FMMC - 2017
2017/745 - Medical Device Regulation (MDR)

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May 9th, 2017
Changes
Time Table – The big picture

MDR / IVDR

ISO 13485:2016

MDSAP

ISO 9001:2015
Official Journal of the European Union

Legislation

Contents

1  Legislative acts

REGULATIONS


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Overview

1. Overview of the MDR
2. Changes in QMS to MDR
3. Changes in Classification
4. Changes in Clinical Requirements
5. Changes in Reporting
History

2008:
- Commission started so-called MDD RECAST (public hearing on the need of changes to directives)
- Centralized product approval
- Limited activities for Notified Bodies, reduced to QM audits
- Improvement for market surveillance by authorities
- Improved transparency

2010:
- Official closure of recast
- Hundreds of responses received
- Authorities did analysis of improvements needed

2011:
- PIP Scandal
- Commission reacted with an action plan to improve the situation, to calm down public

2012:
- First draft of the new regulation, influenced by the PIP scandal

2014:
- EP did accept the draft regulation

2016:
- Council did accept a compromise (new draft double size of first draft published by Commission)
- Another draft circulated by Commission to authorities only based on feedback from stakeholders

2017:
- May 5th, 2017 – Publication in the Official Journal of the European Union
AIMD + MDD = MDR

- 90/385 AIMD Directive
- 93/42 MD Directive
- 98/79 IVD Directive
- 17/745 MD Regulation
- 17/746 MD Regulation

May 2017
Publication  
May 2017  

Total number of pages  
174  

Word “clinical”  
677 (81)
MDR - Timelines

Manufacturer / Importer → Place a device on the market → Dealer → Makes a device available → Hospital → Puts a device into service
MDR – Timelines

Short transition – 3 years!!!

- **2017 May 25**: Entry Into Force (EIF)
- **2020 May 25**: Date of Application (DOA)
- **2024 May 25**: 4 years after DOA

**Placing a device on the market**

**Making available & putting into service**

*Notification of all Notified Bodies acc. To AIMD/MDD will end in 2020 May 25th*

“BY FALING TO PREPARE, YOU ARE PREPARING TO FAIL.”

- Benjamin Franklin
Important Changes and Improvements

- **Stricter pre-market control of high-risk devices** with the involvement of a pool of experts at EU level
- **Reinforcement of the criteria for designation and processes for oversight of notified bodies**
- **Inclusion of certain aesthetic products** which present the same characteristics and risk profile as analogous medical devices
- **Introduction of a new risk classification system** for diagnostic medical devices based on international guidance

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**EUDAMED - EU database** on medical devices and a device traceability system

EU-wide requirement for an 'implant card' to be provided to patients

Reinforcement of the rules on clinical data, including an EU-wide coordinated procedure for the authorisation

Reinforced requirement for manufacturers to collect data about the real-life use of their devices
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WHAT DOES IT DO?

- PREMARKET SCRUTINY PROCESS
- CLINICAL REQUIREMENTS
- NEW CLASSIFICATIONS*
- REPROCESSING OF SINGLE USE
- RESTRICTION OF HAZARDOUS SUBSTANCES
### Overview

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Manufacturers shall establish, execute, maintain and document a system for risk management (Article 10)

Manufacturers who consider or have reason to believe that a device is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that product into conformity, withdraw it or recall it (Article 10)

Upon request by a competent authority, the manufacturer AND EU Representative shall have the technical documentation permanently available. (Article 11)

EU Rep shall be legally liable for defective devices (Article 11)
Importer shall keep a register of complaints, non conformities, recalls, withdrawn products and deliver them to the manufacturer / authorized representative upon request. (Article 13)

A PLM is considered a manufacturer and has to have the full technical documentation permanently available.

Manufacturers shall have available within their organization at least one person responsible for regulatory compliance (Article 15)

Conduct clinical evaluation (Article 61)

Manufacturers of custom-made devices shall draw up, keep up to date and keep available to competent authorities documentation pursuant to Section 2 of Annex XI.

Manufacturers of class III custom-made implantable devices shall be subject to the conformity assessment.
Claims

In the labelling, instructions for use, making available, putting into service and advertising of devices, it is prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device’s intended purpose, safety and performance by:

• ascribing functions and properties to the product which the product does not have
• creating a false impression regarding treatment or diagnosis, functions or properties which the product does not have
• failing to inform of a likely risk associated with the use of the product in line with its intended purpose
• suggesting uses of the product other than those declared in the intended purpose when the conformity assessment was carried out.
General safety and performance requirement

For devices that incorporate software or for standalone software that are devices in themselves, the software shall be developed and manufactured according to the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.
What You Need to KNOW

- All devices for European Market: classification must be reviewed

- Procedures must be in place for MDR requirements (Including Clinical Investigations, UDI, EUDAMED, Clinical Reporting & Evaluation… etc)

- Devices may have additional Clinical (testing) requirements!
  - This may lead to design changes!

- MDR Quality Management System Requirements
  - ENISO 13485:2016
  - ENISO 14971:2012

- Technical Documentation must be remediated (if required)
What You Need to KNOW

- Devices that fall into class III implantable and class IIb that adds or removes a medicinal substance

THERE IS A NEW APPROVAL PROCESS

60 days for the opinion delivery or after that proceed
May continue after 21 days if informed accordingly by panel
What You Need to KNOW
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## Classification

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<td>• Invasive Devices</td>
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<td>Rule 9-12</td>
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Rule 6/7
Devices intended specifically for use *in direct contact* with the heart or central circulatory system or the central nervous system, in which case they are in class III
- Active implantable devices or their accessories are class III

- Breast Implants or Surgical Meshes are class III

- Total and partial joint replacements are class III (Ankles, TMJ, Elbow etc..)  
  with the exception of ancillary components such as screws, wedges, plates and instruments. (IIb implantable new category)

- Spinal disc replacement implants and implantable devices that come into contact with the spinal column are class III  
  with the exception of components such as screws, wedges, plates and instruments. (IIb implantable new category)
Classifications

Reusable Surgical Instruments Class I BUT.....

Conformity assessment of Notified Body limited to the aspects related to the reuse of the device; in particular cleaning, disinfection, sterilization, maintenance and functional testing, and the related instructions for use (That’s most of the technical file for these devices)

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.
Classifications - Class IIb Implantable?

Technical Documentation Requirements

…general safety and performance requirements should be based on clinical data that, for class III medical devices and implantable medical devices, should, as a general rule, be sourced from **clinical investigations** to be carried out under the responsibility of the manufacturer…. 
Active therapeutic devices with an integrated or incorporated diagnostic function, which significantly determinates the patient management by the device are in class III, such as closed loop systems or automated external defibrillators.

e.g. dialysis machines with feedback systems or infusion pumps that are controlled by closed loop
All devices incorporating or consisting of nanomaterial are:

- Class III if they present a high or medium potential for internal exposure.

- Class IIb if they present a low potential for internal exposure.

- Class IIa if they present a negligible potential for internal exposure.
Overview

1. Overview of the MDR
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Clinical Data means the information concerning the safety or performance that is generated from the use of a device and that are sourced from the following:

- clinical investigation(s) of the device concerned,
- clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated,
- reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated,
- other clinical data coming from the post-market surveillance system (PMS), in particular the post-market clinical follow-up (PMCF)
MDR Clinical Equivalence

Equivalence has to be demonstrated

- **Technical**: similar design, used under similar conditions, similar specifications and properties, similar deployment methods, similar principals of operations and critical performance requirements.

- **Biological**: Use same materials or substances in contact with the human tissue or body fluids for a similar kind and duration of contact; similar release characteristics of substances, including degradation products and leachable.

- **Clinical**: Used for the same clinical condition or purpose (including similar severity and stage of disease), at the same site in the body, in a similar population (including age, anatomy, physiology), have same kind of user, have similar relevant critical performance according to the expected clinical effect for a specific intended purpose.

- These characteristics shall be similar to such an extent that there would be no clinically significant difference in the clinical performance and safety of the device.

- **Considerations of equivalence** must always be based on proper scientific justification. Manufacturers must be able to clearly demonstrate that they have sufficient levels of access to the data on devices to which they are claiming equivalence in order to justify that claimed equivalence.

Results to be documented in Clinical Evaluation Report which is a part of Technical Documentation
In the case of implantable devices and devices falling within class III, clinical investigations shall be performed, except if:

- the device has been designed by modifications of a device already marketed by the same manufacturer

- the modified device has been demonstrated by the manufacturer to be equivalent to the marketed device

- the clinical evaluation of the marketed device is sufficient to demonstrate conformity of the modified device with the relevant safety and performance requirements.
General requirements regarding clinical investigations

- Verify the **performance**
- Verify **clinical safety** and **efficacy**
- Verify **intended benefits** for the patient,
  - when used in intended purpose,
  - in target population,
  - in accordance with instruction for use
- Determine **undesired side effects**
- Reliable and robust
- Design, conduct, record & report
# Overview

## Overview of the MDR

## Changes in QMS to MDR

## Changes in Classification

## Changes in Clinical Requirements

## Changes in Reporting
NEW REPORTING REQUIREMENTS

CER: Clinical Evaluation Report
All

PMS: Post Market Surveillance Plan
All

PSUR: Periodic Safety Update Report
Class IIa, IIb and III

SSCP: Summary of Safety and Clinical Performance
Class III and Implantable

PMCFR: Post-Market Clinical Follow-Up Evaluation Plan & Report
Class III and Implantable

- Start after approval
- Prepare by considering the post-market experience
- Summarise the technical documentation

\[t = 0Y\]

\[t = 1Y\] NOW START AGAIN
Throughout the lifetime of the device concerned this report shall set out:

- the conclusion on the benefit risk determination
- the main findings of the Post Market Clinical Follow-up Report (PMCFR)
- the volume of sales of devices
- estimate of the population that use the device involved
- and, where practicable, the usage frequency

**PSUR Frequencies:**
- Annually: Class III and IIb
- Every 2 year: Class IIa

**NB reviews annually off site:**
Class III and Implantable PSURs

**NB reviews during audit:**
Sampled PSURs for other devices
The SSCP is for the **USER** and shall be:

For class III and implantable devices, other than custom-made or investigational devices, **the manufacturer shall draw up a SSCP**

SSCP must be written in a way that is **clear to the intended user** and, if relevant, to the **patient**

SSCP shall be **updated at least annually** with data from PMCFR (if indicated) see Art. 49.4.

SSCP is part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with Article 42

Validated and **final version of SSCP** uploaded to EUDAMED/Electronic System by NB

Information where the SSCP can be found must be provided on the **label of a device**
The clinical evaluation and its documentation must be **actively updated** with data obtained from the **post-market surveillance (PMS)**.

Where **post-market clinical follow-up (PMCF)** as part of the **post-market surveillance plan** for the device is not deemed necessary, this must be duly justified.

PMCF is an **active** collection of **Clinical Data** to determine safety, previously unknown side effects, emergent risks, determination of risk benefit ratio, and **systemic misuse or off label use**.
Post-Market Clinical Follow-up (PMCF)

The clinical evidence together with non-clinical data generated from non-clinical testing methods and other relevant documentation shall allow the manufacturer to demonstrate conformity with the general safety and performance requirements and shall be part of the technical documentation of the device in question.

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<th>STEPS FOR CLINICAL EVALUATION</th>
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<td>Identify the regulatory requirements that must be supported by clinical data.</td>
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<tr>
<td>Identify available clinical data that is relevant to the subject device and the state of the art concerning the intended use.</td>
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<tr>
<td>Determine whether the available data is sufficient to establish the safety and performance of the device.</td>
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<tr>
<td>Generate additional clinical data as necessary to address any outstanding safety or performance concerns.</td>
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<tr>
<td>Determine the clinical safety, performance and benefit/risk ratio of the device based on an assessment of all of the clinical data collected.</td>
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</table>
Every year for class III class, IIb implantable devices, PSUR and SSCP shall be uploaded to EUDAMED, the reports are further validated by the Notified Body and that validation report is then uploaded to EUDAMED. These documents will be made public and may be reviewed by the competent authorities, and other regulatory bodies (public).
Take away

“If failing to prepare, you are preparing to fail.”

- Benjamin Franklin

If you start the preparation today
IT IS ALREADY LATE!

Consider pre-certification services by your NB!

Clinical audit
Mock evaluation of TD / DD
Mock MDR audit
Take away

[Image of a stopwatch with a red tick]
Questions, Comments?

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Global website: www.tuv-sud-america.com/medical
Stay informed and updated with our Healthcare & Medical Device newsletter: www.tuv-sud.com/essentials