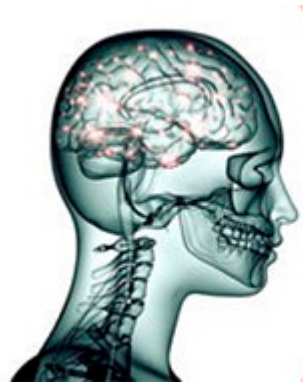
Contact us
+44 345 080 9000
medicaldevices@bsigroup.com



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.

The last two years have been unlike anything faced in our lifetime. However, the industry has stood up to many challenges, and together we have weathered the storms, continuing to keep patients safe and bringing much-needed innovation to the global market.

BSI remains committed to enabling patient safety and innovation more than ever. We are proud to have been able to limit the disruption to our services during the pandemic to date.

As the health and safety of our colleagues and clients remains our priority, we will continue to provide remote audits. We have collected promising supporting data around the safety and efficacy of a hybrid auditing model and are in final discussions with our various authorities globally. We plan to start a staggered roll-out of hybrid auditing from Q1 2022, significantly reducing our carbon footprint by reducing our auditors' travel, supporting the BSI sustainability agenda. In addition, from a clients perspective, it will allow access to BSI expertise without geographical constraints, allowing easier planning and increased flexibility and limiting exposure whilst the pandemic continues to impact. Thank you to those clients that have supported us so far in testing this approach.

We continue to invest in our business, having expanded our Medical Devices team from 750 to more than 900 colleagues last year; we expect to recruit additional colleagues into our talent pool in 2022. We will also realise significant benefits in our digital transformation journey, incorporating digital customer communication, visibility of the application journey, and billing. You will have seen the successful launch of our first stage: the digital pre-application portal, back in 2021.

The deadline for the Date of Application of the IVDR is approaching fast and, with manufacturers required to transition before May 2022, it will continue to be a busy time for all of us. We have now received confirmation of the approval of the changes to the transition timelines, and this should provide much-needed breathing space for this sector.

We will prepare manufacturers for the new UKCA certification, building on our great start as a UK Approved Body in 2021. The UK is currently working towards new legislation, and we expect to see further details in 2022.

We continue to provide valuable thought leadership, and I am excited to see a clinical masterclass series of webinars running. **In 2022 we plan to roll out a talent academy for regulatory assessors. We ran a successful pilot in 2021, and we will be sharing further details later in the year.** As a notified body with world-leading expertise, we want to share our broad and detailed experience with the industry to address common issues such as the talent shortage. The talent academy aims to drive an increase in patient safety globally.

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 business areas, and I am excited to see what our investments in this area will bring to BSI.

All that remains to say is a heartfelt thank you to our clients, industry partners and internal team for your trust, flexibility and commitment during another challenging year. Together, we ensure that patients have uninterrupted access to much-needed treatment and that innovation continues to make the world a brighter place.

As we cannot meet easily for the foreseeable future, we encourage all our clients to maintain close communications with us and stay up to date with the latest guidance.

I wish us all a prosperous and more stable year in 2022.

Dr Manuela Gazzard
Group Director, Regulatory Services

Confirmed IVDR transition timelines

On 14 October 2021, The European Commission proposed to amend the transition period of devices covered by the In Vitro Diagnostic Regulation (IVDR) 2017/746. 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. In addition, the move to the IVDR has been substantially impacted by the COVID-19 pandemic and the impact it has had on the volume of IVD devices available after the Date of Application (DoA), 26 May 2022.

The member states have approved the proposal, and the amendment will be published in the Official Journal of the European Union (OJEU) before entering into force. **Once in force, the DoA for the IVDR will remain unchanged from 26 May 2022.** However, the IVDR will have new transition periods for devices placed on the market after this date, subject to conditions.

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 quality management systems, and EN ISO 15223-1:2021 on symbols. Other important harmonised standards such as EN ISO 14971:2019 and its amendment A11:2021 on risk management should be included in the next proposals by CEN and Cenelec to be submitted in January 2022, in view of new publications in the OJEU likely in March 2022.

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