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Regulatory review

Your monthly medical device update
January 2021

Success of 2020 and the year ahead

As we start the New Year, Dr Manuela Gazzard, Group Director of Regulatory Services at BSI, celebrates the achievements of the Medical Devices team in 2020, despite being a challenging year for us all. Manuela also provides an update on BSI's leadership, the expansion of the Medical Devices team to support clients with IVDR, MDR and QMS applications, and the full-scope designation of BSI UK to the new UKCA scheme, as we remain committed to our mission of ensuring patient safety while supporting timely market access to medical device innovation.

Watch video

IVDR and MDR Article 16: Cases in which obligations of manufacturers apply to importers, distributors or other person

We shared an update in December 2020 about Importers and Distributors who carry out activities such as repackaging a device or translate labelling and the new requirement for certification under Article 16 of IVDR and MDR. If this applies to you, you will need certification by the relevant date of application, 26 May 2021 under MDR and 26 May 2022 under IVDR.

We encourage you to read Article 16 in full and assess if it applies to your situation. We are awaiting clarification from the European Commission for the exact requirements for the Article 16 certificate.

We would like to ask for feedback on your plans for Article 16 certificates. Please complete **one** of the surveys below to share your plans with us:

- **Yes**, I want to apply for an Article 16 Certificate with BSI:
- **No**, I will not be applying for an Article 16 Certificate with BSI:

Your feedback will allow BSI to plan in capacity and identify processes to meet your requirements. Thank you.

BSI issues its first certificate to the In Vitro Diagnostic Devices Regulation

BSI announces that it has certified its first group of products to the In Vitro Diagnostic Devices Regulation (IVDR) EU 2017/746 via its Netherlands Notified Body (2797).

The Annex IX Chapter I & III certificate covers two Class C Generic device groups for Monoclonal Antibodies/Flow Cytometry. Prior to the new, more stringent, legislation coming into force, these were classified as self-declared devices and did not need to be reviewed by a notified body under the IVD Directive.

The certificate has been granted to BD (Becton, Dickinson and Company), a leading global medical technology company based in Franklin Lakes, NJ.

Find out more

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UKCA for Medical devices and IVDs, are you ready?

Dr Jayanth Katta,

Sr. Regulatory Lead & Head of UK Approved Body

ISO 20916 IVD - Clinical performance studies

Dr Marco Rost,

Training Lead Regulatory Services (IVD)

Watch more on demand webinars

Have you seen our collection of free medical device whitepapers?

BSI's medical device whitepapers give in-depth insight into standards, regulatory requirements and technological innovations. Written by industry experts, these whitepapers are available as free downloads from the BSI website.

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