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Regulatory review

Your monthly medical device update
September 2019

Are you on track to meet the May 2020 MDR deadline?
Time is running out – don't lose your market access

The Medical Device Regulation (MDR) fully applies from 26 May 2020. From this point, BSI will not accept any new applications for device assessments under the old Directive.

We have previously advised you that we were the first Notified Body to be designated to the MDR in the UK. We'd also like to take this opportunity to update you on the progress of our Netherlands Notified Body application for full scope designation to the Medical Devices Regulation. We are in the final stages of the process and expect designation in the early Autumn of 2019.

Critical information for manufacturers

The MDR has introduced a lot of new and additional requirements, so if you manufacture and sell devices in Europe, it's crucial you're aware of these to ensure you comply with the new legislation and are able to maintain the CE Mark.

There are several devices that are available on the market that do not require a CE certificate from a

Notified Body under the current Medical Device Directive (MDD). Some of these, however, will require Notified Body certification under the Medical Device Regulation (MDR).

Class I reusable surgical instruments fall into this category.

If you are a BSI client and have any Class I reusable surgical instruments within your product portfolio, we need you to advise us how many products you have in your portfolio that will need to be certified to the new regulation, and recommend that you submit your application for conformity assessment to BSI soonest.

We also recently published some guidance on Phthalate requirements, eVigilance and Implant cards so please take some time to read this thoroughly in case these requirements apply to you.

For more general information visit our MDR Transition page.

Transition to MDR

New white paper: Risk management for medical devices and the new ISO 14971

Risk management is an important aspect in the development of medical devices. Patients are already in a vulnerable position and, during diagnosis and treatment, they should be protected from risks that could further impact their health.

Discover how regulations and standards for medical devices have developed over the recent decades, including the risk management process as described in ISO 14971 and the main changes in the third edition.

Download white paper

Register for our upcoming webinars

Join these free-to-attend webinars to learn about some key standards related to medical devices. Both are presented by Dr. Peter Bowness, who is Technical Team Manager for the Medicinal and Biologics Team at BSI, chair of the British Standards technical committee for symbols and labelling in medical devices, and a member of the UK technical committee for risk management in medical devices.

Symbols to be used on labelling (ISO 15223) and information to be provided by the manufacturer (ISO 20417)

Wednesday 9 October, 4.00pm BST

Register now

ISO 14971:2019 Risk Management for Medical Devices

NEW DATE: Wednesday 13 November, 4.00pm GMT

Register now

Events we're attending – will you be there?

MedTech Digital Week | Webcast Series | 28-31 October 2019 | Details available soon

Medica | Dusseldorf, Germany | 18-21 November 2019 Learn more >

US Med Tech Summit | Chicago, USA | 19-20 November 2019 Learn more >

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