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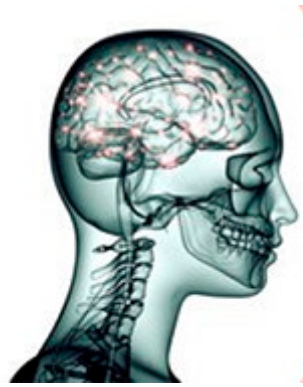

Regulatory review

Your monthly medical device update
March 2021

Featured in this Newsletter

BSI's first UKCA and AIMD certificates

We are proud to announce that we have issued our first UKCA certificate under the UK MDR 2002 legislation for medical devices via our newly designated UK Approved Body (0086). We have also certified our first Active Implantable Medical Device (AIMD) to the EU Medical Device Regulation. This certificate is our first to meet the EU Technical Documentation Assessment

Certificate, Regulation (EU) 2017/745, Annex IX, Chapter II.

AIMD - Read full story

UKCA - Read full story

Want to know more about BSI Medical Devices?

Our recent BSI Medical Devices (Capabilities) brochure provides you with information on all of the services we offer medical device manufacturers, from CE marking under the EU IVDR and MDR, and UKCA marking under the UK MDR (2002), to Quality Management Systems (QMS) certification and Medical Device Single Audit Program (MDSAP) audits.

We have also updated our brochures for Ophthalmic Medical Devices and Wound and Skin Care Medical Devices. These provide information on the extensive experience of our technical specialists and the services we offer to support you through the process of certifying your medical device.

Read capabilities brochure

MDR Company Information Form - Device Schedule tutorial

We have developed a short tutorial video, which guides you through the process of completing the 'Device Schedule' section of the Company Information Form (CIF). The Device Schedule provides BSI with the information we need to fully understand the scope of your application and the information to be included on the certificate of conformity; it also ensures that we, as a Notified Body, are complying with the Regulation.

Watch video

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

Fast track your understanding of MDSAP requirements

Did you know that you can expedite your understanding of MDSAP requirements with Compliance Navigator's new guidance? Authored by Eamonn Hoxey, this comprehensive guidance document includes seven sections on: management; device marketing authorization and facility registration; measurement analysis and improvement; medical device adverse events and advisory notices reporting; design and development; production and service controls; and purchasing. Watch this video to find out more about the benefits of a subscription to Compliance Navigator.

Watch video

Knowledge is key - start your training with the BSI Academy

We have made a selection of the most popular training courses for you to gain deep knowledge in relevant topics of medical devices regulation.

ISO 13485 Lead Auditor - view dates

Clinical Evaluation for Medical Devices - view dates

Post Market Surveillance and Vigilance under the MDR and IVDR - view dates

Introduction to Medical Devices Software - view dates

Are you ready for topics like information security or health and safety?

BSI's success in inspiring trust for a more resilient world is founded in its expertise and commitment to sharing knowledge, innovation and best practice. Discover our complete portfolio of training course topics, covering also international standards like ISO 27001, ISO 22301 and ISO 45001.

Download our training portfolio

Events for your calendar

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

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