General Conditions for Certification of Management Systems and QM-based Conformity Assessment Procedures for medical devices

1. Scope

The Certification Condition of TÜV NORD CERT GmbH (TN CERT) apply to the execution of certification for quality management systems and QM-based conformity assessment procedures for medical devices. The basis for such assessment shall be deemed to be the DIN EN ISO standards applied for as well as the Regulation (EU) 2017/745 on Medical Devices, and those of the national legislation on which the accreditation / designation of the certification body / Notified Body is based.

2. Duties of TN CERT

2.1 General duties

Before the start of any audit, TN CERT will inform the client about the name(s) of the auditor / auditing team.

2.2 Confidentiality/Secrecy

We will treat as strictly confidential all information made accessible to the certification body, and/or which becomes known to the said authority, about the business activities of the client and which - either expressly or by its nature - is not intended for disclosure to any third parties. This does not apply with regard to the data and information which is or becomes apparent. Reports to the arbitration body in cases of dispute, and the information duty in respect of our accreditation bodies are excluded here from. The client can release the certification body from this duty of silence and confidentiality in certain circumstances.

2.3 Information duties

The certification body informs the client about any changes in the certification procedure, which affect him directly.

After the accreditation of the certification body is terminated, the client will be informed in this regard; from this date the client may no longer use this certification for advertising purposes.

3. Duties of the client

3.1 Inasmuch as the scope provides for a Stage 1 Audit the client undertakes to provide to the auditor or the subcontractor designated by TN CERT at the agreed date and time all applicable and valid documentation relating to the management system (manual, procedures, process descriptions, other relevant documents, records of any internal audits and management reviews carried out). In all procedures the relevant documents must be provided in good time (14 days) before the audit.

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

3.3 Until the actual date of the certification audit, and before the surveillance audits, the client has a duty to carry out a full internal audit (all elements of the relevant standard as well as the locations / production sites relevant for the scope of the certificate and, if necessary, development sites must be audited) as well as an assessment of the management system.

3.4 During the audits the client grants the team of auditors access to the records affected by the scope of the audit as well as to the organisation units involved. In addition, the client ensures the inclusion of important suppliers and subcontractors, who have a considerable impact, in the certification procedure, regardless of the existing supply chain length. This expressly includes visiting the affected organisation units and employees. The certification body decides on the degree of significance.

3.5 The client designates a senior management contact person with responsibility for the execution of audits. In general this is the representative who has been appointed for the respective management system.

3.6 A final meeting takes place at the end of the onsite audit. At least those employees take part in the meeting who have management functions within the organisation and whose areas were included in the audit.

3.7 If nonconformities were identified in the Level 1 audit, these must be corrected by the client before the Level 2 audit.

3.8 The client undertakes to maintain the approved quality assurance system such that its suitability and effectiveness remain assured.

3.9 The client has a duty to inform the certification body about all significant changes in the organisational structure and process organisation of his company (this concerns e.g. any changes with regard to the legal or organisational form, the economic or ownership situation of the organisation and the management [such as key members of staff in management positions, decision-making or specialist personnel etc.], the contact address and the company sites and locations, the scope of the certified management system as well as any significant changes to the management system or the range of products and processes included therein.

3.10 The client is obliged to maintain records of all complaints addressed to it with respect to the conformity of a product with the requirements of the standard concerned and make these accessible to the certification body at all times upon request.

In the case of serious complaints, the certification body is to be notified immediately in writing. Furthermore, the client is obliged to take reasonable and appropriate measures if the complaints are based on actual defects, which negatively affect fulfilment of the certification requirements. These measures are to be documented accordingly and reported to the certification body.

3.11 On request, the client shall grant to competent power-conferring authority granting the approval with responsibility for the area of notification the right to participate in the certification procedure in order to meet its duties and obligations in connection with the notification.

4. Rights of TN CERT

4.1 The certification body reserves the right to publish for the information of consumers a listing of certified clients, relevant applicable standards documents, the scope of validity and the geographical location. Access to certain specific items of information may be restricted, if requested.

4.2 If a certificate is declared to be invalid or expires, this fact may be published.

4.3 If a certificate for using a CE marking accompanied by ID number 0044 is issued, in order to assure a consistent product quality, the certification body carries out regular inspections of the production and testing facilities as well as the QA system; the costs shall be borne by the client.

4.4 In addition, the certification body may perform unannounced audits and audits for a specific reason at the expense of the client, in particular when there if justified doubt regarding the conformity of the products or the effectiveness of the QM System. This expressly includes visiting the affected organisation units and employees of important suppliers and subcontractors, who have a considerable impact. The certification body decides on the degree of significance.

4.5 In addition, the certification body can at any time, at the expense of the client and without prior announcement, view the production shops and operating facilities and the storage facilities stated in the certificate (in the case of foreign certificate holders also the storage facilities of the authorised parties and the branch offices, and in the case of importers also their storage facilities) and to remove products, for which a certificate has been granted for testing purposes.

4.6 If the performance of TN CERT has been defective, TN CERT choose at its discretion to remove the defect and/or to reperform the said defective performance free from any such defect.

4.7 At any time TN CERT may terminate the contractual relationship for good cause with immediate effect.

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5. Rights of the client

5.1 If he so requests, the client may ask for background information on each member of the audit team, with the client being entitled to object on one occasion within 7 calendar days to the appointment of a specific auditor or specialist after the name(s) have been announced. The certification body reserves the right to reassemble a new team within 14 days of any such well-founded objection and to inform the client accordingly.

5.2 It is possible to raise an objection against certification decisions and complaints against the execution of procedures. Any complaints / appeals received will be investigated, dealt with appropriately, and the certification body will make a suitable effort to clarify the issue(s).

5.3 The client may only pass on reports with their full wording and stating the date of issue. Any publication or duplication is subject to prior permission from the issuing body.

5.4 The permission for using a CE marking accompanied by ID number 0044 only applies to that company and to those operating facilities as well as to those products, which are listed in the certificate. If it is intended to move an operating facility, or to transfer a company to another company or another owner, the client will inform the certification body in good time. Only the certification body has the right to transfer the certificate to any third parties. The certification body decides on the further procedure.

5.5 If TN CERT should have rendered a defective performance, the client must grant TN CERT at least twice the opportunity for subsequent fulfilment within an appropriate period of time, inasmuch as this is not unreasonable in individual cases or if there are special circumstances which - taking into account mutual interests - would justify an immediate withdrawal of the client. If such subsequent fulfilment fails, the client shall have the right to reduce the remuneration or to withdraw from the contract; there is no right of withdrawal and no claims for damages are possible, if the deviation from the contractually owed property is insignificant only.

5.6 Following any restriction, suspension, cancellation or revocation, the client / applicant shall be prohibited from continuing to use in any way the certificate granted by TN CERT and the corresponding CE marking accompanied by ID number 0044.

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

6.1 A certificate expires with immediate effect without the need for any prior announcement, if e.g.

- the General Agreement on Certification of Products and Award of Mark ends,
- the client gives up the certificate,
- the client does not recognise as legally binding any changes to the terms and conditions of business or the prices of TN CERT following expiry of a specified period,
- the client goes bankrupt or if any application against him for the opening of bankruptcy proceedings is denied due to lack of assets,
- surveillance audits cannot be carried out for reasons that the client must be held responsible for,
- the rules upon which the certificate is based and, if necessary, transitional periods have expired. The validity of the certificate is extended if it is proven by a follow-up check at the cost of the client, and within a specified period, that the certified products or the certified QA system also corresponds to the new rules.

6.2 The certification body may also suspend, declare to be invalid or cancel a certificate if

- permanently or to a serious degree, the certified management system does not meet the certification requirements, including the effectiveness of the management system,
- following a reminder, the payments are not made within the specified period. If the payments do not relate to a certain certificate, then the certification bodies shall decide which certificate the measure is to be extended to,
- the client continues to use an incorrect CE marking accompanied by ID number 0044 on his products although TN CERT has pointed out to the client his illegal use of the CE marking accompanied by ID number 0044 and requested him to use such marks in a legal fashion only,
- following a reminder by TN CERT, the client continues to contravene his statutory information duties existing in relation to the bodies.

6.3 TN CERT may also suspend a certificate for a limited period of time, if there are circumstances which - in accordance with the above conditions - would justify the withdrawal, revocation or restriction of the certificate, but if it is foreseeable that these circumstances will only be of a limited duration. The TN CERT's right as to withdrawal, revocation or restriction of the certificate will not be limited by the right to suspension.

7 Infringements of the certification conditions

If any culpable infringements of these certification conditions are found, in particular in the case of any illegal use of CE marking accompanied by ID number 0044, the certification body shall be entitled to demand a contractual penalty of up to □10,000.00 for each case of breach. It is also an illegal use of CE marking accompanied by ID number 0044 if products bearing CE marking accompanied by ID number 0044 are offered or put into circulation before a certificate is granted, or if non- permissible advertising is effected.

8 Coming into force and amending the certification conditions

8.1 The certification conditions come into force on 22.11.2018.

8.2 TN CERT reserves the right to amend the certification conditions, which become valid immediately upon the respectively applicable version coming into force.

8.3 The clients will be informed specifically about the new conditions coming into force or the invalidation of the present certification conditions. This notification may be given by email.

9. Arrangements regarding occupational health and safety

9.1 Arrangements to be undertaken by the client

- Before performance of the contractual services, the client shall provide information regarding risks, hazards and stress, which could originate from the working environment in the client's factory or at the client's premises. This information shall include information regarding hazardous substances in test pieces. The client shall provide information concerning whether and if appropriate, to what extent, risk and hazard assessments are required for the activities that have been ordered.
- The client shall have sufficient arrangements in place for first aid, alarm and rescue, and shall name contacts and responsibilities in this regard.
- The client shall ensure that employees of TÜV NORD CERT only perform work when accompanied by an employee of the client.
- The client shall provide the employees of the certification body with instruction on the basis of risk and hazard assessment(s) and work and operating instructions. The instruction shall include communication of emergency telephone numbers and collection points in case of danger, and also a description of the functioning and safety of any

equipment to be used under such circumstances.
- The client shall supply any necessary personal protective equipment which may be necessary and which is not provided by the certification body (helmet, safety boots or shoes, ear and eye protection – e.g. ear defenders, safety spectacles /goggles) free of charge.

9.2 TN CERT
- Before performance of the contractual services, the client shall provide information regarding risks, hazards and stress, which could originate from the working environment in the client's factory or at the client's premises. This information shall include information regarding hazardous substances in test pieces. The client shall provide information concerning whether and if appropriate, to what extent, risk and hazard assessments are required for the activities that have been ordered.

10. Special agreements on the execution of conformity assessment procedures according to (EU) 2017/745

10.1 Addition to item 2; warranty

The performances of TN CERT relate solely to the functionality and correctness of the approved quality assurance system but it does not relate to the functionality, correctness or freedom from defects of the individual medical device manufactured by the client.

10.2 Addition to item 2; duties of TN CERT

10.2.1 Before any decision is made on the restriction, suspension, withdrawal or revocation of the certificate, TN CERT will give the client or his authorised representative based within the European Economic Area an opportunity to present his view, unless such a hearing is not possible due to the urgency of the measures to be taken. The TN CERT will provide the client with a written justification of any such withdrawal or revocation of the certificate.

10.3 Addition to item 3; duties of the client

10.3.1 The client hereby confirms that his application for the execution of a conformity assessment procedure for the same products has not been submitted to any other authority.

10.3.2 The client undertakes to set up a systematic process and to maintain the same up to date, by means of which experiences with products, in particular complaints, are evaluated during the phases subsequent to manufacture, and to take measures to carry out the necessary corrections. The client grants TN CERT access to these records.

10.3.3 The client undertakes to inform the competent authorities immediately about all notifiable events, in particular any malfunctions or changes in features and/or the performances as well as any incorrectness of the marking or in the instructions for use of a product, which have led or may lead to a serious deterioration of the state of health or the death of a patient or user.

10.3.4 The client undertakes to communicate any notifiable event that has led to the systematic recall of products of the same type by the manufacturer.

10.3.5 Stocks of finished products bearing the CE marking accompanied by ID number 0044 must be made known immediately to the certification body on request, presenting an affidavit, which is suitable for use before a court of law.

10.3.6 The parties agree that - in the internal relationship of the parties - the client is solely responsible for the legal use and utilisation of the CE marking accompanied by ID number 0044, in particular also in regard to competition law.

10.4 Addition to item 4; rights of TN CERT

10.4.1 The certificate is only valid for the full product. However, in special cases the certification body may permit the client to disassemble for shipping purposes products bearing the mark, to the extent that this is normally done for installing the product into a plant. In addition, an extensive disassembly for shipping purposes into individual parts may be permitted in cases where the client designates an assembly shop which must then be subject to control by the certification body in the same way as the initial production shop.

10.4.2 In connection with the application procedure TN CERT will review the conformity of the technical documentation including the post market surveillance system for product of Class Is, Im, Ir, IIa, IIb and Class III according to the requirements defined in the respective procedures. As part of the annual surveillance audits of the client, technical documentations of products will be reviewed based on representative samples.

10.4.3 Additionally, depending on the risk class of the device, TN CERT is obliged to disclose client documentation to respective competent authorities and takes their assessment results into consideration.

10.5 Addition to item 5; rights of the client

10.5.1 In principle, the CE marking accompanied by ID number 0044 granted and issued may be used pursuant to the applicable law on medical products. The marking of the certified products with this CE marking accompanied by ID number 0044 shall be presented to the certification body before being put into circulation.

10.5.2 The client has a duty to carry out correctly the manufacture of the products bearing the CE marking accompanied by ID number 0044 such that it is continuously in accordance with the test inspections defined in the test regulations or required by the certification body.

10.6 Restriction/suspension/revocation/termination of the rights of use

10.6.1 In addition to item 6, the certification body may also declare to be invalid or cancel a certificate if
- products bearing a CE marking accompanied by ID number 0044 are not in agreement with the certified scope of validity,
- faults not evident or not ascertained during the test are subsequently found in the products,
- the product or the product category was incorrectly designated as medical devices,
- the medical device or the medical device category were assigned to a lower class, and a corresponding incorrect declaration was made in respect of them,
- the testing of products bearing a CE marking accompanied by ID number 0044 yields any defects,
- the CE marking accompanied by ID number 0044 is used for misleading or otherwise non-permissible advertising,
- due to facts that could not be clearly recognised at the time of testing, any further use of the CE marking accompanied by ID number 0044 would not be justifiable in view of its meaningfulness in the market,
- a correct execution of the fabrication inspections in the operational facilities of the client or in any other test facility is not proven within 4 weeks in spite of a corresponding request in writing by the certification body,
- the client refuses to allow an inspection of the production and testing facilities or the storage facility by the delegated representative of the certification body or if he refuses to allow the removal of products for the purpose of testing by the certification body.

The certification body is entitled to suspend or terminate a certificate, and hereby the entitlement to use the test mark, if the certification body subsequently becomes aware of new information pertaining to the assessment of the certification procedure or its result.

10.6.2 On expiry of the validity of a certificate, or if it is declared to be invalid, the certificate must be returned to the certification body, even if permission has been obtained to sell and distribute any remaining stocks bearing the CE marking accompanied by ID number 0044

10.6.3 After the validity of a certificate has expired, the stock of ready-to-use end products may still be marketed, but only for a maximum period of 12 months. Permission may be given to assemble the prefabricated parts already available at the time the certificate expires, and which were intended to make the end product in its originally certified design, for a number of units of the end product to be specified by the client, but only for a maximum period of 6 months from the date on which the validity of the certificate expires.