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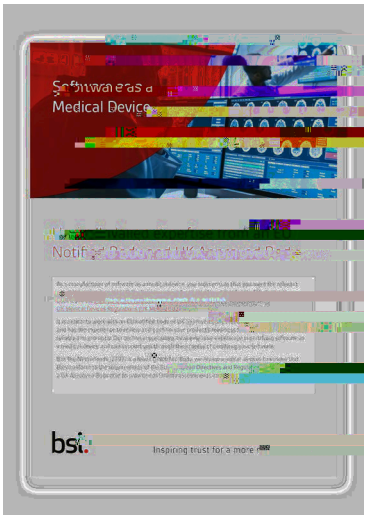
# Regulatory review

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
- 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

# 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.

## 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

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## 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

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## 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