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Regulatory review

Your monthly medical devices update

May 2024

Featured in this Newsletter

Access Global Markets with BSI

Discover the comprehensive country guide to medical devices certification services BSI provides to manufacturers around the globe. Contact us today and benefit from our experienced team to access global markets.

Learn more

The time for your MDR application is now!

In March 2023, the Regulation (EU) 2023/607 amending the MDR was published in the OJEU with immediate effect. The 26 May deadline is fast approaching! We encourage you to read our Amending Regulation (EU) 2023/607 FAQs to find answers to most frequently asked questions on the MDR transition and associated topics.

To know more visit our MDR dedicated webpage.

Apply now

Notified Body capacity and lead times

We are pleased to share BSI Notified Body capacity and lead times for MDR and IVDR applications and Conformity Assessments. This information is based on BSI's interpretation of these terms, considering our operational processes and client feedback relating to information that would be the most useful in enhancing transparency and predictability of MDR/IVDR applications, and certification processes for manufacturers.

BSI commits to updating the capacity and lead times on a regular basis, and the capacity and lead times presented below should be considered as indicative at the time of publication.

To know more visit our dedicated webpage.

Read the document

Transfer of Appropriate Surveillance

Do you know that among the conditions set out in Regulation (EU) 2023/607, the NB that issued the Directive certificate for your devices will continue to be responsible for the appropriate surveillance, unless you have agreed with the NB you signed an MDR written agreement with, that it will carry out such surveillance?

Check out our guide to learn more on how to Transfer the appropriate surveillance of your medical devices to BSI under (EU) 2023/607.

To know more visit our MDR dedicated webpage.

New guide

BSI establishes new regulatory team: Software as a Medical Device (SaMD)

We are proud to introduce our new regulatory team, focusing on Software as a Medical Device (SaMD). Led by Thomas Doerge, Global Head SaMD, this initiative underscores our commitment to innovation while ensuring the highest standards of quality and compliance in healthcare.

In response to the surge in software-based medical solutions, we've established this team to streamline processes; delivering safer, high-quality products more efficiently. SaMD represents the future of healthcare, and at BSI, we're setting new standards for quality and compliance to stay ahead.

Click below to read the full story, and find out how we are working with organisations to shape the future of healthcare together.

Read the full story

ISO 13485 - Quality Management System

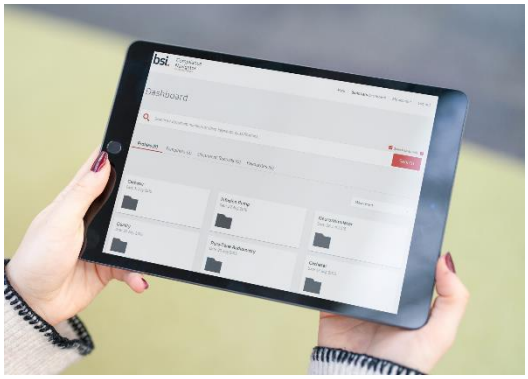
In today's rapidly evolving healthcare landscape, the quality and reliability of Medical Device Quality Management Systems (QMS) is paramount.

ISO 13485 is an effective solution to meet the comprehensive requirements for your QMS, and adopting it provides a practical foundation for manufacturers to address MedTech regulations and responsibilities, as well as demonstrating a commitment to the safety and quality of medical devices.

Whether you're a manufacturer, importer, supplier or distributor; ISO 13485 can enhance your organization's trust and marketability. Find out more about BSI's ISO 13485 Certification services by downloading the brochure or visiting our dedicated webpage.

Download brochure

BSI Compliance Navigator



Appointed by the UK Government in 1901 as the world's first National Standards Body, BSI represents UK interests at the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC) and the European Standards Organizations (CEN, CENELEC and ETSI).

Our fully digital document management system, Compliance Navigator, with over 7000 documents available, was designed by BSI and regulatory experts to help medical device manufacturers access pertinent medical device and IVD device regulations, standards and supporting guidance quickly, and organise them efficiently for reference and in preparation for regulatory audits.

Learn more

Events for your calendar

On demand webinar - Extension IVDR Timelines

Listen back to our webinar Extension to IVDR transition timelines. The webinar discussed the actions that manufacturers will need to take to ensure timely compliance with the IVDR, especially with regards to legacy IVD devices.

Listen on demand

On demand webinar - Shaping Trust in AI: Ensuring Conformity of AI - enabled Medical Devices amid Regulatory Changes

Listen back to our second webinar in the Shaping Trust in AI series; Ensuring Conformity of AI – enabled Medical Devices amid Regulatory Changes. The webinar discussed how the EU AI Act will interplay with the MDR and provided insights where tensions and inconsistencies are likely to emerge.

Listen on demand

MedTech Summit

Event: 10 - 14 June 2024

We are thrilled to participate in this year's MedTech Summit, which will take place from June 10 to 14, 2024 in Brussels. Join us to connect with our team and engage in cutting-edge discussions, with over 100 conference sessions featuring practical industry case studies, experts panels, and real-world feedback designed to streamline your path to regulatory compliance.

Don't miss our key sessions:

Wednesday, 12 June 2024, 10:10 - 10:40

Rollout of EU Reference Laboratories for IVDR

Alex Laan, Head of IVD Notified Body

Thursday, 13 June 2024, 10:10 - 10:40

Understanding the Challenges to AI-enabled Medical Devices Software Conformity Assessments, including Cybersecurity Aspects

Inma Perez Ruiz, Regulatory Lead - AI Notified Body

Thomas Doerge, Global Head Active Implantable Medical Devices (AIMD)

Details here

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Inspiring trust for a more resilient world.