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Regulatory review

Your monthly medical devices update

September 2024

Featured in this Newsletter

MDR 26 September deadline approaching

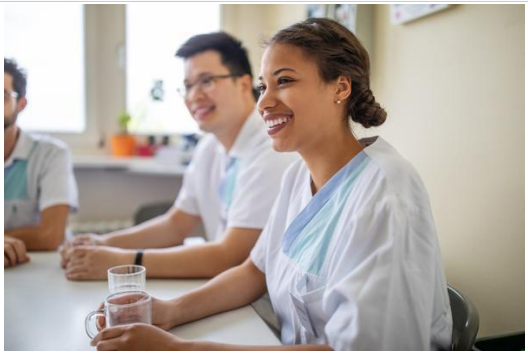
In March 2023, the Regulation (EU) 2023/607 amending the MDR was published in the OJEU with immediate effect. By 26 September 2024 you must have signed a MDR written agreement with a Notified Body and the Appropriate Surveillance for those legacy devices you wish to continue placing on the market must have been transferred to the Notified Body you have your MDR written agreement with. The 26 September 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, read our **e-news**.

Visit our dedicated webpage

Vascular Medical Devices

Our vascular team is ready to work with new and established clients to ensure the vascular medical devices comply with the EU MDR requirements. We provide a range of product review services to bring your vascular device to market. Trust BSI for expert and reliable support throughout your product's lifecycle, helping you navigate the regulatory landscape.



For more information, please visit our page.

Visit our dedicated webpage

Rollout of EU Reference Laboratories for IVDR Class D devices

BSI Regulatory Services is committed to keep IVD manufacturers informed on EU regulatory framework developments. Check-out our latest e-news on the rollout of EU Reference Laboratories (EURLs) for IVDR Class D devices.

Read our e-news

Make the most of the extended IVDR transition timelines - Act today

IVD manufacturers planning to transition legacy devices under the IVDR should act promptly to benefit from the extended validity of the Directive certificates, provided these **specific conditions are met**.

- The manufacturer has implemented an IVDR compliant QMS no later than 25 May 2025.

- The manufacturer has lodged a formal application with a Notified Body for IVDR Conformity Assessment by May 2025 for IVDD certified and class D self-declared devices, by May 2026 for Class C self-declared IVDs and by May 2027 for class B and A-Sterile self-declared IVDs.
- The manufacturer has signed a written agreement with a Notified Body by September 2025 for IVDD certified and class D self-declared devices, by September 2026 for Class C self-declared IVDs and by September 2027 for class B and A-Sterile self-declared IVDs.

Act today. Reach out to BSI to discuss your transition plans:

Request a quote

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

BSI Regulatory Services Annual Training Meetings

Over the past month, BSI colleagues from around the world gathered for our Regulatory Services Annual Training Meetings. These events provided a unique opportunity to meet in person and gain a deeper understanding of the impact medical devices have on patients globally.

We hosted meetings in three regional locations: Lake Ashi in Japan, New Orleans in the United States, and Liverpool in the United Kingdom. Attendees had the chance to ask questions, share challenges, hear local perspectives, expand their networks, and, of course, celebrate BSI's achievements over the last year together.

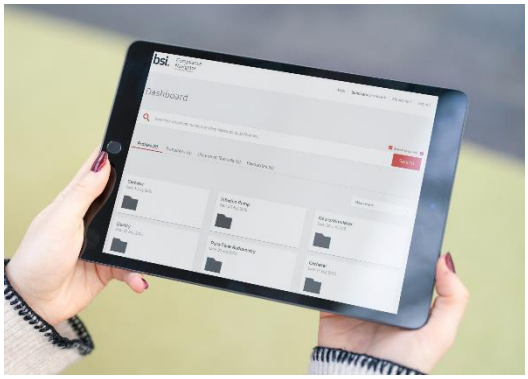
A heartfelt thank you to everyone who attended and participated with such enthusiasm. Here's to being partners in progress and future-ready!

For more information about joining BSI Regulatory Services, please visit our careers page.

BSI Careers

BSI Compliance Navigator

Compliance Navigator now contains MDSAP documents



To find out more about the new MDSAP documents being added to Compliance Navigator, click below to find out more. A member of our team will be in touch to provide a comprehensive overview of what is included, as well as a brief review of the 7000 other regulations, standards and guidance documents pertaining to the EU MDR, EU IVDR & FDA you can access via the online platform.

Request more information

Events for your calendar

Webinar - Rollout of EU Reference Laboratories for IVDR Class D devices

26 September 2024 | 09:00 and 16:00 BST

Register now for the 'Rollout of EU Reference Laboratories for IVDR Class D devices' webinar, 26 September 2024. Hear our subject matter experts Alex Laan, Head of Notified Body – IVD, Sara Fabi, Regulatory Lead – IVD, as they discuss the newly enrolled EURL regulation.

Register here

Webinar - ISO 13485: A Beginners Guide

2 October 2024 | 16:00 BST

Join us for our engaging and informative webinar, "ISO 13485 – A Beginners Guide," 2 October 2024, designed to provide a comprehensive introduction to this essential standard.

In this beginner-friendly session, we'll demystify ISO 13485:2016, the international standard for quality management systems (QMS) specifically tailored for the medical device industry and supporting contract manufacturers. Our expert speakers will guide you through the fundamental principles, requirements and benefits of implementing ISO 13485 within an organization.

Register here

Webinar - Clinical Evaluation of Orphan Devices & MDCG 2024-10

16 October 2024 | 16.00 BST

Register now for the 'Clinical Evaluation of Orphan Devices & MDCG 2024 -10' webinar, 16 October 2024. This webinar will provide BSI's interpretation of MDCG 2024 - 10 guidance and will provide manufacturers with guidance on how to apply for a conformity assessment of an orphan device.

Register here

TOPRA Symposium 2024

September 30 - October 2 | Rotterdam, Netherlands

Connect with us at the TOPRA Symposium in Rotterdam, Netherlands, from September 30 to October 2. Our leading experts will present key insights on AI as a Medical Device under the EU AI Act, UK MDR requirements, and the role of Responsible and Experienced PRRC for MDR and IVDR.

Details here

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