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Regulatory review

Your monthly medical device update
December 2019

Download our new white paper: Explaining IVD classification issues

Download this BSI medical devices white paper, authored by Mika Reinikainen and Dr Maurizio Suppo, for a historical overview of the development of medical device and IVD device classification; an explanation of the new IVDR classification rules; and an analysis of the implications of these new rules.

Download now

Supporting your healthcare business needs

Providing peace of mind in healthcare is vital. With the ever-changing healthcare landscape, from technological advancements, digitization and complex regulations, BSI can help organizations adapt and embrace these changes. Watch this video to learn more.

Watch video

Announcing the BSI EU IVDR Spring 2020 Roadshow

In response to the success of our recent events, the BSI EU In Vitro Diagnostic Regulation (IVDR) Roadshow will be returning to various locations across Europe at the beginning of next year:

- Munich, Germany – 18 February 2020
- London, UK – 3 March 2020
- Amsterdam, Netherlands – 25 March 2020*

We are working on an even more insightful agenda to ensure you have access to the latest IVDR updates from BSI. The event is also a unique opportunity for you to engage face-to-face with the only Notified Body currently designated with full-scope to the IVDR.

Start your preparation today – register your interest now!

Register interest

*subject to final confirmation

Listen back to our webinar on Article 120 (3) – What is due in 2020?

Hear Dr Suzanne Halliday, Regulatory Director and Head of Notified Body, talk about what manufacturers need to think about in 2020 to meet the requirements of Article 120 (3).

View webinar

Happy Holidays to all our clients and we look forward to working with you in 2020!

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