

OPPORTUNITIES FOR COMPLYING WITH THE EUROPEAN MDR



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1.0 INTRODUCTION

In May 2017, the European Union established the Medical Device Regulation (MDR 2017/745) by publishing the regulations in the Official Journal of the European Union (OJEU). This action started the clock on a transitional period that ends with full implementation in May 2020. The transition period is important, because the MDR includes a series of requirements that can have profound implications for medical device companies. Companies that are not prepared to have compliant systems, processes and products by the implementation date may find themselves unable to market their products in the EU after May 2020. Significantly, the regulations apply to all medical devices marketed in the EU – no grandfathering – so legacy devices will need to meet all relevant requirements, including General Safety and Performance Requirements (GSPR) and the associated technical documentation, taking account of the generally acknowledged "state of the art".

2.0 WHAT IS THE EUROPEAN MDR?

2.1 Why MDR? Why is it important?

The MDR is, in large measure, the EU's response to device safety issues that have received broad visibility in recent years (e.g., silicone breast implants and metal-on-metal joint replacement devices). Specifically, the MDR "aims to ensure the smooth functioning of the internal market as regards medical devices" and "sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other."

The MDR doesn't present many concepts that will strike mindful medical device companies as new. Companies that have developed methods for complying with the Medical Device Directive (MDD) and/or the Active Implantable Medical Device Directive (AIMDD) and relevant MEDDEV guidances will likely not be greatly affected by the changes, although several evaluation and administrative tasks may need to be undertaken. However, some products, particularly those being up-classified and legacy devices that may have lagged the "state of the art", may require substantial work to achieve compliance.

2.2 What are the changes?

Most importantly,

1. The Eudamed database will be renovated and require additional informational inputs, much of which will be made available to the public.
2. The concept of Unique Device Identification (UDI) is introduced (not new to US companies which have responded to existing FDA requirements), with associated labelling changes.
3. Manufacturers will be liable (and need to carry attendant insurance coverage) for defective devices, with Authorized Representatives (AR) jointly and severally liable for the devices they represent.
4. Devices with direct contact with the heart or central circulatory system have been up-classified to Class III, requiring a review and possible remediation of technical documentation. Other devices, e.g., surgical mesh and joint replacement devices, have also been up-classified (see Annex VIII to the MDR for complete details).
5. There are new, rigorous requirements for clinical evaluations and investigations. Devices must have a risk-benefit ratio established based on clinical evaluation data.
6. There are new technical documentation requirements for Post-Market Surveillance (PMS), Vigilance and Clinical Follow-up.

2.3 What devices are covered?

The MDR is scoped to include all devices previously covered under the MDD and AIMDD. This accounts for virtually all medical devices, excepting in-vitro diagnostic devices and a variety of device combination products, which may be governed under other regulations. New to the MDR is the inclusion of products without a medical purpose (e.g., colored contact lenses).

3.0 COMPLIANCE WITH THE NEW REGULATIONS

The MDR's General Safety and Performance Requirements (GSPR) are very specific and comprehensive, requiring consideration of "the state of the art" when compared to similar devices. As such, companies may need to update what used to be called "technical files" or "design dossiers" under the old device directives to qualify their devices for CE Marking. Changes to labeling will be required for most devices, and up-classified devices may require additional testing or clinical evaluation to procure a CE Mark. One example of change likely to be required in the technical documentation is a demonstration that the company has undertaken some form of Human Factors Engineering (Annex I, Chapter 1, section 5). Some legacy products may have been introduced before guidance reflecting current expectations were established, and could require reassessment and possible re-testing.

4.0 REVALIDATION - REQUIREMENTS AND OPPORTUNITIES

The MDR will almost certainly require each medical device manufacturer to comprehensively evaluate the current state of their technical documentation and ensure that it meets all the requirements of the MDR, including labeling, UDI and GSPR. Understanding the requirements for testing, revalidation, or redesign to support that can be a daunting task. Nordson MEDICAL has extensive experience and highly-qualified engineers that can support those efforts and ensure that any other benefits, such as quality or cost savings, can be built into the program for long-term improvements.

Nordson MEDICAL has 50+ years of experience designing, developing, and manufacturing finished medical devices and subassemblies leveraging our deep expertise in component technologies. This vertical integration helps teams reduce costs, mitigate risk, streamline supply chain, and ensure consistent quality. Our capabilities include a robust design transfer process and tools; new product introduction including process design and development and product verification and validation testing; DFM/DFA analysis and redesign; a global quality system; global manufacturing for cost improvements; and robust continuous improvement initiatives.

5.0 CONCLUSION

In order to meet requirements for the EU MDR, which must be implemented by May 2020, companies should be preparing to ensure they will have compliant systems, processes and products, or they may be unable to market their products in the EU. Nordson MEDICAL can support the efforts around testing, revalidation, or redesign to meet the new requirements, as well as identify any other possible benefits that could be achieved during that process.

About Nordson MEDICAL

Nordson MEDICAL is a global expert in the design, development, and manufacturing of complex medical devices and component technologies. We serve interventional, surgical, and specialized markets with technologies that save or enhance lives. As an integrated, single-source partner, we enable our customers to save costs and speed time to market. Visit Nordson MEDICAL at nordsonmedical.com.

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