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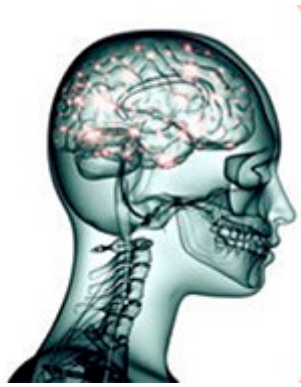

Regulatory review

Your monthly medical device update
August 2021

Featured in this Newsletter

Digital pre-applications for CE marking, UKCA and QMS services

We are delighted to announce that all our digital pre-applications for CE marking, UKCA and QMS services are now online and form part of our pre-application portal. The portal will allow you to access

the pre-application process through a digital interface. We are excited to share our new journey into digital applications and the replacement of our Company Information Forms.
In addition, we have ensured that the system intelligently routes pre-application activities and issues alerts and notifications to you with inbuilt validation of the data you input. This will allow you to have greater interaction with the portal with all your applications in one, easy to access place, whilst tracking your application in real-time.

Please chat to your BSI Commercial contact to arrange access to the system. Or if you are new to BSI please complete the online form:

Complete the form

Listen back to our most recent webinar - Person Responsible for Regulatory Compliance (PRRC) – what you need to know

This webinar was presented by Maddalena Pinsi, Regulatory Lead, BSI. The webinar offered notified body insights for all people involved in working towards an IVDR and MDR application.

If you missed the webinar or were not able to join you can view the recording and presentation slides here.

Upcoming Webinar - MDR Rule 14 Devices – conformity assessment process and documentation requirements for submissions

Join BSI's Theresa Jeary, Technical Specialist and Scheme Manager, as she explains more about the conformity assessment process for medical devices containing an ancillary medicinal substance.

This webinar will be helpful for those looking at strategic planning considerations and for those who would like to understand more about the timelines to facilitate MDD to MDR transition planning.

Please join us for this insightful webinar and choose from one of two sessions:

Wednesday 8 September: 10:00 - 11:00 CET **Register now**

Wednesday 8 September: 17:00 - 18:00 CET **Register now**

Upcoming webinar - The new regulatory approach for SaMD and MDSW according to MDR

Software as a Medical Device (SaMD) and medical devices software (MDSW) has gained in importance over the last years. The new regulatory approach for SaMD and MDSW according to MDR (EU) 2017/745 is defined in the General Safety and Performance Requirements in Annex I and outlines expectations of the regulation. Our webinar will help you to understand possible ways of how to implement the regulation into your daily practice of software development, software manufacturing and launching it on the market considering relevant post market requirements.

Please join our expert Dr Frank Stein for this insightful webinar:

Monday 13 September: 15:00 CET **Register now**

Are you a manufacturer of Vascular medical devices?

Our Vascular Medical Devices brochure provides information on the extensive experience of our technical specialists and the services we offer to support you through the process of certifying your medical device under the EU MDR and UK MDR 2002.

If you have any questions about new product applications please contact us and our experts will be able happy to assist.

Vascular Medical Devices brochure

Events for your calendar

BSI at Swiss Medtech Day 2021, 8 September in Bern - Switzerland

BSI will exhibit at Swiss Medtech Day 2021, 8 September 2021 in Bern – Switzerland. The event is designed to highlight and understand the key role of medical technology in the digitalization of healthcare and awards the most innovative medtech product.

SWISS MEDTECH DAY 2021

Visit us at booth #6 and learn more about our certification services and how we can support your access to global markets.

Find more information here

BSI at Norddeutscher Dialog in der Medizintechnik, 23-24 September in Hamburg - Germany

The "Norddeutscher Dialog in der Medizintechnik" will take place for the 10th time in Hamburg, Germany, from 23-24 September. National and international speakers will provide a detailed overview of the current legal framework in the European Economic Area. BSI experts Dr Heike Möhlig-Zuttermeister and Anna Mirabelli will join this event with presentations about lessons learnt from the perspective of a

Notified Body for IVDR and MDR.

Find more information here

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

Phthalates and endocrine disruptors | New whitepaper published

Many phthalates have the potential to cause hormonal disruption, however, it was only recently (January 2020) that experts produced a useful consensus paper (La Merrill et al., 2020) which defined the key characteristics of endocrine-disrupting (ED) chemicals as a basis for the identification of their intrinsic hazard. This whitepaper summarizes the evaluation of phthalates and ED substances in medical devices.

Download whitepaper

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