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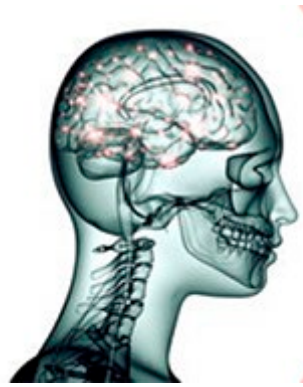


Regulatory review

Your monthly medical device update
July 2021

Featured in this Newsletter

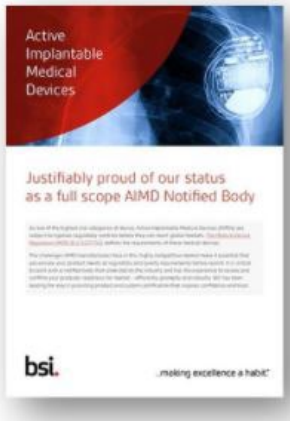
A Notified Body's perspective on the clinical evaluation requirements under Regulation (EU) 2017/745 on medical devices

Understanding of the clinical evaluation process for medical devices against the requirements of the Medical Device Regulation (MDR – (EU) 2017/745), relevant Medical Device Coordination Group (MDCG) guidance documents is critical for all manufacturers. Hear from BSI's Richard Holborow, Head of Clinical Compliance in his recent article in the Journal of Medical Device Regulation on the main requirements for

clinical evaluation under the MDR from a Notified Body's perspective and how to meet those requirements.

Read 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 MDR Best Practice Guidelines

Find out more

Book now – Person Responsible for Regulatory Compliance (PRRC) – what you need to know

Join BSI's Maddalena Pinsi, Regulatory Lead, to hear about the Person Responsible for Regulatory Compliance (PRRC), the regulatory expert the companies shall have at their disposal as per the MDR and the IVDR.

This webinar will offer notified body insights for all people involved in working towards an IVDR and MDR application, whether you are a novice or have significant experience of working with a notified body.

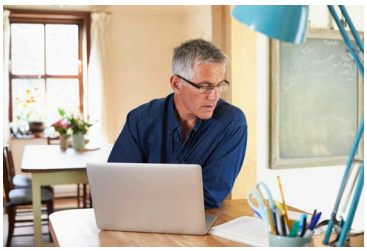
Please join us for this critical update around Person Responsible for Regulatory Compliance (PRRC) and what you need to know.

Choose from one of the two sessions:

Wednesday 28 July: 10.00 – 11.00 CET **Register now**

Wednesday 28 July: 17:00 – 18:00 CET **Register now**

Upcoming trainings for your agenda



Expand your knowledge and become an expert with our training courses

ISO 13485 Internal Auditor, 29 July 2021 - **Book now**

ISO 13485 Lead Auditor, 23 August 2021 - **Book now**

Post Market Surveillance and Vigilance under MDR and IVDR, 05 August 2021 - **Book now**

View all training courses

The convergence of the pharmaceutical and medical devices industries

Download the latest BSI medical devices whitepaper for a discussion of the different categories of combination products within the EU along with the regulatory pathways designed to ensure they are safe and perform as intended.

Download whitepaper

Events for your calendar

Find out the latest information about BSI Medical Devices Events and Conferences.

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