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EU Medical Device Regulation (MDR)

Device Testing

What is the MDR?

On May 25, 2017, the European Union adopted a new set of regulations that replaces the Medical Device Directives (MDD) and Active Implantable Medical Devices Directive (AIMD). It applies to all medical device manufacturers who intend to market their devices in the European Union.

A result of the MDR is that by May 2020, all new devices and devices with an expiring CE mark under the old MDD or AIMDD may no longer be marketed or put into service unless they have been resubmitted and fully comply with MDR. By 2025 all medical devices must comply with the MDR.

Key Changes for Medical Device Manufacturers


The MDR Regulation replaces the Medical Device Directive (MDD) and the Active Implantable Medical Devices Directive (AIMD).


A wider scope of regulated medical devices - some devices will be “up classified.”


Greater pre-market scrutiny for high-risk devices.


More stringent clinical evidence and documentation requirements.


No devices will be grandfathered under the new MDR.


A strengthening of post-market surveillance.


New classification for reusable surgical devices (Class Ir) requiring notified body oversight.

Nelson Labs is here to help you with MDR compliance. Let us help you:

- understand the MDR requirements pertaining to laboratory testing.
- conduct a gap analysis of your current compliance readiness.
- perform all applicable testing needed to ensure MDR compliance.

The details of the evaluation process will depend on the number and range of devices being evaluated and their clinical use history.

Contact our team of experts today
to learn how we can help your products comply with the MDR.

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Gap Analysis

Nelson Labs experts can help evaluate changes in regulatory standards under which previous testing was performed on your medical devices, and compare them to the most current regulatory standards. Any additional testing needed for device compliance will be given to you in a written report.

Biocompatibility

Manufacturers of modern-day, complex devices need to assess the biocompatibility of their medical device materials and processes by taking a holistic risk-based approach to their biological safety evaluations - which includes Chemical Characterization. Manufacturers must perform a gap analysis of previous testing to help bring their devices into compliance with the updated ISO guidelines and the new MDR.

Packaging

The new MDR focuses on the entire lifecycle of the device, which puts emphasis on the importance of the package maintaining the sterile barrier from its manufacture through the point of use. Evaluation of the packaging system needs to include data that demonstrates a successful challenge to the packaging system from distribution and handling through the established product expiry date.

Reusable Devices

The new standards are more organized and rigourous than previous versions - especially with the heightened scrutiny of patient-contacting, critical reusable devices. There are new classifications for reusable surgical devices, a broadened definition of medical devices which require reprocessing, and an increased scope of cleaning instructions which now include disinfection, sterilization, maintenance, and functional testing (Article 52).

Sterility Assurance

With the implementation of the MDR, many medical devices have been reclassifed into categories that are more conservative than in the past. In addition, some devices that were previously exempt from regulations are now in the scope of the new MDR. Therefore, you should have the availability and quality of all sterility assurance data for your devices reviewed as soon as possible.

Your Next Steps

1. Perform a gap analysis for each of your products.
2. With expert help, use the gap analysis results to identify areas that require additional data.
3. Perform testing that will show that your product is up to current standards.
4. Perform a review of your test results and make a final conclusion based on gathered evidence.

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ML-0024a rev1