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Regulatory review

Your monthly medical device update
April 2021

Featured in this Newsletter

- Resources and new webinar for IVD medical device manufacturers
- Medical Device Digital Week 2021
- MDR Lessons Learnt webinar & New Extended Webinar
- New Compliance Navigator PRRC brochure
- Events for your calendar

Resources for IVD medical device manufacturers

Our IVD team has extensive industry and regulatory experience, and is able to provide conformity assessments under the EU IVDR and the UK MDR 2002. We have updated our IVD Medical Devices brochure, providing you with all the information you need about our dedicated IVD team and our services.

IVD Medical Devices brochure

To support you through the certification process, we have also developed an EU IVDR Transition Toolkit, which provides you with information about all of our IVDR guidance documents, training courses, webinars and whitepapers.

EU IVDR Transition Toolkit

Medical Device Digital Week 2021

Join us at the Software as a Medical Device Digital Week 2021 to hear Dr Fiona Dunn and Dr. Aris Tzavaras present on Medical Device software, Regulatory Requirements and the MDR.

The session will cover the MDCG guidance on software, software classification, state of the Art and AI and much more.

Register and find out more

Book now - MDR Lessons Learnt Webinar

Join BSI's Kevin Madden, Team Training Lead and Technical Team Manager in the Orthopaedic and Dental technical team, to hear the critical lessons we have learnt and how you can use these to improve your submissions to BSI. We will share notified body experience and common pitfalls and learnings. Kevin will be joined for the Q&A section by Chris Wylie, Associate Global Head, Orthopaedic & Dental Devices, BSI.

Choose from one of the two sessions:

Wednesday 5 May 09:00 – 10.00 BST - **Register now**

Wednesday 5 May 16:00 – 17:00 BST - **Register now**

New extended webinar, 12th May - IVDR – Lessons Learnt Webinar

Join this insightful extended webinar to hear from Dr Erica Conway, BSI's Global Head of IVD Medical Devices, talk about IVDR lessons learnt so far, as well as tips on making applications and the Performance Evaluation requirements under the In Vitro Diagnostic Regulation (IVDR).

This is a special extended webinar and Dr Conway will also be joined by subject matter experts, Dr Heike Möhlig-Zuttermeister, Judith Prevoo, and Dr Liz Harrison.

Wednesday 12 May 14:00 – 17:00 BST - **Register now**

Person Responsible for Regulatory Compliance (PRRC) brochure

With the IVDR and MDR European regulators aim to ensure companies have a regulatory expert – a Person Responsible for Regulatory Compliance (PRRC) – at their disposal, to ensure that the company is meeting certain specific EU requirements.

Download this free medical devices whitepaper today for an overview of the requirements of MDR/IVDR Article 15

Download brochure

Events for your calendar

Find out the latest information about BSI Medical Devices Events and Conferences.

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