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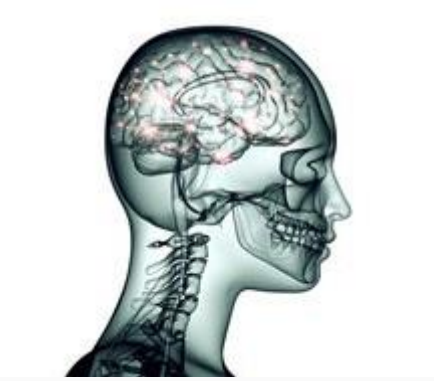
+44 345 090 9600
bsigroup.com/medical



Regulatory review

Your monthly medical device update

May 2017

Medical Device and IVD Regulations are FINALLY a reality

The EU Parliament has adopted the proposal for the Medical Devices Regulation (MDR), which will replace the current Medical Devices Directive (93/42/EEC) and Active Implantable Medical Devices Directive (90/385/EEC), and the IVD Regulation (IVDR), which will replace the current IVD Directive (98/79/EC).

Following entry into force, medical device manufacturers will have only 36 months, and IVD manufacturers only 60 months, to meet the new requirements. It is **crucial** that you start to plan your transition as soon as possible to ensure you meet the new stringent requirements in time.

Keep up to date and find useful resources on our dedicated transitions webpages:

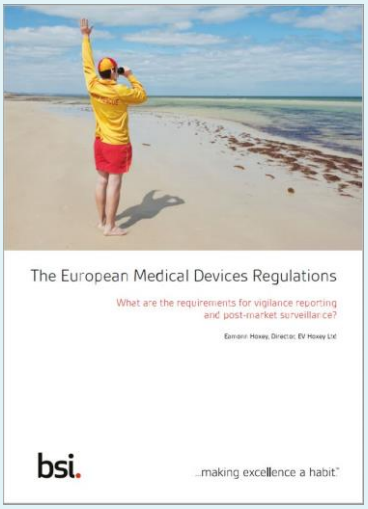
> MDR Revision

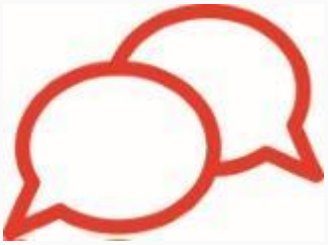
> IVDR Revision

NEW White paper: Vigilance Reporting and Post-Market Surveillance

Learn more about the Vigilance and Post-Market Surveillance (PMS) requirements under the new European Medical Devices Regulation with your complimentary copy of the latest white paper from BSI Compliance Navigator.

Download now





Do you like the new newsletter?

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

NEW MDSAP: Fundamentals and readiness training course

Will you be using the Medical Device Single Audit Program (MDSAP)? Our new two day training course will help you prepare to host a MDSAP audit. It will also allow you to determine if your internal QMS processes are consistent with the requirements of the MDSAP audit model for the jurisdictions where your products are marketed.

Note: It is important that you understand the requirements if you plan to sell into Canada beyond 2019; Health Canada will only accept MDSAP certificates in place of the current CMDCAS program.

If you are currently certified to CMDCAS, please complete our short survey to help us understand what possible information Certification Bodies, such as BSI, can provide to you during this critical transition.

Find out more

One year has passed. Have you started your ISO 13485 transition?

There's only two years left for the ISO 13485:2016 transition; missing this deadline will mean you need to recertify to the standard.

Following our **Best Practice Transition Journey** will allow you to plan your transition effectively and highlight the activities you need to consider.

Download Now

Compliance Navigator Blog

Read the latest updates and commentary on the new medical device and IVD regulations, and innovations in the medical device industry.

Read the blog

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