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The impact of **new European Medical Device Regulations**

Medical device and diagnostic manufacturers are preparing to realize compliance

The New Regulation (EU) 2017/745 for medical devices (MDRs), which went into effect on May 26, 2021, is a major update to the regulatory framework in the European Union (EU). Although the regulation varies from product to product, the primary additions are related to documentation, with additional product information and traceability requirements. Although the new regulation does not impact the functionality or risk profile of the products, medical device manufacturers' compliance requirements are significant. As such, the entire industry is focusing on preparing for compliance. This article gives you the critical facts about the regulations, and what medical device manufacturers should be doing to ensure they will be compliant.

What is addressed in the new requirements?

The expanded documentation requirements in the new regulation include:

- **Label changes** – Additional information, including unique device identifier (UDI) and new symbols, such as carcinogenic, mutagenic and reprotoxic (CMR)/ endocrine disrupting phthalates (ED) substance indications
- **Instructions for use** – Additional information and clarification, covering areas such as intended user, CMR/ED substances, implanted device and an explanation of the new label symbols
- **Certificates issued by a notified body** – Additional information including UDI and the registration number of the manufacturer
- **Declaration of conformity** – Additional information, including UDI, registration number of manufacturer and of the European authorized representative
- **Scope and classification** – Changes to the classification rules in Annex VIII of the MDR may result in a higher risk class for some devices, subjecting them to more stringent conformity assessment requirements
- **Certificates of free sale** – New data, including basic UDI and notified body certificate number

EU medical device manufacturer obligations

Beyond the expansion of documentation requirements, medical device and diagnostic (MD&D) manufacturers must meet many obligations to operate in the EU.

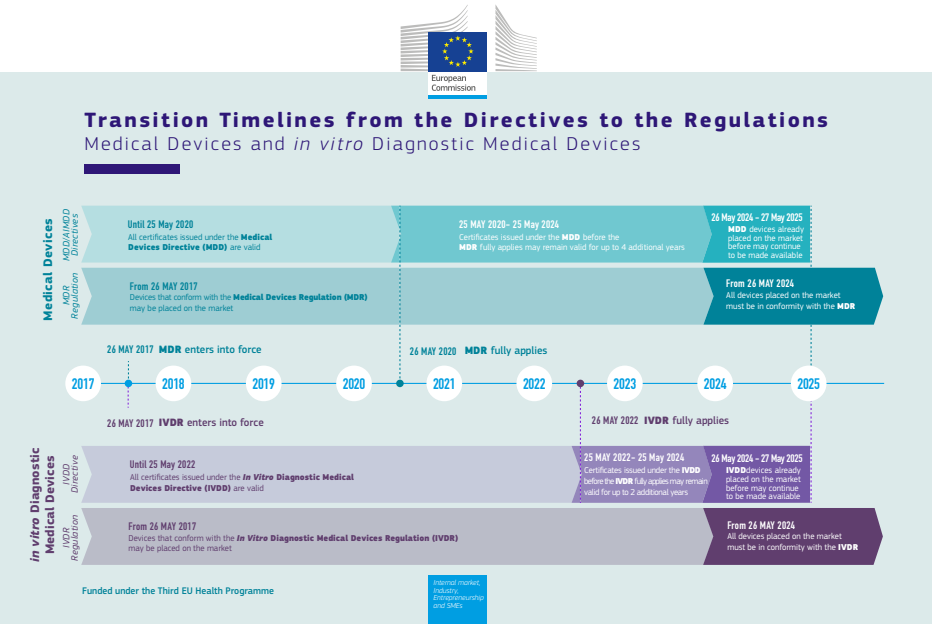

Figure 1. Transition timelines from the directives to regulations.

Manufacturers are required to have systems for both risk management and quality management. In addition, they are required to conduct clinical evaluations, compile technical documentation and apply conformity assessment procedures.

Manufacturers must be able to cover any financial damages caused by defective devices, and they are required to have systems in place to ensure they can meet potential financial responsibilities of such harm. They must also name a person responsible for regulatory compliance within their organization. In addition, manufacturers outside the EU/European Economic Area (EEA) must have a contract with an authorized representative inside the EU/EEA. These requirements highlight the necessity for medical device manufacturers to quickly identify devices subject to recall. These recalls can have devastating effects on manufacturers, both from a financial and brand reputation perspective. With proactive manufacturing execution systems (MES) that provide granular genealogy in place, MD&D manufacturers are able to detect and minimize production defects before the product is even shipped. In the event a recall is needed, the MES enables the firm to isolate the recall to the specifically affected devices instead of issuing broad product recalls.

The new regulation transition period will extend through May 27, 2024. Different provisions will come into force at various times throughout the transition period. For example, notified bodies and the Medical Device Coordination Group will be effective earlier, while UDI labeling will be effective later in the transition period (figure 1).

How are EU manufacturers preparing for compliance?

Preparing for compliance is not unique to the new EU regulations. To ensure compliance, manufacturers have a quality management system (QMS) in place where they can update product classifications and support clinical evaluation.

They have adopted paperless manufacturing with the implementation of MES, which automates the generation of the electronic device history records (eDHRs) and electronic batch records (eBRs). In addition to supporting and containing product recalls stated above, an MES provides proactive enforcement to ensure the right procedures, operators, equipment and materials are used within specification and in the right sequence. MES enables you to build in quality, preventing errors by enforcing as-designed production and reducing the risk of defective devices and recalls.

Further, the MES automates labeling and packaging requirements and supports the QMS during production. The MES also supports post-market surveillance, returning critical performance data back to engineering to continuously improve quality.

Manufacturers trust Siemens as the manufacturing solutions leader in MD&D

Opcenter™ EX MD&D software, which is part of the Xcelerator™ portfolio, the comprehensive and integrated portfolio of software and services from Siemens Digital Industries Software, is a leader in MES for medical device manufacturing. Using Opcenter enables the user to proactively enforce the 5Ms of manufacturing – man, material, method, measure and machine – reducing human error and standardizing processes with e-procedures. Using Opcenter creates end-to-end visibility throughout the production process.

Because Opcenter facilitates the automation data capture throughout production, a natural byproduct of the MES is the eDHR and eBR. Incorporating nonconformance management into the production process, compliance management is streamlined. Opcenter functionality is regulation-validated.

Based on the new EU MDR regulations, Opcenter is a leading solution to handle the changes related to product labeling and documentation. Opcenter enables users to automatically print product and tracking labels from original specifications and real-time manufacturing data, making sure that labels are complete and accurate, are produced in a timely manner and are attached to the proper unit, lot or batch. These capabilities provide significant benefits for MD&D manufacturers, including:

- **Providing a standardized identifier** that allows manufacturers, distributors and healthcare facilities **to more effectively manage medical device recalls** and **prevent issues from happening in the first place**
- Providing a **foundation** for a global, secure distribution chain, helping to **address counterfeiting and diversion** and **prepare for medical emergencies and expediting containment when issues arise**

- Leading the development of a medical device identification system that is **recognized around the world**
- Allowing **more accurate reporting, reviewing and analyzing of adverse event reports** so problem devices **can be identified and corrected more quickly**
- Reducing **medical errors** by enabling health care professionals and others to more rapidly and precisely identify a device and obtain important information concerning the characteristics of the device

Opcenter EX MD&D supports manufacturers' ability to adapt to changing regulations quickly and cost effectively while facilitating compliance and improving product quality. All of these things help position manufacturers to lead their respective markets.

For more information about the new regulations, see The European Union official website or ec.europa.eu.

To learn more about how Siemens is helping medical device manufacturers facilitate compliance with regulations, visit our Opcenter EX MD&D solution link.

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