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Regulatory review

Your monthly medical device update

January 2018



Did you miss our update on the MDR General Safety and Performance requirements?

The Medical Devices Regulation transition period has started, we are now working towards a greater understanding and clarity around the changes we are facing. You need to interpret how the changes impact your organization and begin to implement your transition.

The BSI team has created a comprehensive guide to the General Safety and Performance Requirements of the MDR. Our experts talk through the key points to note in an online webinar, which is supported by an extensive white paper.

Not had chance to listen back? Click here to listen to the update now.

Listen back

Don't forget to download your copy of the General Safety and Performance Requirements white paper.

Do you want to continue receiving our newsletters?

The General Data Protection Regulation (GDPR) is coming on 25 May 2018. It requires organizations to only send emails to those who have requested to hear from them. Re-register with us today to continue receiving our monthly updates.



Yes, please send me the medical devices newsletters



Register now for our new complimentary webinars

Stay up to date with the latest changes and information from BSI experts:

Join Paul Sim, Knowledge Manager at BSI Knowledge Solutions, to learn about the latest progress on the harmonization of key standards, with a focus on labelling.

European Harmonization - MDR Requirements and Progress on key

Standards and Labelling - 23 January, 4pm GMT

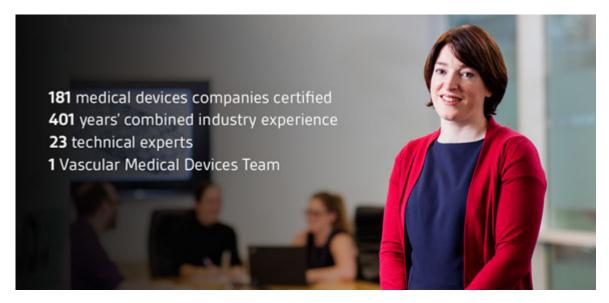
Understand the regulatory requirements of the MDR and IVDR with relation to your QMS from Vicky Medley, BSI Global QMS Manager, Medical Devices.

QMS Aspects of the MDR and IVDR - 27 February, 4pm GMT

Have you missed any of our recent webinars? Listen back now to learn about the Medical Device Single Audit Program, Usability requirements, the MDR Technical Documentation requirements and more.

Listen back now

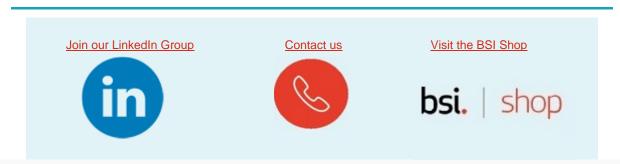
Experience and expertise at the heart of your business



The BSI Vascular medical devices team has real-world experience with a range of devices, from guidewires to drug-eluting stents, and collectively holds over 80 patents. This gives our global team the knowledge and experience to provide a robust assessment, ensuring confidence is at the heart of your certification.

Find out more

Find out more about our Vascular devices team today.



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