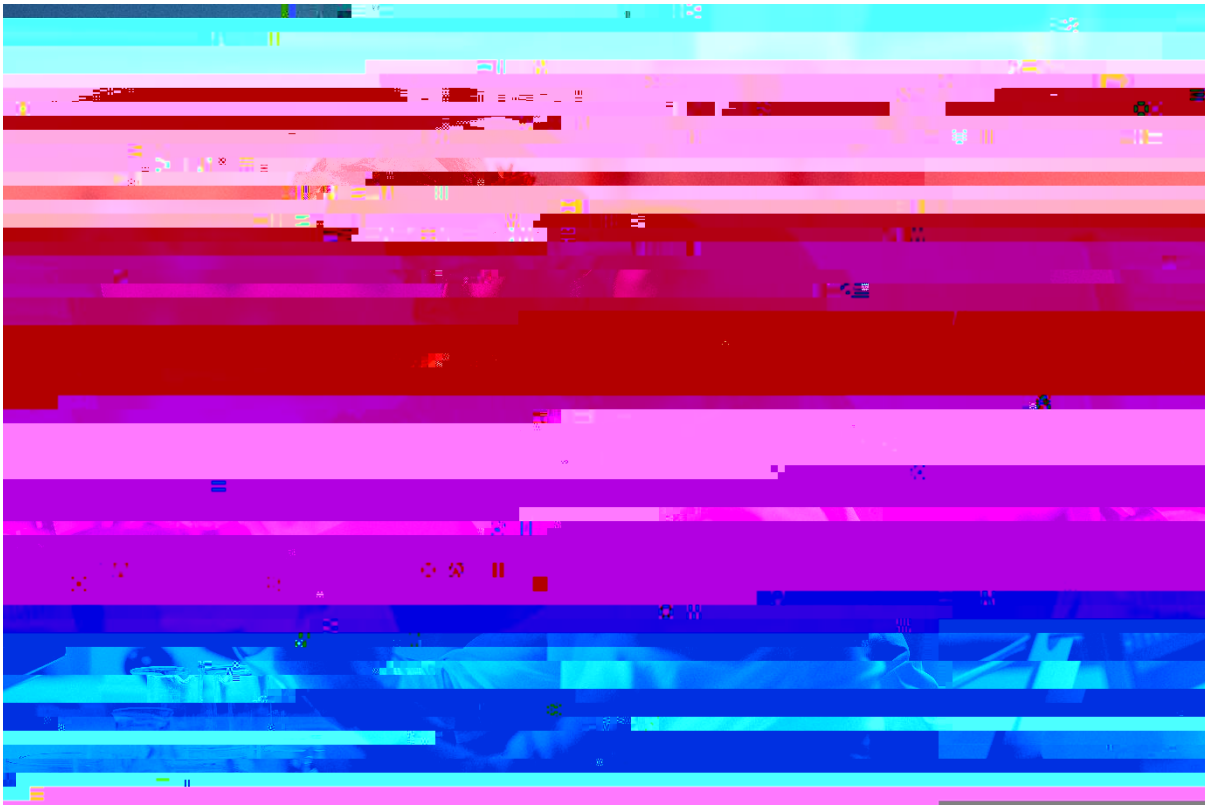
Medical Devices Newsletter View Online



According to Amending Regulation (EU) 2023/607, if you are transitioning your devices to the MDR, you will be able to benefit from extended validity of your directive certificates (until the end of 2027/2028 based on the device classification) for legacy devices if specific conditions are met.

Among these, by 26 May 2024 you must to put into place an MDR compliant QMS and lodge a formal application with a Notified Body for a MDR Conformity Assessment. No later than 26 September 2024, a formal agreement with the Notified Body must be signed.

We strongly recommend that you do not wait until May 2024 to make your MDR application. We encourage you to apply with BSI as soon as possible and well in advance of the above deadlines.

For more guidance visit our _____ and our _____.

We have recently launched our re-imagined UK website, marking a significant

digital client experience. The new UK website represents a greater integration of our

RAPS Euro Convergence, the most comprehensive regulatory affairs conference in Europe, focusing on the latest developments in healthcare products in Europe and beyond - medical devices, IVDs, pharmaceuticals, and combination products.

Jayanth Katta - Regulatory Director & Head of Medical Device Notified Body
Suzanne Halliday - VP Regulatory, Regulatory Services
Vishal Thakker - Senior Regulatory Lead & Head of UK Approved Body

Alex Laan - Head of IVD Notified Body
Sara Fabi - Regulatory Lead, IVD Notified Body
James Kerr - Technical Specialist & Scheme Manager, IVD Notified Body

Richard Holborow - Head of Clinical Compliance
Rachel Mead - Clinical Regulatory Lead
Sally Humphreys - Clinical Compliance Manager

Aris Tzavaras, Head of AI Notified Body
Inma Perez Ruiz - Regulatory Lead, AI Notified Body
Sarah Mathew - Regulatory Lead, AI Notified Body

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