



## **TATA ELXSI**

7 ways how the EU MDR is Impacting the  
Global Medical Devices Industry

The countdown to the implementation date of the [European Union Medical Device Regulation \(EU MDR\) 2017/745](#) has begun. In the past three years, since its introduction in 2017, a lot of information has become available on what the MDR is, what necessitated its implementation, and how it would be an improvement over the erstwhile MDD.

Nonetheless, medical device manufacturers are still at a loss in grasping the new MDR requirements in their entirety. Take, for instance, MDR's impact on non-EU countries. How will the medical device manufacturers in the US, Japan, and China be affected by this regulation? The new regulatory regime created by the MDR will likely create a number of challenges for medical device manufacturers. Some of these challenges are listed below:

- 1. Additional compliance:** The improved regulatory system in the form of the MDR will usher in the introduction of unique device identification (UDI). It will be a part of the EUDAMED (European Database on Medical Devices) and function as a tool for medical device traceability in Europe. The MDR also requires that the medical devices conform to the GSPR (General Safety and Performance Requirements) and [incorporate improvements in labeling](#). It also involves the implementation of more stringent clinical evaluation and Post Market Surveillance (PMS) activities. Additional administrative requirements are represented in the form of conducting product tests and design verification. All these additional compliance requirements are expected to demand an [investment of approximately € 7.5 billion by the medical device industry](#).
- 2. Regulatory uncertainty:** Non-EU geographies like Russia, Australia, Mexico, etc., mainly rely on CE (Conformité Européenne) compliance. The MDR changes significantly impact non-EU regulatory product submissions. It might so happen that a non-EU country's local regulatory submission differs from the central documentation, which primarily includes technical documents, labels, and IFU (Instructions for use). Such a scenario may lead to local authorities like excise departments [rejecting these medical devices during the import-export process](#).

Medical device manufacturers who market in multiple countries face a unique challenge on this front. Its solution lies in [assessing the impact if there is a mismatch](#) between the local regulatory submission and central documentation and addressing the solution for all dependent geographies.

- 3. Classification of new products as medical devices:** There are [several new classifications of medical devices within the scope of the regulation](#) for the first time now. For example, accessories that assist a device also fall under the definition of a medical device with the new regulation. The devices that were earlier included are now witnessing a reclassification into stricter standards. Several medical devices have been classified upwards now as compared to their earlier classification. As a result, many such devices would require the intervention of NBs (Notified Bodies) for the first time. The MDR has also introduced a stricter classification of software, particularly apps, under Rule 11, which states that:

"Software intended to provide information which is used to make decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

- Death or an irreversible deterioration of a person's state of health, in which case it is in class III; or
- Serious deterioration of a person's state of health or surgical intervention, in which case it is classified as class IIb

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb. All other software is classified as class I.

Reclassification of medical devices may pose some challenges such as reapplying for CE markings, getting the medical device re-evaluated by Notified Bodies, and keeping a [repository of more clinical evidence than before.](#)"

4. **Revisions in EU conformity procedures:** Revisions in EU's conformity assessment procedures may lead to delays in market approval of the medical devices. With the advent of stricter rules for equivalence demonstration and only three regulatory conformity assessment pathways, medical device manufacturers will be forced to spend more time and resources. This challenge will be further amplified for manufacturers of medical devices that are perceived to be riskier and hence classified higher.
5. **Shortage of Notified Bodies (NBs):** Delays in market approval may also arise from the [shortage of Notified Bodies that are available for medical device approval](#) in the EU market. The number of qualified [Notified Bodies that can issue approvals for EU medical devices could fall to as low as 40](#) reducing the number of NBs that existed earlier by almost 50%. Such a significant reduction in approval bodies can potentially create a bottleneck in approvals for introducing medical devices of non-EU manufacturers to the EU market.
6. **Foregone sales:** Most innovative medical devices have [short lifespans ranging between 18 to 24 months](#). Delay in getting market approval could result in months of foregone sales for these firms while their medical devices keep awaiting approvals.
7. **Requirement of authorized representatives:** According to Article 11 of the EU MDR, manufacturers from non-EU geographies are required to designate a sole authorized representative to place the medical device in the EU market. The authorized representatives perform the tasks that are specified in the mandate agreed between them and the manufacturers. These tasks usually include verifying the EU declaration of conformity and ensuring that the technical documentation of the medical devices is prepared. They may also verify whether the manufacturer has carried out an appropriate conformity assessment procedure.

The [implementation of EU MDR](#) does involve specific challenges. However, it is important to note that it provides the medical device manufacturers with some interesting opportunities to be astute and [promptly align their manufacturing process to the new regulatory regime](#). The new regulations are here to stay and are likely only to get stricter as the years pass. In such a scenario, OEMs (Original Equipment Manufacturers) who are revamping their regulatory structure in accordance with the EU MDR stand to benefit from it in the long haul. These changes are likely to improve the quality of commercialized medical devices and reduce the probability of failure and adverse events. This may eventually lead to strengthening the perception of patients and physicians regarding medical devices. Challenges provide a breeding ground for ingenuity and innovation. Medical device manufacturers with foresight can use the MDR as an opportunity to harmonize and upgrade their processes and technology to gain a competitive edge in the market.





## ABOUT TATA ELXSI

Tata Elxsi, a part of Tata Group, is among the world's leading providers of design, engineering, and regulatory compliance services. With 15+ years of experience in catering to medical device and healthcare companies, Tata Elxsi has built a comprehensive services and solutions portfolio that adds value at every stage of the customer's product development lifecycle. Tata Elxsi is an established name in technology consulting, new product design, development, verification and validation, and regulatory compliance services.

Tata Elxsi also provides solutions and services for emerging technologies such as IoT (Internet of Things), Big Data Analytics, Cloud, Mobility, Virtual Reality, Cognitive Computing, and Artificial Intelligence (AI). Tata Elxsi has a global presence and is supported by a talent pool of over 6,500 employees, a network of ISO 13485 certified design and development centers, and a robust ecosystem of technology, manufacturing, and internationally accredited testing partners.

For more information, please visit [www.tataelxsi.com](http://www.tataelxsi.com) click here 

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