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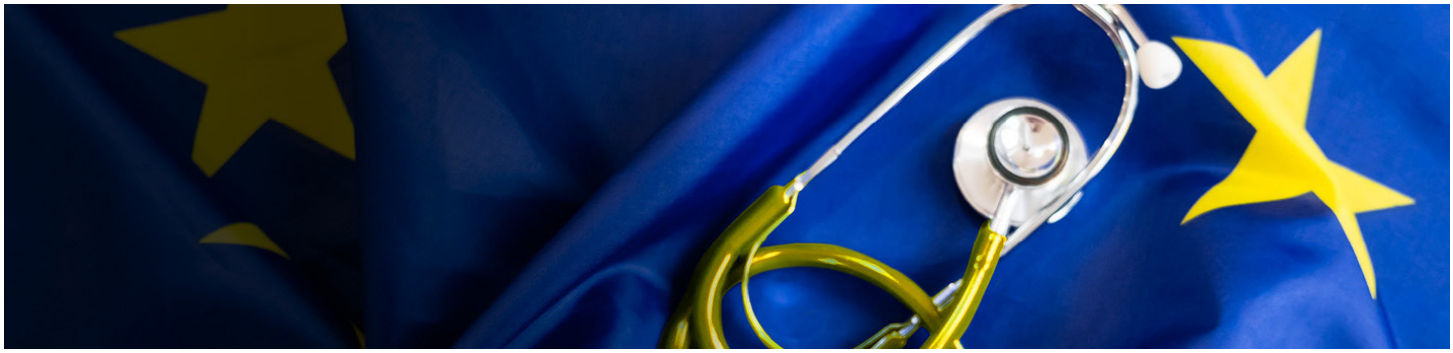
EU MDR Overview, Compliance, and Implementation Strategy Services



The new EU Medical Device Regulation (MDR) was published in the Official Journal of the European Union on May 5, 2017. The Regulation entered into force on May 25, 2017. The new EU MDR replaces the Medical Device Directive (MDD) [93/42/EEC] and the Active Implant Medical Devices Directive (AIMD) 90/385/EEC.

Transition Period for EU MDR Compliance

The Transition Period began on May 27, 2017 for medical device manufacturers selling medical devices into Europe.

The Transition Period through 2025 and sell-off through 2026 applies only to products as certified by May 26, 2021. Any product modification requiring new Conformity Assessment has to comply with the MDR, if placed on the market after May 26, 2021. Therefore, if manufacturers plan to modify their products, they should get them certified by their Notified Body before May 26, 2021.

After the Transition Period, devices not in conformance with the MDR must be removed from the European market.

Certificates issued under the Medical Device Directive (MDD) [93/42/EEC] and the Active Implant Medical Devices Directive (AIMD) [90/385/EEC] prior to May 25, 2017 shall remain valid until the end of the period indicated on the Certificate, except for Certificates issued in accordance with Annex IV (EC Verification) of the Medical Device Directive (MDD) [93/42/EEC] and the Annex IV (EC Verification) of the Active Implant Medical Devices Directive (AIMD) 90/385/EEC, which may remain valid at the latest on May 27, 2021 (at which point the Certificates become void.)

Certificates issued under the Medical Device Directive (MDD) [93/42/EEC] and the Active Implant Medical Devices Directive (AIMD) [90/385/EEC] from May 25, 2017 shall remain valid until the end of the period indicated on the Certificate, which shall not exceed (5) five years from its issuance. These Certificates become void on May 27, 2024.

Value Proposition

The new EU Medical Device Regulation (MDR) includes 123 Articles and 17 Annexes. Please refer to the table below for a complete list of the Articles and Annexes.

Chapters 1 - 10

Chapter I – Scope and Definitions

- Articles 1 – 4

Chapter II – Making Available on the Market and Putting into Service of Devices, Obligations of Economic Operators, Reprocessing, CE Marking, Free Movement

- Articles 5 – 24

Chapter III – Identification and Traceability of Devices, Registration of Devices and of Economic Operators, Summary of Safety and Clinical Performance, European Database on Medical Devices (EUDAMED)

- Articles 25 – 34

Chapter IV – Notified Bodies

- Articles 35 – 50

Chapter V – Classification and Conformity Assessment - Classification

- Articles 51 – 60

Chapter VI – Clinical Evaluation and Clinical Investigations

- Articles 61 – 82

Chapter VII – Post-Market Surveillance, Vigilance and Market Surveillance

Section 1 – Post-Market Surveillance

- Articles 83 – 86

Section 2 – Vigilance

- Articles 87 – 92

Section 3 – Market Surveillance

- Articles 93 – 100

Chapter VIII – Cooperation between Member States, Medical Device Coordination Group, Expert Laboratories, Expert Panels and Device Registries

- Articles 101 – 108

Chapter IX – Confidentiality, Data Protection, Funding and Penalties

- Articles 109 – 113

Chapter X – Final Provisions

- Articles 114 – 123

Annexes

Annexs I – XVII

Expanded Scope of the Rules to Include Other Device/Products

The scope of the rules have been expanded to include devices used for:

- Cleaning, Disinfection or Sterilization
- Certain Aesthetic Implantable and Invasive Products with No Medical Purpose
- Products using Non-Viable Human Tissues and Cells that do not fall under the EU's Advance Therapy Medicinal Products (ATMP) Regulations

The EU MDR Classification Rules may reclassify existing devices into higher risk categories, thus requiring manufacturers to ensure conformity with the specific requirements of the MDR.

General Obligations of Manufacturers under the New EU MDR

Pursuant to Article 10, General Obligations of Manufacturers of the EU MDR, the Manufacturer must comply with the following general requirements:

Article 10 General Obligations of Manufacturers	
Compliance with the EU MDR Requirements	
1.	When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.
Risk Management System per Section 3 of Annex I (General Requirements)	
2.	Manufacturers shall establish, document, implement and maintain a system for Risk Management as described in Section 3 of Annex I.
Clinical Evaluation per Article 61 (Clinical Evaluation) and Annex XIV (Clinical Evaluation and Post-Market Clinical Follow-Up), Including a Post Market Clinical Follow Up (PMCF) Study	
3.	Manufacturers shall conduct a Clinical Evaluation in accordance with the requirements set out in Article 61 and Annex XIV, including a PMCF.
Technical Documentation Requirements per Annex II (Technical Documentation) and Annex III (Technical Documentation on Post-Market Surveillance	
4.	Manufacturers of devices other than custom-made devices shall draw up and keep up to date Technical Documentation for those devices. The Technical Documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The Technical Documentation shall include the elements set out in Annexes II and III. The Commission is empowered to adopt delegated acts in accordance with Article 115 amending, in the light of technical progress, the Annexes II and III.

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	Documentation Requirements for Custom-Made Devices per Section 2 of Annex XIII (Procedure for Custom-Made Devices)
5.	Manufacturers of custom-made devices shall draw up, keep up to date and keep available for Competent Authorities documentation in accordance with Section 2 of Annex XIII
	Declaration of Conformity Requirements per Article 19 (EU Declaration of Conformity) and CE Marking of Conformity per Article 20 (CE Marking of Conformity)
6.	Where compliance with the applicable requirements has been demonstrated following the applicable Conformity Assessment Procedure, manufacturers of devices, other than custom made or investigational devices, shall draw up an EU Declaration of Conformity in accordance with Article 19, and affix the CE marking of conformity in accordance with Article 20.
	Implementation of Unique Device Identification (UDI) System Requirements per Article 27 (Unique Device Identification System) and Registration Obligations per Article 29 (Registration of Devices) and Article 31 (Registration of Manufacturers, Authorized Representatives and Importers)
7.	Manufacturers shall comply with the obligations relating to the UDI system referred to in Article 27 and with the registration obligations referred to in Articles 29 and 31.
	Requirements for Manufacturer to Maintain Certificates of Conformity for Competent Authority per Article 56 (Certificates of Conformity)
8.	Manufacturers shall keep the Technical Documentation, the EU Declaration of Conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56, available for the Competent Authorities for a period of at least 10 years after the last device covered by the EU Declaration of Conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market. Upon request by a Competent Authority, the manufacturer shall, as indicated therein, provide that Technical Documentation in its entirety or a Summary thereof. A manufacturer with a registered place of business outside the Union shall, in order to allow its Authorized Representative to fulfill the tasks mentioned in Article 11(3), ensure that the Authorized Representative has the necessary documentation permanently available.
	Requirements for Manufacturer to Implement Conformity Procedures for the Quality Management System (QMS)
9.	Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in device design or characteristics and changes in the harmonized standards or CS by reference to which the conformity of a device is declared shall be adequately taken into account in a timely manner. Manufacturers of devices, other than investigational devices, shall establish, document, implement, maintain, keep up to date and continually improve a Quality Management System that shall ensure compliance with this Regulation in the most effective manner, and, in a manner that is proportionate to the risk class and the type of device. The Quality Management System shall cover all parts and elements of a manufacturer's organization dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Regulation. The Quality Management System shall address at least the following aspects: a. A strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system; b. Identification of applicable general safety and performance requirements and exploration of options to address those requirements; c. Responsibility of the management; d. Resource management, including selection and control of suppliers and sub-contractors; e. Risk management as set out in Section 3 of Annex I; f. Clinical evaluation in accordance with Article 61 and Annex XIV, including PMCF;

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9.	g. Product realization, including planning, design, development, production and service provision; h. Verification of the UDI assignments made in accordance with Article 27(3) to all relevant devices and ensuring consistency and validity of information provided in accordance with Article 29; i. Setting-up, implementation and maintenance of a post-market surveillance system, in accordance with Article 83; j. Handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders; k. Processes for reporting of serious incidents and field safety corrective actions in the context of vigilance; l. Management of corrective and preventive actions and verification of their effectiveness; m. Processes for monitoring and measurement of output, data analysis and product improvement.
Post-Market Surveillance Requirements per Article 83 (Post-Market Surveillance System of the Manufacture)	
10.	Manufacturers of devices shall implement and keep up to date the post-market surveillance system in accordance with Article 83.
Labeling Compliance with Localization Rules (i.e. Native Language Requirements) per Section 23 (Label and Instruction for Use) of Annex I (General Requirements)	
11.	Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.
Recall Requirements and Requirements for Certificates of Conformity per Article 56 (Certificates of Conformity)	
12.	Manufacturers who consider or have reason to believe that a device which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the device in question and, where applicable, the authorized representative and importers accordingly. Where the device presents a serious risk, manufacturers shall immediately inform the Competent Authorities of the Member States in which they made the device available and, where applicable, the notified body that issued a certificate for the device in accordance with Article 56, in particular, of the non-compliance and of any corrective action taken.
Requirements for Recording/Reporting Incidents and Field Safety Corrective Actions per Article 87 (Reporting of Serious Incidents and Field Corrective Actions) and Article 88 (Trend Reporting)	
13.	Manufacturers shall have a system for recording and reporting of incidents and field safety corrective actions as described in Articles 87 and 88.
Requirements for Manufacturer to Maintain Certificates of Conformity for Competent Authority per Article 56 (Certificates of Conformity)	
14.	Manufacturers shall, upon request by a Competent Authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language determined by the Member State concerned. The Competent Authority of the Member State in which the manufacturer has its registered place of business may require that the manufacturer provide samples of the device free of charge or, where that is impracticable, grant access to the device. Manufacturers shall cooperate with a competent authority, at its request, on any corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market or put into service.

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	Requirement for Electronic System for Registration of Economic Operators per Article 30(1) (Electronic System for Registration of Economic Operators)
15.	Where manufacturers have their devices designed or manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 30(1).
	Requirement for Manufacturers to Carry Product Liability Insurance for Products
16.	Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law. Manufacturers shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law.

RCA Service Offerings to Assist Existing/New Clients with Implementation of the EU MDR Requirements.

1. Perform a Comprehensive Review of Client's Entire Product Portfolio and Current Certificate Expiry Dates

   - Review and Assess the Client's entire Product Portfolio including its:
     - Legacy Products [CE marked devices under the Medical Device Directives (MDD) 93/42/EEC or the Active Implantable Medical Device Directive (AIMD) 90/385/EEC];
     - Modified Legacy Products; and/or
     - New Products currently in the Design/Development Phase.
   - Confirm whether any Legacy Products and/or Modified Legacy Products have been affected by the new MDR Definitions and/or Reclassification of certain types of products in to higher risk classes of devices;
   - Reassess current classification of devices based on MDR Classification Rules;
   - Prepare Product Rationalization Strategy Reports for Legacy Products, Modified Legacy Products, and New Products (as appropriate and applicable) which may assist the Client in making internal decisions about whether to maintain and/or bring such products in compliance with the MDR;
   - Check the status of MDD Certificate expiry dates and prepare an EU MDR Certificate Compliance Strategy for each device

2. Staff Augmentation and Support

   - Readiness Audits / Pre-Certification Audits and/or Assessments

3. Perform a Gap Assessment of the Client's Current Quality Management System (QMS) and its Current Processes and Procedures for MDR Compliance with particular attention to the following:

- Review and Assess the Client Quality Management System (QMS) requirements including all current policies, processes, and procedures against ISO 13485:16 requirements
- Technical Documentation requirements (Technical Files and/or Design Dossiers) against MDR requirements
    - Labeling requirements (including required languages in each Member States) against MDR requirements
    - FDA Unique Device Identification (UDI) System against MDR UDI requirements
        - Requirements for the data to be entered into the EU MDR UDI Database per Article 28
        - Requirements for device registration per Article 29 EUDAMED Database
    - Requirements for data to be entered into the EU MDR EUDAMED Database per Article 33
    - Risk Management System (RMS) against MDR requirements
        - Risk Management Plan and Report for each device
    - Clinical Data Requirements against MDR requirements
        - Clinical Evaluation and MDR requirements regarding Clinical Investigations conducted to demonstrate conformity of devices
        - Clinical Evaluation Plan
        - Clinical Evaluation Report (CER)
        - Post-Market Clinical Follow Up (PMCF) requirements per MDR requirements
        - PMCF Plan
        - PMCF Report
        - Clinical Investigation requirements per MDR including Clinical Investigation Plan and Report
    - Safety and Performance Requirements against MDR requirements
        - Summary of Safety and Performance Requirements (SSP) for Implantable Devices and Class III Devices
    - Post-Market Surveillance System (PMS) against MDR requirements
        - Post-Market Surveillance Plan
        - Post-Market Surveillance Report
        - Periodic Safety Update Report

- Vigilance Activities against MDR requirements
    - Reporting of Serious Incidents and Field Safety Corrective Actions
    - Trend Reporting
    - Analysis of Serious Incidents and Field Safety Corrective Actions
    - Analysis of Vigilance Data
- Market Surveillance Activities against MDR requirements
    - Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance
    - Procedures for dealing with devices presenting an unacceptable risk to health and safety
- Requirements regarding Design and Manufacture of Devices per MDR requirements

4. Remediation and Implementation of EU MDR Compliance Plan

- Supply Chain Requirements against MDR requirements
- Development/Implementation of an EU MDR Compliance Plan for systems and devices
- Remediation of EU MDR Compliance Gaps noted during Assessment
- Development and Implementation of EUDAMED Database compliance plan for all of the following six pillars of the EUDAMED
    - Actor Registration
    - Unique Device Identification
    - Certificate
    - Clinical Investigation
    - Vigilance
    - Market Surveillance