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Regulatory review

Your monthly medical devices update

Summer 2024

Featured in this Newsletter

We've combined this edition of your Regulatory review into a summer edition. Your monthly medical device updates will be back in September.

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.

Visit our dedicated webpage

Navigating Annex XVI Compliance

Annex XVI regulates non-medical products, including certain contact lenses, body modifiers, fillers, adipose tissue reducers and removers, lasers and intense pulsed light equipment, and non-invasive brain stimulators. BSI specializes in providing regulatory compliance services for medical device manufacturers and distributors. Our team of experts is well-versed in the requirements of

Annex XVI requirements. We help you navigate the regulatory landscape, and we assess your product compliance with MDR safety and quality requirements.

Watch webinar on demand

Regulation (EU) 2024/1860

On 9 July, the EU Commission published **Regulation (EU) 2024/1860** as regards a gradual roll-out of EUDAMED, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices. Check out our guidance resources:

- IVDR timeline
- IVDR transition guidance
- IVDR Q&A
- EUDAMED

To know more, visit our IVDR dedicated webpage.

Visit our dedicated webpage

We are now accepting applications for Singapore Accreditation Council (SAC) accredited ISO 13485 certification

Effective 1 January 2025, ISO 13485 certificates accepted for HSA medical device dealer license applications would be those issued by SAC-accredited certification bodies. BSI is accredited by the Singapore Accreditation Council (SAC), and we are now accepting applications for manufactures wishing to meet the HSA deadline of 1 Jan 2025, or for importers and wholesalers seeking to leverage their ISO 13485 QMS for bringing and supplying medical devices into Singapore.

Read the press release

Follow Our New IVD LinkedIn Showcase Page!

We're pleased to announce our new LinkedIn showcase page dedicated to In Vitro Diagnostics (IVD) is now live!

This new dedicated page shares key regulatory updates, industry news, and expert perspectives as we navigate the dynamic landscape of IVDs. You can like and follow the page here.

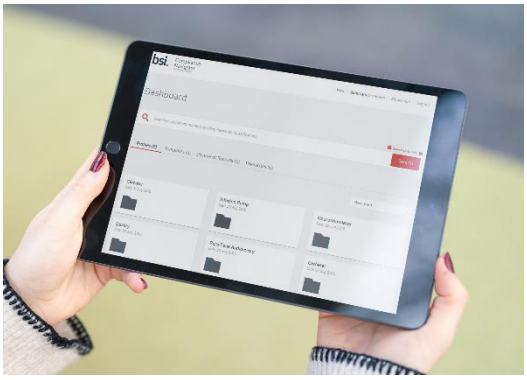
Follow now

BSI celebrates issuing its 1500th MDR Certificate

BSI is proud to announce the issuance of its 1,500th MDR certificate, marking a significant achievement in our commitment to ensuring the safety and quality of medical devices placed on the EU market. This milestone reflects our dedication in guiding medical devices manufacturers navigate the complex regulatory landscape, highlighting the efficiency and thoroughness of our excellence review services and certification pathways.

Visit our webpage

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

Intelligent Health 2024

September 11-12 | Basel, Switzerland

Join us at Intelligent Health 2024 in Basel, Switzerland, on September 11-12! This premier AI in medicine summit will feature global voices in Healthcare and AI, showcasing cutting-edge use cases, tech talks, innovation insights, workshops, and roundtables from leading clinicians, researchers, and tech companies.

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

bsi.