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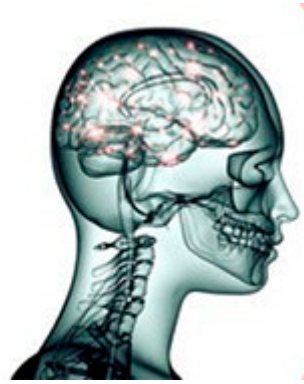

Regulatory review

Your monthly medical device update
November 2022

Featured in this Newsletter

New Active Medical Devices brochure now available

Used for a wide range of treatments in various specialized fields, active medical devices represent a significant and profitable segment of the healthcare industry. As a manufacturer of active medical devices, one of your biggest challenges is navigating the regulatory process efficiently.

Our Active Technical and Clinical Specialists have a broad range of industry and regulatory experience, including product design and development, manufacturing and testing.

We will support you through the process of certifying your device.

Discover how and take a look to our new Active Medical Devices Brochure.

Download Active Medical Devices brochure

UKCA Update

MHRA has now officially announced a twelve-month extension period to the current standstill period to comply with UKCA marking Regulations. From **1st July 2024**, legislative transitional arrangements will apply for placing all Medical Devices and In-Vitro Diagnostic Medical Devices on the Great Britain market.

Stay up to date on our dedicated UKCA webpage and download the revised timeline.

Further guidance can be found at GOV.UK dedicated webpage.

Webinar - Article 54 – Understanding the Clinical Evaluation Consultation Process (CECP) and Expert Panel Roles

Join Richard Holborow, Global Head of Clinical Compliance, as he talks about the MDR requirements in relation to Article 54. Richard will also be joined by Sheila Walsh, Clinical Regulatory Lead, Clinical Compliance Team

This webinar will provide the required information to manufacturers of class III implantable, and class IIb active rule 12 administer or remove medicinal substances (ARMS) devices of the new clinical evaluation consultation procedure (CECP) in accordance with Article 54 of the Medical Device Regulations EU 2017/745.

Choose from one of the two sessions on **Wednesday 23 November**:

Register for AM webinar:

9.00 – 10.00 GMT **Register**

Register for PM webinar:

16.00 – 17.00 GMT **Register**

Keep track of changes to standards with Compliance Navigator

When the standards you work with change, it is essential that you know about it. Researching the latest publications, however, can be laborious and time-consuming. Read this client story to find out how Cibiltech, a French medical tech start-up, keep track of changes to standards with Compliance Navigator.

Download Client story

Events for your calendar

There are lots of events happening in November and December.

Don’t miss the opportunity to interact with BSI experts or connect with our commercial team to discuss your certification requirements. Find out more about our latest Events and Conferences.

bsi.

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Inspiring trust for a more resilient world.