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Regulatory review

Your monthly medical devices update

June 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.

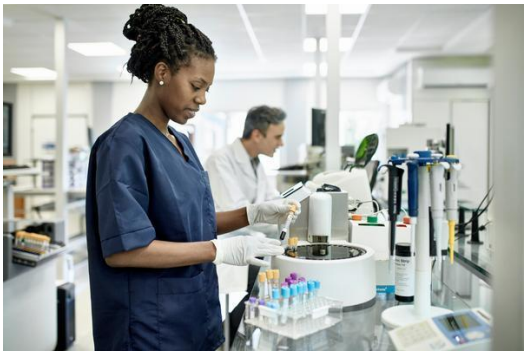
Visit our dedicated webpage

Medical Device Lifetime Requirements

To demonstrate compliance with MDR GSPR 6, manufacturers must determine the lifetime of their device and assess the effects of the device's lifetime on safety and performance. Check out our new whitepaper, to access guidance on how to determine medical devices lifetime based on design characteristics to meet MDR requirements.

Download our whitepaper

Fostering progress towards IVDR transition



We remain committed to enhancing transparency and predictability of IVDR applications, and certification processes for manufacturers to support their IVDR transition plans. In this poster we present a summary of the certificates issued by BSI Group The Netherlands B.V. (2797) up to April 1 2024, based on first time certificates issued. Download our poster to gain a better understanding of the types of devices that have already transitioned to the IVDR and of the diversity across different IVDR certificates.

Download poster

New IVD LinkedIn page coming soon!

Coming soon! We are excited to share, our new LinkedIn page dedicated to In Vitro Diagnostics (IVD) will be launched this summer. This new dedicated page will share key regulatory updates, industry news, and expert perspectives as we navigate the dynamic landscape of IVDs. In the meantime, check out our Medical Devices LinkedIn page. Watch this space!

BSI Medical Devices

New SMEs space dedicated

Are you encountering major challenges in navigating Regulatory Schemes and certification processes?

Globally, 85% of the manufacturers BSI works with across all regulatory certification services are SMEs. We fully understand the difficulties you may encounter to place your medical device on the market.

To help you navigate the highly regulated MedTech sector, we developed an SMEs dedicated space where you can explore and learn about the certification process from application through conformity assessment and much more!

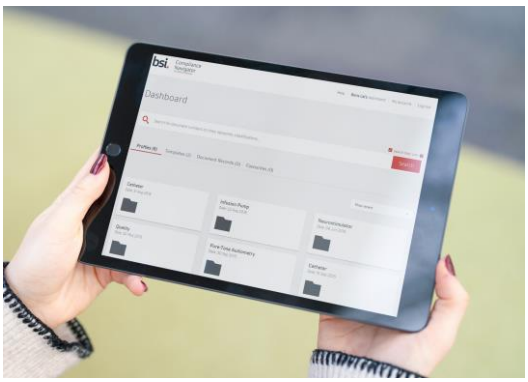
Visit our dedicated webpage

Your MDSAP journey with BSI

BSI is a recognized Auditing Organization for the Medical Device Single Audit Program (MDSAP), having completed numerous audits for both world-leading medical device manufacturers and SMEs. Our services encompass streamlined application and conformity assessment processes, seamless transfer services and access to a wide portfolio of guidance resources. With a global network of over 200 MDSAP assessors, we ensure expertise and coverage across regions, backed by more than 240 ISO 13485 QMS assessors worldwide, ensuring thorough assessments. Choose BSI to get MDSAP certified.

Find out more

BSI Compliance Navigator



After a medical device is CE marked, the manufacturer is required to set-up, implement, and maintain a Post-Market Surveillance (PMS) System and carry out PMS activities over the whole life cycle of a medical device, as defined in European Medical Device Regulation 2017/745 (MDR) Article 2 (60), with requirements as per Chapter VII Section I, Articles 83 through 86. Detailed requirements for a PMS System are given in Article 83.3. Further guidance is given in PD CEN ISO/TR 20416:2020, Medical devices - Postmarket surveillance for manufacturers, which aligns the PMS process with BS EN ISO 13485:2016+A11:2021, Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes, and BS EN ISO 14971:2019+A11:2021, Medical devices - Application of risk management to medical devices.

Download our whitepaper

Events for your calendar

Maintaining Compliance: IVDR - Post certification activities

On demand webinar

Listen back to our webinar Maintaining Compliance: IVDR – post certification activities. The webinar gave a brief overview of IVDR post-certification activities as well as providing an in depth look at what to expect from IVDR Technical Documentation surveillance reviews.

Listen on demand

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.

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