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

Regulatory review

Your monthly medical devices update

October 2023

Featured in this Newsletter

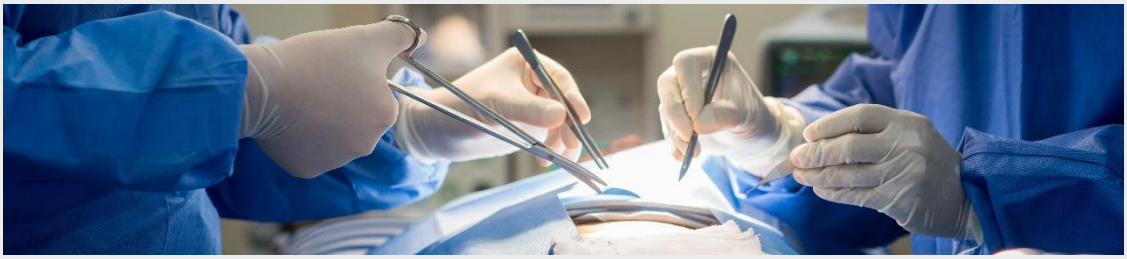
Time for your IVDR application is now!

BSI has capacity across the full scope of our IVDR designation and we are accepting IVDR applications. For IVDD-Certified Class D devices, time is pressing. The deadline for certification under the IVDR is 26 May 2025. It is crucial that manufacturers of Class D devices understand that they need to submit their application now or run the risk of not completing the conformity assessment process in time.

Email us today at medicaldevices@bsigroup.com or directly request a quote.

Apply now

Time for your MDR application is now!



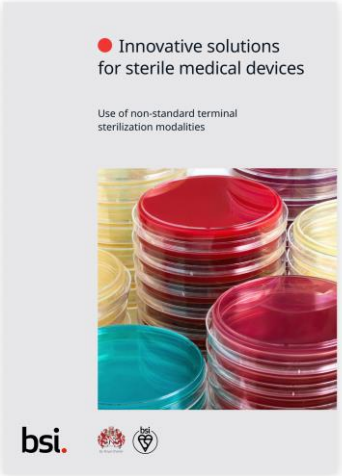
According to Amending Regulation (EU) 2023/607, if you are transitioning your devices to the MDR, you will be able to benefit from extended validity of your directive certificates (until the end of 2027/2028 based on the device classification) for legacy devices if some conditions are met.

Among these, by 26 May 2024 you have to put in place an MDR compliant QMS and lodge a formal application with a Notified Body for MDR Conformity Assessment. No later than 26 September 2024, a formal agreement with the Notified Body must be signed.

We strongly recommend that you do not wait until May 2024 to make your MDR application. We encourage you to apply with BSI as soon as possible and well in advance of the above deadlines.

For more guidance visit our MDR dedicated webpage and our FAQs.

Innovative solutions for sterile medical devices



Our Microbiology and Sterile Medical Devices Team just released a new whitepaper on "innovative solutions for sterile medical devices – use of non-standard terminal sterilization modalities".

Click here to download and read our whitepaper to learn more about the use of non-standard terminal sterilization modalities.

Visit our dedicated webpage

Webinar - Understanding IVDR Software and Cybersecurity

Tuesday 31 October 2023

Join this insightful webinar to hear BSI's subject matter experts, Dr Elizabeth Harrison, Global Head of IVD and Thomas Doerge, Global Head Active Implantable, discuss BSI's expectations of cybersecurity documentation of IVD software. In this webinar we will talk about lessons learned from technical documentation reviews of IVD software as well as specific feedback on IVD software technical documentation assessments performed thus far.

Register for one of the two time slots on Tuesday 31 October 2023

Register for AM webinar:

9:00 – 10:00 GMT - Register

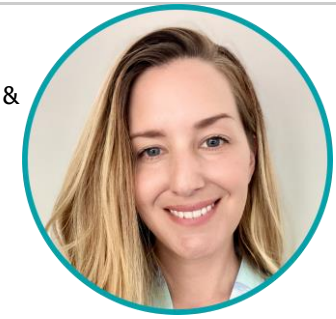
Register for PM webinar:

16:00 – 17:00 GMT - Register

Register now

On demand webinar - IVDR Companion Diagnostics Update

Listen back to our extended webinar on IVDR Companion Diagnostics Update. Hear from subject matter experts, Liz Linch, Technical Specialist & Scheme Manager and Liz Harrison, Global Head of IVD, as they talked about the latest BSI knowledge and best practise with regards to IVDR Companion Diagnostic conformity assessment.

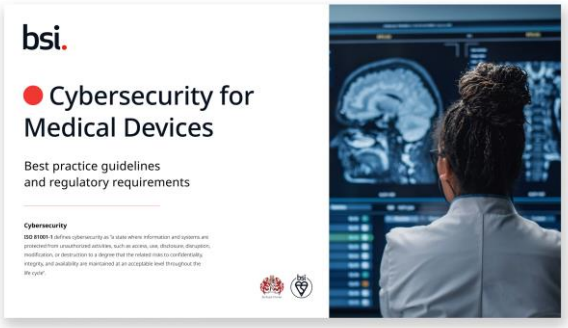


Watch on demand webinar

Cybersecurity for Medical Devices

Manufacturers are required to ensure that medical devices placed on the EU and UK markets meet the new technology challenges related to cybersecurity risks.

Take a look at our new Best Practice Guidance on Cybersecurity for Medical Devices here.



Download best practice guidance

Introducing BSI's AI On-Demand Training Courses

BSI is developing a series of artificial intelligence (AI) training courses that will provide an overview of the standards and regulatory landscape for artificial intelligence, including applications, key principles, ethical considerations, and legal frameworks, helping you gain an understanding of AI standards, regulation and the implications and benefits they bring.

The first two training courses are on Neural Networks. A 30-minute awareness course and a more in-depth 2.5-hour introduction course explore the importance and impact of implementing robust deep learning systems.

Course details

Blog series EN 60601 - Medical electrical equipment and systems

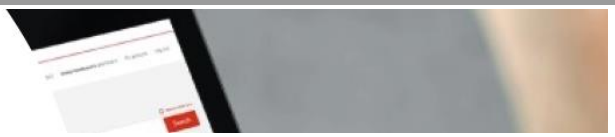
At BSI we provide not only testing services for medical devices electrical safety against EN 60601 requirements for European market access under the Medical Devices Regulation, but we are also operating as IEC System for Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE) Certification Body (CB), Scheme for Active Medical Devices. The scheme gives you access to 53 countries around the globe.

To find out how your organization can benefit from our testing services, visit our dedicated blog.

Find out more

BSI Compliance Navigator

bsi. compliance navigator



The digital revolution in regulatory document management

Compliance Navigator is the smart, simple way to work with medical and IVD device standards and regulations. Designed by regulatory experts, our online workflow tool helps teams discover, organise, and mitigate potential risks in their compliance process.

Key features:

- **Save time** - Access and search over 6500 relevant documents and standards and add the most relevant ones for your product to your own bespoke dashboard

- **Reduce risk** - Get advance warning of upcoming changes to medical device BS standards and BS-adopted medical device standards that affect your compliance
- **Coordination** - Unlimited number of users with simultaneous access
- **Expert Commentary** - Interpret standards and regulatory information via independent expert commentary and smart support guides

Start a free trial today

Events for your calendar

We have some fantastic events for 2023. Take a look now at our calendar of events for 2023.

Don't miss the opportunity to interact with BSI experts or connect with our commercial team to discuss your certification requirements. Find out more about our latest Events and Conferences.

bsi.

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