New challenges of the medical device sector in the era of Regulation (EU) 2017/745

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Abstract

The new Medical Device Regulation (MDR), adopted on 5 April 2017, brings about a period of great change, uncertainty and opportunity within the medical technology sector. The new rules will apply on May 2020, after a transitional period of 3 years. The MDR will replace the existing Directives.

This new regulation aims to establish a modernized and more robust EU legislative framework to ensure better protection of public health and patient safety, bringing higher traceability, transparency and homogeneity between European countries. To address this, the MDR contains a series of important improvements to modernize the current system.

Keywords: *Medical Device, EU Regulation*

References

[1] Regulation (EU) 2017/745, Official Journal of the European Union (5 April 2017)