Navigating the EU MDR - Strategies for Success

With continuous advancements in technology, more medical devices are being developed. Though new and innovative devices can transform healthcare, there’s a growing need to regulate the MedTech industry - not only to protect the patients but to leverage its full potential.

The new European Union Medical Device Regulation (EU MDR) brings a wider and clearer regulatory scope which enforces stricter requirements on manufacturers and notified bodies. Altogether, this brings new challenges in achieving regulatory compliance. But it also comes with a more effective path to reach a common goal – ‘A safer healthcare ecosystem’.

“As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for medical devices by ensuring, among other things, that data generated in clinical investigations are reliable and robust and that the safety of the subjects participating in a clinical investigation is protected” - Official journal of the EU (2017/C 116/1)
Date of Application and Transition Period

The regulation was published on in the Official Journal of the European Union on May the 5th, 2017. The official transition start date was on May the 25th, 2017. The Regulation will be fully applicable in 2020 for medical devices and in 2022 for in vitro diagnostics (IVD) devices.

During the transition period, or grace period, manufacturers are to become familiar with the new requirements and start working towards compliance.

Below you can see the graphical representation of the individual transition timelines for the MDR.

Transition Timelines MDR Article 120

*Dates are <<estimates>> based on our current understanding on the process/steps to be completed

Figure 1 - EU MDR Transition Timeline
How does this impact Medical Device Manufacturers?

The new MDR will both repeal and amend a few existing EU directives and regulations. It is important to state the difference between the two because EU countries interpret and implement the current rules in different ways.

A directive is a legal Act that set out conformity assessment rules and must be transferred into EU Member State national law to be effective. A regulation is a mandatory jurisdiction that is directly applicable and enforceable in all EU member states.

Because the MDR is a regulation, this means that the requirements stated in the MDR will be mandatory for all the EU member states. This means, that all Medical Device manufacturers who want to be present in the EU market will have to adhere to this regulation from now on.

Because the MDR clearly states that there's “no grandfathering” allowed, manufacturers with products on the market will have to re-certify all of their devices. That is, currently available compliance documents will have to be evaluated towards the new MDR/IVDR requirements.

The Most Notable Changes

The MDR calls for stricter rules, more transparency, and increased availability of evidence and data. Although much of what the regulation states is clear, there are still a few areas of concern and articles that will require further clarification.

It’s difficult to state how each article will be supervised in the different member states and by notified bodies, but as we get closer to the first date of application, we can hopefully expect further guidance documents from industry leaders and authorised representatives (AR).
This does however not change the fact that there are a number of requirements that must be put into planning already.

Here are some of the more notable changes in the EU MDR

- Wider and clearer scope for EU legislation e.g. include implants for aesthetic purposes
- Stronger supervision of assessment bodies by national authorities
- More power to assessment bodies to ensure regular checks on manufacturers and unannounced factory inspections
- Clearer rights & responsibilities for manufacturers, importers, distributors, applicable to diagnostic services and internet sales
- Introduction of 'The Eudamed database' which will allow for information exchange on medical devices' market surveillance, clinical investigation information, and safety and clinical performance.
- Medical devices in the EU will also be tracked online with a Unique Device Identification (UDI) number, making it easier to glean information on individual products. These UDI numbers will be located in Eudamed.
- Stricter requirements for clinical evidence & clinical evaluation
- Notified bodies can request access to clinical evidence data
- Updated classification rules
- Better coordination between EU-Commission and national surveillance authorities
- Incorporation of International guidelines into EU law.

The Importance of Clinical Evaluation and Data

One of the more comprehensive changes is the increased focus on clinical evaluation, post market surveillance, and access to data. This places a higher strain on both regulatory and clinical operations.
Previously it was a common practice to refer to an equivalent (predicate) medical device and its scientific data, in order to document clinical effectiveness. Now, the MDR is forcing all manufacturers to document their own device effectiveness, safety, and usability. In addition, driving the path towards transparency.

’The evidence, whether it’s clinically related or not, is the gold of any Medical Device and should be treated as such.’

Clinical evidence of is the essence behind any device, and there’s no doubt that with a more rigorous clinical evaluation plan, organizations will be better fit to document the quality, safety, and efficacy of their device. Additionally, this will further help secure market access and funding.

Manufacturers will now have to put more time into planning their clinical investigations and post-market activities to be in line with the product life cycle.

Figure 2 – Adapted illustration from Adi Ickowicz, presented during a seminar in Tel Aviv, April 2018.
For many manufacturers this can prove troublesome to implement and might even require a complete overhaul of the organization. Because manufacturers have not had to comply with similar requirements before. The tools and methods currently being used to generate and manage such evidence will have to be revised.

One of the main focus areas during the transition period will be to gain access to the right tools to overcome these challenges. And with the implementation of the Eudamed database, the request for digital tools that can comply with the requirements of transferring required data to the Eudamed database will become evident.

What to Expect?

After reviewing the new MDR, there’s a long list of changes and actions that the industry can expect to unfold. Some of which are

- Long queuing times at Notified Bodies – because they will be fewer;
- Notified Bodies, which stopped their activities or discontinued certification of certain devices or in certain regions;
- In-depth technical file assessments that has not been experienced so far;
- Unannounced audits;
- Product testing performed by Notified Bodies;
- Constantly increasing requirements for clinical evaluations;
- Increasing requirements in OEM/PLM procedures;
- Competition for personnel in the quality and regulatory field.
- Cost to operate will increase
- Early access to technological innovation likely to be impacted due to expected prolonged market authorization timelines
- In the transition period EU ‘first to launch’ markets may not be as attractive
- Regulation imposes clear and detailed rules which do not give room for divergent transposition by Member States.
• Introduction of “expert panel led” scrutiny process will be a significant change
• Impacts for the Notified Bodies are substantial, likely to see further consolidation
• Substantial costs to remediate are anticipated
• Strategic imperative for all businesses which will demand leadership attention

The New MDR Driving ‘A safer healthcare ecosystem’

Due to the steep road towards compliance with the new MDR, it is important to plan ahead by analysing the requirements and allocating the required resources needed. Manufacturers will e.g. have to analyse and evaluate

• The clinical and performance evaluation data - for example consider a post-market clinical follow-up (PMCF) trials also for old products
• Liability of the manufacturer and review corporate liability cover
• Device classification
• Employee qualifications
• Notified body contracts and cooperation
• Supply chain changes (impact on supplier agreements)
• Commercial plans for the transitional period
• How to accelerate clinical evaluation

It’s clear that the regulation enforces a need for increased technical documentation. But this can only benefit the device as it will better determine and demonstrate the efficiency and safety. However, this will also drive increased costs in the overall R&D and regulatory processes – which will require further evaluation of the current organization methods and tools.

One of the main contributions brought about by the EU MDR is ‘The Eudamed database’ which will allow for information exchange on market surveillance, clinical investigations, and safety and performance.
Medical devices in the EU will also be tracked online with a Unique Device Identification (UDI) number, making it easier to glean information on individual products. These UDI numbers will be located in Eudamed as well.

Conclusively, the contributions made by the EU MDR will most definitively help the industry working towards a safer future, with trust, transparency, and traceability in mind.

With increased requirements, we might see a drop in new innovative devices reaching the market because the changes will affect the cost of R&D and market access. It's therefore important that manufacturers start looking towards more cost-efficient tools and methods-of-work in order to cope with the increasing demand of new and safer medical technology.