Are you ready

for EU MDR 2020?

What is MDR 2020?

The Regulation on Medical Devices (MDR) - 745/2017 will be replacing the current EU directives governing the medical devices regulatory framework. The EU MDR transition period of 3 years will end in May 2020. The EU MDR introduces new obligations for all entities throughout product supply chain, including distributors.

20 articles
60 pages
12 annexes

97 articles
369 pages
16 annexes

Directives: Legislation that sets out general rules that are then transferred into national law by each member state.

Regulations: Legislation that is directly applicable in all EU member states; no room for local interpretation.

The implementation of EU MDR is expected to establish a more robust legislative framework to ensure enhanced protection of public health and patient safety, while aligning the regulatory requirements with the current technological developments and healthcare trends.

The new regulations are developed to improve market surveillance and product traceability throughout product supply chain, while driving more transparency for the public on product clinical outcomes.

In summary new Regulations will ensure:

- a framework supporting a high level of health and safety protection for EU citizens using medical devices
- a pathway adapted to the significant technological and scientific progress occurring in this sector in the last 20 years

The main changes will include:

- stricter control for high-risk devices via a new pre-market scrutiny mechanism with the involvement of a pool of experts at EU level
- new criteria for designation and continuous assessment of Notified Bodies involved in approval of manufacturers 'technical files
- improved transparency through the establishment of a comprehensive EU database on medical devices and of a device traceability system based on Unique Device Identification
- the reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorization of multi-center clinical investigations
- the strengthening of post-market surveillance requirements for manufacturers
- improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance
- roles and responsibilities of economic operators involved in medical devices distribution, such as importer and distributors

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How MDR will impact the distributor business?

Under EU MDR, distributors play a key role in the product supply chain and have multiple obligations. Failure to comply with the requirements can significantly impact product distribution, up to the point of product quarantine at distributor warehouse or even distributor banned for medical devices distribution etc.
New Regulations define roles and responsibilities which will be audited by the local Regulatory authorities:

- documented verification of manufacturer 'compliance with EU MDR – ie. CE mark, Declaration of conformity, identification of dedicated resources to document and implement the verification process
- Importer information is supplied to the end user – ie. distributors' ERP changes
- Documented procedure for product complaints and communication mechanism for informing manufacturer, authorized representative and importer - ie. Dedicated resources, processes in place to implement the process

Partnering with Stryker to be EU MDR ready

Stryker's RAQA local departments will collaborate with you to assess your readiness for EU MDR through a questionnaire that will come your way through the Compliance Desktop. The objective of this evaluation is to help you identify areas of strength and opportunities for improvement. Saving lives together is our mission and we are committed to support you in your efforts of complying with latest regulatory changes.