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Regulatory review

Your monthly medical device update
October 2022

Featured in this Newsletter

UKCA FAQs now available

Given the stringent requirements on patient safety and device performance, accessing the UK market brings challenges that can delay your product launch.

Our new UKCA FAQs brochure based on our latest webinar, is now available for you to better understand how to gain market access into Great Britain with UKCA marking approval.

Take a look to our UKCA dedicated webpage and access UKCA webinars and additional resources to support you.

Visit UKCA Webpage

New Vascular brochure now available

As a manufacturer of vascular medical devices, one of your biggest challenges in breaking into, or continuing your success in this market, is navigating the regulatory process efficiently.

Our vascular technical specialists are product experts who are highly trained in working with vascular medical device manufacturers and understand the specifics of these complex devices. BSI vascular team has just released a new brochure. We will guide you along the route for placing your vascular medical device on the market.

Take a look and see what's new on our vascular webpage.

Visit Vascular 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**

Reaching our Sustainable Development Goals

In line with our Sustainable Development Goals, BSI Germany is proud to announce that they are cutting back on unnecessary marketing materials, and have instead launched a more sustainable partnership with Planet Tree: an organization who works with urban and state forests across Germany to plant trees there upon donations.

Through this partnership, BSI will be planting a tree for every single registration we receive at our DACH events!

Booth visitors will be given the opportunity to make a valuable contribution to climate protection by planting a tree. They will also receive a follow-up email to keep them updated on the number of trees we have planted, so they can follow the positive impact we're having on compensating CO2.

This initiative launched at the Swiss Medtech Day back in June, and since then we're thrilled to share that we've since planted over **100** trees in association with Planet Tree.

Events for your calendar

There are lots of events happening in October and November.

Don't miss out 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.

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Inspiring trust for a more resilient world.