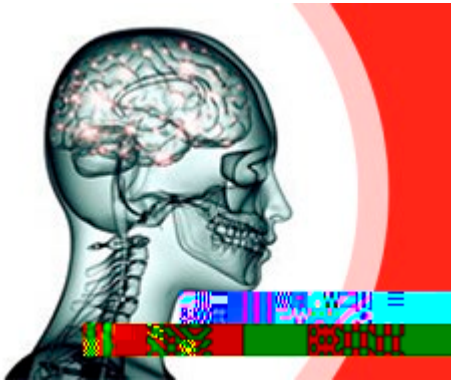


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Our monthly medical device update
May 02

- Clinical Series toolkit
- Hybrid audit - webinar and video
- IVDR Date of Application
- Medicinal Dossier
- Events for your calendar
- Using standards to demonstrate conformity

Discover our new Clinical Toolkit

Webinars Whitepapers View on Demand Clinical Guidance

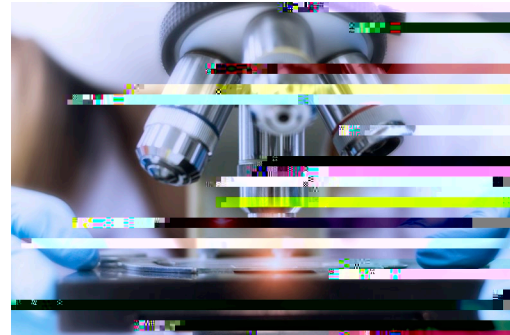
A dark blue banner with a red circle on the left. The text 'Discover our new Clinical Toolkit' is in white. Below the text are four light blue circles containing the words 'Webinars', 'Whitepapers', 'View on Demand', and 'Clinical Guidance'.

Our Clinical Masterclass series of webinars is now completed, and we hope you enjoyed the series.

[Watch the Hybrid audit video](#)

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

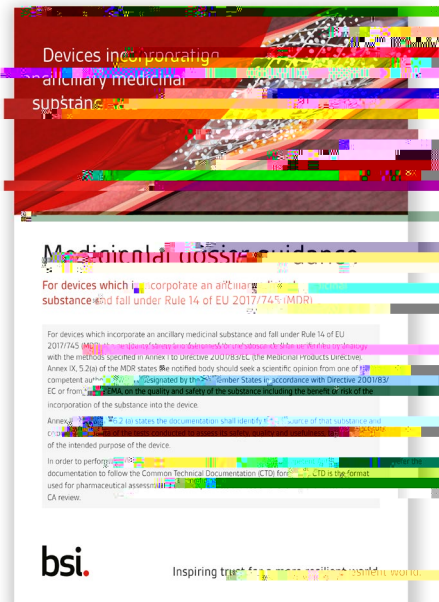


To keep up to date with the timelines of the transition from IVDD to IVDR follow the weekly updates on the _____ and the _____

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](#)

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 in the last few years. This is due to the fact that the regulatory requirements for medical devices have become increasingly stringent, and manufacturers are seeking ways to ensure compliance with these requirements. Standards provide a clear and concise way to define the requirements for medical devices, and they are widely accepted and used by manufacturers and regulators alike. This has led to a significant increase in the number of standards being developed and updated, and it is expected that this trend will continue in the future.

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