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Regulatory review

Your monthly medical device update

May 2023

Featured in this Newsletter

Discover what you need to know about Notified Body and Approved Body certification and MedTech legislations!

To know more, visit our dedicated

BSI IVD team has just released a new brochure. Take a look and discover our IVD team expertise, products covered and relevant information to comply with requirements and increase your market readiness.

For additional resources visit our dedicated IVD and IVDR webpages!

View Brochure

Ethical and Trustworthy Artificial Intelligence

As the AI technology rapidly evolves, so does the regulation governing its use.

When it comes to navigating the AI regulatory landscape and placing your device on the market, proactivity and readiness are essential.

To help you navigate the complex AI regulatory landscape, we have created a dedicated whitepaper: Ethical and Trustworthy Artificial intelligence - BSI's introduction to the European Artificial Intelligence Draft Act (AIA).

Download the Whitepaper

On demand webinar - Pathways to IVDR Compliance

Listen back to our extended webinar to hear subject matter ext tendedexi.7 (i) (i)12 6 H(s)-2( )]TEMof48 19.

understanding of the status related to high-risk CDx & Class D devices.

The webinar included:

- History Lesson: Key IVDR changes… why and when?
- Telling a Story: Creating effective technical documentation
- Clinical Evidence: Understanding the requirements
- High Risk update: Current status of CDx & Class D devices
- Q&A sessions with panel