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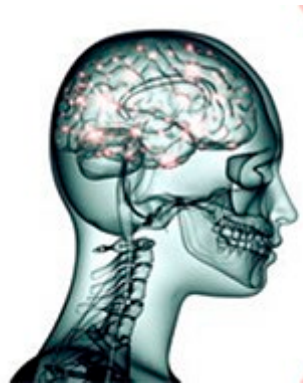


Regulatory review

Your monthly medical device update
May 2021

Featured in this Newsletter

- New Software as a Medical Device and Mobile Medical Device brochures
- UKCA resources to support you
- Vascular Medical Devices brochure
- Listen back - MDR Lessons Learnt webinar
- MDR Breakfast series in German language
- BSI/AAMI International Standards & Regulations Conference
- Person Responsible for Regulatory Compliance whitepaper

Is my Software a medical device?

As a Medical Device manufacturer of Software, you must ensure that you meet the relevant regulatory requirements before placing your product onto the market. Useful information on Software as a Medical Device can be found on our new information page, including FAQ's, webinars and guidance documents.

Software as a Medical Devices brochure

Mobile medical devices and the regulatory requirements

Mobile devices allow for remote management of patients with a range of chronic diseases or patients recovering at home.
Mobile medical applications are also transforming healthcare, and the COVID-19 pandemic has heightened the need for remote healthcare.

Find out more about the regulatory requirements you will need to meet.

Mobile Medical Devices brochure

Related training courses

Gain an understanding of medical device software lifecycle processes, classification rules, and development activities to meet regulatory requirements with our dedicated trainings. Ensure that your networked medical devices meet cybersecurity requirements in accordance with medical device regulations.

Introduction to Medical Devices Software - view dates

Medical Device Software with Cybersecurity - view dates

Discover our training portfolio

UKCA resources to support you

UKCA marking came into force in Great Britain in January 2021 when the UK left the European Union. UKCA Certification may be required for certain classifications of medical devices and is available from the UK appointed Approved Bodies, such as BSI (0086).
There will be a transition period to 30 June 2023 to allow existing CE certifications to be replaced by the new UKCA mark.

Find out more

Swiss Medtech Webinar - The UK: Still an attractive place to do Medtech business?

The UK left the EU, and there are new requirements for Medical Device manufacturers to place products in the UK. What are the UK authorities doing to still attract the latest innovations for their patients?

Join this webinar on **11 June, 12:30 CET**, **hosted by Swiss Medtech.** Listen to Maddalena Pinsi and Jayanth Katta from BSI's UK Approved Body together with Phil Brown from ABHI association.

Register at the event page

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.

Vascular Medical Devices brochure

Listen back - MDR Lessons Learnt Webinar

Listen back to our recent webinar on MDR Lessons Learnt with Kevin Madden, Team Training Lead and Technical Team Manager in the Orthopaedic and Dental technical team. Kevin looked at critical lessons we have learnt and how you can use these to improve your submissions to BSI. Kevin was also joined by Chris Wylie, Global Head, Orthopaedic & Dental Devices, BSI for the Q&A session.

View the On Demand recording

MDR Webinar Series in German Language: Virtuelles MDR Expertenfrühstück

We have conducted a webinar series about relevant topics of the Medical Device Regulation (MDR) in German language. Listen back to our recent webinars on "Technische Dokumentation gemäß MDR – was wir bis jetzt gelernt haben" and "Bedeutung der klinischen Prüfung für die MDR".

View full agenda and recordings

Don't miss our last upcoming session of this series:

Post Market Surveillance gemäß MDCG 2019-9 und MDCG 2020-7 und -8:

Tuesday 8 June 10:00 - 11:00 CET - **Register now**

BSI/AAMI International Standards & Regulations Conference

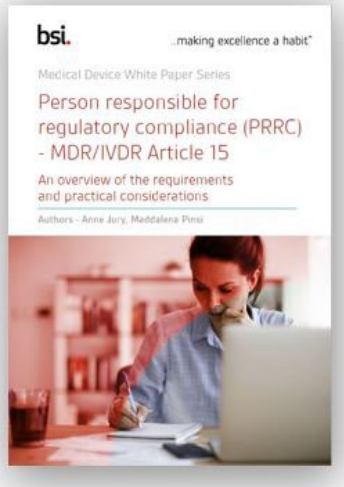
BSI and AAMI are running a free online event held over two consecutive afternoons on June 29 and 30 during which invited healthcare subject experts, regulators, medical device manufacturers and standards-makers share their knowledge, insights and perspectives on the key issues affecting the medical device sector now and in the next couple of years.

This year's conference will continue our emphasis on regulatory compliance and patient safety and will also reflect on COVID-19's impact on the future of healthcare technology.

Find out more

Person Responsible for Regulatory Compliance (PRRC) whitepaper

With the IVDR and MDR, European regulators aim to ensure companies have a regulatory expert – a Person Responsible for Regulatory Compliance (PRRC) – at their disposal, to ensure that the company is meeting certain specific EU requirements.



Download this free medical devices whitepaper today for an overview of the requirements of IVDR/MDR Article 15.

Download whitepaper

bsi.