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Regulatory review

Your monthly medical device update
March 2022

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BSI's perspectives on Article 117 and drug-device combinations

Introduced by the European Commission under the Medical Devices Regulation (MDR), **Article 117** requires manufacturers placing drug-device combination products onto the market as an integral device and marketing them as a "medicinal product" to seek a Notified Body Opinion (NBOp).

Visit our dedicated page to find useful resources, including our Webinar and our article for the Journal of Medical Devices Regulations on combination products under the MDR, including Article 117.

Find out more

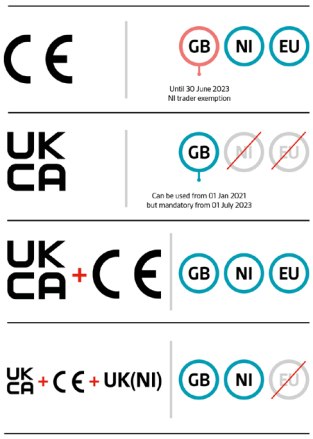
Hybrid audits: Access our experts without geographical constraints

Access to our Technical Experts is scheduled based on the technology of the medical device submitted and the right qualifications for the reviewer; please refer to MDCG guidance on MDR Codes and IVDR codes. The use of specialist reviewers ensures patient safety remains our focus. This means that the person looking at your product specializes in the technology and can understand your submission.

The technical qualifications of our auditors can sometimes lead to scheduling challenges due to the geographical location of people with the specific expertise you require. Using a hybrid process will allow our highly qualified experts to support you no matter the geography, giving you direct access to the right person. In addition, remote scheduling should make our resources plans more efficient and improve your service.

Find out more about BSI experience of hybrid audits

United Kingdom Conformity Assessment (UKCA) updates

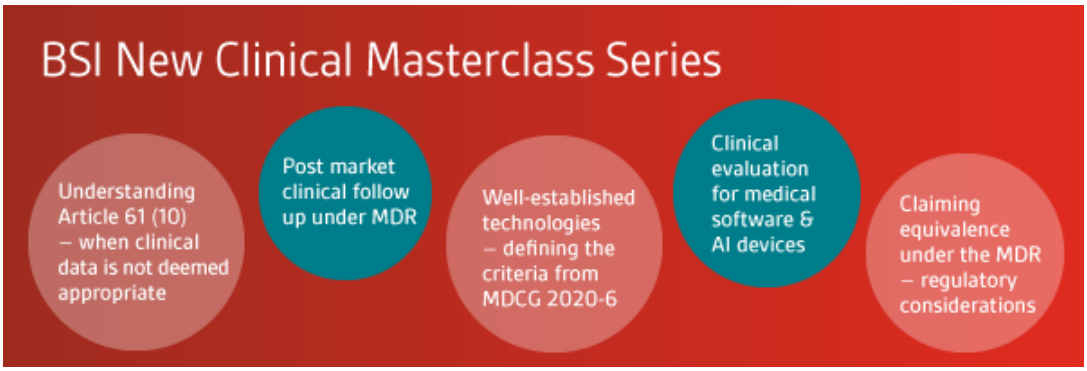


UKCA marking came into force in Great Britain in January 2021 when the UK left the European Union. UKCA Certification may be required for certain classifications of medical devices and is available from the UK appointed Approved Bodies, such as BSI (0086). There is a transition period to 30 June 2023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

We have lots of resources for you to use to ensure you maintain market access in the UK. Please refer to our detailed FAQ document online, which covers many questions you may have around UKCA and our website.

Choose from two sessions and register to join us for the UKCA - are you ready for the future' webinar being held on April 27.

Register now for BSI's Clinical Masterclass Series



The timelines for ensuring your product maintains EU market access under the new, more stringent Medical Device Regulations (MDR) are challenging.

These five insightful webinars will help you focus 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.

Listen back to our first webinar of the series; **Well Established Technologies - Defining the criteria from MDCG 2020-6**

Our second webinar of the series; **Understanding Article 61 (10) – When Clinical Data is not deemed appropriate**, took place on 2 February and looked in detail at BSI's understanding of the occasions when it is appropriate that no clinical data is required for clinical evaluation.

Listen back to our third webinar of the series; **Claiming Equivalence under the MDR – Regulatory Considerations**, from the 16th February. The webinar looked at new requirements on the regulatory aspects of claiming equivalence.

The fourth webinar in the series took place on the 2nd March and covered **Clinical Evaluation for Medical Software & AI Devices**.

To register for our final webinar, **Post Market Clinical Follow Up under MDR**, on the 16th March, please click below:

View the full Clinical Masterclass series and Register

Clinical investigations and the MDR

This paper was first published by BSI in 2018 and has been revised in light of the publication of BS EN ISO 14155:2020. The paper discusses important requirements for pre-market and post-market clinical investigations under the European Medical Device Regulation (2017/745) (MDR), relevant European guidance documents and BS EN ISO 14155:2020, and how this updated standard can help in meeting MDR requirements.

Download whitepaper

Events for your calendar

Find out the latest information about BSI Medical Devices Events and Conferences.

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