Fact Sheet

Transition Rules for MDSAP, CMDCAS and ISO 13485:2016

TÜV®

TÜV NORD

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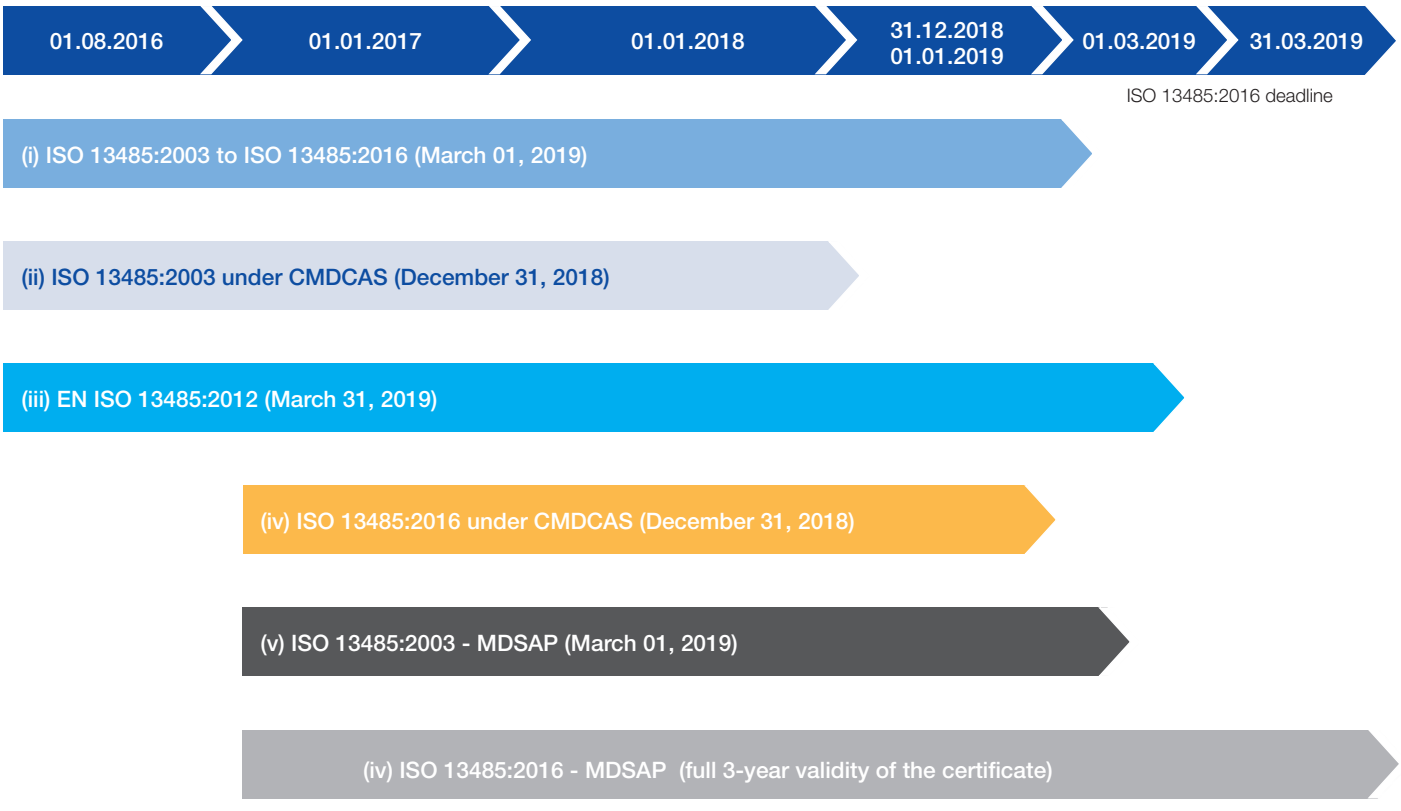
ISO 13485:2016

ISO 13485:2016 was published on March 01, 2016. The transition period from ISO 13485:2003 to the new 2016 version is three (3) years from the date of publication of the 2016 version of the standard.

Medical Device Single Audit Program (MDSAP)

In accordance with the direction received from Health Canada, all clients certified to ISO 13485:2003 (under CMDCAS) need to transition the CMDCAS Certificate to an MDSAP Certificate, latest December 31, 2018. TUV USA is responsible for the MDSAP program performance in the TÜV NORD Group.

The following is the official deadline and transition time for both certification schemes:



TUV USA, Inc. / TUV NORD will be pleased to work with you to complete your transition.

Based on the type of certification scheme you have with TUV USA / TUV NORD, it is recommended that you start planning to transition your ISO 13485:2003 to ISO 13485:2016 as soon as possible.

If your company is CMDCAS-certified please plan your transition to the MDSAP program as well.

We will inform you soon about the following:

- When we will be starting to issue the new ISO 13485:2016 certificates
- The deadline of submitting your transition plan to the ISO 13485:2016 and/or MDSAP Program

TÜV NORD CERT is an internationally recognised and reliable partner for inspection and certification services. Our experts and auditors possess in-depth knowledge and are all employed full-time at TÜV NORD. This guarantees independence, neutrality and continuity when providing support to our customers. The advantage to you is self-evident: Our auditors accompany and support the development of your company and provide you with objective feedback.

Further information and an overview of all locations can be found at
www.tuev-nord-cert.com

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