

Transition policy of TÜV NORD CERT GmbH Regarding ISO 13485 / CMDCAS / MDSAP for clients with existing ISO 13485:2003 certifications under CMDCAS

TÜV NORD CERT GmbH has defined the following transition plan for ISO 13485 under CMDCAS and under MDSAP (Medical Device Single Audit Program):

Before April 01, 2018 - TÜV NORD CERT GmbH will conduct audits in accordance with ISO 13485:2003 (under CMDCAS), unless the certified company is ready to be audited to the new version (ISO 13485:2016)

April 01, 2018 onwards – All ISO 13485 **recertification** audits conducted by TÜV NORD CERT GmbH will be in accordance to ISO 13485:2016 (under CMDCAS) version.

April 01, 2017 ~ March 31, 2018 – Certifications according to ISO 13485:2003 (under CMDCAS) program can be transferred to ISO 13485:2016 (under CMDCAS).

Before March 31, 2018 Companies with an existing ISO 13485:2003 Certification (under CMDCAS) and are seeking re-certification in 2017/2018 are requested to start planning for transition to ISO 13485:2016 (under MDSAP) well in advance

General note: For manufacturers of medical devices who are certified according to ISO 13485:2003 (under CMDCAS) TNC recommends to apply for a certification according to MDSAP based on ISO 13485:2016 as soon as possible. Please consider that an access to the Canadian market after January 2019 needs a MDSAP certification of the manufacturer.

Medical Device Single Audit Program (MDSAP)

- Please note that on **January 01, 2019** – the CMDCAS program will be terminated
- A new certification according to **MDSAP** can be performed as of now.
- Our office in USA - TUV USA Inc. - is a member of the MDSAP pilot phase and will be responsible for the accreditation. Please contact TÜV NORD CERT GmbH if you are interested in this certification. We will support you.

Certificate validities

Due to the end of CMDCAS program all new, modified or revised ISO 13485:2003 certificates issued by TÜV NORD CERT GmbH will have an expiration dates as below

- ISO 13485:2003 (under CMDCAS) valid until December 31, 2018
- ISO 13485:2016 (under CMDCAS) valid until December 31, 2018
- ISO 13485:2003 (under MDSAP) valid until Feb 28, 2019
- ISO 13485:2016 (under MDSAP): full three year validity

Recommendation to our clients

What steps need to be taken by your organization?

- Develop a Quality Plan for the implementation of ISO 13485:2016 and also, if applicable, the plan for implementation of the MDSAP program.
- Identify organization gaps, including training needs to address and meet the new requirements of the ISO 13485:2016 and if applicable, the MDSAP Program
- Update the existing Quality Management System to meet the new requirements and complete the internal audit and management review prior to the on-site audit by TÜV NORD CERT GmbH
- Work with TÜV NORD to complete your transition to the new ISO 13485:2016 and if applicable to the MDSAP program
- Please note: Organizations wishing to transition to the MDSAP Program need to contact TÜV NORD/TUV USA at least 120 days (4 months) prior to their scheduled transition audit.

For further questions please use the contacts mentioned below:

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