Transition policy of TÜV NORD CERT GmbH
Regarding ISO 13485 / CMDCAS / MDSAP
for Initial Certifications

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

New ISO 13485 Certification (Initial Certification) under CMDCAS

- Companies who do not have an existing ISO 13485 Certification and are seeking certification to it under CMDCAS, are encouraged to implement the ISO 13485:2016 version
- **Starting from January 01, 2018** – all Initial Certification under CMDCAS will be performed by TÜV NORD CERT GmbH according to ISO 13485:2016 only
- Certificates according to ISO 13485:2003 and ISO 13485:2016 (under CMDCAS) will be valid until **December 31, 2018**

New ISO 13485 Certifications (Initial Certification) under MDSAP

Medical Device Single Audit Program (MDSAP)

- Please note that on **January 01, 2019** – the CMDCAS program will be terminated
- For manufacturers of medical devices who want to have access to the Canadian Market and don't have a valid CMDCAS Certificate we recommend to apply directly for a certification according to MDSAP based on ISO 13485:2016
- MDSAP certificates according to ISO 13485:2016 will have a normal three year validity
- MDSAP certificates according to ISO 13485:2013 are valid until Feb 28, 2019
- 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.

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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