EU MDR: How to Prepare for the Upcoming Changes in Regulation
What is EU MDR?

Nearly everyone will be exposed to a medical device at some point in their life. Therefore, it is imperative that medical devices are safe, effective and perform as intended. Recognizing the need to enforce heightened safety measures and risk management processes, the European Parliament and the Council of the European Union developed the Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) in 2017. These regulations are set to replace the current Medical Device Directive (MDD) established in the early 1990s. In short, the new regulations are intended to increase the transparency of the approval and usage of medical devices as well as improve patient experiences and outcomes.

Under the new regulations, medical devices and in vitro devices must receive a CE Marking (symbol for European conformity to regulations established by the European Commission [EC], European Parliament [EP] and European Union [EU] member states) certificate by the set deadlines.

Med devices without the MDR/IVDR CE Mark won’t be permitted to be sold in the EU, which means they won’t be available for use in health care systems.¹

Glossary of Terms

- **CER** (Clinical evaluation report): Consists of analyzed data collected either from a clinical investigation of a device, or the results of other studies on substantially equivalent devices.
- **EUDAMED** (European Database on Medical Devices): A web-based database for storing and exchanging data related to all aspects of medical device development.
- **GUDID** (Global Unique Device Identification Database): Administered by the U.S. Food and Drug Administration (FDA) and serves as a reference catalog for every device with a Unique Device Identifier (UDI).
- **IMDRF** (International Medical Device Regulatory Forum): Established in February 2011 as a forum to discuss future directions in medical device regulatory harmonization.
- **MDD** (Medical Device Directive): The current medical device regulation for CE approval.
- **NB** (Notified Body): Organization designated to review and grant CE approval of medical devices.
• **PMCF** (Postmarket clinical follow-up): Continuous process that updates the clinical evaluation of a medical device — addressed in the postmarket surveillance plan.

• **PMS** (Postmarket surveillance): Process for how a medical device manufacturer will ensure its device remains safe after it is on the market.

• **PSUR** (Periodic safety update report): Document that provides an evaluation of the risk-benefit balance of a medicinal product at defined time points after its authorization.

• **SSCP** (Summary of safety and clinical performance): Required for certain types and classes of devices and is expected to consider diagnostic or therapeutic options addressed in the CER.

• **UDI** (Unique Device Identifier): Device identification system set up to adequately identify medical devices from manufacturing through distribution to patient use.

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**Time Line for MDR/IVDR Compliance**

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<tr>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
<th>2024</th>
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<td><strong>May 26, 2020</strong></td>
<td><strong>Deadline for compliance with MDR.</strong></td>
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<td><strong>May 26, 2024</strong></td>
<td><strong>End of grace period extended to specified products with a valid certificate issued under the Medical Devices Directive (MDD).</strong></td>
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<td><strong>Deadline for compliance to IVDR.</strong></td>
<td><strong>May 2022</strong></td>
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Changes You Will Likely See With the New Regulations

- More premarket regulatory obligations.
- More stringent risk management requirements.
- Creation of European and global medical device databases.
- New identification and traceability requirements for existing and new devices.
- Medical device classifications expanding to new areas.
- More postmarket regulatory obligations.
- New Notified Body (NB) accreditation requirements.
- Changes to technical documentation requirements.
- New requirements for quality management system compliance.

Premarket Regulatory Obligations

The essential premarket conformity requirements — now called general safety and performance requirements — will increase. Manufacturers will need to plan and implement a systematic process to continuously generate, collect and analyze clinical data pertaining to a device in order to verify and sustain the device’s safety and performance.

Risk Management

Risk management will need to be a continuous iterative process throughout the device’s entire life cycle, including regular systematic updates. For compliance, manufacturers will be required to:

- Establish and document a risk management plan for each device.
- Identify and analyze the known and foreseeable hazards associated with each device based on factual evidence.
- Estimate and evaluate the risks that could occur when a device is used as intended as well as risks due to potential misuse.
- Eliminate or control all risks.

Global Database for Medical Devices

Medical devices are constantly evolving in performance and sophistication, which can present challenges in medical device development and usage. The European Database for Medical Devices (EUDAMED) was developed to help alleviate the challenges and foster more harmonization with device quality and safety requirements.

Manufacturers will need to enter reports of all incidents, injuries and deaths involving their devices into EUDAMED.
EUDAMED

The database is a secure, web-based portal designed to:

- Function as a central repository for information on all medical device product life cycles.
- Help European authorities conduct pre- and postmarket surveillance on medical devices through information exchange.
- Enhance overall transparency through better access to information for both the public and health care professionals.

Data contained in the EUDAMED will include:

- Data related to the registry of manufacturers, authorized representatives and devices.
- Data related to the certificates issued, modified, supplemented, suspended, withdrawn or refused according to established procedures.
- Data obtained in accordance with the vigilance procedure on incidents or near-incidents, which occur during the use of the medical device.
- The summary of safety and clinical performance (SSCP) of medical devices, which is entered in EUDAMED by the NB.

New Device Identification and Traceability Requirements

Traceability of devices is essential to ensure that data can be tracked to a specific device to facilitate urgent action in the event of a recall. The FDA has established a Unique Device Identifier (UDI) system to effectively identify devices throughout their product life cycle. As part of MDR, this identifier will be required on all device labels.

Medical Device Classification

Under EU MDR, many medical devices will be reclassified. Some, depending on the device’s purpose, will be bumped up to a higher risk class. These include:

- Devices incorporating nanotechnology.
- Orthopedic implants such as spinal disk replacements or implants that come in contact with the spinal column.
- Surgical meshes.
- Life-saving active therapeutic devices such as closed-loop systems and automated external defibrillators.
- Software that drives a device or influences the use of a device will fall within the same class as the device.

The definition of a medical device will expand to include non-medical and cosmetic devices not previously regulated, these might include:

- Aesthetic products such as colored contact lenses, cosmetic implants, lipoplasty devices and laser products used for hair removal.
- Cleaning products used for disinfecting and sterilizing medical devices.
- Various contraception products.
**Reusable Devices**

A new Class I category is being created for reusable devices (Class Ir) such as surgical instruments and endoscopes.

It’s important to be aware that these devices will not be granted extensions and grandfathering in legacy devices will be prohibited.

**IVDR Classification**

One of the biggest changes to IVDR will be the risk classification of these devices. Instead of naming specific IVD devices or medical conditions, the risk classification of a device is determined by its intended purpose and takes into consideration not only the risk to the individual but also the risk to public health. In vitro devices will be classified into four risk classes, each requiring a review by the NB.

<table>
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<tr>
<th>MDR Class</th>
<th>Risk Profile</th>
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<tr>
<td>A</td>
<td>Low individual risk and low risk to public health.</td>
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<tr>
<td>B</td>
<td>Moderate individual risk and/or low risk to public health.</td>
</tr>
<tr>
<td>C</td>
<td>High individual risk and/or medium risk to public health.</td>
</tr>
<tr>
<td>D</td>
<td>High individual risk and high risk to public health.</td>
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**Note:** Class A devices will be self-certified by their manufacturers unless they are sold as sterile devices. Class B, C and D devices will require a conformity assessment by the NB.

**Postmarket Regulatory Obligations**

Regulatory requirements for postmarket surveillance will become more granular and stringent. Once a product is on the market, the manufacturer will be required to continue gathering clinical data and examining the product through postmarket surveillance (PMS). As stated in the new Article 83 of MDR, the PMS system is used to:

- Update the clinical evaluation.
- Update the benefit-risk determination.
- Update the instructions for use in the product’s labelling.
Conclusions from the review of PMS data must be summarized in a report. This report needs to be reviewed by the NB and passed to an expert panel, which may provide an opinion with respect to the device.

Postmarket clinical follow-up (PMCF) data is required for high-risk devices where long-term safety and performance data is unknown or where European Commission (EC) certification is based on equivalence.

**Notified Body Accreditation**

Notified Bodies (NB) must be redesignated under the new regulation, which means they will be required to meet more stringent regulatory criteria, particularly with clinical competence. NBs cannot perform recertifications until they have met the designation requirements. As a medical device manufacturer, you need to clarify these items with your NB:

- Is your NB fully designated as an MDR approver?
- Does the scope of your NB’s designation cover all your products?
- Does your NB have the availability to evaluate and approve your device by the deadline?
- Does your NB require additional data on your devices?
- Is your NB knowledgeable about the transitional provisions of the new regulation?

**Note:** The designation process could take up to 12 months or more. It’s important to take this into account when planning the certification of your products.

**Technical Documentation**

Technical documentation requirements will change substantially under EU MDR. For starters, the regulation will no longer include the design dossier, currently required for the MDD. The dossier information and all other documentation will fall under the category of technical documentation. Some of the key technical documents include:

- Risk analysis.
- Clinical data analysis.
- General safety and performance requirements.
- Quality assurance SOPs.
- Labelling updates.
- Postmarket clinical follow-up (PMCF), which includes the clinical evaluation report (CER) and periodic safety update report (PSUR).
Manufacturers should perform a gap analysis to determine how the new clinical investigation requirements will impact the existing clinical investigation for new devices.

**Quality System Compliance**

The FDA's quality system regulation (21 CFR Part 820.3) requires that all companies developing regulated products must implement a quality management system (QMS) to ensure that finished devices will be safe, effective and in full compliance with the U.S. Federal Food, Drug and Cosmetic (FD&C) Act.

With more robust regulatory requirements enforced by MDR, companies will need to revisit their core quality system processes, including quality assurance, risk management and postmarket expectations to ensure they are able to comply with the new requirements. The requirements for the manufacturer’s QMS largely correspond to ISO 13485. This is part of the global effort to harmonize medical device quality management. However, compliance to ISO 13485 doesn’t guarantee that a medical device will be fully compliant with EU MDR. It’s important to understand the new requirements and identify any areas that your current QMS fails to meet the requirements of the new regulation.

**Preparing for EU MDR Compliance**

Doctors in hospitals need to have the necessary medical devices at the ready to perform procedures. Unless a device is fully compliant with EU MDR by the deadline, it cannot be used where it is needed.

The medical device industry is advancing fast. To keep up with the rapid pace, manufacturers need to be agile and willing to adopt digital technologies for managing quality and compliance.

- NBs will not rely on historic product performance or reviews.
- You need to have current data.
- You need to have immediate access to up-to-date documentation from new clinical studies.
- The certification time frame is tight, which means there is little to no margin of error and no do-overs in pursuing regulatory compliance.

**Digital Solutions Simplify Compliance With EU MDR**

MasterControl Quality Excellence™ Solution

Modernizing your quality management system and processes gives you the confidence to sufficiently prepare for and achieve compliance with the requirements of EU MDR. The MasterControl Platform enables you to break down silos, eliminate human errors, reduce costly delays and provide regulators and customers the assurance that you consistently produce high-quality, safe and effective products.
References


3. "6 Tips for a Successful Transition to the EU MDR," Jenny Lin, GxP Lifeline, Aug. 29, 2019, [https://www.mastercontrol.com/gxp-lifeline/6-tips-for-a-successful-transition-to-the-eu-mdr/]


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