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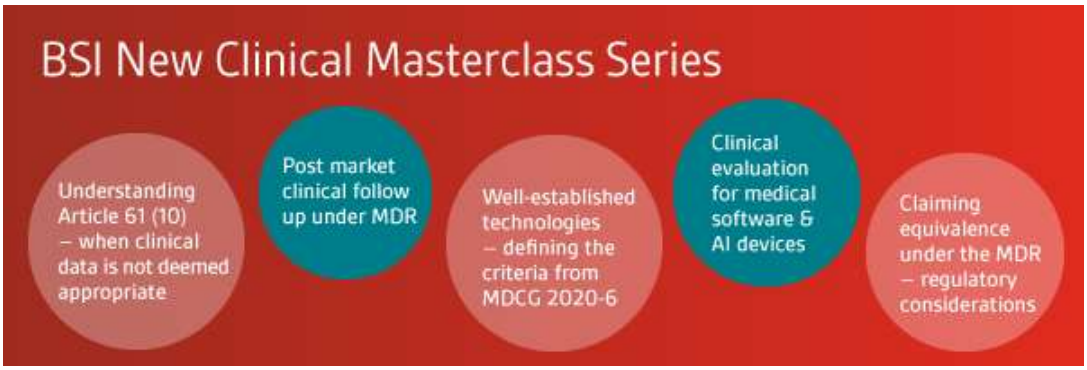
Regulatory review

Your monthly medical device update
April 2022

Featured in this Newsletter

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.

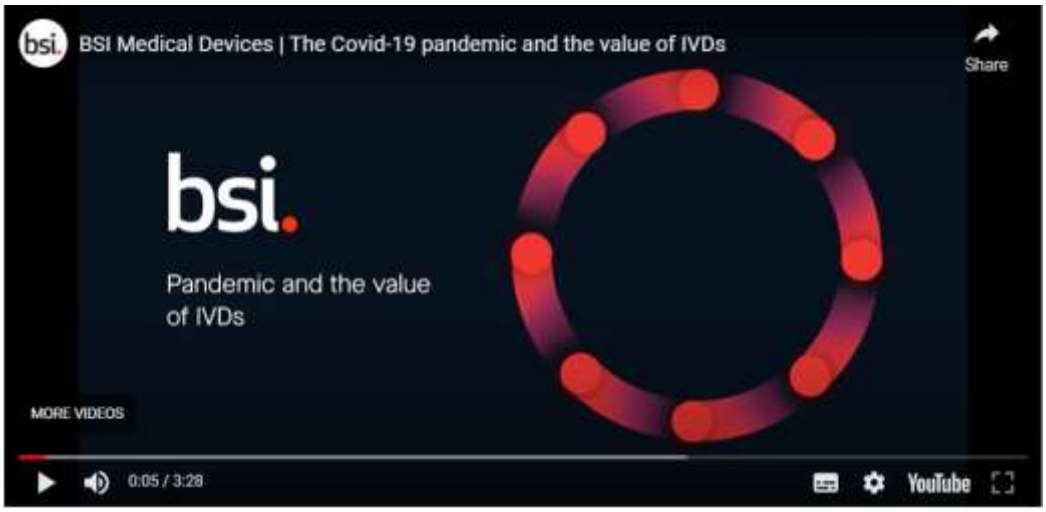
Our Clinical Masterclass series of webinars is now completed, and we hope you enjoyed the series.

These five insightful webinars focussed on various aspects of the MDR, from looking at postmarket clinical follow-up, to helping you with your medical device software and when a clinical evaluation is required.

Our fifth and final webinar Post Market Clinical Follow Up under MDR, took place on the 16th March and looked closely at the requirements relating to general and specific PMCF activities.

View the full Clinical Masterclass series

Watch the IVD video with Dr Liz Harrison



On 14 October 2021, The European Commission proposed to amend the transition period of devices covered by the IVDR. The delay in the transition periods was partly down to the impact of the pandemic on the implementation of the Regulation.

The Date of Application for the IVDR remains unchanged from 26 May 2022.

Watch this video with Dr Liz Harrison, Head of IVD, Regulatory Services, as she discusses the importance of In Vitro Diagnostics (IVDs) in our everyday lives.

Watch video

Time saving feature for multi-device applications

A new multi-device upload feature is now live on BSI's Digital Pre-Application portal.

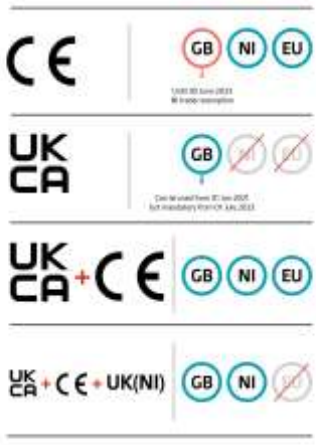
The multi-device template, which is completed offline and then uploaded as part of an application submission, has been well received by clients and will save a significant amount of time when applying for multi-device certifications.

You can find out more about how to use the multi-device template, and other features of the application portal, by visiting the help and resources page here.

Digital pre-applications for IVDR and MDR videos

Managing multiple device uploads QC

Register for the *United Kingdom Conformity Assessment (UKCA) - are you ready for the future?* webinar



The deadline for UKCA marking is fast approaching, with many medical device manufacturers still not applying for UKCA certification.

This webinar will offer approved body insights for all people involved in working towards a UKCA application, whether you are a novice or have more significant experience of working with an approved body.

Register from two sessions on:

09:00-10:00 Wednesday 27 April **- Register now**

16:00-17:00 Wednesday 27 April - **Register now**

We also 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.

Events for your calendar

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

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