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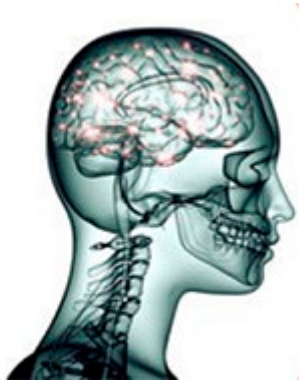

Regulatory review

Your monthly medical device update
November 2020

Medical Devices, Brexit and UKCA

As you are aware, the UK will leave the European Union on 31 December 2020. We are currently reviewing the implications of the new United Kingdom Conformity Assessment (UKCA) regulation, and we would like to confirm our intention to work as a UKCA Approved Body completing conformity assessments for the UK. UK Notified Bodies for the Medical Device, Active Implantable and In Vitro Diagnostic Directives (MDD, AIMD and IVDD), will have their designations rolled over automatically.

Find out more

New Microbiology and Sterile Medical Devices brochure

As a manufacturer of a sterile medical device, meeting the necessary ISO 13485 regional and global regulations can be a challenging and complex process. It is critical to work with a notified body that understands the industry and has the experience to review and confirm your product's readiness for market – efficiently, promptly and robustly. Our new brochure provides you with all the information you need on a typical microbiology assessment from BSI and the certification process for your sterile medical device.

Download the new brochure

ISO 20916 IVD - Clinical Performance studies Webinar

Join this webinar to hear Dr Marco Rost, Training Lead Regulatory Service (IVD) for BSI, talk about the new standard ISO 20916 In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice. ISO 20916 is a new standard, which fills a long-recognized gap by addressing requirements for clinical performance studies on IVD medical devices. The standard defines good study practice for the planning, design, conduct, recording and reporting of clinical performance studies carried out to assess the clinical performance and safety of IVD medical devices for regulatory purposes.

Please join us for this critical update around the new standard for Clinical Performance.

Choose from one of two sessions:

Wednesday 2 Dec 09:00 - 10:00 BST - **Register now**

Wednesday 2 December 16-00 - 17:00 BST - **Register now**

Listen back to our On Demand webinars

Maintaining your CE Certification under the IVDR, a Life cycle Approach – with Dr Heike Möhlig--Zuttermeister

Clinical evaluation under the MDR – do you understand the requirements? – with Richard Holborow

Discover how immersive technology has helped prioritize patient care

BSI is proud to have participated in the UK Government's 'Rapidly Manufactured Ventilator Scheme' initiative during the Covid-19 pandemic. Our teams adapted quickly, enabling them to provide remote audits for both new and existing ventilator producers, prioritizing patient access to critically needed devices.

Discover more about the Immersive Technology Solutions that enabled this response, including the role it can play to protect front line teams and deliver critical patient care in our latest edition of Innovation insights.

Download Innovation insights

Have you read the latest Compliance Navigator blog posts

If you'd like to stay up to date with the latest regulatory, technological and standards-related developments within the medical devices sector, then subscribe to the Compliance Navigator blog. Written by industry experts, blog posts are published once every two weeks

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