The New European MDR- Harmonization Effort with International Regulatory Requirements for Medical Devices
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Europe
TOPICS

- Introduction to MDR
- New Key Decision Makers
- Review of Major Changes
- Implementation and Transition Timelines
- Key Impact
- Implementation Steps
MDR – Introduction

Timelines

- **Q1/2017**: Adoption of MDR
- **Q2/2017**: Entry into Force
- **3 Year Transition Period**
- **Notified Bodies Re-accreditation Process**
- **2020**: End of transition Date of Application
- **5 Year MDD Cert Grace Period**
- **2024**: Last possible granted MDD certificate expires
## MDD vs. MDR

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<th>MDD</th>
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<td>- 60 Pages (MDD only)</td>
<td>- 352 Pages (MDD + AIMD)</td>
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<td>- 23 Articles</td>
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**D=Directive:** Legislation that sets out rules and must be transposed into national law to be effective

**R=Regulation:** Mandatory Jurisdiction that is directly applicable and enforceable in all EU Member States.
Key Objectives of the MDR

• Fundamental revision of existing MDD and AIMD
• Reinforce key elements of the existing regulatory approach, such as:
  - Patient’s Health and Safety
  - Scientific Clinical Evaluation and Clinical Data Requirements
  - Post-Market Surveillance and Post-Market Clinical Performance
  - Role and Supervision of Notified Bodies
  - Consistency and Transparency in Conformity Assessment Procedures
• Introduce provisions for transparency and traceability regarding devices to improve health and safety.
Key Objectives of the MDR

• Promote the global convergence of regulations.
• Set high standards for quality, safety and clinical performance for medical devices including IVDs.
• Regulate devices without a medical purpose
• Set out the regulatory obligations of economic operators

Establish a robust, transparent, predictable and sustainable regulatory framework for Medical Devices including IVDs in Europe
New Key Decision-Making Players

- European Commission (EC)
- EU Competent Authorities (NCA)
- Medical Device Coordination Group (MDCG)\(^1\)
- Notified Bodies (NB)
- (Special) Notified Bodies (NB)\(^2\)

*Note:* 1 is a new player. 2 is an existing player with special accreditation based on very stringent competency and organizational requirements.
Scope of MDR: Devices with Medical Purpose

Article 2(1) ‘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 specific medical purposes of:

- 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 an 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,

And which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Products specifically intended for the cleaning, disinfection or sterilization of medical devices and devices for the purpose of control or support or conception shall be considered medical devices.
Scope of MDR: Devices without Medical Purpose

Preambel (12): Certain groups of products for which the manufacturer claims only an aesthetic or another non-medical purpose but which are similar to medical devices in terms of functioning and risks profile should be covered by this Regulation (common specifications adopted).

Article 1(2): This regulation shall also apply to the groups of products without an intended medical purpose that are listed in Annex XVI as from the date of application of common specifications adopted pursuant to Article 7...taking into account the state of the art, and in particular existing standards for analogous devices with a medical purpose, based on a similar technology.
Software - New Classification Rules

• **Software** is considered an *active medical* device [Article 2 Definitions, Clause (4)]

• Classified into classes I, IIa, IIb or III depending on the intended use of the software and a risk profile:

• **Decision Software**: intended to provide information which is used to take decisions with diagnosis or therapeutic purposes.
Software - New Classification Rules

If decisions have an impact that may directly or indirectly cause:

- **Class III** - the death or an irreversible deterioration of the state of health
- **Class IIb** - a serious deterioration of the state of health or a surgical intervention
- **Class IIa** - otherwise
“Monitoring Software”:

- **Class IIa**: if intended to monitor physiological processes:

- **Class IIb**: If intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient

- All other software is in Class I.
Software- Other Important Changes

• Introduced **concept of Interoperability** to devices including software:
  - the **ability to exchange information** and use the information that has been exchanged for correct execution of specified function without changing the content of the data, and/or
  - communicate with each other, and/or
  - **work together** as intended.

• **Interoperability (and compatibility)** must be reliable and safe

• **Software change evaluation**: new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability
MDR – Major Changes

Pre-Approval

• **Four (4) Device Classifications:** no more AIMD -> Class III, Class IIb; Class Ila; Class

• **New “clinical evaluation consultation procedure ”** for all class III and certain Class IIb devices.

• **Mandatory clinical investigations** for implantable devices and Class III devices with few exceptions

• **Common [Technical] Specifications (CS)** to be devised and followed for product groups.
MDR – Major Changes

Post-Approval

• Centralized Post Market Surveillance System (PMS) for all devices classes.

• New and different reporting requirements
  - **PMSR**  Post Market Surveillance Report,
  - **PSUR**  Periodic Safety Update Report,
  - **SSCP**  Summary of Safety & Clinical Performance,
  - **PMCFR**  Post Market Clinical Follow Up Reports
Post-Market Surveillance, Vigilance and Market Surveillance [Chapter VII]

Post-Market Surveillance
Explicit provisions on manufacturers’ responsibilities for the follow-up of the quality, performance and safety of devices placed on the market:

- Post-Market Surveillance (PMS) Plan.

- Periodic Safety Update Report (PSUR)
  - Class IIa (every 2 years) and IIb/III (annually) incl. the volume of sales.
  - For class III, Notified Body Review and Assessment.
  - For class III, PSUR and NB Assessment posted within an Electronic Database available to all National Competent Authorities.
MDR – Changes

New centralized databases (EUDAMED):
- Conformity Assessment; Vigilance (incidents and recalls);
- Universal Device Identifier (UDI);
- Device Registration;
- Surveillance Reports;
- Clinical Investigations
- Notified Bodies
Increase powers of the Competent Authorities to ensure swift and effective response to safety problems:

- CA may intervene in a manufacturer’s investigation or initiate an independent investigation

- Following risks identified and the analysis of vigilance data, CA may request manufacturer or the EC Authorized Representative to take “necessary” field corrective actions

- **New high-level of involvement** of Competent Authorities and Notified Bodies in any filed actions (alias recalls).

Reporting of serious incidents within **15 days** and **Field Safety Corrective Actions** through an **Electronic System**
- Cooperation between CA and European Medicines Agency (EMA) for drug-device combination products in case of Serious incidents or FSCA.

- Explicitly advises manufacturers “not to play down the level of risk” in field safety notices.

- Mandatory review of Field Safety Notice (FSN) by CA.

- FSN entered into an Electronic System accessible to the Public.
Quality Management System Requirements

Greater emphasis and detailed QMS responsibilities.

Legal Manufacturer

- **Person responsible for Regulatory Compliance**- a new provision with explicitly defined:
- **Qualification requirements**- specific education, training and experience
- **Responsibilities**- conformity of device verified before product release, technical documentation are kept up-to-date, PMS obligations are complied with, etc.
- **Provision for ability to make decision** (“shall suffer no disadvantage in relation to the proper fulfillment of his duties …”)
UDI: Identification and Traceability of Devices

- **UDI system** (Unique Device Identification System) to enable global device traceability

- **EUDAMED**: Establishment of an electronic system on UDI

- **EUDAMED Implementation by the EU Commission** (the later date):
  - MDR **Entry Into Force** (EIF) + three (3) years (alias **Date of Application** of the MDR), or
  - **Six (6) months** after publication of the EUDAMED Implementation Notice
UDI: Identification and Traceability of Devices [Chapter III]

• **UDI system** (Unique Device Identification System) to enable global device traceability

**UDI System**

- **DI** (Static Data)
  - **PI** (Variable Data)
- **AIDC** (Machine-Readable)
  - **PI** (Clear Text)
- **Database with static data Access via UDI**

**DI** = Device Identifier  
**PI** = Product Identifier  
**AIDC** = Automatic Identification and Data Capture  
**HRI** = Human Readable Interpretation
UDI: Identification and Traceability of Devices [Chapter III]

• **UDI system** (Unique Device Identification System) to enable global device traceability
UDI: Identification and Traceability of Devices [Chapter III]

UDI Implementation Timelines by Manufacturers:

- UDI carrier must be affixed to devices by the following time limits after the Date of Applications of the Regulation:
  • Implantable and Class III devices - Within 1 year
  • Class IIa and IIb devices - Within 3 years
  • Class I - Within 5 years
Clinical Evaluation and Clinical Investigations [Chapter VI]

New understanding of Clinical Evaluation:

A systematic and planned process to continuously generate, collect, analyze and assess the clinical data to verify the safety and performance of a device when used as intended by the manufacturer.

• Clinical Evaluation Report is required for all classes of devices and throughout the product life cycle process.
Clinical Evaluation and Clinical Investigations [Chapter VI]

Stringent new requirements for demonstrating equivalency:

- Only be based on a single CE-Marked Device
- Equivalency based on all three (3) design characteristics
- No clinically significant difference in performance and safety
- All differences need to be disclosed and critically evaluated
- Notified Bodies may challenge equivalent device selection as well as equivalent safety and performance data

Demonstration of Equivalency must be endorsed by the Notified Body.
Clinical Evaluation and Clinical Investigations [Chapter VI]

Clinical Evaluation shall be based on the following principals:

- Critical evaluation of all relevant scientific literature
- Critical evaluation of the results of all available clinical investigations
- Consideration of currently available alternative treatment options for claimed intended use.
- Optional consulting with an expert panel prior to its clinical evaluation or clinical investigation as well as mandatory clinical investigations for Class III and Implant Devices.
- Notified Body to review and approve advertising and promotional materials (Ad& Promo Review)

Note 1: Refer to guidance MEDDEV 2.7.1 Rev. 4 of June 2016
Transitional provisions [Article 120]

Clinical investigations which have started to be conducted in accordance with Article 10 of Directive 90/385/EEC or Article 15 of Directive 93/42/EEC prior to the application of this Regulation may continue to be conducted… [Clause 11]
MDR Implementation Timeline

The MDR is not approved by the European Council and European Parliament yet.

- **Entry into Force (EIF)** = Publication date in the OJ + 20 day (Article 123)
- **Date of Application (DOA)** means a date when the application of the new MDR Regulation becomes mandatory.
- **Date of Application = Entry Into Force (Q2/2017) plus 3 years = 2020**
Transitional provisions [Article 94]

MDD/AIMD Certificates Issued Prior to Entry into Force

Certificate Issued
Certificate valid for max. 5 years until 2021
Entry Into Force
2017
End of Transition
2021

By way of derogation from Directives 90/385/EEC and 93/42/EEC, devices which comply with this Regulation may be placed on the market before its date of application.
Transitional provisions [Article 94]

MDD/AIMD Certificates Issued after Entry Into Force

Devices which were lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to the date referred to in Article 97(2) (=DOA) may continue to be made available until 5 years after that date.
General Obligations of Economic Operators

‘Economic operators’ means:

- Legal Manufacturer
- EC Authorized Representative
- Importer
- Distributor
- Person who puts together [refer to Article 22 [1] or sterilizes [refer to Article 22[3] system or procedure packs
General Obligations of Economic Operators

EC Authorized Representative [Articles 10 and 11]

- Verify that the EU declaration of conformity and technical documentation have been drawn up and an appropriate conformity assessment procedure has been carried out by the manufacturer.

- EU Representative keeps a permanent copy of:
  - Technical documentation
  - EU Declaration of Conformity
  - Relevant certificates including any amendments and supplements

- Comply with the any required registration obligations and verify that the manufacturer has complied with the registration obligations

- If requested, provide competent authority with all the information and documentation necessary to demonstrate the conformity of a device in an official Union language determined by the Member State concerned.
More responsibilities for Importers:

Specific verification responsibilities include:

- CE marked devices and valid declaration of conformity
- Identification of legal manufacturer and designated EU Authorized Representative in accordance with Article 9
- Labeling in accordance with this Regulation and accompanied by the required instructions for use;
- Unique Device Identification - assigned and registered

• Obligation to cooperate with the legal manufacturer, AR and Competent Authorities to ensure the necessary corrective action to bring device into conformity, or to result in its withdrawal or recall.
General Obligations for Economic Operators

- Supplier
- Manufacturer
- Subcontractor
- Importer
- Distributor
- End User

- Post market surveillance and vigilance
- Regulatory compliance of device
- Verify compliance with requirements
Key Changes for Notified Bodies

• No grandfathering of Notified Bodies!
• Current NB designations will expire with the DOA of the MDR.
• All Notified Body Applicants for MDR Accreditation must go through the Re-Designation Process [Chapter IV Notified Body].
Key Changes for Notified Bodies

EU Commission shall within six (6) months of EIF of MDR draw up a list of codes and corresponding types of devices to describe the scope of the designation of Notified Bodies.

Notified Bodies must satisfy organizational, quality management, resource and processes.

**Good news:** After the re-designation: process, the NB number will remain the same / will NOT change!

**Bad news:** Some NBs will not be around and only selected few will have a scope for Class III high-risk devices (alias SNB).
Conformity Assessment
Specific Procedure [Annex IX Section 5)

Applies to Class III implants and Class IIb active devices intended to administer and/or remove a medicinal product
Conformity Assessment
Specific Procedure [Annex IX Section 5)

Applies to all Class III and Class IIb active devices intended to administer and/or remove a medicinal product:

- Medical Device Expert Panel - clinical evaluation assessment report
- Adds to approval timeline (min. 60 days- max ???)

Specific Procedure is not required for:

- Modified Devices from same manufacturer and differences accepted by NB to not adversely affect the established risk/benefit ratio.
- Devices complying to devised CS (set out by Commission & MDCG)
- Renewals of Certificates.
Key Impacts

✓ New Regulatory Requirements
✓ Pre-Market Clinical Data Requirements
✓ Post-Market Reporting Requirements
✓ UDI & Distribution Channels
✓ QM System and Manufacturing
✓ Changing Notified Body Role
MDR- Preparing to Implement

Be informed, be prepared, identify opportunities and implement in time …

• Assess your device portfolio
• Impact Assessment and Gap Analysis
• Portfolio/ Product Pipeline analysis for challenges and opportunities

MDR Implementation Plan

- Dossiers, clinical evaluation, PMCF & PMS integration
- System approaches, QMS, contracts, supplier control, RA knowledge
- Resource management (internal/external) including NB commitment/ selection
- MDR Master Plan what needs to be done and when according to the MDR implementation timeline
MDR- Preparing to Implement

Be informed, be proactive, identify opportunities and implement in time …

• Communicate Master Plan with your Notified Body
• Plan for Contingencies and Delays
• Execution of Implementation
• Internal Monitoring / Internal audits
• Carefully Plan MDR Conformity Assessment with Notified Body
Thank You!