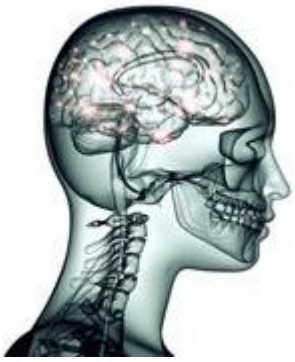
Contact us
+44 345 080 9000
bsigroup.com/medical



Regulatory review

Your monthly medical device update

October 2018

New whitepaper: Developing and maintaining a quality management system for IVDs

There are many different requirements with which in vitro diagnostic manufacturers must comply in order to place product on the market. At the core of most of these requirements is a fundamental need to have a good quality management system (QMS) in place. This paper primarily examines the QMS requirements in the new In Vitro Diagnostic Device Regulation (IVDR) 2017/746 which has entered into force as of 26 May 2017 and will serve as the basis for access to the European market.

bsi. ...making excellence a habit.™

Download now

Does your device require an implant card under the MDR?

The Medical Devices Regulation brings with it a number of new requirements, including the requirement for implantable devices to come with an implant card. Implant cards are given to the patient and include some important information about the device, including device name, lot number and legal manufacturer. Other information that must be supplied to the patient include warnings, precautions, expected device lifetime and any other information to ensure safe use of the device by the patient.

Join us on Thursday 29 November at 4pm GMT for our webinar and learn more about the requirements from Kevin Madden, BSI Orthopaedic and Dental Technical Specialist Training Lead & Technical Team Manager.

Register now

Listen back to our latest update: The regulatory implications of Brexit

In our recent webinar, we provided an update on the latest regulatory implications of Brexit, and how the implementation of the new Medical Device and IVD Regulations will be affected. Listen back to Gary Slack, SVP Notified Body and Brexit Strategist, to find out more.

Listen back now

Come and visit us at Medica 2018

Sign up now for a personal appointment at our booth and benefit from our expert-knowledge to help you reduce costs of delayed product launches and get your devices to patients and healthcare professionals all over the world.

Find out more

Join our LinkedIn Group

Contact us

Visit the BSI Shop

bsi. | shop

bsi. ...making excellence a habit.™