Rules for System Certification of TÜV Rheinland InterCert Kft. for manufacturers of medical devices

1. Objective

This regulation (ORTSZ) determines how Medical Devices Department (OE) of TÜV Rheinland InterCert Kft. (TRI) performs system certification procedure according to MSZ EN ISO 13485:2016, MSZ EN ISO 13485:2016/A11:2022 / EN ISO 13485:2016, EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021 and its rules for performing conformity assessment procedures.

2. Scope

This procedure applies to system certification and conformity assessment carried out by the Department Medical Devices (OE) within the Business Field Products (GB P).

This regulation relates to TÜV Rheinland InterCert Kft as certification and notified body and the Applicant being in relation with the certification body, taking services of certification body for the purposes of demonstration of appropriate operation of its management system and to verify the compliance with MSZ EN ISO 13485:2016, MSZ EN ISO 13485:2016/A11:2022 / EN ISO 13485:2016, EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021 standard requirements.

Present regulation shall be used in conjunction with the facts contained by the contract of commission concluded between the parties above.

3. Terms and definitions

Auditor: person qualified and registered by Department OE who has got the necessary competence and experience to conduct an audit.

Audit leader: a lead auditor who has been designed to manage an audit.

Expert: person who has verified education and experience in a predefined professional field and who supports the task of auditors within the certification procedure in order to assure the suitable professional competence. The expert does not have a valid auditor appointment.

System Certification Organization (Department Medical Devices): independent organizational unit of TRI that is professionally competent and whose task is to assess and verify the conformity of management system of the applying organization (applicant).

Head of Department OE: a person appointed to manage the system certification and notified body organization of TRI who has got appropriate education and experience for auditing, too.

Applicant: organization applying for system certification at Department OE (customer).

License Holder: organization having system certificate granted by TRI (customer).

Authority: authorities supervising the operation of the TRI

4. Description of the regulation

General Terms and Conditions (GTC) of TRI are also valid together with this regulation.

4.1. Rights and obligations of Department OE

Duties and obligations of the personnel of Department OE taking part in the system certification procedure or other persons (auditors, experts, and certifier) commissioned by this Department are as follows:

- To handle information gained confidentially, not to forward it to third parties, except for the contents of audit reports, which may be shared with the Authority upon request or, in the case of on-site audits, the TRI or its external evaluation bodies may observe the TRI's inspection activities on the spot, in which case, after prior notification, the client accepts the presence of the Authorities' Evaluation Team at the inspection.
- To conduct the procedure in accordance with the provisions of relevant standard(s) and instruction for procedure concerning Department OE;
- To make known persons of auditors and external experts for the applicant/holder prior the certification procedure;
- To be in consent with the applicant/holder regarding the person of trainee auditor participating on the audit;
- Data recorded in the non-conformity and audit report be realistic;
- To take into account the wishes of the applicant/holder at determination of audit timing;
- To record the data regarding granted, suspended or withdrawn certifications in the public database TÜVdotCOM and/or at the website of TRI;
- To investigate the circumstances in case of application transferred by another accredited certification body, with particular attention to the followings:
    - reason of the applicant, for why the change has been initiated;
    - origin, expiry date and scope of the existing accredited certification;
    - audit reports of the previous certifying or re-certifying audits and follow up audits (including handy records, checklists). When these are not available or the surveillances delayed the applicant shall be considered as a new one (data transfer is not possible);
    - received complaints and actions taken concerning them;
    - status of the present certification cycle;
    - engagement of the applicant to any assessment body (e.g. designated body) derived from need for legal conformity (e.g. conformity assessment procedure).
- in case of limitation or withdrawal of its accreditation or notification, shall assist the License Holder to transfer to another certification or notified body by the following:
    - provision of all necessary information to the new certification or notified body to facilitate a smooth transfer of responsibilities

- To inform the applicant/holder about changes in the certification procedure (including any circumstance that may lead to limitation or withdrawal of its accreditation) in duly time, and to initiate the modification of contract concerned, if needed
- According to the GTC the department ensure that the certification activity is always covered under a liability insurance contract; which includes the withdrawal, reduction or suspension of certificates.

Rights of the Head of Department OE:

- To nominate auditors conducting certifying audits, if needed to involve external expert with the examination;
- To charge the applicant/holder expenditures incurred regarding actions specified in the contract after their finalization, furthermore other fees according to the paying conditions laid down in the contract, too;
- To modify prices according to the actual scale of fees when the quotation was accepted after 3 months calculated from its issue, either if the deadlines stated in the contract have been expired, or the data submitted by the applicant for contracting in the period of certification are no longer realistic;
- To break the certification procedure until the question will be cleared if the applicant does not settle its financial obligations in time, or to initiate the withdrawal of certificate granted;
- To start with the next certification phase only when the applicant/holder the pre-calculated costs has been paid in advance, if the applicant/holder violated its financial obligations, and has paid only after more notices to pay.
- if deemed necessary based on information reported or otherwise gathered (eg from internal inspection), in the surveillance period TRI has the right to perform unannounced extraordinary audit (visit and inspection) at the client and (following client approval) their critical supplier.
- The notified body has the right to end the contract as soon as their permanent unannounced access to the premises of the manufacturer or its critical subcontractors or crucial suppliers is no longer assured.

4.2. Rights and obligation of the applicant/ license holder

Rights of the applicant/ license holder:

- To make a proposal for the audit-leader concerning the time intervals of pre-audit, certifying audit (first and second period), re-audit or surveillance audits within the time frame agreed in the contract and to get a consent in this matter;
- To make remark, or in justified case to disapprove, shut out in advance of the persons for auditors, experts, trainees, translators appointed by the head of Department OE;

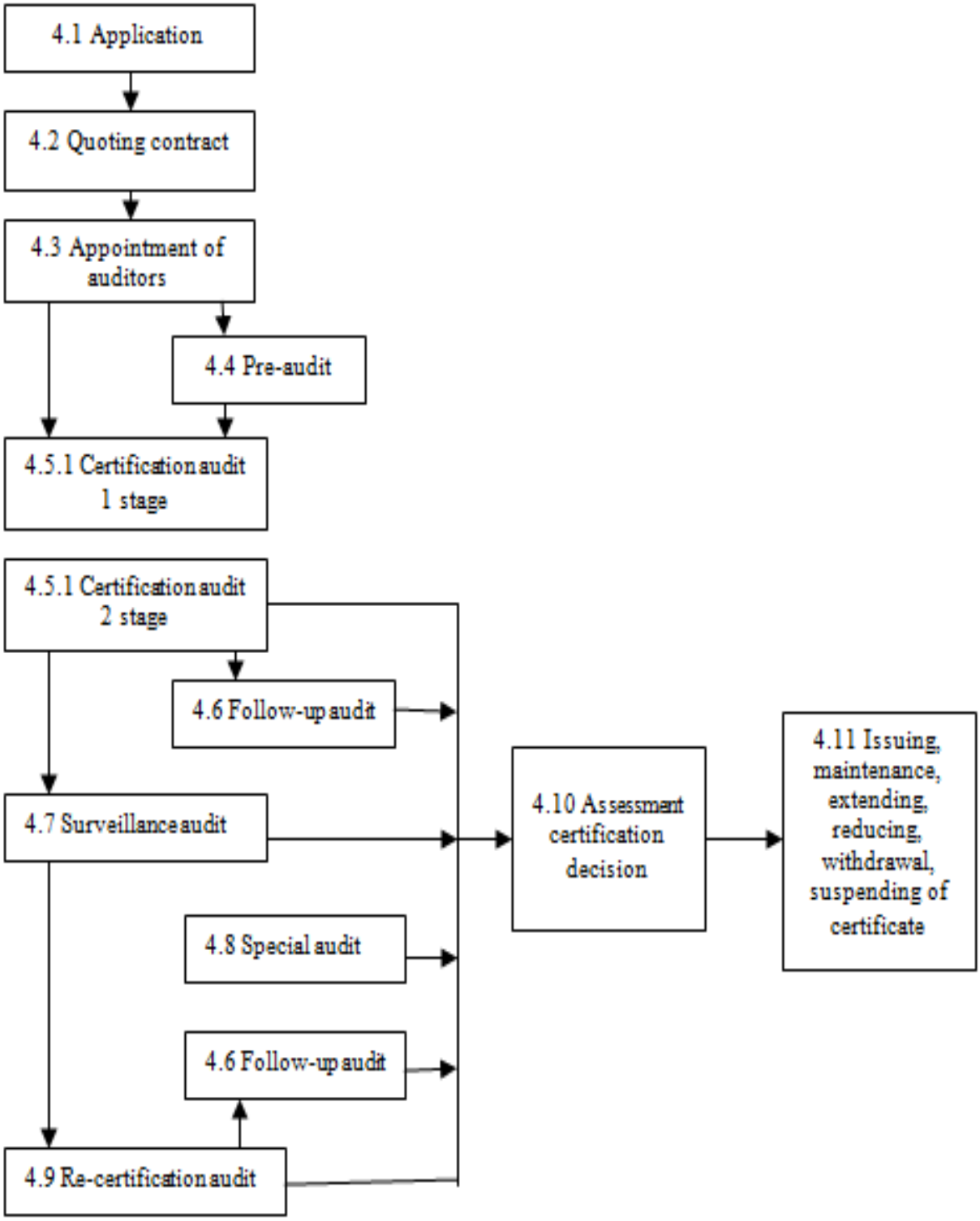
- To disapprove of data stated in the non-conformity reports;
- To waive its claim regarding the contract, to stop certification procedure, if all the paying obligations have been settled till the time of stopping;
- To complain regarding the eventual unprofessional activities of the auditors or statements recorded in the audit report at the Head of Department OE. To appeal against the decisions on certification, or when its matter would not be settled by mutual consent a procedure may be initiated at the competent court;
- To take a view of, to check and to confirm the data of granted, suspended and withdrawn certificates in the public database TÜVdotCOM (www.tuvdotcom.com) and/or on the website of TRI (www.tuv.hu);
- To transfer its certification to another accredited certification body, when no debit exists against TRI;
- To initiate change of a certifying audit to a pre-audit if it becomes clear that the results of audit do not make possible to grant a certificate. This occasion may be allowed only once during a certification procedure and the applicant shall accept the surcharges derived from this.
- Declare a declaration on the product's packaging of its certified quality management system in no way implying that the product, service or process has been certified in this way and include a reference to: Identification of the certified customer (brand or name), the type of management system and the standard used, and the certification body issuing the certificate.

Obligations of the applicant/ license holder:

- To keep at all the relevant provisions of the certification procedure in case of contracting;
- To forward -based on a preliminary negotiation- to audit-leader the necessary, approved system documentation (quality management manual, documented procedures, records of management review and internal audits) at least 3 weeks before the audit begins;
- To support the work of auditors;
- To submit realistic information necessary for certification, with particular attention to the already existing accredited certification status and/or participation in conformity assessment procedure;
  - not to lodge application for any given product to multiple notified bodies
  - notify the certification body about the planned and significant change in the quality system and/or organization.
- To inform TRI in writing if they want to transfer their certification to another accredited certification body or notified body, and:
  - the date until which TRI NB is responsible for the transferred products (up until the starting of validity of the newly issued EC certificate)

  - the last date when the already manufactured TRI approved products were distributed
  - to send the certificate issued by the new notified body following a successful transfer
  - (if applicable) to inform the regulatory authorities (eg the National Competent Authority) about the fact of the transfer
  - provide for the new notified body all necessary information (technical information, TRI audit reports including nonconformity reports, corrective actions, etc.)
  - In writing agrees with TRI about the period until which they can use already manufactured product labels, product brochures and advertisement materials bearing the CE 1008 marking. This period may not exceed 6 months.
  - to pay TRI's all costs related to the transfer
- To allow the auditors to look at the management system related documents, records and working processes, to make possible the visit at all the areas concerned and meeting all the competent persons;
- To confirm carrying out of certain certification phases by his/her signature;
- To settle the financial obligations independently of the audit results or decision on certification;
- To agree with the Head of Department OE about new deadlines if the contractual deadlines have not been kept;
- To give information regarding certification exclusively on the field covered taking into account the relevant requirements of Department OE;
- Not to misuse its certificate, do not publish false or misleading information to Department OE, do not generate that feeling as if its product or service would have already been certified;
- To give up promoting its certification in case of suspension or withdrawal of the certificate(s) and let the asked certificate(s) send back to Department OE;
- To record all the certified system related complaints and the actions taken in conjunction with them, to show these records on the wish of Department OE, or during audits.

4.3. The Certification Process of the Medical Department



5. Use of TÜV Rheinland LOGO

5.1. Right for use of TÜV Rheinland LOGO

After an successful certification porocess the client gain the right for using the TÜV Rheinlad LOGO in the following manner:

Valid contract of agency, valid certicate and keeping the contractual requirments are prerequisite for having right for usage of certification LOGO:

5.2. Meaning of TÜV Rheinland LOGO

The LOGO shows that the managment system is certified and the system fulfils the metioned standard requirments. Use of the LOGO is permitted only in connection of the certified managment system, scope and sites coverd by the certificate. The LOGO is owned by the CB. The client only gainin groght for use the LOGO until the managment system is certified by TRIC. The certificate holder is responsible to TRIC for LOGO use, ensuring that the LOGO use in advertising or other activities takes place within these conditions. The use of the mark is limited to legal persons and must not, be transferred to third parties.

5.3. Terms and scope of use of the TÜV Rheinland LOGO

The logo may be used directly by the applicant and solely in connection with the Company's name or company’s mark.
The logo may not be placed on the Customer's product, on the packaging of the product, in an inspection report or in any other place, so that a third party from the use of the logo has the wrong conclusion that the certified status relates to the Customer's product.

The applicant may not use the logo misleadingly in his ads. The applicant must ensure that you do not feel, that certification is an official review or approval.

The symbol (logo) can be used to keep the ratios at the desired size. The mark contains the logo of the certification body, the standard number of the certification. The Applicant is not entitled to change the logo. If the logo has to be changed for any reason, then the Applicant is required to contact the Certification Body in writing to make a change. The reason for the request must state the reason and purpose of the change. The certification body shall, on the basis of the legitimate request, meets the changes requested for the logo. The costs associated with changing the logo are borne by the Applicant.

5.4. Regular check of use of TÜV Rheinland LOGO

The usage of the LOGO regularliy checked during the surveillance audit and during market surveillance activity.

5.5. Unauthorised use of the LOGO

If the certification body get claims from the market resulted form misuse the certificateion LOGO, than it is the requirment of the user of the LOGO to release the CB from any liability aganst the third party. The user of the LOGO thake the responsibiltiy if the CB get claims from a third party resulted by a deceiving advertisement

5.6. Cancelling of the right of LOGO use.

The certificate holder loses the right to use the LOGO

- If certification is expired and the certificate holder has not applied for recertification of the Quality
- If certification is withdrawn in accordance with the certification requirements of TRIC.
- If the contract for Certification process is cancelled by either the certificate holder or Certification Body.

If the Certificate holder infriges the contract with TÜV Rhinland InterCert Kft or break the rules ectablished in this document, than TRIC keep the right to terminate the use of LOGO, and enforce a claim for compensation.

6 Relevant regulation

GTC General Terms and Conditions of TÜV Rheinland InterCert Kft.

TÜV Rheinland InterCert Kft.
H-1143 Budapest, Gizella út 51-57.
telefon +36-1-2888-454
telefax: +36-1-4611-199
e-mail: **tuv@hu.tuv.com**
www.tuv.hu