Description of the QM system certification procedure EN ISO 13485 and conformity assessment procedure according to Regulation (EU) 2017/745

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This description is applicable to the certification of a management system based on the standard EN ISO 13485 and conformity assessment procedures according to Regulation (EU) 2017/745 (MDR) for medical devices. The extent of activities to be carried out in order comply with normative and regulatory requirements is strongly depending on the range of activities carried out by the organization, their role and depending on the classification of their medical devices, if applicable.

1 CONTRACT AND APPLICATION ACTIVITIES

Information about certification and conformity assessment procedures can be obtained on the of TUV NORD Cert webpage. Potential clients can submit a questionnaire which is used by the certification body / Notified Body for a pre-check. Based on the results of this initial evaluation, potential customers receive an offer for a contract and a detailed application review. First assessments under MDR will be treated as initial certification. Potential clients for MDR submit the application form. The potential clients are informed, if the application review reveals that no certification service can be delivered. After the contract has been signed, audit activities start in case of EN ISO 13485 customers (section 2). For customers under MDR, conformity assessment starts with technical file assessment (section 3).

2 AUDIT ACTIVITIES

2.1 Audit preparation

Based on the available information, the Certification Body / Notified Body allocates an audit team with specific expertise for the products and technologies that are employed by the organization. The audit team is planning the audit dates and prepares for the audit with information sent by the organization (e.g. short notice changes, Quality documents and procedures). Audit duration is based on international guidelines (e.g. IAF MD9). For MDR procedures, prior to any audit, a review of the technical product files of the organization has to be conducted.

2.2 Audit Stage 1

The Stage 1 audit is conducted in order to audit the management system documentation of the organization, to assess the site and site-specific conditions of the organization. Necessary information regarding the scope of the management system, the products, the processes and location(s) of the organization, and related statutory and regulatory aspects and compliance are collected and analysed. Internal audits and management review and will be evaluated during stage 1 Audit. The lead auditor is collecting evidence that the level of implementation of the management system substantiates that the organization is ready for the stage 2 audit. If nonconformities were identified in the stage 1 audit, they must be corrected by the organization before the stage 2 audit. If nonconformities cannot be resolved or the audit has to be prematurely terminated, the certification process stops after stage 1. The lead auditor is responsible for the coordination of the activities of the stage 1 audit and if necessary for co-ordination and cooperation of the auditors.

2.3 Certification audit (Stage 2 audit)

The customer receives an audit plan prior to stage 2 audit. The plan is agreed with the customer in advance. The audit program can include regular supplier audits. The audit begins with a start-up meeting, in which the participants are introduced to each other. The procedure to be followed in the audit is explained. Within the framework of the audit at the organisation's premises, the auditors review and assess the effectiveness of the introduced management system according to the applicable standard as applied for and the relevant MDR conformity assessment procedure, if applicable. The task of the auditors is to compare the application of the management system with the documented processes and to assess them in relation to fulfilment of the requirements of the normative and regulatory framework. This is achieved by means of questioning of the employees, examining the relevant documents, records, orders and guidelines and also by visiting relevant areas of the organisation. A final meeting takes place at the end of the onsite audit. At least those

employees take part in the audit who have management functions within the organisation. The lead auditor reports on the individual elements and explains the positive and negative results. The lead auditor may recommend issuance of the certificate(s). In the case of nonconformities, corrective measures will be expected from the audited organization within a defined period of time depending on the severity of the nonconformities. In case of minor nonconformities, an action plan shall be established and approved by the Notified Body within three months after the audit. The implementation of measures will be followed up in the subsequent audit. In case of major nonconformities, immediate actions might be taken by the organization. Additionally, a re-audit or additional documentation review by the Notified Body may be deemed necessary. If nonconformities cannot be resolved or the audit has to be prematurely terminated, the certification process stops after stage 2. The lead auditor is responsible for the coordination of the activities of the stage 2 audit and if necessary for coordination and cooperation of the auditors. The certification procedure is described in section 4.

2.4 Surveillance audit

Surveillance audits must be conducted once per year during the period of validity of the certificate (3 years EN ISO 13485, 5 years MDR). The sequence of events of each surveillance audits is equal to stage 2 (section 2.3). Effectiveness of measures in regards to non-conformities issued in the previous audit will be assessed. Obligatory elements from the normative and regulatory elements have to be audited. In addition, each year the audit can focus on specific products, processes or other current topics. After the Audit, the lead auditor may recommend the prolongation of the certification.

2.5 Recertification audit

This section is only applicable to EN ISO 13485 procedures. Recertification audits must be completed before the end of the period of validity of the certificate, including review of the measures for correction of nonconformities. Prior to the audit, a review of the quality management system of the organisation, and of the audit program of the previous certification period is conducted. The sequence of events of each surveillance audits is equal to stage 2 (section 2.3). All applicable normative and regulatory elements have to be audited. In addition, the audit can focus on specific products, processes or other current topics. After the audit, the lead auditor may recommend the recertification.

2.6 Unannounced Audit

This section is only applicable to MDR procedures. Depending on the risk class of the certified medical devices at least once in 5 years, a planned unannounced audit will be conducted. This audit can also include supplier audits and focusses on manufacturing and control of products. Samples from production or warehouse are analysed against the specifications of the technical file. After the audit, the lead auditor may recommend the prolongation of the certification. The organization may announce production free times for each calendar year for consideration by the Notified Body.

3 TECHNICAL FILE REVIEW AND SURVEILLANCE ACTIVITIES

This section is only applicable to MDR procedures and depending on the risk class of the medical device. Prior to the certification audits, all relevant technical files of the manufacturer are assessed by a team of experts, involving at least product, clinical and biocompatibility experts. They will evaluate, if requirements according Annex I-III of (EU) 2017/745 including clinical evaluation and related documents and activities (e.g. if applicable PSUR, SSCP, PMS and PMCF activities) have been fulfilled by the organization. For specific products, the assessment may require involvement of external authorities (e.g. products intended to administer and/or remove a medicinal product). Results of the evaluation are summarized in a report. The expert team may recommend the start of audit activities as per section 2 leading to certification of the respective products as described in section 4. If nonconformities have been detected, corrective measures will be expected from the organization within a defined period of time. If nonconformities cannot be resolved, the certification process stops. After initial certification, all products are subject to surveillance by the Notified Body according to a sampling plan, defining the scope and the frequency of reviews for the whole certification cycle, depending on the risk class of the medical devices.

4 CERTIFICATION PROCEDURE

All certificates are issued in a three-step procedure. Audit / document assessment is checked formally (Veto 1) and with regard to content (Veto 2) by respective experts and is followed by a certification decision (Veto 3). The person who reviews and releases the procedure may not have participated in the audit / document assessment. The certificate can only be issued when the nonconformities have been eliminated i.e. the corrective measures have been accepted or verified by the audit / assessment team. In addition, for initial certifications under MDR, certificates will only be issued after successful technical file review. The certificate may also be issued with obligations. The quality management certificates under EN ISO 13485 are valid for 3 years. MDR certificates have a validity of 5 years. The Notified Body will report certificate details to European databases. After approval and certification audit reports, technical file reports, other reports and – if applicable – non-conformity reports are made available to the organization. Noncompliance of the organization in regards to normative and regulatory requirements may lead to restriction, suspension and even withdrawal of certificates. This in turn may have consequences for the organization to place medical devices or deploy activities on the European market.

5 SPECIFIC ACTIVITIES

5.1 Notification of significant changes

The organization is obliged to notify significant changes to the Certification Body / Notified Body prior to their implementation. The Certification Body /Notified Body will assess the changes and their impact on the certificates in regards to quality management system and/or products of the organization. This assessment may involve additional audit or document assessment activities. The organization may continue with the implementation of the change only after approval by the Notified Body.

5.2 Vigilance

This section is only applicable to MDR procedures. The organization is obliged to announce all serious incidents with their medical devices to the Notified Body once they have been introduced to the market and the organization gets aware of them. As part of their surveillance tasks, the Notified Body investigates such vigilance cases and may report details to relevant European databases and authorities. The result of this assessment may affect the status of the certificate.

5.3 Sampling from the market

This section is only applicable to MDR procedures. In accordance with specified criteria, the Notified Body may withdraw product samples from the market and subject them to analysis in a laboratory to investigate if they conform to the specifications provided by the manufacturer. The result of this investigation may affect the status of the certificate

6 TRANSFER OF CERTIFICATION FROM OTHER CERTIFICATION BODIES

In general, only certificates from accredited certification bodies (QM systems according to DIN EN ISO 13485) or Notified Bodies or recognized bodies (conformity assessment procedures according to MDR) can be accepted. Organisations with certificates issued by non-accredited certification bodies or non-recognized or non-notified bodies shall be treated as new customers. A "pre-transfer review" shall be carried out by a competent person of the accepting certification body, usually consisting of a review of important documents and a visit to the customer. In addition, for MDR procedures, technical file assessment including clinical and PMS activity review and database analysis have to be part of the initial review. Furthermore, a tripartite contract between the organization, the previous Notified Body and the Notified Body of TN Cert has to be established in accordance with legal requirements. Suspended certificates or certificates that are in danger of being suspended will not be accepted. Open non-conformities should, be clarified with the previous certifier and the organization prior to acceptance. The further certification programme is based on the previous one.

7 CERTIFICATION OF COMPANIES WITH MULTIPLE LOCATIONS (MULTI-SITE)

If a company with several locations is certified, these locations must also be audited. The certification of companies with several production sites/branches/locations etc. with a similar activity profile and under a uniform management system is carried out by applying a sampling procedure.