After a one-year delay, time is running out to prepare for the European Medical Device Regulation (EU MDR). Starting May 26, 2021, companies must adhere to the new regulations governing the production and distribution of medical devices in Europe, which replace the Medical Devices Directive (MDD).
The EU MDR broadens the scope of covered products to include devices that are not intended for medical use (common examples include colored contact lenses and liposuction equipment).

For the purposes of regulation, the EU MDR defines a medical device as “any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,
- and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.”

The full scope of covered products also includes “devices for the control or support of conception” and “products specifically intended for the cleaning, disinfection or sterilization of devices.”

Looking for Step-by-Step Guidance on EU MDR Compliance?
The European Commission’s Implementation Model for Medical Device Regulation provides a 12-step action plan that covers:

- Pre-Assessment
- Gap Analysis
- Quality Management System
- Legal Entities
- Portfolio
- Master Implementation Plan
- Notified Bodies
- Regulatory Training
- Execution of Master Implementation Plan
- Review Efficiency and Effectiveness
- Notified Body Submission
- Ongoing Monitoring
The EU MDR doesn’t just increase the number of products considered ‘medical devices.’ It expands the entire scope of medical device regulation. Whereas the MDD focused on the pre-approval stage of manufacturing, the MDR encompasses the full product lifecycle, from research and development through vigilance and post-market surveillance.

Four key areas of change focus on technical documentation, traceability, transparency, and clinical evidence.

**Detailed Technical Documentation:**
Unlike the MDD, which did not include clear direction around technical documentation, the EU MDR is highly prescriptive. It establishes more than 40 content elements for Technical Documentation, plus more than 15 content elements for Technical Documentation on Post-Market Surveillance.

**Improved Traceability:**
All medical devices for sale in the EU must have a Unique Device Identification (UDI)—which includes a device identifier (UDI-DI), as well as a production identifier (UDI-PI) denoting the batch or production series. Whereas UDI was already a requirement in the United States, it was not previously included in the European regulations.

**Increased Transparency:**
The European database on medical devices (Eudamed), which was previously a restricted repository, will be broadly accessible under the EU MDR. The newly public tool will give Notified Bodies, medical device companies, consumers, regulators, and other stakeholders access to the latest data on medical devices for sale in the region. In addition to housing the UDI database, Eudamed includes electronic systems for clinical investigations and product registration, as well as vigilance and post-market surveillance.

**Expanded Clinical Evidence:**
The EU MDR extends MDD requirements to establish a process for updating clinical evaluations throughout a medical device’s lifespan. While pre-market requirements include a Clinical Evaluation Plan and a Clinical Evaluation Report (CER), the most significant changes focus on post-market oversight. As part of the Post-Market Surveillance (PMS) Plan, for example, manufacturers will need to produce a Post-Market Clinical Follow-up (PMCF) Plan and a PMCF Evaluation Report. These reports must be part of the manufacturers’ technical documentation. In short, companies will need to generate more data to back up safety and performance claims.
In the face of the EU MDR’s expanded regulations, efficient information management is more important than ever. If the Notified Bodies were to run the same medical device development study, for example, you should be confident they would find the same articles and generate the same results. To avoid raising red flags or failing an audit, you need to be able to:

- Produce a fully auditable Clinical Evaluation Report
- Prove your approach and process for getting the results (including information on where you obtained your scientific articles)
- Review the literature of devices brought to market (as part of your post-market surveillance)

In other words, you need to have a documented, justified, and repeatable process in place. The quickest way to do that is by using a regulatory-compliant, automated literature review platform to conduct systematic reviews, track your processes, and produce audit-ready CERs.

How Much Clinical Data Is Enough?

Under the EU MDR, you will need to generate more data to back up safety and performance claims. But how much data is considered adequate?

In general, you will need to “specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.” Article 61 of the EU MDR provides in-depth information on the level of documentation required for various types of medical devices.

As you seek to collect relevant literature and identify gaps in your clinical evidence, a solution that provides quick, seamless and copyright-compliant access to cross-publisher scientific literature can serve to further augment and accelerate your systematic literature review workflows.

At Research Solutions, we partner with leading providers of literature review software such as Evidence Partners’ DistillerSR to provide even more value to customers and streamline workflows—giving researchers fast, frictionless access to the articles needed for EU MDR compliance.

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