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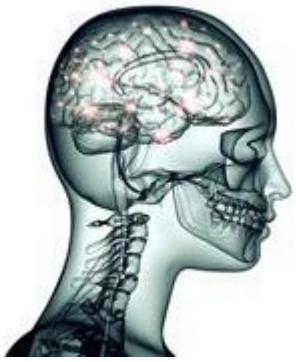

Regulatory review

Your monthly medical device update

July 2018

The Medical Device Single Audit Program (MDSAP): What does the Health Canada update really mean?

Health Canada recently announced an update to the transition process from the Canadian CMDCAS program to MDSAP. While they have **not changed** the deadline, they have provided an alternative pathway for manufacturers that will not have completed their transition and received their certificate before 31 December 2018.

Health Canada have confirmed that manufacturers that have recertified to ISO 13485:2016 can continue selling their medical devices in Canada until the MDSAP certificate is available, as long as they submit the following documents to the Medical Devices Bureau using form F202 by 31 December 2018:

- A valid ISO 13485 certificate under CMDCAS issued after 1 January, 2016 and valid to 31 December, 2018.
- A valid ISO 13485 certificate issued after 1 January, 2016 by a MDSAP Auditing Organization.

- A MDSAP Surveillance Audit Confirmation Notification for a MDSAP Surveillance Audit having taken place in 2018 OR that they have made arrangements to undergo a MDSAP Audit during their existing certification cycle in 2019 (e.g. a signed certification agreement).

This allows manufacturers to maintain existing certification cycles through the MDSAP transition. They will not receive a MDSAP certificate until a full MDSAP certification audit is completed.

If you have any further questions about how this impacts your transition, speak with your BSI Scheme Manager. You can find out more about MDSAP via our dedicated web page, or talk to us today about your MDSAP certification.

Find out more

Critical action: Finalize your MDR transition plan or risk your certification.

The three year Medical Devices Regulation transition period started in May 2017, and we're almost halfway through. It is **crucial** that you now finalize and begin to implement your transition plans to ensure you are ready to complete the transition.

Use our interactive Readiness Review to complete a gap analysis of your current documentation and systems against the requirements of the MDR. Detail how you intend to meet the new requirements, and list the documents and records that allow you to demonstrate conformity to the Regulation.

Use our Mapping Guide to compare the Safety and Performance Requirements (SPRs) of the Medical Devices Regulation to the Essential Requirements of the Medical Devices Directive (MDD) and the Active Implantable Medical Devices Directive (AIMDD), and decide on your priorities for your transition.

Review the other resources available, including our expert-led webinars on the upcoming changes, and our detailed white papers that review the new requirements.

Access all MDR resources

BSI & AAMI co-sponsor International Conference on Medical Device Standards and Regulations

On 19 and 20 June 2018 BSI and AAMI teamed up to host the International Conference on Medical Device Standards and Regulations. The conference was a great success with 150 delegates attending from all over the world and we saw huge amounts of engagement and debate from the audience.

Speakers from the FDA, MHRA and BSI presented on hot topics facing the medical device industry today including a European Update, Brexit, US FDA activity including work on ISO 13485 and the US FDA Quality System Regulations, IEC 60601 and other related standards, Medical Algorithms/Artificial Intelligence and next steps for quality systems. Read our full article to learn more about the event.

Find out more

Listen back to our recent Brexit webinar

Get clarity on the impact of Brexit on the medical devices industry and hear about our plans to minimize the impact on you. Listen back now to hear **BSI CEO, Howard Kerr**, provide details on our commitment to the medical devices industry. Also hear from **Gary Slack, Senior Vice President, Global Medical Devices,** as he gives more insight on the impact Brexit will have, specifically on the implementation of the MDR and IVDR.

Listen back

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