TÜV NORD
Zertifizierung

Medical Device Single Audit Program (MDSAP): Health Canada announces changes to the transition period for the Canadian market

The Medical Device Single Audit Program (MDSAP), which is intended to create a common standard for quality management audits in the area of medical devices, has been adopted in five different markets (Australia, Brazil, Canada,Japan and the USA).

With respect to Canada, the official health authority Health Care expected that the medical device industry would transfer to the MDSAP programme by 1 January 2019. The previous CMDCAS Program ends on 31.12.2018. As Health Canada recognises various challenges facing the sector, such as planning of audits and timely issuance of certificates, it has now been officially announced that manufacturers who undertook an MDSAP audit in 2018 but did not receive a certificate by 31 December 2018, will not be subject to enforcement measures on the part of the Canadian health authority.

In order to further support the manufacturers during the transition period, existing certification cycles according to ISO 13485 under CMDCAS can be retained, if the manufacturer fulfils the following criteria:

- An initial or recertification audit according to ISO 13485 (under CMDCAS) was successfully undertaken on or after 1 January 2016;
- The validity of the CMDCAS certificate does not end before 31 December 2018;
- An ISO 13485 certificate (not under CMDCAS) exists which is valid beyond 1 January 2019 which was issued by an organisation recognised for auditing to MDSAP;
- An MDSAP surveillance audit has already been carried out or a contractual relationship exists with an organisation auditing to MDSAP for performance of an MDSAP audit in 2019.

For manufacturers who wish to change over to MDSAP within the framework of a surveillance audit, several documents, in accordance with the aforementioned criteria have to be submitted to Health Canada (Medical Device Bureau) by 31 December 2018. These include a valid ISO 13485 certificate according to CMDCAS, a valid ISO 13485 certificate (not under CMDCAS) and an official confirmation from the organisation auditing according to MDSAP that an MDSAP surveillance audit was carried out or that an MDSAP audit is planned.

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