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Regulatory review

Your monthly medical device update
January 2022

Featured in this Newsletter

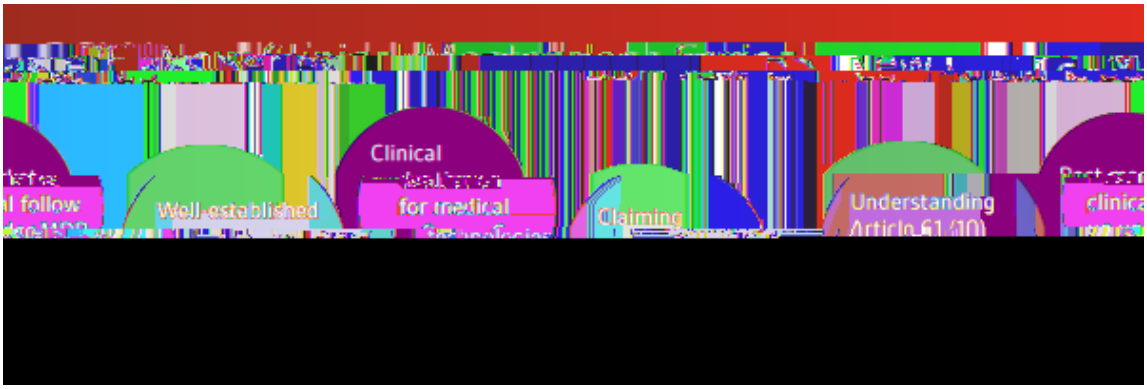
Thank you for 2021, and best wishes for the year ahead

A warm welcome to 2022. I hope you were able to enjoy the break despite the many disruptions faced around the globe, impacting the ability to celebrate and see family and friends.

2022 will bring an exciting new dimension to our business as we establish a medical device artificial intelligence notified body. The designation will secure our future parallel success to our traditional

View table of proposed changes

Register now for BSI's Clinical Masterclass Series



Join us for our new clinical masterclass series of webinars. 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. In addition, participants will gain a better overall understanding of the post-market requirements as listed under Articles 86 and 87 of the MDR.

There's still time to register for the first webinar in the series – Well Established Technologies - Defining the criteria from MDCG 2020-6.

Choose from one of two sessions on Wednesday 19 January 2022:

Wednesday 19 January: 09.00 – 10.00 GMT Register now
Wednesday 19 January: 16:00 – 17:00 GMT Register now

To view more information about the upcoming series or to pre-register ahead of time for the other webinars please click below.

View the full Clinical Masterclass series

EU Regulatory news

Two Commission Implementing Decisions with new, additional references of harmonised European standards in support of Regulation (EU) 2017/745 on medical devices (MDR) and of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) were adopted on 4 January 2022 (MDR) and on 6 January 2022 (IVDR). It has been published in the Official Journal of the European Union (OJEU).

These new publications, amending and enlarging those issued in July 2021, will include very important and horizontal harmonised standards such as EN ISO 13485:2016 and its amendment A11:2021 on