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Regulatory review

Your monthly medical device update
May 2022

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Clinical Masterclass Toolkit

Our Clinical Masterclass series of webinars is now completed, and we hope you enjoyed the series. These five insightful webinars focussed on various aspects of the MDR, from looking at post market clinical follow-up, to helping you with your medical device software and when a clinical evaluation is required.

View the full Series

Following the success of the Clinical Masterclass Series, we've also launched the Clinical Toolkit. The new comprehensive Clinical toolkit will hopefully make your journey of understanding to the MDR smoother. The toolkit will focus on the Clinical Masterclass series of webinars as well as:

- On-demand videos
- White papers
- Internal and external guidance documents

To access the Toolkit click here

Hybrid audit - webinar and video

Watch our on demand webinar on hybrid audits – the new way of working post pandemic. We will share our audit lessons learnt during the pandemic
as well as how best to plan for future audits. We will focus on unannounced audits and maintaining regulatory compliance, whilst also focussing on our sustainability commitment.
Hear from Linda Moon, Global Quality & Accreditation Manager, Regulatory Services, as she talks about why we are using hybrid audits and how they can help improve better client service levels. Linda will also be joined by subject matter expert Dr. Yoann Buisson, GQA Technical Manager, Regulatory Services.

Watch on demand webinar

Watch the Hybrid audit video

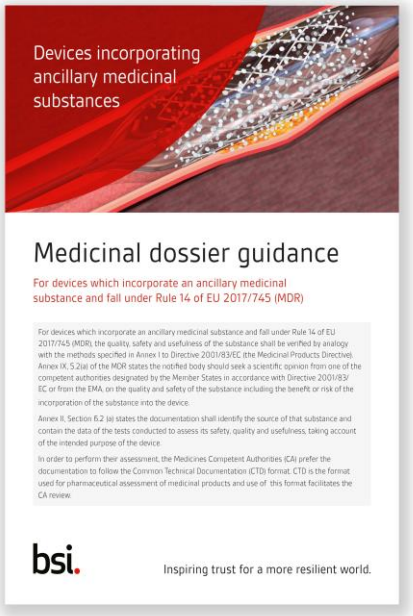
IVDR Date of Application arrives

The IVDR EU 2017/746 entered into force in May 2017 with a five-year transition period. Manufacturers have the duration of this period to update their Technical Documentation to meet the requirements and comply with the Regulation before the **Date of Application on 26 May 2022.**

To keep up to date with the timelines of the transition from IVDD to IVDR follow the weekly updates on the **BSI Medical Devices LinkedIn page** and the **BSI website.**

New BSI Medicinal dossier guidance

For devices which incorporate an ancillary medicinal substance and fall under Rule 14 of EU 2017/745 (MDR), the quality, safety and usefulness of the substance shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC (the Medicinal Products Directive). Annex IX, 5.2(a) of the MDR states the notified body should seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or from the EMA, on the quality and safety of the substance including the benefit or risk of the incorporation of the substance into the device.



Download our guidance for devices which incorporate an ancillary medicinal substance and fall under Rule 14 of EU 2017/745 (MDR).

Find out more on our website.

Download our guidance

Using standards to demonstrate conformity | New white paper available for download

One important characteristic of standards is that they are voluntary – there is no obligation to apply them or comply with them, except in those few cases where their application is directly required by regulations. However, the application of standards in the medical devices sector has

undoubtedly been accelerated by their use to support regulation by providing a voluntary means to demonstrate conformity with regulatory requirements.

Download whitepaper

Events for your calendar

Register for the MedTech Summit 2022 and find out more about our latest Events and Conferences.

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