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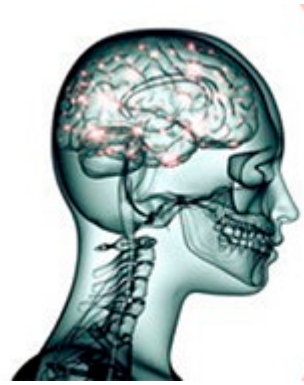


Regulatory review

Your monthly medical device update
October 2020

New MDSAP guidance brochure

The Medical Device Single Audit Program (MDSAP) is a way that medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States.

As an Auditing Organization, BSI is authorized by the participating Regulatory Authorities to audit your Quality Management System (QMS) under MDSAP requirements. We understand the industry and have the experience to review your QMS efficiently, promptly and robustly.

Download the new brochure

Clinical Evaluation webinar

Understanding of the clinical evaluation process for medical devices against the requirements of the Medical Device Regulation (MDR – (EU) 2017/745), MEDDEV 2.7/1 Revision 4 and relevant Medical Device Coordination Group (MDCG) guidance documents is now critical for all manufacturers.

Join this webinar to hear Richard Holborow, Global Head of Clinical Compliance for BSI, talk about

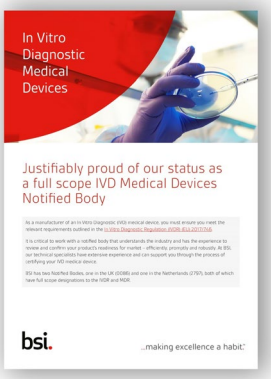
Clinical evaluation under the MDR – do you understand the requirements?

Choose from one of two sessions:

Tuesday 17 November 09:00 – 10:00 GMT - **Register now**

Tuesday 17 November 16:00 – 17:00 GMT - **Register now**

New IVDR resources



The IVDR brings with it significant changes to the regulatory requirements for IVD medical device manufacturers and introduces a new rule-based classification system with stricter notified body oversight, as well as significant changes to the depth and requirements of the associated Technical Documentation. It is critical to work with a notified body that understands the industry and has the experience to review and confirm your products' readiness for market – efficiently, promptly and robustly.

- Download our new IVD brochure
- Your IVDR application to BSI
- **Register** for our upcoming webinar on **Maintaining your CE Certification under the IVDR, a Lifecycle approach** on 28 October at **09:00 (GMT)** **or** **16:00 (GMT)**

Find out more

Want to understand how EUDAMED will work?

The European Comission has confirmed the Actor registration module will be live from December 2020. Please refer to MDCG 2020 15 (published in August 2020) for further details.

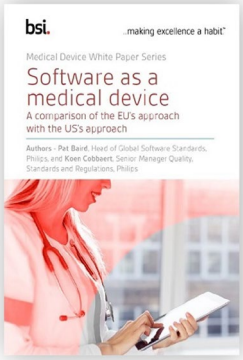
View short presentation of the EUDAMED Actor registration module *Please note, this is a YouTube video not contained within the BSI website.

On Demand webinar

Listen back to Dr Jayanth Katta, Senior Regulatory Lead, to hear the Notified Body perspective on the announcement regarding the new **UK Conformity Assessed (UKCA)** mark.

Listen back

SaMD Regulation in the EU and US | Latest BSI Medical Devices White Paper Published?



The International Medical Device Regulators Forum (IMDRF) aims to accelerate international medical device regulatory convergence. Through the IMDRF, regulators reached consensus on what software is considered a medical device. Regulators call it 'software as a medical device' (SaMD). This paper provides a comparison of how SaMD is regulated in the US and in the EU.

Download whitepaper