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Regulatory review

Your monthly medical device update
August 2020

New Active Devices brochure

As a manufacturer of an active medical device, you must ensure that you meet the relevant requirements outlined in the Medical Device Regulation (MDR) (EU) 2017/745 before placing your product onto the EU market. It is critical to work with a notified body that understands the industry and has the experience to review and confirm your products' readiness for market – efficiently, promptly and robustly. As an Active Medical Devices Notified Body our technical specialists have extensive experience and can support you through the process of certifying your active medical device.

Talk to us today about your CE Marking requirements.

Download Active Devices brochure

Find out more

Active Implantable Devices resources

Active Implantable Medical Devices (AIMDs) are one of the highest risk categories of device and are subject to rigorous regulatory controls before they can reach global markets. Download our latest AIMD brochure, clinical investigations whitepaper and MDR best practice guidelines to help you when preparing and structuring your Technical Documentation for a conformity assessment under the MDR.

Download the AIMD brochure

Download the clinical investigations whitepaper

Download the MDR Best Practice Guidelines

Find out more

Performance Evaluation under the In Vitro Diagnostic Regulation (IVDR) Part 2 webinar

Join this webinar on **Wednesday 23 September 2020** to hear Dr Erica Conway, BSI's Global Head of IVD Medical Devices and Dr Liz Harrison, IVD Technical Team Manager at BSI, talk about the Performance Evaluation requirements under the In Vitro Diagnostic Regulation (IVDR) – Part 2. Topics covered will include:

- Clinical performance as part of the Performance Evaluation, including clinical performance studies under Annex XIII
- Post-market Performance Follow-up (PMPF) and the continuing the process of maintaining clinical evidence
- This will include initial lessons learned from our first IVDR submissions, and areas under discussion

Choose from one of two sessions:

23 September, **09:00 BST** – Register now

23 September, **16:00 BST** – Register now

Stay on top of medical devices news with the Compliance Navigator blog

The Compliance Navigator medical devices blog is dedicated to coverage of regulatory, technological and standards-related developments. Read our weekly blog posts, written by industry experts, and stay up to date with the latest developments in the medical devices sector.

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