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Regulatory review

Your monthly medical device update
December 2021

Featured in this Newsletter

Dr Manuela Gazzard, Thank you

I am immensely proud of the dedication, hard work, and passion at BSI Regulatory Services and the difference the team has made throughout the year. 2021 has again been a challenging year for all of us with the continued impact of the global COVID-19 pandemic. However, our values and mission of ensuring patient safety and bringing innovation to market timely remained at the heart of what we do.

Our team keeps growing to ensure we have the capacity to support manufacturers with conformity assessments under the IVDR, MDR and UKCA whilst maintaining all our strict compliance responsibilities. We plan to have more than 900 colleagues by the end of the year as we welcome more diverse newcomers into our talent pool globally.

As you will know, the process for the United Kingdom Conformity Assessment mark is beginning to take shape, and we started accepting applications from January 2021. The date of MDR application arrived in May, and I am proud of the whole team's efforts to ensure that all clients met this deadline, with no client being left behind. We end the year with a positive vote for the changes to the IVDR transition timelines addressing a concern the entire industry shared; we look forward to the formal announcement of the changes.

This year we launched the innovative digital pre-application portal, the first stage of our ongoing digital transformation. We are pleased about the positive feedback on the improvements you already realise in your applications to BSI.

As the year draws to a close, I would like to say a huge and heartfelt thank you to you for your flexibility and commitment during this challenging year.

Please continue to stay safe, and I wish you, your families and loved ones a restful festive season and a more stable year in 2022.

New for 2022 - 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.

Our first webinar of the series is **Well Established Technologies - Defining the criteria from MDCG 2020-6**, on the **19 January**.

Discussions will include the concept of well-established technologies under the medical device regulations and how to interpret the four criteria defined in MDCG 2020-6. This session will also cover the levels of clinical evidence required for these devices to support your clinical evaluation.

To register for this webinar please choose from one of two time slots below;

Wednesday 19 January 2022 10:00 - 11:00 CET **Register now**
Wednesday 19 January 2022 17:00 - 18:00 CET **Register now**

Click below to view the full upcoming Clinical Masterclass series of webinars

View the full Masterclass series

Hybrid audits for Medical Devices

The COVID-19 pandemic has forced the medical device and IVD sector to consider new and innovative ways of meeting regulatory demands while keeping patient safety at the forefront of our role. As a

sector, we have risen to the challenge of COVID-19 with professionalism and resilience, and we have found new ways of ensuring we meet our responsibilities.

Despite its severity, the pandemic has also managed to inspire some positive changes. For example, Auditing Associations have increased the use of immersive technologies to conduct remote audits. This experience has provided solid learnings and evidence around the use of the new technology.

To find out move about new way of working post-pandemic click below.

Find out more

IVDR Classification

The In Vitro Diagnostic Regulation (IVDR) (EU) 2017/746 is the new EU legislation applicable to in vitro diagnostic (IVD) medical devices. Entering into force on the 25 May 2017 marking the start of a five-year transition period for manufacturers and economic operators, the IVDR replaces the EU In Vitro Diagnostics Directive (IVDD) 98/79/EC.

Manufacturers wishing to apply to a notified body for a conformity assessment of their IVD medical device have until the Date of Application of the IVDR in May 2022 to update their Technical Documentation to meet the requirements and comply with the new, more stringent Regulation.

On 14 October 2021, The European Commission proposed to amend the transition period of devices covered by the IVDR. This urgently drafted proposal to change the implementation arrangements of the

IVDR is in response to the exceptional circumstances associated with the significant differences between the Regulation and the IVD Directive. Please read the full details here to ensure you are prepared.

All devices will need to be divided into classes. This classification map will allow you to allocate your device correctly under the IVDR.

Download the IVDR classification rules

Listen back to our most recent Webinar

The AIMDD to MDR transition- what you need to know webinar, was presented by Thomas Doerge, BSI's Global Head of Active Implantable Medical Devices, supported by subject matter experts Concetta Gallo and Jazzmyne Buckels.

The webinar looked in detail at the important topics to be considered when transitioning from the Active Implantable Medical Device Directive to the Medical Device Regulation.

If you were unable to attend you can view the recording here.

Prioritizing People - Insights into psychological well-being

As part of BSI's continuing Prioritizing People campaign, this month we look at prioritizing the psychological and physical health, safety and well-being of our employees and how this reinforces trust

and demonstrates to internal and external stakeholders that you are doing the right thing.

We look at work-life balance for optimum outcomes through a series of videos from Claudette Bedeau, HR Director, Haydar Jaafar, Operations Delivery Director, and Gary Slack, Senior Vice President, from BSI's Medical Devices division.

Find out more

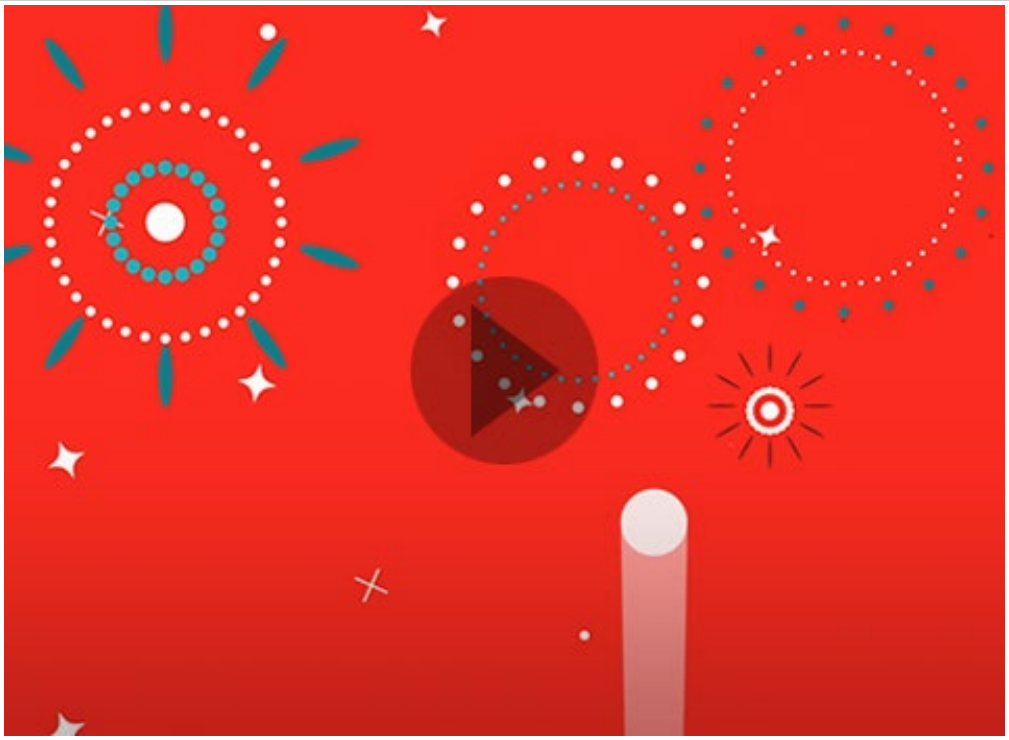
Clinical evaluation under EU MDR | Latest White Paper

There has been significant evolution in the European regulatory landscape over the past 10–15 years, particularly with respect to requirements for clinical evaluation. These changes have been driven in part by a series of medical device failures, which fuelled a perception, particularly amongst regulators and clinicians, that clinical evidence for medical devices was not receiving sufficient scrutiny in Europe.

Download whitepaper

Wishing you a Happy New Year

Thank you for working with us in 2021 and we look forward to working with you in 2022.



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