Contact us
+39 02 4441 8150
marketing.italy@bsigroup.com

Regulatory review

Your monthly medical devices update

November 2024

Featured in this Newsletter

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

UKCA marking with BSI

Our step-by-step guide helps you navigate the UKCA Certification process, from submitting your application to receiving your UKCA Certificate.

Access the full guide here

Guide to Conformity Series - Medical Device Single Audit Program (MDSAP)

MDSAP allows a single audit of a medical device manufacturer's QMS, which satisfies the requirements of multiple regulatory jurisdictions. Through MDSAP, medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets.

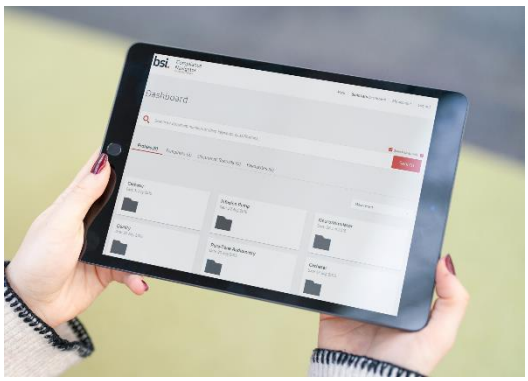
To know more, visit **our dedicated webpage**.

Watch the video now

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 - Article 16(4) Certification Scheme

Monday, 25 November 2024 | 09:00 and 16:00 GMT

Join us for this insightful webinar Article 16(4) Certification Scheme on 25 November 2024. BSI Notified Body launched its Article 16(4) Certification Scheme on the 25 of September. This webinar will discuss Article 16 MDR/IVDR and BSI's Article 16(4) Certification Scheme.

Register for webinar

Learn about ISO 13485:2016 for medical devices

Webinar on-demand

This webinar covers the importance of compliance, benefits for manufacturers and why BSI is the right Notified body, providing expertise. Gain insights through a Q&A session to support your journey toward safer, quality-focused products.

Watch our webinar on-demand

On Demand Webinars

- Best practice for PSUR's

- Prepare for ISO 42001 – a framework for the management of AI
- Clinical Evaluation of Orphan Devices & MDCG 2024-10
- Rollout of EU Reference Laboratories for IVDR Class D devices

bsi.

Inspiring trust for a more resilient world.