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Regulatory review

Your monthly medical device update
December 2020

End of year message from BSI

2020 has been a challenging year for all of us. Despite the global COVID-19 pandemic, we stayed true to our values and mission of ensuring patient safety and bringing innovation timely to market. Hear from Dr Manuela Gazzard, Group Director, Regulatory Services, BSI about her thoughts on 2020 and the year ahead.

Watch Video

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

Importers and Distributors who carry out activities such as repackaging a device or translate labelling will require certification under Article 16 of IVDR and MDR. If this applies to you, then you will need certification by the date of application, 26 May 2021 under MDR and 26 May 2022 under IVDR.

We encourage you to read Article 16 in full, and we would like to highlight the wording from the regulations:

> Within the same period of 28 days, the distributor or importer shall submit to the competent authority a certificate, issued by a notified body designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system of the distributor or importer complies with the requirements laid down in paragraph 3.

We are awaiting clarification from the European Commission for the exact requirements for the Article 16 certificate. However, the timelines are short, and we wanted to ensure you have considered the implications of this article. We will communicate with you again in January to ask for your feedback around the volume of Article 16 certificates BSI should expect to receive before the date of applications.

Listen back to our most recent webinars

Clinical evaluation under the MDR – do you understand the requirements?

Richard Holborow,

Global Head of Clinical Compliance

ISO 20916 IVD - Clinical performance studies

Dr Marco Rost,

Training Lead Regulatory Service (IVD)

Our useful resources from 2020

We are committed to providing you with access to information that helps you stay up to date with all of our available services, the latest regulatory changes, and guidance on completing your applications for conformity assessment under the IVDR and MDR. These are some of the most popular resources from the last year we thought might be useful for you:

Brochures

- Active Medical Devices brochure
- AIMD Medical Devices brochure
- MDR Best Practices Guidelines and MDR Conformity Assessment Routes Guide
- IVDR Best Practices Guidelines and IVDR Conformity Assessment Routes Guide
- Your IVDR application to BSI
- Your IVDR Transition Toolkit

Webinars

Our webinars focused on a range of topics in 2020, from clinical evaluation under the MDR and performance evaluation under the IVDR, to IVDR conformity assessment routes and symbols to be used on labelling for your medical device. All of our webinars are available on our website, where you can listen back on these and other topics.

Whitepapers

These provided thought leadership on current industry trends, including medical device clinical investigations under the MDR, risk management for medical devices and software as a medical device. Visit our website for more information.

Have you read the latest Compliance Navigator blog posts

If you'd like to stay up to date with the latest regulatory, technological and standards-related developments within the medical devices sector, then subscribe to the Compliance Navigator blog. Written by industry experts, blog posts are published once every two weeks.

Read blog posts

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