1. Introduction

Subject of this process description is the certification of quality management systems (called quality system in the following) according to:
– EN ISO 13485
– EN ISO 9001

This process description is part of mdc's General Terms of Business.

Every certification project is divided into the following steps:
– Phase 1: preparation phase
– Phase 2: assessment phase
– Phase 3: certification phase
– Phase 4: surveillance phase

2. Description of the phases

2.1. Preparation phase

2.1.1. Offer and application

The certification procedure is based on the information that mdc receives via a questionnaire with the complete necessary information on the applicant organization. On the basis of complete information, a written certification offer is submitted to the interested party. This offer is based on the assumption that all documents are provided in German or English language. Should this not be the case for individual documents, the applicant has to inform mdc of this fact in order to allow a modification of the offer.
A meeting with mdc or discussions on the phone is to explain the certification process and the requirements. These explanations cannot replace personal information regarding the relevant legal requirements, appropriate training and/or consulting if necessary.
After accepting the offer, the interested party (hereinafter: client) sends back in duplicate the filled in and legally signed application form, which has been sent by mdc together with the offer. In the application form, the client specifies the scope of the certification. After reception of the completed application, mdc reviews the application. In case an application cannot be accepted by mdc, mdc starts the process to clarify any issues within one month after reception.
With the signature of mdc, this application turns into a legally valid certification contract.
After acceptance of the offer the client will receive a written confirmation, which specifies the documents to be submitted. Furthermore, the client will be informed in good time before the audit about the auditors in the form of personal records. An audit team usually consists of a lead auditor and an additional auditor.
If any personnel is not directly employed by mdc the client has to confirm within two weeks in writing the involvement or rejection of the proposed personnel. In case of rejection by the client, mdc and the client shall clarify the matter and change the audit team if necessary. In case of agreement by the client, the audit team will be instructed by mdc. As a rule, the lead auditor will agree with the client on the details of the assessment.

2.2. Assessment phase

2.2.1. Audit (2 stages)

Initial certification procedures need to be audited in a 2-stage procedure. This procedure is usually structured as follows:
Stage 1:
- Review of QM documentation
- On-site audit (stage 1) to determine the certification maturity and as evidence of the QM system's implementation as well as

Stage 2:
- On-site certification audit (stage 2)

In special cases, the stage 1 on-site audit may be omitted. These cases include the existence of a QM certificate from an accredited certification body or Notified Body as well as additional criteria applied by mdc.
For the audit of stage 1 and 2 the lead auditor will create two separate audit plans with the appropriate audit scope, which need to be countersigned by the company. The audit plan for stage 2 is provisional until the completion of stage 1 and may then need to be adjusted.

2.2.1.1. Assessment of QM documentation

During stage 1 an assessment of the QM documentation, which has to be submitted at least 4 weeks prior to the first planned audit date, is performed by the lead auditor. The results of the assessment are documented in a report and made available to the company promptly before the audit.

The assessment according to **EN ISO 9001** essentially includes the following documents:
– QM manual of the company (if available)
– Scope of application of the QM system
– Quality policy / Quality objectives
– Documented procedures / process descriptions
– Regulations for the control of documented information

and additionally for EN ISO 13485:
– QM manual of the company
– Documented procedures / process descriptions concerning:
  - Control of documents and records
  - Work environment and contamination control
  - Competence and training of personnel
  - Management review
  - Design and development (product realization)
  - Purchasing
  - Control of production and service provision
  - Installation and servicing activities
  - Validation of processes for production and service provision
  - Validation of the application of computer software in the quality management system
  - Particular requirements for sterile medical devices
  - Identification
  - Traceability
  - Preservation of product
  - Control of monitoring and measuring equipment
  - Feedback
  - Complaint handling
  - Reporting to regulatory authorities, if applicable
  - Internal audit
  - Control of nonconforming products
  - Advisory notices
  - Analysis of data
  - Corrective actions
  - Preventive actions
  - Risk management

In agreement with the client the assessment of the quality management documentation can completely be performed on-site. In this case all related additional costs (including all travelling times and travel expenses) shall be covered by the client.

If major nonconformities are found during the inspection of the QM documentation, the customer is granted sufficient time for the correction. If no stage 1 audit is carried out on site or if a stage 1 audit is carried out on site in direct connection with the stage 2 audit, all major nonconformities must be corrected before the audit. In case of a considerable number or significance of deviations, the stage 1 on-site audit shall also be performed only after correction of the major nonconformities. Minor nonconformities must also be corrected on the client's own responsibility.
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2.2.1.2. Audit (stage 1 on-site)

Subsequently the stage 1 audit will be performed on-site, in order to assess comprehensively the implementation in the company and thus the maturity for certification. At this stage the basic readiness for being audited will be determined based on a company tour and interviewing of employees. The audit shall cover the required procedures of the applicable standards and the assessment of the following requirements:
– Scope and extent of the quality management system
– Site-specific conditions
– Processes and equipment used

– Information on applicable statutory and regulatory requirements

If major nonconformities from stage 1 of the procedure (assessment of QM documentation or on-site audit) are not corrected, the audit shall not be continued with stage 2 and the client needs to be given sufficient time for correction. Only after successful completion of the stage 1 audit without open major nonconformity, the stage 2 audit can be conducted.

The maximum time between stage 1 audit (completion of the audit) and conduct of stage 2 may be 6 months. Otherwise another stage 1 audit will be required. In exceptional cases, i.e. small-scale companies or in case of difficult travelling conditions, the stage 2 audit may be conducted directly after positive completion of stage 1.
The stage 1 audit may be conducted only by the lead auditor or with the full audit team together.

2.2.1.3 Audit (stage 2)
Prior to the audit, mdc and the client agree on an audit plan, which is confirmed in writing by the client. The audit in the client's or, if applicable, at subcontractors'/suppliers' facilities is conducted according to this audit plan, with the possibility for the audit team to deviate, if necessary. During the audit the audit team systematically checks the quality system regarding the realization of all requirements of the normative base and the QM documentation. This includes in particular:
– Scope and extent of the quality management system
– QM documentation with control of documents
– Resource management, human resources and infrastructure / work environment
– Management responsibility, quality policy, quality objectives and management review
– Process performance, planning and results of internal audits
– Feedback from customers / customer satisfaction
– Applicable statutory and regulatory requirements (e.g. information about reportable incidents and recalls)
The client provides all required personnel, facilities and documents for the audit and fully supports the audit team to fulfill its assessment tasks; this also includes the provision of evidence to be retained in the audit by the auditor.
The audit is logged in checklist. If it is determined during the audit that the requirements of the normative base are not fulfilled, the lead auditor will be obliged to inform the client immediately. Nonconformities which are identified during the audit are documented in nonconformity reports by the auditors. For performing corrective actions, a certain period of time is defined by the audit team. The nonconformity reports are signed by the client.
In order to eliminate nonconformities and to verify the implementation of measures the following options exist:
– immediate realization of the agreed corrective actions during the audit,
– agreement of corrective actions and short-term proof of the realization of these measures in writing,
– agreement of corrective actions and checking of the realization within a follow-up audit,
A maximum period of 2 months shall apply for the elimination of major nonconformities.

A follow-up audit has to be conducted, if:
– the company does not support a proper execution of the audit (providing competent interview partners, inspection of documentation, inspection of work stations),
– the function of the quality system must be questioned fundamentally because of the types and number of nonconformities,
– the realization of corrective actions cannot be verified sufficiently in writing.
At the end of the audit, the audit team reports about the audit results in a closing meeting. This oral report does not contain a certification decision but only a recommendation of the audit team to the certification body.
After the audit, the client will receive a written report including a recommendation regarding the granting of the certificate and main focus for the next surveillance audit. In certain cases, the auditor can also recommend a surveillance audit prior to the usual time span.

2.3. Certification phase
The decision to grant a certificate is taken by one or more persons who were not involved in the assessment.
Primarily, the assessment reports including submitted evidence from the audit are the basis for this decision, however, further available documentation, the submitted documentation as well as all correspondence and working documents may be used in addition. The client is informed about the results in writing. This information may particularly include conditions for the maintenance of the certificate or in case of a rejection conditions which must be fulfilled for the granting of a certificate.
For the use of certificates and symbols separate rules have to be observed.
The client receives one original certificate in English or German according to his request. Translations into other languages are also available as originals against payment.
If the granting of the certificate is rejected, the client has the opportunity to object to the certification board in writing within four weeks. This statement is subject of a re-examination of the procedure (see General Terms of Business).

2.4. Surveillance phase
Requirement for the maintenance of the certificate is the successful performance of surveillance audits once per calendar year. They will take place on an annual basis 12 weeks before the reference date at the earliest and not later than 6 weeks after the reference date (date of the last day of the initial audit or follow-up audit). However, the first surveillance audit after the initial certification has to be performed prior to the certification decision date.
Planned changes concerning the location, organization, production technologies, relevant subcontractors/suppliers and product range must be notified to mdc regardless of the surveillance dates using the form for the notification of changes available on the mdc website. These changes are always subject to the surveillance audit. However, if extraordinary surveillance activities are deemed necessary by mdc, an additional review of the documentation or an extraordinary audit may be performed. In case of change of address or change of name any valid certificates must be reissued at the expense of the client. In case of special events (e.g. incidents, recalls), mdc may carry out additionally special audits (short-term or unannounced) at any time.

If a notification of a change or a surveillance activity leads to a change in the scope of the certification, a certification process according to section 2.2 and 2.3 will be necessary. The extent of the document review or an on-site audit will be determined individually.
The client will also receive a written report on the special audit carried out. In certain cases, the auditor can also recommend a surveillance audit prior to the usual time span. For the elimination of nonconformities also a period of a maximum of 2 months shall apply, which, however, may not exceed the aforementioned reference date by more than 2 months. In case this timeframe is not kept, the certificate will be suspended.
After each surveillance audit, a separate decision on the maintenance of the certificate is made.

3. Recertification and renewal of the contract
For the renewal of the contract, the client must solicit a quotation in sufficient time and apply for recertification no later than 6 months prior to the expiry of the certificate respectively the contract. The process of recertification complies with the one of the initial certification, with stage 1 only having to take place in case of significant changes to the QM system or a large number of identified deficiencies. It is intended that mdc performs a full assessment according to the current regulatory requirements and the current state of the art.

The recertification audit has to be performed prior to expiry of the certificate. In case this is not possible an initial certification procedure with prolonged audit duration has to be performed. As a rule, the renewal certificate receives the expiry date, which is no more than 3 years after the expiry date of the previous certificate. If the recertification is not carried out earlier, the follow-up certificate will begin to be valid on the first day after expiry of the previous certificate, unless the decision on the renewal can be taken later.
If the procedure for the renewal cannot be completed within 6 months after the expiry of the previous certificate, no renewal certificate can be issued but a full procedure of an initial certification has to be performed.