In May 2017, the European Union established the Medical Device Regulation (MDR 2017/745). This action started the clock on a transitional period that ends with full implementation in May 2020. 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.

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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.

REVALIDATION - REQUIREMENTS & 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.