Terms of ISO 13485 Certification

1. General

Sertio Oy (hereinafter Sertio) is an impartial, independent Certification Body to assess the conformity of the client for the assessment (hereinafter client) quality management systems (QMS) according to the standard ISO 13485. Any organization (hereinafter Client) which requests audit of its management system to be certified according to ISO 13485 or EN ISO 13485 shall have a role in medical device / IVD medical device product realization life cycle. A role can be for example manufacturer, subcontractor, supplier, importer, authorized representative, sterilization service provider, specification developer or other role.

This document describes the assessment process followed by the client and Sertio and presents the terms that Sertio undertake over the ISO 13485 certification assessment.

Sertio is responsible to carry out the assessments according to the requirements of the relevant standards and other legal requirements. Sertio shall treat all the client's information strictly confidential.

Client has the responsibility of its QMS and device compliance. ISO 13485 certification does not release the client from compliance with any requirements, provisions of the relevant standards and legal requirements.

Client is responsible for maintaining the QMS continuously to achieve intended results and conformity with the requirements. Client is responsible to inform Sertio in writing of any plan for significant changes to the approved QMS.

Client shall allow representatives of Sertio to conduct regular QMS and possible short-notice or unannounced audits in their premises. Client shall also agree with their critical subcontractors and crucial suppliers that representatives of Sertio may be in contact with them and conduct audits, short-notice audits or unannounced audits in their premises.

Client shall inform Sertio of any serious incidents and field safety corrective actions that are also reported to competent authorities.

Client shall use the Sertio ISO 13485 Certification mark and Sertio name only as stipulated in section 6 of this document. Client must stop using Certification mark immediately if the certification becomes invalid.

2. Certification process

2.1 Application and Contract

Conformity assessment is applied for by filling out an application form provided by Sertio. The form contains information of the client and the scope of the certification.
The application must be submitted within three (3) months of acceptance of the quotation / offer. Otherwise, the quotation / offer expires and the client must request a new quotation / offer.

The application shall be reviewed at Sertio. Sertio shall inform the client of the approval or rejection of the application. .

Contract between the applicant and Sertio Oy is formed when the client has signed quotation and has submitted the signed application and accepts the terms:
- 502-Annex-1 General Terms of business
- C-004 Terms of ISO 13485 Certification

Validness of contract is starting from the date when application for ISO 13485 certification is signed by manufacturer and returned to Sertio Oy. Electronic signature / conventional signature are both valid ways of signing. Contract is valid until it is terminated by the customer.

The assignment shall begin within nine (9) months of signing the quotation. Otherwise, the quotation expires, and the process of applying for the conformity assessment starts from the beginning.

A Project leader shall be assigned to the assessment, who will be mainly responsible for the communication with the client. A Lead auditor shall be assigned to the assessment, who will be responsible for planning, conducting, and reporting the audits. A Decision maker shall also be assigned, who will be responsible for reviewing the documentation and making the certification decisions.

Other roles such as technical expert or interpreter can also be assigned to the assessment.

2.2 Stage 1 Initial audit

Appointed Lead auditor performs Stage 1 audit is prior to Stage 2 audit to evaluate readiness of client's QMS for Stage 2 audit. Stage 1 audit can be performed as off-site documentation review or on-site at client's premises especially when higher risk devices are concerned.

Lead auditor prepares Stage 1 audit report, which is communicated to the client including documented conclusions, fulfillment of objectives, readiness for Stage 2 audit and any identified areas of concern that could be classified as nonconformity during Stage 2 audit.

Based on the readiness for Stage 2 audit, Sertio verifies the suitable time for Stage 2 audit. The initial arrangements or plans for Stage 2 audit may need to be revised after Stage 1 audit. Stage 1 audit may need to be repeated, if there are significant changes that would affect the client's QMS. Results of Stage 1 may also lead to postponement or cancellation of Stage 2 audit.

2.3 Stage 2 Certification Audit

The Stage 2 audit of the management system is performed on the premise(s) of the client and, if necessary, on the premise(s) of critical subcontractors or crucial suppliers of the client.

Audit team, led by the Lead Auditor, shall evaluate the conformity of the client's QMS using ISO 13485 as audit criteria. The assessment is based on the review of quality documentation, interviews of personnel as well as evaluation of processes, premises and equipment to the extent that gives a general view of the client's activities as a whole.

As a result of the audit, an oral summary of findings will be presented to the client. Any detected nonconformities will be classified as major or minor. The client shall provide within the set time limit a proposal for the corrective actions for the nonconformities raised. Sertio shall evaluate the proposal for the planned corrective actions and decide whether additional actions are required. The auditee will always receive the audit report also in writing. Implementation of major nonconformities shall be verified within 6 months after last day of Stage 2 audit, otherwise the Stage 2 audit shall be conducted again.

If major nonconformities are detected during the initial audit, the Lead Auditor shall recommend certification only after corrective actions have been implemented and approved. In the case of minor nonconformities, only an approved proposal for the planned corrective actions to correct detected nonconformities is required.

2.4 Surveillance audits

A surveillance audit is an on-site audit conducted during the period of validity of the certificate issued to the client to ensure that the client's QMS continues to fulfil requirements of the relevant standard and is operating effectively. Surveillance audit can cover the entire QMS or only part of it.

Lead auditor will plan, conduct and report the surveillance audit results. In general, lead auditor can do the conclusions and decision regarding maintenance of client's certification. In case of major nonconformity or nonconformities are issued, competent Decision maker different from those carrying out the audit shall do the review of nonconformity or nonconformities and confirm that the certification activity is operating effectively.

The first surveillance audit shall be conducted within 12 months from the certification decision. Thereafter, surveillance audits are conducted at least once a calendar year. The timing of the surveillance audits will be agreed by the Project Leader with the client.

2.5 Recertification audits

A recertification audit is an on-site audit conducted when a certificate issued to a client is expiring. The recertification for the new certification period requires a recertification audit.

The certificate may be renewed, if the client's QMS still continues to fulfil the requirements of the relevant standard and is operating effectively. The recertification is applied by a separate application.

If major nonconformities are detected during the recertification audit, the Lead Auditor shall recommend certification only after corrective actions have been implemented and approved. In the case of minor nonconformities, only an approved proposal for the planned corrective actions to correct detected nonconformities is required.

If Sertio has not completed the recertification audit or is unable to verify the implementation of corrections and corrective actions for any major nonconformity prior to the expiry date of the certification, then recertification shall not be recommended, and the validity of the certification shall not be extended. Sertio can restore certification within 6 months provided that the outstanding recertification activities are completed, otherwise at least a stage 2 audit shall be conducted. The expiry date shall be based on prior certification cycle.

2.6 Special audits

2.6.1 Follow-up audit

If the audit resulted in several major nonconformities, follow-up audit may be performed to verify the effective implementation of corrective actions. Follow-up audit can be performed as short-notice or unannounced audit, if there are justifiable concerns about implementation of corrective actions, compliance with standard or regulatory requirements.

2.6.2 Short-notice audit

Short-notice audit can be performed to investigate issues that becomes known to Sertio. These issues can be investigation of complaints, response to notification of change or follow up on suspended client.
Examples of following issues include:
- new ownership,
- modification, extension, or new site regarding to manufacturing or design,
- new processes or modification of special processes (e.g. sterilization),
- changes in defined authority of the management representative that could impact QMS effectiveness, regulatory compliance or to assure safe and effective devices are released,

- new products or product categories,
- changes in standards or legal requirements,
- post market surveillance or vigilance.

None of these examples should automatically trigger a short-term audit. When justified and evaluated necessary, Sertio can perform short-notice audit also as unannounced.

2.6.3 Other special audits

In response to an application for extension of the scope of a certification already granted, the procedure for Notification of changes (2.7) shall be followed. Sertio shall determine whether a special audit is required before the extension may be granted. This may be conducted in conjunction with a surveillance audit. A decision will be issued as a result of the extension, and the certificate will be updated accordingly.

2.7 Notification of changes

Sertio is obligated to notify client without delay any changes to its requirements for certification. Sertio shall verify, that the client complies with the new requirements in agreed time.

The client is obligated to notify Sertio without delay any significant changes that may affect the capability of the QMS to continue to fulfill the standard or legal requirements. These include for example:

- the legal, commercial, organizational status or ownership,
- organization and management,
- contact address and sites,
- scope of operation under certification,
- major changes to the QMS and processes.

Sertio will assess the notification of change and supporting documentation issued by the client. If, during the course of the assessment, significant shortcomings in the extent or contents of the documentation provided by the client are observed, the client shall perform necessary actions and deliver the corrected and/or missing documents. If the change affects the certificate issued to the client, the certificate shall be updated.

Change notification signed by authorized person from client is included within the scope of previously signed, valid contract.

2.8 Transfer of certificate

Before performing a transfer of certificate, client shall submit to Sertio at least the following documentation:

- the current valid ISO 13485 certificate,
- latest ISO 13485 audit report,
- latest corrective actions for any nonconformities issued by current certification body.

Sertio shall review the documentation and determine whether the certification transfer is eligible. If it is not possible to do the certification transfer, the client shall be informed and approached as a new client. If the certification transfer is successful, the validity of to be issued certificate shall be the same as the previously issued certificate.

3. Certificate decision, issuing and validity of certificate

If the QMS are found to fulfil all the provisions of the relevant standard and regulatory requirements, Sertio will make a certification decision and prepare the ISO 13485 certificate. The certificate shall specify the holder, site(s), the standard, scope, issuing date and validity. The maximum validity period of a certificate is three (3) years.

4. Suspending, withdrawing, or limiting the scope of certification

The client can apply limitation the scope of certification or withdraw the certification at any time. The procedure for Notification of changes (2.7) shall be followed. A decision will be issued as a result of the limitation, and the certificate will be withdrawn or updated accordingly.

Sertio may suspend or withdraw the certificate, or limiting the scope of certification under the following conditions:

- the QMS or device(s) does not fulfil the provisions of the standard or legal requirements,
- client does not implement corrective actions for nonconformities within the agreed schedule,
- client violates the terms of conformity assessment,
- client does not allow the execution of audits,
- client does not provide all information necessary for the assessment,
- manufacture does not allow execution of subcontractor audits where necessary,
- fees from client are delayed,
- client goes under bankruptcy or is placed in liquidation,
- client goes out of business or terminates the production,
- confirmed fraudulent activity,
- repeated serious incidents without appropriate corrective actions,
- failure to comply with the notification of significant changes,
- misleading use of ISO 13485 Certification mark,
- other reasons which indicate that the QMS or the device(s) no longer meet the requirements of the standard or legal requirements.

Sertio will decide which procedure is applicable according to the severity of defect or cause. Sertio shall notify the client of the suspension, withdrawal or limitation of the certificate as well as the reasons for the decision and the possible time limits via formal hearing process.

5. Public information regarding certification

After the Certificate is issued or modified, information about the certification is supplied to the iafcertsearch.org -database. This information is publicly available and searchable in the database. This information includes: company name, company address and site addresses, certificate ID number, certified standard, scheme, IAF sector code, scope of certification, certificate issue date and expiry date, certification status, certification body name, accreditation body name and company ID number.

6. Appeals and complaints

If the client wants to appeal against the assessment procedure, the appeal must be submitted to Sertio within two weeks from the issue of the certification decision (e.g suspension, withdrawal or scope reduction). Sertio shall give the client a written answer within one month after receiving the appeal.

Appeals shall be sent as signed letter to Sertio postal address. In case of complaints or feedback, Complaint/Feedback -form at Sertio website shall be used.

Disputes, other than those over the assessment procedure and the assessment decision, will be decided by the District Court of Helsinki. Finnish law shall be applied, excluding its rules on choice of laws.

7. Use of subcontractors in conformity assessment

Sertio may use subcontracted auditors or technical experts. If Sertio uses a subcontractor in the assessment, Sertio shall ensure that the subcontractor complies with the relevant requirements of competence and policies set by Sertio. Subcontractors shall not further subcontract work to other organizations or personnel.

8. Use of ISO 13485 Certification mark and Sertio name

Use of ISO 13485 Certification mark is stipulated in Terms of Sertio ISO 13485 certification mark. Terms of ISO 13485 certification mark will be sent to client together with the Sertio ISO Certification mark, when the ISO 13485 certificate is issued.

The use of the name Sertio in advertising and publication of the confidential documents even partially is permitted only with prior written authorization from Sertio.

9. Access to Accreditation body and regulatory authority

Client shall accept and enable accreditation body or regulatory authority to access its facilities for conducting a witness audit for Sertio auditor(s). Client shall accept accreditation body or regulatory authority to inspect client's documentation provided to Sertio, audit documentation prepared by Sertio or any documentation reviewed during the witness audit.

10. Other terms

The General Terms of Business of Sertio shall be applied in all other respects. If these terms are controversial, the order of application is: 1) Mandatory legislation and regulatory requirements, 2) these terms and 3) General Contract Terms of Sertio.

The obligation of confidentiality applies to all auditors and assessors used by Sertio.
Sertio does not perform conformity assessment for companies fully or partially owned by Sertio or its affiliates.

The assessment is conducted in Finnish or English.

Conformity assessment service is subject to availability.

11. Contact information

Certification Body

Sertio Oy
Biokatu 10
FI33520 Tampere FINLAND
info@sertio.fi