Critical software

Medical Devices Regulation 2020 Everything You Need to Know

An overview of the key regulatory changes, their impacts and how to prepare for them.

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Am I Ready?

According to the World Health Organisation (WHO), there are about 1.5 million different medical devices in the world. These devices range from basic equipment like thermometers and syringes, through to more complex surgical instruments, pacemakers, prostheses, catheters, and therapeutic and diagnostic equipment. These more complex, high-risk devices are often responsible for protecting and sustaining human life.

Doctors and other health professionals expect medical devices to assist them more and more during diagnosis and treatment. At the same time, there is a revolution underway in the medical devices industry – putting embedded software at the heart of many complex and critical devices. As the number and complexity of these medical devices continues to rise, so does the demand for safety and efficiency. Yet industry regulation has struggled to keep up.

For example, regulation to date has failed to consider software's own role as a medical device, ignoring thousands of health apps for patients and health professionals that are available without stringent checks. However, continued scientific and technical developments have pushed the industry to a point of change that will impact software apps and medical devices as a whole.

In 2017, the European Council and Parliament tried to catch up with this new reality by approving the new Medical Device Regulation (MDR). This new regulation will come into effect on May 2020, introducing significant changes that are mandatory for companies to comply with. Medical devices can no longer be delivered to the European market without conforming to the strict safety requirements of the European Union's new regulations.

Placing medical devices in the European market is a complex process, so many companies have turned a blind eye and deferred implementing new measures to conform to the new regulations. To help medical device companies prepare for these changes, this paper explores the impact of them, and best practice to allow companies to transition in as pain free a way as possible.

WHAT CAN I EXPECT?

The formal regulation of medical devices in Europe started in the early 90s, pretty late compared to other critical industries - even compared with the pharmaceutical sector, for example.

With the rapid growth in the availability and complexity of medical equipment, a crucial directive was then developed, the Medical Devices Directive (MDD), the current core of the relevant legislation.

This legal framework consists of three directives:

- **Medical Device Directive (MDD 93/42/EEC)**
- **Active Implantable Medical Device Directive (AIMDD 90/385/EE)**
- **In Vitro Diagnostic Medical Device Directive (IVDMDD 98/79/EC)**

These three directives have guided the production of medical devices. However, the new MDR will replace the existing Medical Devices Directive (MDD) and the Active Implantable Medical Device Directive (AIMDD).

What Does This Change Mean?

1. NEW CLASSIFICATION RULES

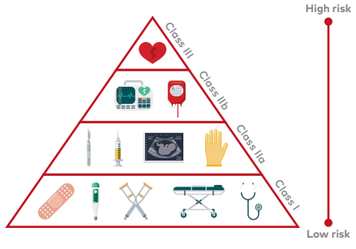
According to the European framework, there are four classes of medical devices: Class I (including Is – sterile - and Im - measuring), IIa, IIb and III.

Class I - Lowest perceived risk. Includes devices which do not interact with the internal body, for example, sterile plasters (Is) or thermometers (Im).

Class IIa - Medium perceived risk. For example, surgical gloves and diagnostic ultrasound machines.

Class IIb - Also medium risk. Some unique controls are required, similar to IIa, and here we find examples like surgical lasers and infusion pumps.

Class III – The highest perceived risk. Examples include implants that require permanent monitoring.



With the MDR, all medical devices need to be re-assessed, to ensure that they comply with the regulatory certification and to identify any possible new device classes.

From now on, all devices containing software, including those medical apps that were not previously considered medical devices, will be classified as Class I at least. There are other contexts where the software will be classified as a higher class. For example, software can be considered a device Class IIa if it is intended to provide information which is used to make decisions with diagnosis or therapeutic purposes. If those decisions have an impact that may cause death or an irreversible deterioration of a person's state of health, the software is considered Class III.

Also, devices that were self-certified, have been reclassified to a higher class. If that's the case, manufacturers will need to re-submit requirements and update their documentation, labeling and clinical information. All of these aspects will increase the time and cost of processes.

These new changes will see the establishment of a scrutiny procedure for notified bodies, which leads us to the second significant alteration.

2. MORE TRANSPARENCY

One of the main priorities of the MDR is to increase the amount of information available relating to medical devices. Detailed data should be easy to access by competent authorities, manufacturers, notification bodies and the public.

To achieve this, the EU has established a Unique Device Identification (UDI) system to improve the identification and traceability of medical devices along the supply chain.

The UDI will be placed on the label of the device and include, for instance, the activities of distributors.

The new MDR also includes the creation of a European database (Eudamed) with all kinds of medical devices information on conformity assessments, certificates and investigations, (post-) market surveillance and vigilance. This information should be provided and kept up-to-date by manufacturers.

3. MORE PRESSURE ON NOTIFIED BODIES

In the EU, ensuring the compliance and security of medical equipment is made via a conformity assessment, performed by notified bodies, designated by EU Member States.

One of these is the affixation of the CE (Conformité Européenne) conformity mark, where a rigorous process is followed to achieve conformity assessments. This typically involves an audit of the manufacturer's quality system and, depending on which type of device is being appraised, a review of the manufacturer's technical documentation covering the device's safety and performance.

At the end of this process, manufacturers can place a CE mark on a medical device if it has passed the conformity assessment, meaning it is ready to be used in the industry.

The new classification rules introduced by the MDR will increase the number of devices that need to be submitted to the notified bodies' evaluation process. However, in practice, it is not economically feasible or justifiable to subject all medical devices to the same, most rigorous conformity assessment procedures available. It may mean that certification processes take longer and cause delays in launching a new device, bringing big costs and denying care.

4. ASKING MORE OF MANUFACTURERS

Manufacturers will need to:

- Set up new quality processes to ensure the safety of devices.
- Implement an appropriate system to monitor the post-market performance of devices and keep it up-to-date.
- Install a system for recording and reporting incidents and corrective actions.
- Establish, document, implement and maintain a risk management system (Annex I) and a quality management system with the information acquired through post-market surveillance.
- Provide patients with as much information as possible about the device, potential side effects and alternatives.
- Keep technical documents, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, available for 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 is at least 15 years.
- Report all incidents, injuries and deaths into an EU portal that will contain relevant data, so patients have access to the information.

These represent a significant increase in manufacturers' responsibilities and they need to understand the new regulation and work with notification bodies to prepare for these changes.

5. UNIFORM EVALUATION OF HIGH-RISK DEVICES

The MDR introduces specific classification rules for each device class. Naturally, the rules have become more stringent on high-risk devices, which also means that manufacturers will need to invest more time and money to get a device to market.

For instance, for high-risk devices, the involvement of a notified body is now compulsory.

However, the most significant change is related to general safety and performance evaluations. Manufacturers now need to present a summary of safety and clinical performance, which should be available via EUDAMED. This should be based on clinical data, sourced from clinical investigations that have been carried out under the supervision of a sponsor, who will take responsibility for the clinical investigation. Also, any clinical investigations will require a detailed review of the clinical strategy and the post-market follow-up plans.

DON'T PANIC!

NOT EVERYTHING WILL CHANGE

Although we have focused on the changes the MDR will introduce, some previous regulations will still be in place, supporting the new MDR compliance. The most important ones are summarised in the table below.

Abbreviation	Title	Why it's useful
IEC 62304:2006/Amd 1:2015	Medical device software - software life cycle processes	The most common standard for companies that develop medical devices with critical software
ISO 13485:2016	Medical devices - Quality management systems -Requirements for regulatory purposes	Used to demonstrate that medical devices and related services consistently meet customer and applicable regulatory requirements
IEC 82304-1	Health software - Part 1: General requirements for product safety	A standard for products designed to operate on general computing platforms and intended to be placed on the market without dedicated hardware
ISO 14971:2007	Medical devices - Application of risk management to medical device	Specifies the process for a manufacturer to identify the hazards within medical devices
IEC 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices	Regulates the usability of products

Nonetheless, despite the number of existing regulations and directives for medical devices, this new MDR will have a significant impact on how medical device companies operate going forward.

A New Dawn

The EU has provided a transition period of three years (or less) according to the class of the medical device, that will culminate in very rigorous supervision from 25th May 2020.

The primary objective of the regulation revision is to ensure a regulatory framework that is sustainable, forceful, foreseeable and clear. This is essential for ensuring that the level of safety is extremely high within the healthcare sector.

It's undeniable that a new era for medical devices is beginning.

The MDR will strongly impact both distributors and importers and there will be no grandfathering of existing products from the current EU Medical Devices Directive (MDD).

This means that all currently approved devices must be reviewed and recertified according to the new requirements (exemptions are still under negotiation right now). For example, if you are a company based in the US, and you want to sell your devices in Europe, you will also need to reassess your devices against the new regulation.

The notification bodies, themselves having already raised concerns about all of their extra responsibilities, will also have the right and duty to perform unannounced on-site audits of manufacturers. Products without an appropriate quality system can be banned by the authorities. If your medical device doesn't comply with the up-to-date rules and regulations it can be recalled.

Being non-compliant can also injure your business's reputation elsewhere, for other products and services.

On the manufacturers' side, legacy devices that are already sold to the industry will need to be updated according to the new MDR. Post-market surveillance, not previously required, will now be mandatory for all devices. Implementing the regulations for new devices and ensuring that legacy products meet the new requirements will require extra effort, increasing the total cost of producing and maintaining medical devices.

As all medical devices will be reclassified based on stricter rules, it is expected that 40% of manufacturers will be forced to register their products in a higher class. This can be problematic for manufacturers, and it may result in the reduction of product lines and increasing costs for market access.

Therefore, a very balanced and defined software development process is critical to help mitigate these problems.

Start Preparing Now

Although these changes can seem daunting, there are actions that can be taken to get yourself ready.

1. Study the new MDR and take notes on where it impacts you.

2. Perform a more detailed analysis of the changes.

3. Put together a list of tasks in order to evaluate what the next steps are:

- **Are you able to do it alone?**
- **Or do you need to look for a partner to help you understand and implement some of these changes?**

4. Create a plan that includes a timeline and resource allocation.

5. Adapt and adjust existing tasks and processes according to the new regulations.

Naturally, this is just the start. Quality processes will need to be redefined frequently to ensure continued compliance. It's crucial to maintain a transparent quality management system: verification of the UDI assignments, risk management plan and activities, management of corrective and preventive actions and verification of their effectiveness, among others. Not just before launching a medical device to market, but also afterwards. You should consider retaining high-levels technical expertise for validation and verification activities or investing in training for substantial and robust knowledge, for example, in embedded development for safety-critical systems.

Without developing a plan to comply with the MDR, tailoring a solution to adapt company processes to the new regulation, companies risk obtaining a major non-conformity from notification bodies, which may result in fines from the National Competent Authorities (NCAs) or products being recalled and banned. No company wants this. Now is the time to prepare.

NOTES ON THE FUTURE

The medical device industry is transforming.

The changes in technical and clinical documentation, improvements in the quality management systems, the implementation of UDI and the post-market surveillance will significantly increase what is demanded of manufacturers.

In particular, risk management systems should be carefully aligned with the clinical evaluation of devices, including the clinical risks to be considered as part of investigations, assessments and post-market follow-ups. Risk management and clinical evaluation processes should be inter-dependent and regularly updated.

Manufacturers will need to adopt a proactive approach to understanding and implementing the new regulation, starting with a gap analysis, followed by a solid transition plan that includes realistic resource allocation. Only with a combination of mature processes, high-quality standards and effective risk management plans – utilising expert partners to support them where necessary - will manufacturers be able to keep up with what's now demanded of them.

Are you ready?

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About Critical Software

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We were founded in 1998, with NASA our very first client. Today we work across many international industries and have offices across the globe.

We've tested and developed applications and software in markets that are highly-regulated, complying with demanding international standards to a high-level of dependability. We have over twenty years' experience in embedded systems development and quality assurance, certified against international standards including ISO 13485:2016 and ISO 9001:2015.

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