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Regulatory review

Your monthly medical device update
April 2020

Medical Devices and COVID-19

As the world faces the COVID-19 pandemic together, we would like to reassure you that BSI has been taking extensive actions to safeguard its people by managing the risk of infection within our operations and wherever we work with our clients.

Full update

MDR Date of Application delay confirmed

On Friday 17 April 2020, the European Parliament adopted the European Commission's proposal to postpone the implementation of the Medical Devices Regulation (MDR) 2017/745 by 12 months. This urgently drafted proposal to delay the MDR is in response to the exceptional circumstances associated with the COVID-19 pandemic and the potential impact it may have had on the MDR implementation.

The proposal now also has to be approved by the member states and published in the Official Journal of the European Union (OJEU) before it enters into force. This is expected to be by 26 May 2020 at the latest. Once in force, the new Date of Application (DoA) for the MDR will be 26 May 2021.

Read more

Register to join our upcoming MDR webinar:

MDR Rolling Plan of the Commission – Current knowledge

with Dr Suzanne Halliday and Dr Jayanth Katta


Choose from one of three dates/times:

29 April, 16:00 BST – Register now

30 April, 08:00 BST – Register now

30 April, 12:00 BST – Register now

All webinars

Want to know more about the IVDR application process?

For IVD manufacturers wishing to apply with BSI, this webinar provides guidance on how to prepare a successful IVDR Application.

In Vitro Diagnostic Regulation (IVDR) Application Process

with Todd Moorman and Dr Erica Conway


17 June, 16:00 BST – Register now

Register now

Read our latest white paper: Sterilization – Regulatory requirements and supporting standards

Regulatory requirements for medical devices include particular requirements for devices supplied or intended to be used in a sterile state. These regulatory requirements have been supported by a portfolio of standards on:

- designating products as sterile
- validating and routinely controlling the sterilization process

- maintaining sterility over time with appropriate sterile barrier systems

This paper provides an overview of these regulatory requirements and the standards that support them.

Download white paper

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