

THE RELEASE OF THE MEDICAL DEVICE REGULATION (MDR) EU 2017/745

An event many medical device
manufacturers will never forget.

How Nelson Labs Can Help...

26 th of May 2021 marked D-day, or the Day of Application (DoA) for the Medical Device Regulation (MDR) EU 2017/745. Years of hard work have preceded this date to prepare for this new regulation. The key message of the MDR is to minimize patient risk when bringing a new device to the market; and as such, to provide a better protection of public health and patient safety throughout the lifecycle of the device. Being a part of Sotera Health, it is our mission to Safeguard Global Health®, and at Nelson Labs we have optimized our services to meet the new MDR requirements for medical device assessments. More specifically, our biocompatibility experts can assist you in writing a Biological Evaluation Plan (BEP) for your device that describes all safety risks associated with your device, and the tests that should be applied to mitigate those risks. Especially, manufacturers of aesthetic devices (such as colored contact lenses) might now face challenges they did not face in the past as their products are now falling under the MDR regulation.

Since the release of the new revision of ISO 10993-1 in 2018, there is a large shift away from animal testing and towards using alternative approaches, such as chemical testing. Nelson Labs, with over 25 years of experience in the field of extractables and leachables testing for the Pharma industry, as well as years of service in applying the extractables analysis to medical devices, is considered one of the leaders in the field of chemical characterization.

Since the Reprocessing of devices is now included in the scope of the new regulation, it is important to note that Nelson Labs has extensive expertise in this area and is ready to help you with this requirement. It is now certified to offer this service in Europe for both single use and reusable devices as well. Also, the rules on

clinical evaluation and investigation have been strengthened in the MDR. Our experts can advise you on how to ensure safety throughout your device's lifecycle, including reprocessing or sterilization steps.

Another important change in the MDR is the introduction of more strict requirements on the use of hazardous substances. To identify the use of these substances during manufacturing and reprocessing of the device, a screen for the presence of Carcinogenic, Mutagenic, Reprotoxic (CMR) compounds and Endocrine Disruptors (ED) in extracts of your device can now be added to our chemical characterization reports. This serves as a complementary approach to gathering comprehensive material information from the supplier(s) to demonstrate that the construction materials do not release these hazardous substances to the patient during the intended use of the medical device.

The MDR asks to perform all testing according to the state-of-the-art, or in other words, to test according to the latest revision of the applicable standards. To be aware of upcoming changes, our Nelson Labs experts participate in standard committees making sure we are ready to give advice which includes these upcoming changes. For devices that are already on the market and that need recertification our experts can assist you in reviewing the original testing through a Gap Analysis and guide you toward the recommended approach that will demonstrate compliance to the new MDR.

To guarantee and demonstrate the quality of our services, our laboratories are FDA registered and ISO 17025 accredited and are audited frequently by our clients.

In case the MDR is still causing you headaches or you need advice on the safety requirements, our experts at Nelson Labs are fully prepared and just one phone call or mouse click away.

Contact our Experts Today!

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