General certification conditions for the certification of QM systems and QM-based conformity assessment procedures for medical devices

TÜV NORD Certification

1. Scope of application

The certification conditions of TÜV NORD CERT GmbH (TN CERT) apply to the performance of certification for quality management systems and QM-based conformity assessment procedures for medical devices. The applied DIN EN ISO standards or the respective directives of the European Union in their respective valid version as well as the national legal regulations on which the accreditation / designation of the certification body / notified body is based shall apply as the basis for assessment.

2. Obligations of TN CERT

2.1 General obligations

Before the start of the audit, TN CERT shall inform the client of the name(s) of the auditor(s).

2.2 Confidentiality/ Secrecy

All information made available to the certification body that becomes known to it about the business operations of the client and which is either expressly or by its nature not intended for disclosure to third parties will be treated confidentially. This does not apply to the data and information that is or will be disclosed. This excludes reporting to the arbitration board in the event of disputes and the obligation to notify our accreditors. The contracting entity may, for certain reasons, release the certification body from its duty of confidentiality.

2.3 Information obligations

The certification body shall inform the contracting entity of any changes in the certification procedure which have a direct impact on it. After completion of the accreditation of the certification body, the client will be informed in this regard; from this point on, the client may no longer advertise with reference to this certification.

3. Obligations of the client

3.1 The client undertakes, if the scope provides for a level 1 audit, to make available to the auditor or the subcontractor appointed by TN CERT at the agreed time all valid documents relating to the management system (manual, procedural instructions, process descriptions, other relevant documents, records of internal audits and management assessments carried out). For all procedures, the relevant documents shall be made available in due time (14 days) before the audit.

3.2 All relevant documents shall be presented exclusively in German or English.

3.3 The client is obliged to carry out a complete internal audit (all elements of the relevant standard as well as the sites/production facilities relevant to the scope of the certificate and, if applicable, development sites must be audited) as well as an evaluation of the management system up to the certification audit and before the surveillance audits.

3.4 The client grants the auditing team access to the records affected by the scope during the audits and grants them access to the organizational units involved. Furthermore, the client assures the inclusion of important suppliers and subcontractors of crucial importance in the certification procedure, regardless of the length of the existing supply chain. This expressly includes the inspection of the organizational units and employees concerned. The certification body decides on the materiality.

3.5 The client shall appoint a contact person responsible by the management for the handling of audits. This is usually the representative appointed for the respective management system.

3.6 At the end of the on-site audit, a final discussion takes place. At least those employees who have management functions in the company and whose areas were involved in the audit attend this meeting.

3.7 If non-conformities are identified in the Stage 1 audit, the customer shall remedy them by the Stage 2 audit.

3.8 The Client undertakes to maintain the approved quality assurance system in such a way that its suitability and effectiveness remain guaranteed.

3.9 The client is obliged to inform the certification body of all significant changes in the structural and procedural organization of his company (this concerns e.g. changes regarding: the legal or organizational form, the economic or ownership structure of the organization and the management [such as key personnel in leading positions, decision-making or technical personnel, etc.], the contact address and the locations, the scope of the certified management system as well as significant changes in the management system or the product range and processes covered by it).

3.10 The client is obliged to keep records of all complaints addressed to him concerning the conformity of a product with the requirements of the relevant standard and to make these available to the certification body at any time on request. In the event of serious complaints from clients, the certification body must be informed immediately in writing. Furthermore, the client is obliged to take appropriate and suitable measures if actual deficiencies are identified as a result of complaints which affect the fulfillment of the certification requirements. These measures shall be documented accordingly.

3.11 The contracting entity shall grant the authority responsible for the area the right to participate in certification procedures in order to perform its duties under the designation.

4. Rights of the TN CERT

4.1 The certification body reserves the right to publish a list of certified clients, applicable normative documents, scope and geographical location for consumer information. Upon request, access to certain information may be restricted.

4.2 The invalidation or expiration of a certificate may be published.

4.3 In order to ensure a constant product quality, the Certification Body shall carry out regular inspections of the production and testing facilities as well as of the QM system at the expense of the client if a CE marking with identification number 0044 is approved.

4.4 In addition, the certification body may carry out unannounced audits and audits for special reasons at the expense of the client, in particular if there are reasonable doubts about the conformity of the products or the effectiveness of the QM system. This expressly includes the inspection of the organizational units concerned and employees of important suppliers and subcontractors of decisive importance. The certification body decides on the materiality.

4.5 In addition, the Certification Body may at any time, at the expense of the Client and without prior notification, inspect the manufacturing and operating sites and the warehouses specified in the certificate (in the case of foreign holders of the certificate also the warehouses of the authorized representatives and the branch offices, in the case of importers also their warehouses) and remove products for which a certificate has been issued in order to carry out tests.

4.6 If the TN CERT has provided a defective service, the TN CERT shall have the right to choose between removing the defect and providing a new defect-free service.

4.7 TN CERT may at any time give extraordinary notice of termination without notice for good cause.

5. Rights of the client

5.1 The client may request background information on each member of the audit team, whereby after the name(s) has/have been made known, the client may object once within 7 calendar days to the appointment of a specific auditor or technical expert. The certification body reserves the right to reassemble the team within 14 days of a justified objection and to inform the client of this.

5.2 Appeals may be lodged against certification decisions and complaints may be lodged against the conduct of procedures. Incoming complaints/appeals will be investigated, dealt with expediently and a reasonable effort will be made for clarification on the part of the certification body.

5.3 The Client may only pass on reports in full, stating the date of issue. Publication or reproduction requires the prior approval of the issuing body.

5.4 The permission to use the CE marking with identification number 0044 is only valid for the company and for those production sites as well as for those products which are listed in the certificate. In the case of intended relocation of an operating site or transfer of the company to another company or another company owner, the client shall inform the certification body in good time. The certificate can only be transferred to third parties by the certification body. The certification body decides on the further steps.

5.5 If TN CERT has provided a defective service, the customer shall give it the opportunity to provide supplementary performance at least twice within a reasonable period of time, unless this is unreasonable in the individual case or special circumstances exist that justify the customer's immediate withdrawal after weighing the interests of both parties. If the subsequent performance fails, the customer shall be entitled to reduce the remuneration or to withdraw from the contract; claims for withdrawal and damages shall not exist if the deviation from the contractually owed quality is only insignificant.

5.6 After restriction, suspension, withdrawal or revocation, the client is prohibited from continuing to use the certificate issued by TN CERT and the CE marking with identification number 0044.

6. Restrictions / suspension / revocation / termination of the rights of use

6.1 A certificate shall expire with immediate effect, without prior notice, if, among other things

- the general contract for certification of pro- ducts and awarding of marks ends,
- the client waives the certificate,
- the client does not accept changes to the terms and conditions, the certification conditions or the prices of TN CERT as binding after the expiry of a fixed period of time,
- the client becomes bankrupt or a petition for bankruptcy filed against him is rejected for lack of assets,
- surveillance audits cannot be carried out for reasons for which the client is responsible,
- the rules on which the certificate is based have been changed and, if applicable, transition periods have expired. The validity of the certificate shall be extended if it is proven by a subsequent test at the expense of the client within a specified period that the certified products or the certified QA system also comply with the new rules

6.2 A certificate may also be suspended, invalidated or terminated by the certification body if,

- the certified management system fails to meet the certification requirements - including the effectiveness of the management system - on a permanent or serious basis
- the fees are not paid within the specified period after a reminder has been sent. If the fees do not relate to a specific certificate, the certification bodies shall decide which certificate is to be covered by the measure
- the client continues to use an improper CE marking with identification number 0044 on his products, although TN CERT has informed the client about the illegal use of the CE marking with identification number 0044 and requested proper use
- the client continues to violate his legal reporting obligations to the authorities after a warning from TN CERT

6.3 TN CERT may suspend a certificate for a limited period of time if circumstances exist which would justify the withdrawal, revocation or restriction of the certificate in accordance with the above regulations, but it is foreseeable that these circumstances will only be of limited duration. The right of TN CERT to withdraw, revoke or restrict the certificate shall not be restricted by the right of suspension.

7. Violations of the certification conditions

The certification body is entitled to demand a contractual penalty of up to € 10,000 for each case of culpable infringement of these certification conditions, in particular in the case of unlawful use of a CE marking with identification number 0044. Unlawful use of a CE marking with identification number 0044 shall also be deemed to have occurred if products bearing a CE marking with identification number 0044 are offered for sale or placed on the market before a certificate has been issued or if unauthorized advertising is carried out.

8. Entry into force and amendment of the certification conditions

8.1 TN CERT reserves the right to amend the terms and conditions of certification; this shall apply immediately after the currently valid version comes into force.

8.2 The clients shall be notified of the entry into force of the new certification conditions or the suspension of the present certification conditions; this may also be done by e-mail.

9. Regulations on occupational safety

9.1 Client

- Prior to execution of the order, the client shall provide information on hazards and stresses that may emanate from the working environment in the client's company, including information on hazardous substances in test specimens. The client shall provide information as to whether and, if so, to what extent G. examinations are required for the commissioned activities.
- The client has adequate provisions for first aid, alarm and rescue measures and designates contact persons and responsibilities.The client shall ensure that employees of TN CERT only work in the company of an employee of the client.The client shall instruct the employees of the certification body on the basis of risk assessment(s) and operating instruction(s) including emergency numbers and assembly points in case of danger as well as on the functioning and safety of any equipment to be used.
- The client shall provide, free of charge, any personal protective equipment (helmet, safety shoes, ear protection, safety goggles) that may be required and that exceeds that provided by the certification body.

9.2 TN CERT

- The employee of the certification body may only work if safe conditions have been established. He has the right not to carry out the activity in the event of unacceptable hazards / stresses.

10. Special arrangements for the performance of conformity assessment procedures according to MDD

10.1 Addition to item 2; Warranty

The services of TN CERT refer solely to the functionality and regularity of the tested quality assurance system, but not to the functionality, regularity or freedom from defects of the individual medical device / active implantable medical device manufactured by the client.

10.2 Addition to Item 2; Duties of TN CERT

10.2.1 Prior to the decision on the restriction, suspension, withdrawal or revocation of the certificate, the contracting entity or its authorized representative established in the European Economic Area shall be given the opportunity by TN CERT to present its views, unless such a hearing is not possible in view of the urgency of the measures to be taken. TN CERT shall justify the withdrawal or revocation of the certificate to the client in writing.

10.3 Supplement to Item 3; Obligations of the Customer

10.3.1 The contracting entity hereby assures that its application to carry out a conformity assessment procedure for the same products has not been submitted to any other notified body.

10.3.2 The contracting entity assures to establish and keep up to date a systematic procedure to evaluate experiences with products in the downstream phases of manufacture, in particular complaints, and to take precautions to carry out necessary corrections. The Client shall grant TN CERT access to these records.

10.3.3 The Customer warrants that it shall immediately report to the competent authorities all reportable events, in particular malfunctions or changes in the characteristics and/or performance as well as any improper labeling or instructions for use of a product, which have led or may lead to a serious deterioration in the health condition of a patient or user or to his death.

10.3.4 The Client assures to report any reportable event that has led to the systematic recall of products of the same type by the manufacturer.

10.3.5 During the validity period of the certificates the applicant shall be obliged to inform the notified body of any court judgement / ruling / decision pertaining to the products or quality system covered by the certificate without undue delay.

10.3.6 Stocks of finished products bearing a CE marking with identification number 0044 shall be disclosed to the certification body without delay upon request, accompanied by an affidavit suitable for use in court.

10.3.7 The Parties agree that the Customer shall be solely responsible for the lawful use and application of the CE marking with identification number 0044 in the internal relationship between the Parties, in particular also with regard to competition law.

10.4 Addition to point 4; rights of the TN CERT

10.4.1 The certificate is valid only for the complete product. However, in special cases, the certification body may allow the client to disassemble the products bearing the mark for shipment to the extent that this is normally done for the installation of the product in a plant. In addition, extensive disassembly into individual parts may be permitted for shipping if the client names an assembly site, which must then be subject to the control of the certification body in the same way as the first production site.

10.4.2 Within the scope of the application procedure, TN CERT checks technical documentation for the applied products of classes Is, Im, IIa and IIb for conformity according to the specifications of the respective procedures. Within the scope of the annual monitoring of the client, an evaluation of the technical documentation for products of the classes Is, Im, IIa and IIb is carried out on the basis of representative random samples.
Procedures according to Annexes II.4 of Directive 93/42/EWG are applied for separately. Separate EG design examination certificates are issued for these procedures.separate

10.5 Supplement to Item 5; Rights of the Customer

10.5.1 The granted CE marking with identification number 0044 may basically be used according to the valid medical device law. The CE marking of the certified products with identification number 0044 is presented to the certification body before being placed on the market.

10.5.2 The client is obliged to properly carry out the manufacture of the products bearing the CE marking with identification number 0044 on an ongoing basis in accordance with the control tests specified in the test specifications or required by the certification body.

10.6 Restriction/ Suspension/ Revocation/ Termination of Rights of Use

10.6.1 A certificate may be declared invalid or terminated by the certification body in addition to Section 6 if

- products with CE marking with identification number 0044 do not comply with the certified areas of application,
- subsequently, defects are found in the products that were not visible or were not detected during the inspection,
- the product or product category was incorrectly assigned to medical devices,
- the product or product category has been assigned to a class that is too low and a false declaration has been made for it accordingly,
- the inspection of products bearing the CE marking and the identification number 0044 reveals defects,
- misleading or otherwise inadmissible advertising is carried out with the CE marking with identification number 0044,
- the continued use of the CE marking with identification number 0044 is not justifiable with regard to its significance on the market, due to facts which could not be recognized at the time of the inspection,
- proper performance of the factory inspection tests at the client's premises or at another test facility is not proven within 4 weeks despite a written request by the certification body,
- the client refuses the inspection of the manufacturing and testing facilities or the warehouse by the representative of the certification body or the removal of products for the purpose of inspection by the certification body.

The certification body is entitled to suspend or terminate a certificate and thus the authorization to use the test mark if the certification body subsequently becomes aware of relevant new findings concerning the assessment of the certification procedure or the result of the certification procedure.

10.6.2 After expiration of the validity or invalidation of a certificate, the certificate must be returned to the certification body, even if the authorization to distribute the remaining stocks with the CE marking with identification number 0044 exists.

10.6.3 After the expiry of the validity of a certificate, the further distribution of the existing stock of ready-to-use final products may be permitted, however, for a maximum period of 12 months. The assembly of the prefabricated components already existing at the expiry of the validity of the certificate, which were intended for the manufacture of the final product in its originally certified design, may be permitted for a number of units of the final product to be specified by the client, but for a maximum period of 6 months after the expiry of the validity of the certificate.