Introduction to MDR and IVDR

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Agenda

1. **Introduction:** from Directives to Regulations
2. **Definition:** sterile Medical Device
3. **MDR and IVDR:** classification of medical devices
   - Sterile devices
4. **Timeline:** ordinary devices and legacy devices

1. Introduction

In the EU, medical devices are regulated by:

- **Medical Devices Regulation** (MDR (EU) 2017/745) entered into full force on May 26, 2021 and repealed both MDD and AIMDD
  - ✓ **Date of Application = 26 May 2021**

- **In Vitro Diagnostic Devices Regulation** (IVDR (EU) 2017/746) that will repeal In Vitro Diagnostic Devices Directive on May 26, 2022
  - ✓ **Date of Application = 26 May 2022**

2. Definition

‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

2. Definition

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection, or **sterilisation of devices**

2. MDR and IVDR

From Directives to Regulations: what is new?

Some of the major changes include:

- **Stricter control** for high-risk devices → involvement of a pool of experts at EU level (expert panels, EURLs, EMA)
- Reinforcement of criteria for designation and processes for oversight of **notified bodies**
- **New risk classification system** for in vitro diagnostic medical devices
- Improved **transparency** through EU database and traceability (EUDAMED, UDI)
- Reinforcement of the rules on **clinical and performance evidence**
- Strengthening of **post-market surveillance** and improved **coordination mechanisms**
- **Increased responsibilities** of economic operators

Classification

MDR and IVDR: Classification of medical devices

Why is classification so important?

Classification…

- determines the available product conformity route(s) to achieve **CE mark**
- indicates what is required during the product development process
- helps establish what costs and timescale are involved in getting the product ready for **CE marking**
- determines the post-market activities and documentation required to maintain compliance throughout the product lifecycle

2. MDR and IVDR

Classification: rules and classes

MDR classification

Classes:

- **Class I (s, m, rsi):** low-risk devices
- **Class IIa:** medium risk devices
- **Class IIb:** medium to high-risk devices
- **Class III:** high-risk devices

4 classes, 18 classification rules

IVDR classification

Classes:

- **Class A**: low-risk devices
- **Class B**: low public health risk/low-moderate personal risk
- **Class C**: low public health risk/low-moderate personal risk
- **Class D:** High Public health risk and/or High personal risk

4 classes, 7 classification rules

Sterile devices

Sterile devices

- Shall be designed, manufactured and packaged to ensure that their sterile condition or microbial state is maintained under the transport and storage conditions specified by the manufacturer
- Shall be processed, manufactured, packaged and, sterilised by means of **appropriate, validated** methods.
- Shall be manufactured and packaged in **appropriate and controlled** conditions and facilities.

Conformity route

- The manufacturer shall apply the procedures set out in **Annex IX or in Annex XI MDR**

- NB involvement limited to the aspects relating to establishing, securing and maintaining sterile conditions.

Technical Documentation

- Description of the environmental conditions for the relevant manufacturing steps
- Description of the methods used, including the **validation reports, with regard to packaging, sterilisation and maintenance of sterility.**
- The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues.

Labelling

- Indication of the **sterile** state of the device and the **sterilisation method**, or a statement indicating any special microbial state or state of cleanliness;
- Unambiguous indication of the time limit for using the device safely, expressed at least in terms of year and month and, where relevant, the day, in that order,
- Description of the device, name and address of the manufacturer, month and year of manufacture, instruction to check the IFU in case packaging is damaged or unintentionally opened before use.

EUDAMED

EUDAMED – UDI: to indicate ‘’device labelled sterile (y/n)’’

Timeline

3. Timeline

Important difference: Ordinary devices v. legacy devices

- ✓ Ordinary devices shall fully respect MDR/IVDR by the Date of Application
- ✓ Legacy devices should respect MDD/IVDD and certain MDR/ IVDR requirements on vigilance, PMS, registration of actors and devices after MDR/IVDR Date of Application
- ✓ Legacy device are devices with a:
  - valid MDD/IVDD CE Certificate (Class Is, IIa, …) or
  - MDD/IVDD Declaration of Conformity that will be up-classified and will need to involve a Notified Body under the MDR/IVDR (reusable surgical instruments)

Devices must fully comply with MDR/IVDR when their CE Certificate expires or significant change is made to the device design or intended purpose or when the grace period expired

3. Timeline

MDR date of application = **May 26, 2021**

Ordinary devices (Class I) → Fully MDR compliant **by May 26, 2021**

Legacy devices (Class Irs, Is, IIa, III,…) → Legacy compliance of MDD and certain MDR requirements by
- → **26 May 2024** (last date when shipping to the EU is possible with valid CE Certificate)
- → **26 May 2025** (last date when making available within the supply chain is possible)

No significant change to design or intended purpose is permitted for legacy devices.

3. Timeline

IVDR date of application = **May 26, 2022**

Ordinary devices (Class A) → Fully IVDR compliant **by May 26, 2022**

Legacy devices (Class B, C, D) → Legacy compliance **by May 26, 2022 with**

Placing on the EU market

- **26 May 2025** for **Class D** devices
- **26 May 2026** for **Class C** devices
- **26 May 2027** for **Class B** devices
- **26 May 2027** for **Class A sterile** devices

Making available on the EU market

- **26 May 2026** for **Class D** device
- **26 May 2027** for **Class C** device
- **26 May 2028** for **Class B** device
- **26 May 2028** for **Class A sterile** device

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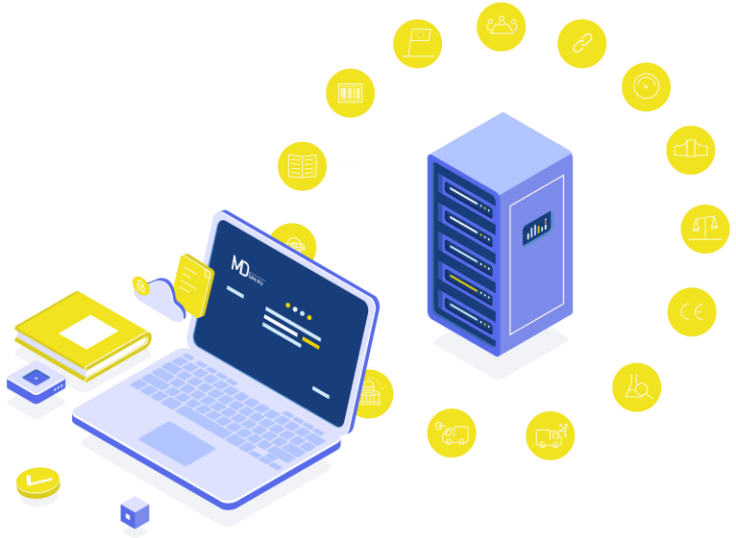

All information on the regulatory framework of medical devices on **MDlaw.eu**

MDlaw.eu gathers reference documents, implementation tools including checklists, guidelines, analysis documents, as well as regulatory updates, all in a single place

ANY QUESTIONS?

THANK YOU!

Stay in touch!

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