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Regulatory review

Your monthly medical devices update

October 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

MDR Annex XVI

MDR Annex XVI regulates products without an intended medical purpose, including devices used for aesthetic indications and dual use products.

Read our dedicated **whitepaper** where Rachel Mead, Clinical Regulatory Lead and Ester Leoni, Global Regulatory Comms Manager, will walk you through Annex XVI regulatory framework.

BSI in accepting Annex XVI applications. If you want to know more or want to discover how BSI can walk you through your compliance journey, access our dedicated resources here.

Visit our MDR webpage

Article 16(4) Certification for EU importers and distributors

As part of BSI's commitment to ensuring patient safety while supporting timely market access to global medical device technologies, we are pleased to inform you that we are expanding our Notified Body services to offer a new certification scheme for MDR and IVDR: Article 16(4) Certification.

According to Article 16(4), importers and distributors performing relabelling and repackaging activities for devices already placed on the market require a certificate from a Notified Body to demonstrate that their QMS complies with the requirements specified in Article 16(3) of the regulations.

Head over to our latest enews to learn more.

Find out more in our enews

Guide to Conformity Series

BSI Medical Devices presents our Guide to Conformity Series!

Stay tuned for the upcoming chapters.

Our mission is to ensure patient safety while supporting timely access to global medical devices innovation. Our efforts in setting the global standard in regulatory and quality management reviews and also in product certification, are highly recognized and trusted worldwide.

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

Watch the video now

Download our whitepaper and discover key insights on the EU AI Act

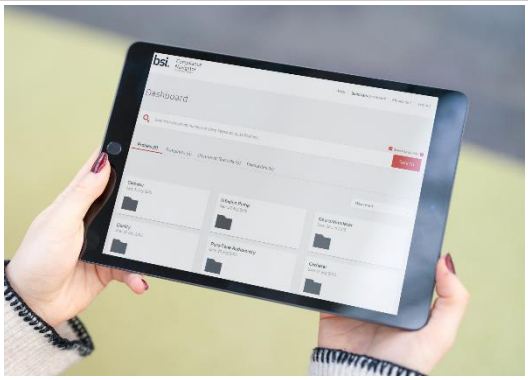
Download now our EU AI Act whitepaper, "The EU AI Act – what AI providers and deployers need to know", expertly written by our AI Regulatory Leads and the Head of AI Notified Body. Our jargon-free whitepaper will provide you with the insights you need to make informed decisions and stay ahead in the AI regulatory landscape.

Download our whitepaper

BSI Compliance Navigator

230 new documents were added to the Compliance Navigator platform in Q3 2024

That takes the total number of new documents added in 2024 to 696 and over 7500 now in total. Documents added include standards from BSI, ASTM, CLSI as well as guidance documents from the FDA, Gov.AU and MDCG



Download the list of new documents **here**.

To find out more about the entire content set and how you could benefit from access to Compliance Navigator, request a free trial below.

Request more information

Events for your calendar

Webinar - Best Practice for PSURs

12 November 2024 | 09:00 and 16:00 GMT

Register for our webinar 'Best practice for PSUR's'. This insightful webinar is an opportunity for BSI to share best practices on compiling and submitting PSURs for notified body evaluation. The webinar will cover topics such as the role of MDCG 2022-21 guidance on PSUR for manufacturers, justification and analysis and change notification via the PSUR.

Register here

On Demand Webinars

- BSI Notified/Approved Body & The Role It Plays In Patient Safety
- ISO 13485: A Beginners Guide
- Rollout of EU Reference Laboratories for IVDR Class D devices
- Understanding and meeting the EU IVDR requirements for In Vitro Diagnostics (IVD) Kits

MEDICA - Trade Fair for Medical Technology & Healthcare

November 11-14 in Düsseldorf, Germany

Come join us at MEDICA 2024, taking place from November 11 to 14 in Düsseldorf, Germany! Stop by our booth 10, to discuss our certification services to place safe and compliant medical devices on the market.

Details here

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Inspiring trust for a more resilient world.