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bsi Medical Devices

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April Medical Device Newsletter, 2017

NEW: Cybersecurity of medical devices



ng excellence a habit

This complimentary white paper from BSI covers the fundamentals of cybersecurity in relation to patient safety and the security of patient health information. The paper assesses risks and challenges of using connected medical devices. It also introduces the US and EU Regulations concerning cybersecurity.

Download your copy of the new BSI white paper now.

Download now

bsi.

Do you want to know more about market access for <u>active medical</u> <u>devices</u> or <u>active implantable medical devices</u>?

<u>Visit our website</u> and learn about how our expert teams can support you.

Do you have questions about the new Regulations?



Last month, the EU Council released the final draft text for the Medical Devices and In Vitro Diagnostic Devices Regulations.

Are you clear on the new requirements?



Selling into Canada: Important information

From January 2019, Health Canada will terminate their current CMDCAS program and only accept Medical Device Single Audit Program (MDSAP) certificates. It is vital that you make the transition from CMDCAS to MDSAP if you wish to continue selling devices into the Canadian Market.

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

Learn more about MDSAP

If you would like to learn more about MDSAP, consider our new training course, <u>Medical Device Single Audit</u> <u>Program: Fundamentals and</u> <u>Readiness</u>. This two day course provides an understanding of how the Program works, allowing you to interpret how to implement the Program effectively in your organisation.

Download our FAQs and make sure you understand the changes:

MDR FAQ

IVDR FAQ

You can find out more about <u>MDSAP</u> and our <u>new training course</u> on our website.

NEW webinar: Your electro-medical market access questions answered



Join BSI and our partner, Canadian Standards Association (CSA) Group, for a complimentary webinar answering the most frequently asked questions relating to electro-medical device market access.

During this live webinar, you can also submit your own questions to our expert speakers.

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Visit the <u>BSI Shop</u> to purchase your copy of ISO 13485:2016.

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