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Regulatory review

Your monthly medical device update
February 2021

Featured in this Newsletter

- BSI issues the world's first UKCA certificate
- BSI certifies its first Active Implantable Medical Device (AIMD) products
- MDR Company Information Form - Device Schedule tutorial
- Clinical evaluation article in the Journal of Medical Device Regulation
- How Compliance Navigator can help with MDSAP
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BSI issues the first UKCA certificate under the new UK regulation for Medical Devices and IVDs

We are proud to announce that we have issued our first UKCA certificate under the UK MDR 2002 legislation for medical devices via our newly designated UK Approved Body (0086). The first UKCA certificate covers theatre instrument sets. The UKCA mark is the new UK product marking that will be required for in vitro diagnostics (IVDs) and medical devices being placed on the market in Great Britain (England, Wales and Scotland).

Read full story

BSI certifies first AIMD product to the Medical Devices Regulation

We have certified our first Active Implantable Medical Device (AIMD) products, Abbott's neuromodulation clinician programmer app and its patient controller app for use on compatible personal Apple‡ smartphone devices, to the Medical Devices Regulation (MDR) (EU 2017/745) via our Notified Body in The Netherlands (2797).

Read full story

MDR Company Information Form - Device Schedule tutorial

We have developed a short tutorial video, which guides you through the process of completing the 'Device Schedule' section of the Company Information Form (CIF). The Device Schedule provides BSI with the information we need to fully understand the scope of your application and the information to be included on the certificate of conformity; it also ensures that we, as a Notified Body, are complying with the Regulation.

Watch video

A Notified Body's perspective on the clinical evaluation requirements under Regulation (EU) 2017/745 on medical devices

Understanding of the clinical evaluation process for medical devices against the requirements of the Medical Device Regulation (MDR – (EU) 2017/745), relevant Medical Device Coordination Group (MDCG) guidance documents is critical for all manufacturers. Hear from BSI's Richard Holborow, Head of Clinical Compliance in his recent article in the Journal of Medical Device Regulation on the main requirements for clinical evaluation under the MDR from a Notified Body's perspective and how to meet those requirements.

Read more

Fast track your understanding of MDSAP requirements

Did you know that you can expedite your understanding of MDSAP requirements with Compliance Navigator's new guidance? Authored by Eamonn Hoxey, this comprehensive guidance document includes seven sections on: management; device marketing authorization and facility registration; measurement analysis and improvement; medical device adverse events and advisory notices reporting; design and development; production and service controls; and purchasing. Watch this video to find out more about the benefits of a subscription to Compliance Navigator.

Watch video

Events for your calendar

Find out the latest information about BSI Medical Devices Events and Conferences.

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