. dev
MDR Building Blocks

- Classification
- Technical Documentation
- Scrutiny
- Clinical Evidence
- Vigilance
- Person responsible for Regulatory Compliance
- Market Surveillance
- Notified Bodies
- UDI
- EUDAMED
MDR Building Block 1

- Recertification of all approved devices
- Reclassification / new classification rules
- Stricter pre-market control (high risk dev)
- Structure of RMF changes / more content
MDR Building Block 2

- New rules/more clinical investigat.
- More rigorous clinical evidence
- Publ. of safety + performance data
- NB’s increased authority (PMS)
- Unannounced audits (MD sample checks)
- Strengthening PMS requirem. MFR
- Periodic Safety Reports (4 types)
Person responsible for:

- product conformity checked before batch release
- Tech. doc up-to date
- Vigilance reports, FSCA, …

NB:
- re-accreditation
- Strengthened designation criteria
- Number will be reduced
MDR Building Block 4

- Classification
- Technical Documentation
- Scrutiny
- Clinical Evidence
- Vigilance
- Person responsible for Regulatory Compliance
- Market Surveillance
- Notified Bodies
- UDI
- EUDAMED
UDI Requirements in a Nutshell

In accordance with the new rules, any manufacturer before placing a device on market shall assign to the device and to all higher levels of packaging a UDI.

The UDI carrier shall be placed on the label of the device, on all higher levels of packaging and in some cases on the device itself.

Before a device is placed on the market the manufacturer shall ensure that the information – related to the device in question - referred to in Part B of Annex VI of the two Regulations (MDR / IVDR) is correctly submitted and transferred to the UDI database.

The manufacturer is the entity responsible for complying with all UDI related requirements.

4 Issuing Entities
GS1 – HIBCC – ICCBBA – IFA
UDI Labeling + Direct marking

**UDI placed on Device Labels**

**AIDC + HRI**
- all package levels (excl. shipper)
- UDI containing DI + PI

**Space constraints**
- on Base Pack → UDI on next Higher Package Level
- to print both AIDC + HRI → AIDC has the higher priority

**Single-use devices of EU risk-class I or IIa**
- no UDI on Base Pack require

**Special rules for certain device categories**

**AIDC technology neutral**

**AIDC Quality** acc. IE rules (ISO quality grade)

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**UDI placed on the Device itself**

**Reusable devices subject of DM**

**AIDC + HRI**
- UDI containing DI + PI

**Permanent readable** throughout the intended lifetime

**Exceptions:**
- DM interferes with the safety/performance
- Technologically not feasible
- Space constraints (AIDC has the higher priority)

**AIDC technology neutral**

**AIDC Quality** according to the IE rules (ISO quality grade)
### UDI Labeling Requirements

**UDI Carrier:** AIDC & HRI

**Remark:** UDI Carrier means AIDC + HRI (human-readable information), in case of significant space constraints on the label → AIDC has the higher priority.

<table>
<thead>
<tr>
<th>Category</th>
<th>Unpackaged Item DM (direct marking)</th>
<th>Base Package</th>
<th>Bulk Package (higher package config.)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-use MedDev</td>
<td>-</td>
<td>-</td>
<td>DI + PI</td>
<td></td>
</tr>
<tr>
<td>• Risk-class 1 + 2a</td>
<td>-</td>
<td>-</td>
<td>DI + PI</td>
<td></td>
</tr>
<tr>
<td>• Risk-class 2b</td>
<td>-</td>
<td>DI + PI</td>
<td>DI + PI</td>
<td></td>
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<tr>
<td>• Risk-class 3</td>
<td>-</td>
<td>DI + PI</td>
<td>DI + PI</td>
<td></td>
</tr>
</tbody>
</table>

**Reusable MedDev**

- all risk-classes: DI + PI

- Bulk Package: DI + PI

- Remarks: need sterilization/disinfect. prior to use

- DM not required if:
  - it interferes with safety or performance of the device
  - not technologically feasible

| Implants                | -                                 | DI + PI      | -                                     |         |
|• active / non-active    | -                                 | DI + PI      | -                                     |         |

- Remarks: active: PI must incl. Serial No, non-active: PI may incl. Serial No

| Others                  | -                                 | DI + PI      | -                                     |         |
|• Systems / Proc. Packs  | -                                 | DI + PI      | -                                     |         |
|• MedDev Software        | DI + PI                           | DI + PI      | -                                     |         |
|• Configurable Devices   | DI + PI                           | -            |                                       |         |
|• OTC exclusively        | -                                 | -            | DI                                   |         |
|• OTC + other channels   | -                                 | -            | DI + PI (non-concatenated)           |         |

### Risk-class depending
- Labeling requirements
- Implementation timelines 2021 – 2023 – 2025 (DM + 2Y)

**Device as per Regulation (EU) 2017/745 (MDR)**

<table>
<thead>
<tr>
<th>Class Ia and Class IIb devices</th>
<th>Class I devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placing UDI-carriers on the labels of devices MDR Article 123(3)(f), Article 27(4)</td>
<td>26 May 2021</td>
</tr>
<tr>
<td>Direct marking of the reusable devices MDR Article 123(3)(g), Article 27(4)</td>
<td>26 May 2023</td>
</tr>
</tbody>
</table>
EUDAMED – Core of the legislation

Complex DB-System with different modules & functionalities

UDI Data for SINGLE devices & package levels (highest data granularity)

Device - Registration
Data for an entire FAMILY of devices

6 Modules:
- REG – Registration
  - ACT – Actor (SRN)
  - DEV – Device (Basic UDI)
- UDI
- CERT – Certificates
- VIG – Vigilance
- PMS – Market Surveillance
- CI – Clinical Investigation

Manufacturer, Authorized Rep, Syst/Proc-Pack Producer, Importer, Notified Body
Device Family: Characteristics + Identification

Consists of one or many family members (single devices)

All family members:
• share the same documentation
  - Certificate (incl. CERT for free-sale)
  - Declaration of conformity (DoC)
  - Technical documentation (Regulatory Master File)
  - Summary of safety and clinical performance
• have the same
  - intended purpose
  - EU device risk-class
  - essential design and manufacturing characteristics

Family to be identified by a ‘BASIC UDI-DI’
Device Identifier Types

Basic UDI-DI  (GS1 Standard = Global Model Number)

**FIGURE 1. Structure of the GMN for regulated healthcare medical devices**

<table>
<thead>
<tr>
<th>GS1 Company Prefix</th>
<th>Model reference</th>
<th>Check characters</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>( N_1 \ldots \ N_i \ X_{i+1} \ldots ) variable length</td>
<td>( X_j \ (j=23) ) ( X_{j+1} \ X_{j+2} )</td>
</tr>
</tbody>
</table>

UDI-DI
- Lowest package level (Base Pack) of the devices with a device label
- Can also be the device itself (e.g. in case of reusable devices / direct marking)

DM-DI
- DI of the unpackaged reusable device (in case the device is direct marked)

Package-DI
- Higher package configurations (e.g. Box of 10 Pieces, Carton of 100 Pieces)
- Shipper case is out of scope

Unit-of-Use DI
- In case the lowest package level (Base Pack) contains more than 1 piece

How does that fit together?
Hierarchy of a Device Family (example)

**Device Family**
- 1 - 1
- 1 - n

**Family Members**
- 1 - 1
- 1 - n

**Package Levels**
- level of GTIN allocation according GS1 Standards (always linked to a pack.level)

- GS1 : DI = GTIN

**RULE**: an UDI-DI can only be linked to ONE Basic UDI-DI

<table>
<thead>
<tr>
<th>Level</th>
<th>Qty</th>
<th>DI</th>
<th>Qty</th>
<th>DI</th>
<th>Qty</th>
<th>DI</th>
</tr>
</thead>
<tbody>
<tr>
<td>UoU-DI</td>
<td>1</td>
<td>D</td>
<td>1</td>
<td>D</td>
<td>1</td>
<td>I</td>
</tr>
<tr>
<td>Base Pack</td>
<td>1</td>
<td>A</td>
<td>15</td>
<td>E</td>
<td>1</td>
<td>I</td>
</tr>
<tr>
<td>2nd</td>
<td>50</td>
<td>B</td>
<td>45</td>
<td>F</td>
<td>10</td>
<td>H</td>
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<tr>
<td>3rd</td>
<td>250</td>
<td>C</td>
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**Device Family**

- Basic UDI-DI
- UDI-DI
- DM-DI
- Unit-of-Use DI
- Package-DI
EUDAMED Data Elements
Modules : DEV & UDI

MODULE

Device Family

Member 1

Member 2

Member 3

UDI

PL1

PL2

PL3

UDI-DI

UoU-DI + DM-DI

Package-DI

3 different data sets

- Data for a device family → Basic UDI-DI
- Data for a single device → UDI-DI (+ UoU-DI + DM-DI)
- Data for a package level of a single device → Package-DI

- Limited data set for Systems or Procedure Packs
EUDAMED – Data input options

Web based forms
- Manual input - time consuming
- Only for a low number of devices suitable

Bulk upload via web form
- XML data – validation against 100’s of rules
- Semi-automatic communication in one direction (failed uploads logged)

Machine-to-Machine (M2M)
- Mass data (high number of devices)
- XML data – validation against 100’s of rules
- Full-automatic communication in both directions
- Requires an access point for secure data transmissions (eDelivery)
EUDAMED Development Roadmap

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<td>ACT</td>
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<td>UDI</td>
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<td>minor</td>
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<td>CERT</td>
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2 years delay!

Decision: 31. Oct 2019

How to bridge the gap?
- apply corresponding MDD provisions

Consequences? (MFR, NB, CA)
- BUDI/UDI-DI assignment?
- Tech. Doc?
- Incident reporting?
- Transition period (May 2024)?
- ...

→ to be analyzed
EUDAMED – what’s so special?

- **Interdependencies** between the EUDAMED modules – it’s not just data, it’s process management.
- **MFR to implement** new processes and to define new roles and responsibilities.
- **Complexity of the IT project.**
- **Late publication** of technical specs + data validation rules for M2M data input option.
- **Digitalization of regulatory processes.** (COM, CA, NB, and EO’s)
Conclusion (1) : Main Obligations in relation to UDI

**Manufacturers**
- UDI assignment
- Placement of the UDI carrier
- Initial data submissions into EUDAMED
- Updates EUDAMED records within 30 days in case of data changes

**Distributors and Importers**
- Verify whether a UDI has been assigned by MFR

**All Economic Operators and Health Institutions**
For risk-class 3 implantable devices:
- Store and keep - preferably by electronic means - the UDI of the devices which they have supplied or which they have been supplied

*Remark: expansion of the scope possible through implementing acts!*
Conclusion (2)

MDR is a complex regulation – **UDI is just one part**

Regulation describes the **WHAT** (available since May 2017)

Tech. Specs + Impl. Guidance to describe the **HOW**
  - Late publication / some are still pending !
  - Growing list of guidance docs available

Concept of **Basic UDI-DI** is a ‘Novum’
  - Must be well defined & implemented by MFR !

**EUDAMED is the heart of the MDR**

**a functioning DB-system is key!**

**MDR implementation is the biggest challenge for MFR since years!**
- new processes + data handling, tech. doc. changes, new certification, multi-million budget -
THANK YOU VERY MUCH FOR YOUR TIME

QUESTIONS?