Contact us
+44 345 080 9000
medicaldevices@bsigroup.com

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

Book now –MDR Lessons learnt webinar

The Medical Device Regulation (MDR) Date of Application (DoA) is approaching. The timelines for ensuring your product maintains EU market access under the new, more stringent MDR are challenging. BSI Notified Body wants to share some of our experience working on Technical Documentation submitted under the MDR.

Join this webinar to hear Join Dr Monisha Phillips, Global Head of Orthopaedic and Dental, talk about the critical lessons we have learnt and how you can use these to improve your submissions to BSI. We will share notified body experience and common pitfalls and learnings. Monisha will be joined for the Q&A section by Kevin Madden, Technical Team Manager & Team Training Lead, Orthopaedic and Dental at

BSI.

Choose from one of to sessions:

Tuesday 30 March 09:00 – 10.00 (BST) - Register

Tuesday 30 March 16:00 – 17.00 (BST) - Register

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

Events for your calendar

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

bsi.