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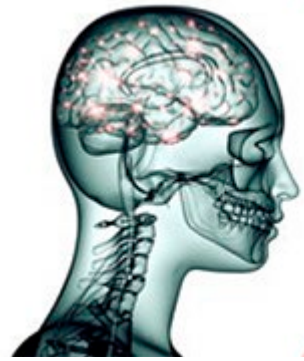
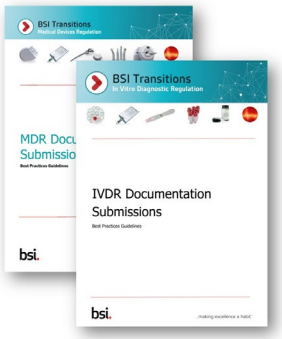


Regulatory review

Your monthly medical device update
June 2020

Are you currently planning your application to BSI for a conformity assessment of a medical device under the MDR or an IVD device under the IVDR?



Incomplete Technical Documentation submissions are one of the most common reasons for delays to the certification process. To make the process more efficient for you, we have updated our Best Practices Guidelines, which provide guidance on preparing and structuring your Technical Documentation. Following these will ensure your submission to BSI is complete and thorough.

View MDR guidelines

View IVDR guidelines

Join our webinar: Understanding the QMS requirements under the IVD Regulation

For manufacturers of IVD devices selling into Europe, join this webinar to hear Judith Prevoo provide guidance about the key changes for meeting regulatory requirements and maintaining a

Quality Management System (QMS) under the IVDR, and to support your preparation for an efficient transition or initial certification. Dr Erica Conway will join at the end for a live Q&A.

Choose from one of two sessions:

16 July, 09:00 BST – Register now

16 July, 16:00 BST – Register now

Are you a manufacturer of drug-device combination products?

You will need apply for a Notified Body Opinion to bring your device onto the EU market. Our new drug-device combination product brochure provides you with all the information you need about applying to BSI for a Notified Body Opinion under Article 117 of the MDR.

View brochure

BSI's perspectives on Article 117 and drug-device combinations

Join our webinar on Wednesday 1 July 2020 to hear from Dr Jennifer Durrant, Global Head of Medicinal and Biologics and Dr Jonathan Sutch, Medicinal Technical Specialist about BSI's perspective on Article 117 and drug-device combination products.

Choose from one of two sessions:

1 July, 09:00 BST – Register now

1 July, 16:00 BST – Register now

More about Article 117

Have you seen BSI's collection of medical device white papers?

Our medical device white papers cover key regulatory, standards and technological topics in the industry. Written by industry experts, they are available to download for free on the BSI website.

Browse white papers

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