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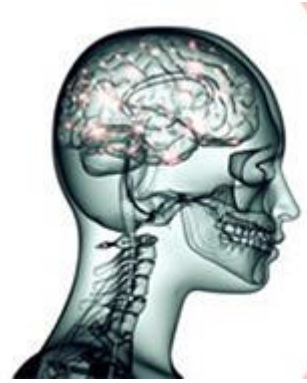
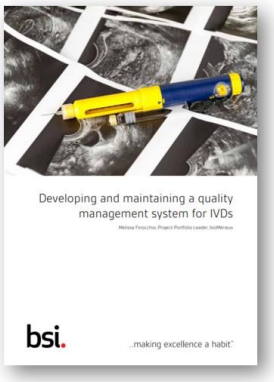


Regulatory review

Your monthly medical device update
August 2019

White paper on Developing and Maintaining a Quality Management System for IVDs



Download this white paper and learn about the QMS requirements under the new In Vitro Diagnostic Device Regulation (IVDR). The white paper includes chapters on risk management, performance evaluation and post-market surveillance, unique device identification (UDI) and continuous improvement activities.

Download white paper

Optimize your risk management system with the international standard on medical device risk management

ISO 14971 helps medical device companies establish, document and maintain a systematic process for reducing the risks associated with medical devices for all stakeholders. A new revision of this standard, BS EN ISO 14971:2019, is coming soon.

ISO 14971

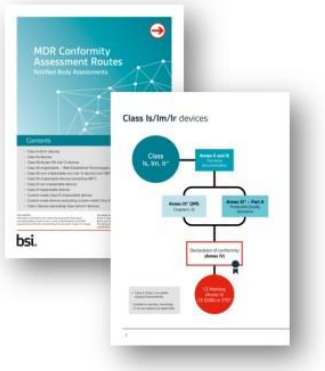
Join our webinar on ISO 14971:2019 Risk Management for Medical Devices

Wednesday 18 September, 4:00pm BST

In the medical device industry, risk management is a vital part of all your company's processes. Hear from Dr Peter Bowness, Medicinal and Biologics Technical Team Manager and member of the UK technical committee for risk management in medical devices, about the upcoming ISO 14971:2019 and what will change from the previous version of the standard.

Register now

Still confused about the MDR Conformity Assessment Routes?



We've created a Conformity Assessment Routes Guide to clearly outline the routes to conformity set out by the Medical Device Regulation (MDR). And in case you missed it, you can now listen back to our webinar where Dr Jayanth Katta, our Regulatory Lead, presented on this topic.

MDR resources

Spotlight on: David Adams – Global Head, Active Medical Devices Team

David Adams joined BSI straight from university almost 37 years ago. He spent over 18 years testing Medical Electrical Equipment at BSI's labs in Hemel Hempstead before transferring to the Notified Body in 2001. He now heads up the Active Devices team, who are passionate about their work assessing a large range of complex products.

We say goodbye to David this month as he heads into early retirement, and thank him for bringing so much energy and passion to the team. He will be replaced by a member of his team Paula Gomes, who has been a Technical Manager since December 2017.

BSI Active Devices

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