

PRESS RELEASE



The Medical Device Regulation Published in the EU Official Journal

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REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

ABHI today welcomes the publication in the Official Journal of the European Union of the new Medical Device Regulation (MDR), which will now come into force 25th May 2017. This Regulation is the culmination of over eight years' development work and will supersede the Medical Device Directive, which has successfully controlled the European-wide placing on the market of devices since the early 1990's.

Whilst strengthening compliance, the new Regulation has not abandoned the principles of the New Legislative Framework (NLF), meaning a continuation of the familiar CE Mark. The NLF has demonstrated over the last 25 years that a proportionate risk based approach to medical devices can effectively ensure appropriate compliance whilst stimulating innovation across many thousands of medical technologies.

Regulation 2017/745 will significantly raise the bar with respect to regulatory compliance, particularly in areas such as clinical performance, quality management, Notified Body interactions and post-marketing surveillance. It is mindful too of the huge technological advances made by the MedTech Industry and truly brings regulatory compliance up to date.

ABHI and its Members recognise the need for ongoing regulatory reform to ensure high levels of public safety and to provide confidence in the UK medical device Industry, critical to the ongoing debates on future UK Industrial Strategies.

ABHI is proud to have been a part of the Industry representation that has shaped this new chapter in regulatory compliance, which has included interactions at both national and international levels. Moreover, the Association stands ready to ensure that this significant step change is effectively implemented for the good of Industry and society at large, by working with its stakeholders during the 3 year transposition period and beyond.

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About ABHI

The Association of British Healthcare Industries (ABHI) is the industry association for the medical technology sector in the UK. ABHI's mission is to champion the benefits and use of safe and effective medical technologies to deliver high quality patient outcomes. With over 250 members, ABHI leads the advocacy of the industry in order to advance access to medical technology. Our membership includes some of the leading multinational businesses in the sector in the UK right the way through to small and medium sized enterprises (SMEs).

For further information, visit the ABHI website: www.abhi.org.uk

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