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Regulatory review

Your monthly medical device update
February 2021

Featured in this Newsletter

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).

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).

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.

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

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