THE NEW EU MEDICAL DEVICE REGULATION

RESHAPING THE MEDICAL DEVICE INDUSTRY IN EUROPE

The medical device industry in Europe is currently undergoing a major transition driven by the European Union's new Medical Device Regulation (MDR). MDR is referred to as the most significant change to European medical device legislation in recent times and inflicts major changes for medical device companies. The task to become compliant, a prerequisite for continued manufacturing and sales of medical devices in the EU, is highly complex, touching every aspect of the value chain – all under a tight deadline. However, doing it right may result in significant competitive advantages on a long-term basis.

In the beginning of the decade, several high-profile incidents compromising patient health and safety brought attention to the weaknesses in the EU legal system for medical devices and the urgent need for improvement. The technological development had outrun the current legal system, and it was agreed that an update of Europe's regulatory framework was necessary.

In May 2017, the European Commission published the new EU Medical Device Regulation (MDR) replacing existing directives. The new regulation is referred to as the most significant change to European legislation for medical devices for nearly twenty years. It will apply after a three-year transition period, in May 2020. All actors in the medical device industry will need to adopt systems, processes and procedures to become compliant. Non-compliance could possibly result in a company losing its license to operate and thus not being allowed to supply medical devices to the European market.

In comparison to the previous directives, the new MDR is four times longer, and the word "safety" appears over seven times more. The new regulation aims to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices to ensure greater protection of public health and patient safety, whilst supporting innovation. For manufacturers of medical devices, the regulation imposes increased liability and a life-cycle approach to selling medical devices. It requires higher-quality clinical data and evidence, increased post-market surveillance and tracking of devices through the value chain.

November 2018 marked the halfway point in the transitional period for the medical device industry to move from the current directives to the new regulation. Companies in the medical device industry should start working on becoming compliant immediately, not doing so would jeopardize the opportunity to provide medical devices to the EU market.

FACTS: MEDICAL DEVICES

A **medical device** is any instrument, software, implant etc. intended by the manufacturer to be used by humans for diagnostic and/or therapeutic purposes. Medical devices range from basic bandages to complex and programmable pacemakers with micro-chip technology.

Medical devices are **classified** into different categories depending on their design complexity, use characteristics, and potential for harm if misused. In the EU, medical devices are classified into four different classes, ranging from low risk to high risk:

- **Class I** – e.g. bandages, compression stockings, walking aids
- **Class IIa** – e.g. hearing-aids, blood transfusion tubes, catheters
- **Class IIb** – e.g. ventilators, intensive care monitoring equipment
- **Class III** – e.g. pacemakers, balloon catheters, prosthetic heart valves

A **Notified Body** is an independent, accredited organization designated by an EU member state to assess conformity to regulation of medical devices. With a Declaration of Conformity, the manufacturer can label the product with a CE-Mark that enables commercialization within the European Economic Area.

WHAT WILL CHANGE, WHEN?

Following the publication of MDR in 2017, the EU medical device industry has three years to become compliant. By then, any certification of a new device, or recertification of a legacy device, as well as all company processes and procedures must be according to the new requirements.

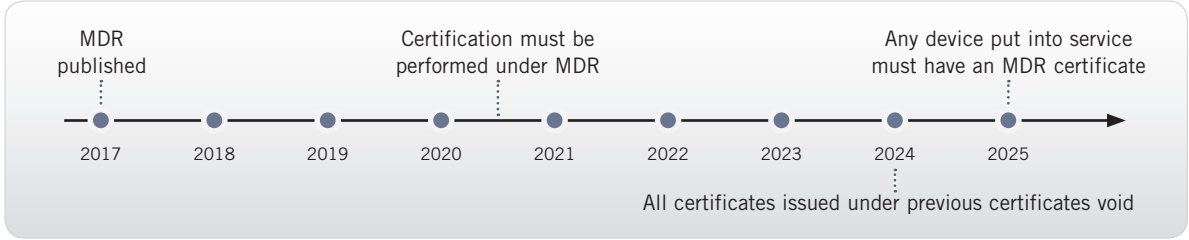
However, the entire product portfolio does not need to be certified under MDR by May 2020. CE-Marked legacy devices have a maximum of five additional years to transition, assuming they are manufactured, packaged, labeled and released on the EU market before May 25th 2020. However, in May 2024, all previous certificates become void, and in 2025 all devices placed on the market under old certificates can no longer be put into service, and must be scrapped.

While these dates may seem far away in the future, companies should begin the transition immediately, because the new regulation will almost certainly require substantial changes. The changes are numerous and affect nearly all functions of companies in the medical device industry. The journey to EU MDR compliance begins with understanding what is changing, when. Triathlon has outlined six major changes that can be seen in the wake of MDR.

1 Definitions and classifications: With the new regulation, the definition of a medical device expands to also include devices intended for cleaning, disinfection or sterilization of other devices, as well as software related to medical devices. Additionally, some medical devices shift to higher classifications and some devices require greater Notified Body involvement.

2 Life-cycle approach: Compared to current directives, MDR places more emphasis on a life-cycle approach to safety. The previous focus, on solely legal manufacturers, will shift to cover the entire value chain and levy higher levels of responsibility and liability at every tier. Not only is this related to increased demands on clinical and post-market surveillance data, but also importers and distributors will be responsible for verifying that a device is CE-marked. All value chain actors must likewise communicate safety and performance issues if identified.

3 EUDAMED: With the creation of an official central European medical device database, EUDAMED, all value chain actors are to report all incidents related to their devices. Information previously stored only internally, will now become available to the public. The objective is to increase transparency and provide healthcare professionals and the general public with access to more and higher quality data.



4 Unique Device Identification (UDI): With the purpose to facilitate traceability of devices and increase effectiveness of post-market safety-related activities, Unique Device Identification (UDI) is a new mandatory requirement. Devices need to be assigned a Device Identifier (DI) and production series will be identified with a Production Identifier (PI). The UDI must be included on the label and other documents related to a device.

5 Clinical evaluation: Numerous medical device companies have previously launched products by demonstrating equivalence (that is, when a device relies on the clinical data of another device). Under MDR this will become more difficult as Notified Bodies will require internally produced, high-quality clinical investigations. The increased demands on clinical data will not only require companies to perform clinical evaluations on already launched devices, but will also increase costs, lengthen development cycles, and require more resources for data collection and reporting during product life-cycles.

6 Technical documentation and labels: The new regulation will require most companies to update the technical documentation and labeling for their devices. MDR demands all technical documentation to be clear and searchable and more information need to added to the labels, including the new MDR symbol. Instructions for Use (IFU) will also have to be available in local languages and worded for a layperson to understand and apply.

KEY SUCCESS FACTORS FOR AN EFFECTIVE MDR IMPLEMENTATION

Transitioning to the MDR might seem overwhelming and many companies don't know where to start. Triathlon has, with support from industry experts, identified five key success factors for the transition towards MDR compliance.

1 Perform a gap analysis

When it has been determined what is changing, it needs to be established whether current systems and processes are sufficient to satisfy the new regulatory requirements and thereby assess the current level of compliance. A thorough gap analysis will create an understanding of the project scope, the risks of non-compliance and generate a task list for updating procedures and documentation.

2 Carry out a portfolio assessment

Based on the gap analysis and outlined needs to become compliant, an assessment of product pipelines and portfolios needs to be performed. The assessment should outline whether the pipeline and existing devices have a financial viability to justify costs and organizational classification, conformity assessment, post-market surveillance and additional gaps in the technical documentation. The decision to rationalize and divest some devices for the broader EU market may pose significant challenges and will require well-reasoned justifications as well as involvement of high-level management.

3 Detail enterprise-wide action plan

Construct a roadmap, including key milestones, for the MDR transition and implementation. Outline a detailed registration plan for when to transfer products to MDR, considering the overall time plan, availability of Notified Bodies and the existing certificate expiry dates. Detail for all devices, following the portfolio assessment, what needs to be updated for MDR compliance. Consider also additional projects and plans within the organization to ensure alignment with MDR requirements.

4 Ensure a pacey implementation

Key to an effective implementation of MDR is to establish a cross-functional project organization and solid project management. Make sure that the project scope is covered by forming sub-projects encompassing organizational resources from all functions of the company, from clinical evaluation to IT. Review efficiency and effectiveness by clear division of responsibilities, effective follow-up and meetings on progress, risks, discrepancies and requirements.

5 Breed MDR awareness

Change management and effective communication is key to a successful MDR transition. Awareness of the changed business needs, operational implications as well as the regulation itself, needs to be created in the entire organization, to facilitate a smooth transition from the start, until full compliance. Develop methods of keeping key stakeholders updated on project achievements and progress to ensure stakeholder engagement throughout the transition.

A proactive approach to implement the new MDR, materializing the five key success factors, should be prioritized by companies in the EU medical device industry as an important organizational milestone. The new regulation presents an opportunity to restructure and update processes to become more efficient and effective, with the ultimate outcome being higher-quality and safer devices. The transition to MDR can be challenging, but the most successful companies could enjoy a substantial competitive advantage.

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