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Regulatory review

Your monthly medical device update
September 2020

New Quality Management System (QMS) Certification brochure

Medical device manufacturing is one of the most regulated sectors in which significant quality systems and product requirements must be satisfied. The regulatory requirements are intended to ensure that manufacturers consistently design, produce and place onto the market medical devices that are safe and fit for their intended purpose.
The ISO 13485 standard is an effective solution to meet the comprehensive requirements for a QMS. Adopting ISO 13485 provides a practical foundation for manufacturers to address the regulations and responsibilities as well as demonstrating a commitment to the safety and quality of medical devices.

Download the new QMS brochure

Update on the new UKCA and future UK regulation for Medical Devices and IVDs

The Medicines and Healthcare products Regulatory Agency (MHRA)has published new guidance on GOV.UK, which sets out how medical devices will be regulated after the transition period with the EU has ended (from 1 January 2021).

Join BSI's Dr Jayanth Katta, Senior Regulatory Lead, to hear the Notified Body perspective on the announcement regarding the new UK Conformity Assessed (UKCA) mark.

29 September, **14:00-15:00 BST** - Register now

Performance Evaluation under the In Vitro Diagnostic Regulation (IVDR) Part 2 webinar

Join this webinar on **Wednesday 23 September 2020** to hear Dr Erica Conway, BSI's Global Head of IVD Medical Devices and Dr Liz Harrison, IVD Technical Team Manager at BSI, talk about the Performance Evaluation requirements under the In Vitro Diagnostic Regulation (IVDR) – Part 2.
Choose from one of two sessions:

23 September, **09:00 BST** – Register now
23 September, **16:00 BST** – Register now
Listen back to Part 1

New Active Devices brochure

As a manufacturer of an active medical device, you must ensure that you meet the relevant requirements outlined in the Medical Device Regulation (MDR) (EU) 2017/745 before placing your product onto the EU market. It is critical to work with a notified body that understands the industry and has the experience to review and confirm your products' readiness for market – efficiently, promptly and robustly. As an Active Medical Devices Notified Body our technical specialists have extensive experience and can support you through the process of certifying your active medical device.

Talk to us today about your CE Marking requirements.

Download Active Devices brochure

Find out more

BSI conferences and events

Our regulatory experts present
at leading industry conferences and events across the world, keeping you up to date on key topics affecting medical device manufacturers, including changes to medical device regulation, clinical requirements, risk management, and the CE marking process.

View full event listing

Want to learn about MDR/IVDR UDI requirements?

Among the many changes that the MDR and IVDR bring to the way that medical devices will be regulated in the EU is the introduction of unique device identification (UDI) system requirements for almost all medical devices and IVDs. Download this free excerpt from Compliance Navigator's Smart Support series of expert commentaries on the new European regulations for insight into the background to the new EU rules relating to UDI and the actions your organization may need to take as a result of them.

Download Smart Support excerpt

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