MDR: navigating the grey or Successful Practices for Procedural Hurdles

Phil, Mindy, Gert
A few examples...
EU MDR/UDI
# MDR UDI Requirements

The Unique Device Identification (‘UDI’) system described in the MDR shall allow the identification and facilitate the traceability of devices, other than custom-made and investigational devices, and shall consist of...

<table>
<thead>
<tr>
<th>Basic-UDI-DI</th>
<th>Device Identification (Label &amp; DM)</th>
<th>EudaMed</th>
<th>Traceability</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Basic-UDI-DI" /></td>
<td><img src="image2" alt="Device Identification" /></td>
<td><img src="image3" alt="EudaMed" /></td>
<td><img src="image4" alt="Traceability" /></td>
</tr>
</tbody>
</table>

a) Assignment of Basic UDI-DI (GMN) - the main 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.

b) A UDI comprised of:
   (i) A device identifier (‘DI’) specific to a manufacturer and a device,
   (ii) A production identifier (‘PI’) that identifies the produced device’s unit and if applicable the packaged devices

c) Application of the UDI on the label of the device or on its package...

d) Application of the UDI on the device itself (direct mark), if a reusable device

e) An electronic database to enable unique identification of devices and to facilitate their traceability Article 33

f) Storage of the UDI by the economic operators, the health institutions and the healthcare professionals, according to the conditions established in Article 27...

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1. MDCG 2018-1 v2
Where Basic UDI-DI and UDI are used

Where UDI (UDI-DI + UDI-PI) is used

Where Basic UDI-DI & UDI are assigned

Premarket

Manufacturing

Distribution

Customer

Post market / Compliance
UDI Implementation Timeline

- MDCG 2019-4 & 2019-5 – Submission of UDI Core data elements MDs – for MDR and legacy devices
- EO registration (Annex VI Part A, Section 1) to obtain SRN
- Assignment of Basic-UDI-DI and UDI-DI

MDR Publication and Entry to Force

May 2017

MDR DATE OF APPLICATION

May 2020

UDI Core Element submissions

May 2021

Labeling Class III & Implantables

May 2022

Labeling Class IIa & IIb (Class D IVDs) & DM Class III

May 2023

UDI Core Element IVDR submissions

May 2024

Labeling Class I (Class C & B IVDs) & DM Class II

May 2025

DM Class I (Class A IVDs)

May 2026

UDI on labels and Direct Marking

May 2027

Nov. 2021

EO registration (Annex VI Part A, Section 1) to obtain SRN

Assignment of Basic-UDI-DI and UDI-DI

Submission of UDI Core data elements MDs – for MDR and legacy devices

Nov. 2023

UDI Core Element IVDR submissions

May 2022
EUDAMED

Gert
When EUDAMED is in place (26-5-2020 or later)

- **Manufacturer**
  - Obtain SRN
  - Assign UDI-DI, UDI-PI, basic UDI
  - Use UDI in vigilance
  - Use UDI in DoC
  - Keep UDI listing
  - UDI tracing in distribution chain
  - Get UDI on FSC
  - SSCP to NB
  - PSUR to NB
  - Vigilance to EUDAMED
  - FSCA / FSN to EUDAMED
  - In time place UDI on labeling (art 123)

- **Manufacturer**
  - Register as EO
  - Provide UDI data in UDI database
  - Potentially provide and upload historic documentation on SSCP, PSUR and vigilance, since start of MDR
When EUDAMED is NOT YET in place

- **Manufacturer**
  - Obtain SRN
  - Assign UDI-DI, UDI-PI, basic UDI
  - Use UDI in vigilance
  - Use UDI in DoC
  - Keep UDI listing
  - UDI tracing in distribution chain
  - Get UDI on FSC
  - SSCP to NB
  - PSUR to NB
  - Vigilance to CA
  - FSCA / FSN to CA

- **Manufacturer to collect information for backfilling EUDAMED within 6 months of go-live date**
  - Registration data as EO
  - UDI data
  - Potentially provide and upload historic documentation on SSCP, PSUR and vigilance, since start of MDR

- **UDI system for UDI**
  - E-system for UDI
  - SRN database
  - CE certificates
  - Clinical
  - Vigilance
  - COEN exchange

- **Manufacturer**
  - In time place UDI on labeling (art 123)
Single Registration Numbers (SRNs)

courtesy: Emergo

• Code used for unambiguous identification of an economic operator (EO) within EU.

• Each SRN is linked to a specific role for a specific EO, and therefore each SRN will have different authorities regarding data entry and access to specific records.

• Local User Administrators (LUAs) are appointed when an SRN has been requested.
  • LUA can authorize local users within SRN. Users may have different access levels.

• The SRN and LUA will be issued/appointed by the relevant National Competent Authority. For EU-based organizations this is the Competent Authority of the Member State where they are based. For non-EU manufacturers this will be the Member State where their AR is based, and for non-EU sponsors this will be the Member State where their Legal Representative is based.
EU MDR: Successful Practices for Procedural Hurdles

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# Unknown Unknowns

<table>
<thead>
<tr>
<th>What I Know</th>
<th>What I Know I don’t know</th>
<th>What I know I really don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDR</td>
<td>Eudamed</td>
<td>NB delays / bottleneck</td>
</tr>
<tr>
<td>Roadmap and Rolling Plan</td>
<td>UDI</td>
<td>Brexit</td>
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<tr>
<td>MDCG Guidance</td>
<td>NB Designation</td>
<td></td>
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<td></td>
<td>Common Specifications</td>
<td></td>
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<td></td>
<td>Implementing Acts</td>
<td></td>
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<tr>
<td></td>
<td>Harmonized Standards</td>
<td></td>
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<tr>
<td></td>
<td>Guidance</td>
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</tbody>
</table>
What I Know

**Europa**


**Roadmap**


**Guidance**


**Rolling Plan**

https://ec.europa.eu/docsroom/documents/34941
What I Don’t Know

UDI
Certificates of free sale
PMCF
Borderline Devices
EUDAMED
Nanomaterials
Notified Bodies Designation
Clinical Evaluation
Common Specifications
Reprocessing of single-use medical devices

Products without a medical purpose
Implementing Acts
Electronic Forms
Expert panels
Interpretation of Notified Body requirements
Delegated Acts
Devices requiring clinical evaluation consultation
Application of GSPR

Market actions
IVD Class D
SSCP
Reporting and FSCA
MDCG Guidance Documents
Reporting and FSCA
PMS
.....the practical approach
Common Specifications

Requirements for:
- Clinical investigation, clinical evaluation, PMCF
- Risk management
- GSPR
- Other?

For specific devices:
- Devices with no medical purpose (Q1 2020)
- Reprocessing single-use medical devices (November 2019)
- Implantable devices
- Class III / Class D
- Class IIb active devices intended to administer and/or remove a medicinal product

Timing:
- Not specified in MDR
### Common Specification: Devices with no Medical Purpose

#### Requirements:
- Classification
- Risk management
- Label and IFU

- Clinical evaluation
- Performance requirements

#### Timing
- MDR applies from DOA of CS, 6 months after entry into force (expected Q1 2020)
- MDD CE certificate remain valid until DOA of CS

#### What does this mean? Is this a problem?
- 6 months to update/create technical documentation demonstration compliance to CS AND obtain CE certification
- 6 months for NB to obtain designation

#### Possible Strategies and Preparation
- Early renewal of MDD CE, when possible
- Obtain copy of draft CS
- Prepare technical documentation based upon MDR requirements
- Close communication with NB on pathway for designation
- Contingency plans

#### Does the strategy change if there is no transition time?
EU MDR
compliance strategies prior to NB Designation
**EU MDR Notified body designation status - MTE**

### NB designation under IVDR/MDR: Overview*

<table>
<thead>
<tr>
<th>Stages of the NB designation procedure</th>
<th>(1) Complete applications received by DG SANTE</th>
<th>(2) Pre-assessment/Off-site activities (e.g. Designating Authority Preliminary Assessment Report)</th>
<th>(3) On-site assessments (Audits by Joint Assessment Team - JAT)</th>
<th>(4) CAPA Plans received by DG SANTE (CAPA: Corrective and Preventive Action)</th>
<th>(5) Applications in Final Designating Steps</th>
<th>Notification in NANDO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>47 (~ 35-40 Notified Bodies)</td>
<td>33</td>
<td>32</td>
<td>11**</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>IVDR</td>
<td>9</td>
<td>6</td>
<td>6</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>MDR</td>
<td>38</td>
<td>27</td>
<td>26</td>
<td>9</td>
<td>2 MDGC recommendations</td>
<td>1 = BSI UK</td>
</tr>
</tbody>
</table>

8 months + 6-10 months + 4-6 weeks

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*Information based on Team-NB surveys and European Commission information (Last updated on 23 April 2019)

** 7 JAT draft opinions + 3 JAT draft opinions under preparation + 1 CAPA plan undergoing translation

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11 applications in final stage of designation

2 MDCG recommendations on applications, awaiting notification in NANDO
When is Compliance required for MD?

- EU MDR “entered into force” on May 27, 2017, no ‘grandfathering’ provisions.
- A 3-year transition period, compliance to EU MDR is mandatory and must be accomplished by May 26, 2020.
- There is an added conditional transition period ending on May 27, 2024.
  - Manufacturers must avoid any significant changes in the design or the intended purpose of their devices.
  - Not all MD or MDR requirements will benefit from this ‘grace’ – conditional transition period.

Entry into force: May 27, 2017

Date of Application: MDR May 26, 2020

Date of Application: IVDR May 26, 2022

End of ‘Conditional transition’ - last date for placing on the market MDD products' May 27, 2024

No conditional transition

Compliance date for registration of Economic operators in Eudamed, QMS- PMS/vigilance, NPD, Class Ire, Annex XVI (6 months after the CS), some software/apps

Sell Off period: May 27, 2025
### Manufacturers preparation by May 2020

#### R&D / MANUFACTURING /NPD- NPI
- New Product introductions and development for all Class devices
- MD (as software) not benefitting from the Grace Period
- QMS MDR certification

#### SCRUTINY FOR INNOVATION – NPD
- Expert panel review of clinical evidence for ‘new’ Class III Implantable plus ‘Class IIb intended to administer/remove medicines’

#### Class I reusable instruments
- Notified Body review for reusable surgical instruments for aspects related to reuse (including IFUs) – by May 2020
- QMS
- Notified Body number on the device...

#### EUDAMED - EU DATABASE
- NB certificate uploads

Red = need NB
Yellow = waiting on common spec and guidance, not NB readiness
Green = within MNF control

#### Awaiting EC guidances
- SSCP
- PSUR
- Implant card and Patient leaflet
- Sufficient clinical data and equivalence
- Software (definition, classification, clinical trials, cybersecurity)

#### Awaiting Common Specs & standards
- Aesthetic use devices – Annex XVI
- Re-processing of Single Use devices
- ISO 15223 standard on symbols

#### Awaiting Implementing Acts
- E-IFU
- Expert Panels
- Expert laboratories
- EUDAMED
- Certificate of Free Sales (CFS)

#### EUDAMED – EU DATABASE
- Manufacturers to identify, assign & have a mandate with AR
- EO’s; importer and distributor roles and responsibilities assigned
- Prepare for Registration of all economic operators
- Assign BASIC-UDI
- Prepare for device registrations (18 months timeline)

#### Manufacturer
- Determine classification as per MDR
- Prepare for new labeling obligations – implant card, patient leaflet; labels, IFU (eg SSCP link)
- Assign PRRC
- Quality management system (internally audited to MDR)
- TD: clear, organized & readily searchable
- Identify RS and justification
- Draft SSCP – awaiting guidance
- Prepare CER’s

#### LIFECYCLE REQUIREMENTS
- Post-market surveillance - MIR and FSCA
- Define lifecycle requirements – PMCF plan...

#### NBmed Conditional transition period position paper
- Red = need NB
- Yellow = waiting on common spec and guidance, not NB readiness
- Green = within MNF control
**Exercise**

Manufacturer of Textured Silicone-filled Breast Implants currently CE-certified under the MDD (expiry June 2021) preparing for EU MDR CE-certification.

**Intended Use:**

- Primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery
- Primary breast reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality, as well as revision surgery to correct or improve the result of a primary breast reconstruction surgery

**Recent concerns:**

- Studies have shown that patients with textured implants face a higher risk of a rare form of cancer – breast implant associated anaplastic large cell lymphoma (BIA ALCL), a cancer of the immune system. Estimated risk 1/1000 – 1/30,000
- 1 Notified Body declined to certify textured breast implants. Some EU authorities and Canada banned textured breast implants. FDA is investigating safety
Prepare for the Unknowns

Identify the unknowns

Minimize Risk of the Unknown

Regulatory Intelligence

Communication

Global Awareness

Contingency Planning
Know that the greatest fear
is fear of the unknown.
Seek to meet the unknown
with courage and a sense of adventure.
- Jonathan Lockwood Huie
Open panel debate
Thank you for your attention

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