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+44 345 090 9600
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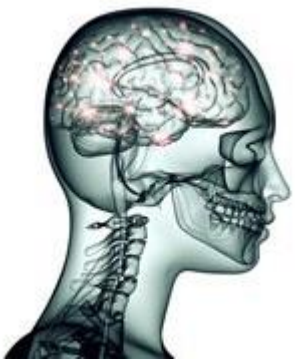


Regulatory review

Your monthly medical device update

June 2017

Medical Devices and IVD Regulations now published

The final texts of the new European Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) have been published in the Official Journal of the European Union. The Regulations entered into force on May 25, marking the start of the transition period. Manufacturers now need to update their technical documentation and processes to meet the new, more stringent requirements.

Make sure you are aware of the major changes and what you need to do now. Use our FAQs to find out about the transition period and other key information, or listen to the BSI short introduction to the changes; share with colleagues to explain the extent of the transition:

Medical Devices Regulation

IVD Regulation

Are you active in many global markets?

Using multiple certification bodies can add to the challenge of managing your compliance. Find out from Opsens, a Canadian fibre optic sensing solutions manufacturer, about how working with BSI across many global markets can reduce the regulatory burden.

Download now

NEW complimentary BSI webinars

Learn about the general Safety and Performance Requirements (SPR) for IVDs

The new IVD Regulation (IVDR) was published in May 2017. Manufacturers of IVD devices will need to understand the new Safety and Performance requirements, with which they will need to comply by May 2022 to continue placing devices on the market in the EU.

Join Dr. Erica Conway, Global Head of IVDs at BSI, on Wednesday, July 12 to find out more.

Sign up now

Do you know the requirements for utilizing biological substances?

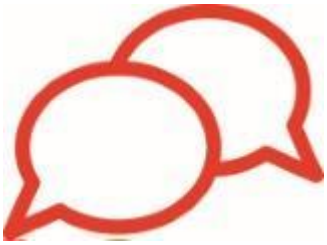
The new MDR requirements for utilizing biological substances apply not only to those devices made of these materials, but any that use them in the manufacturing process.

Make sure you're clear on the requirements – join our biological substance specialist, Dr. Jennifer Durrant, on Tuesday, July 25 to find out more.

Sign up now

Do you like the new newsletter?

Tell us what you think to our new newsletter by completing our short survey.



Find out more about the new requirements for Vigilance and Post-Market Surveillance

This complimentary BSI white paper addresses the changes to the new regulatory requirements under the Medical Devices Regulation (MDR). The white paper covers PMS as an element of the management of clinical evidence throughout the device lifecycle; the PMS system; the PMS plan; preparation of a summary report of PMS information; complaint handling and reporting of vigilance; and, electronic submission of vigilance data and summary reports of PMS.

Download now

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