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Regulatory review

Your monthly medical device update
July 2020

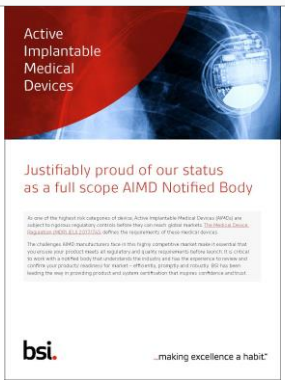
The IVDR transition deadline is approaching

Incomplete Technical Documentation submissions are one of the most common reasons for delays to the certification process. To make the process more efficient for you, access the key resources you need to help you prepare.

- IVDR Transition Toolkit
- Register for our next webinar on Performance Evaluation under the In Vitro Diagnostic Regulation on 26 August at 09:00 BST and 16:00 BST
- Conformity assessment routes recorded webinar
- Conformity assessment routes brochure
- Listen back to our IVDR application process and QMS for IVDR webinars

New Active Implantable Devices brochure

As one of the highest risk categories of device, Active Implantable Medical Devices (AIMDs) are subject to rigorous regulatory controls before they can reach global markets. 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, reliably and promptly.



Talk to us today about your CE Marking requirements.

Find out more

Download the AIMD brochure

Hear Dr Jayanth Katta talk at the MedTech Digital Week

BSI kicked off the MedTech Digital Week run by Informa. Dr Jayanth Katta, Senior Regulatory Lead (Medical Devices) presented on EU Medical Device Regulations, Notified Body Overview and Update from BSI on initial lessons learned from MDR audits.

Listen back to Jay's session

BSI's perspectives on Article 117 and drug-device combinations

Introduced by the European Commission under the Medical Devices Regulation (MDR), **Article 117** requires manufacturers placing drug-device combination products onto the market as an integral device and marketing them as a "medicinal product" to seek a Notified Body Opinion (NBOp).

Listen back to our Webinar to hear Dr Jennifer Durrant, Global Head of Medicinal and Biologics and Dr Jonathan Sutch, Medicinal Technical Specialist about BSI's perspective on Article 117 and drug-device

combination products.

Listen back to the on demand webinar

More about Article 117

New BSI medical devices white paper: Medical device clinical investigations – what's new under the MDR?

The conduct of a clinical investigation is one of the most time consuming and resource intensive activities that a medical device manufacturer can face. This paper discusses important new requirements for pre-market and post-market clinical investigations under the European MDR. It also addresses the importance of defining the regulatory purpose of a study, the relationship of a clinical investigation with quality management system (QMS) practices and strategies for conducting a successful clinical investigation, including the importance of defining the steps for its planning and conduct.

Download white paper

bsi.