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Regulatory review

Your monthly medical devices update

November 2023

Featured in this Newsletter

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- New Medicinal & Biologics brochure available
- Our Training Academy just released the new Healthcare and Medical Devices training brochure
- Webinar - IVDR Regulatory Updates - where do we stand 18 months after DoA?
- On demand webinar - Understanding IVDR Software and Cybersecurity
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- Shaping the future of AI at the World Summit in Amsterdam
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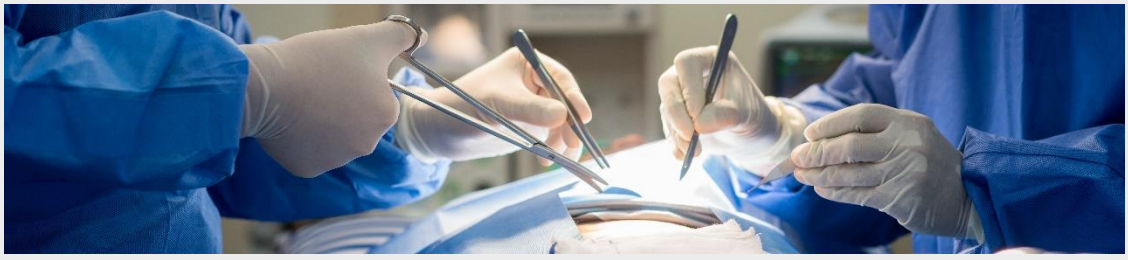
Time for your MDR application is now!



According to Amending Regulation (EU) 2023/607, if you are transitioning your devices to the MDR, you will be able to benefit from extended validity of your directive certificates (until the end of 2027/2028 based on the device classification) for legacy devices if some conditions are met.

Among these, by 26 May 2024 you have to put in place an MDR compliant QMS and lodge a formal application with a Notified Body for MDR Conformity Assessment. No later than 26 September 2024, a formal agreement with the Notified Body must be signed.

We strongly recommend that you do not wait until May 2024 to make your MDR application. We encourage you to apply with BSI as soon as possible and well in advance of the above deadlines.

For more guidance visit our MDR dedicated webpage and our FAQs.

New Medicinal & Biologics brochure available

Take a look to the dedicated webpage to discover the full range of medical devices our M&B team covers from in vitro fertilization and animal tissue devices to organ preservation and much more.

Visit our dedicated webpage

Our Training Academy just released the new Healthcare and Medical Devices training brochure

Our training portfolio provides an in-depth understanding on key topics regulating medical devices, IVDs and QMS to increase your knowledge on compliance, implementation, and maintenance of regulatory requirements.

Visit our dedicated webpage

Webinar - IVDR Regulatory Updates - where do we stand 18 months after DoA?

Tuesday 28 November 2023

With the IVDR having entered into force on 26 May 2022, there are still many questions and challenges for IVD manufacturers facing the difficult task of implementing the regulation.

Join this informative webinar to hear subject matter expert, Alex Laan, Head of IVD Notified Body at BSI, share his knowledge, hints, and tips on latest IVD regulatory updates. You will also gain a better understanding of the status related to IVDR and envision the potential ramifications for manufacturers of these updates.

Register for one of the two time slots on Tuesday 28 November 2023

Register for AM webinar:

9:00 – 10:00 GMT - Register

Register for PM webinar:

16:00 – 17:00 GMT - Register

On-demand - Understanding IVDR Software and Cybersecurity webinar

Listen back to our Understanding IVDR Software and Cybersecurity webinar from 31 October. Hear from subject matter experts, Thomas Doerge, Global Head Active Implantable Medical Devices (AIMD) and Dr. Liz Harrison, Global Head of IVD, as they discussed BSI's expectations of cybersecurity documentation of IVD software.

Watch on demand webinar

UKCA Roadmap

Take a look to our UKCA Roadmap for you to better understand how to place your Medical Devices and IVDs on the GB market according to MHRA recognition of Amending Regulation 2023/607.

Learn more

Blog series EN 60601 - Medical electrical equipment and systems

As EN 60601 series of standards is a complex document, we developed a dedicated blog to help you navigate EN 60601 requirements while increasing your understanding around key topics and concepts to effectively prepare for electrical safety testing.

To know more, visit our dedicated blog.

Find out more

Shaping the future of AI at the World Summit in Amsterdam

During October the AI Regulatory Services team, and AI colleagues from across BSI, attended the World Summit AI at the Taets Art & Event Park in Amsterdam. It was an action-packed two days of presentations, panel sessions and workshops, where we discussed the future of global AI regulations in many meaningful conversations with visitors to our booth.

Key highlights included:

- Craig Civil, Director of Data Science and AI, presented 'Grounding a Moonshot in reality' on the main stage
- We hosted a workshop on 'AI datasets and model testing'
- We hosted a workshop on 'Embracing standardization for innovation'
- Mark Thirlwell, Managing Director, moderated a panel session on 'Strategies for embedding ethical practices in AI business operations'

- David Cuckow, Associate Director, moderated and Neil Musk, Group Director for Knowledge Solutions, took part in a panel session on 'Harmonizing AI's Global Impact - The Power of International Standardization'

BSI Compliance Navigator

bsi. compliance navigator

The digital revolution in regulatory document management

Compliance Navigator is an online tool developed by BSI that transforms how medical device and IVD device manufacturers manage their EU, UK, MDSAP & FDA regulatory information and standards for greater confidence in their compliance process.

Quick, easy and fully digital, Compliance Navigator enables users to organise product specific compliance documents in one place; alerts them to upcoming changes; notifies them when changes happen; and clearly highlights what's changed and what it means for their business.

Contact us to find out more

Events for your calendar

Coming soon, our events for 2024, watch this space!

In the meantime, don't miss the opportunity to interact with BSI experts or connect with our commercial team to discuss your certification requirements. Find out more about our latest Events and Conferences.

bsi.

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Inspiring trust for a more resilient world.