General Terms and Conditions for Medical Devices Certification

Introduction

This document defines conditions, rights and duties, as well as the operating processes for the assessment and certification of medical devices according to 93/42/EEC directive (hereinafter MDD).

It also contains information on certificate maintenance, withdrawal or cancellation as well as handling of complaints, appeals and disputes.

The terms and conditions presented in this document govern the relation between HTCert and its clients and are applicable to all applicants unless exceptions are specifically agreed upon between the parties. In any case, exceptions cannot in any way concern the conformity assessment procedures according to which HTCert is required to operate.

If HTCert, or the client, is unable to fulfill the obligations because of force majeure, an extension period for the fulfilment can be agreed upon between the parties. Force majeure circumstances can be due to weather, strikes, catastrophes of nature, fire, etc.

General Principles of operation

Absence of discrimination

The certification services are available to all customers and are applied without any discrimination of commercial or financial nature or due to membership to any association.

Independence, Impartiality

HTCert ensures objectivity of its certification activities and commits all staff and external personnel to impartiality through signing appropriate written statement.

An Impartiality Committee consisting of representatives from all interested parties is established to ensure compliance with independence and impartiality principles.

HTCert does not offer or provide any consultancy services, does not carry out internal audits to its clients and is not involved in the development, production, installation, sale or maintenance of products or in establishing, implementing or maintaining management systems.

All decisions on granting, refusing, maintaining of certification, expanding or reducing the scope of certification, renewing, suspending or restoring, or withdrawing of certification are based on objective proofs of conformity or nonconformity and are made by personnel not involved in the assessment activities.

Confidentiality

All documents on the conformity assessment activity are considered confidential, except what is required by legislation as specifically regards the Competent Authority and other Notified Bodies. The accreditation body of HTCert has access in all documentation regarding the certification activities. In any other case that availability of information to a third party is legally required, HTCert informs the client, unless prohibited by law.

Access and consultation of certification documents are reserved to personnel involved in the certification process.

All staff and external personnel of HTCert are required to commit themselves to confidentiality through signing appropriate written statement.

Legal and regulatory framework

All assessment and certification activities are performed in accordance to:

- ISO/IEC 17065:2012 “Conformity assessment - Requirements for bodies providing certification of products, processes and services”
- ISO/IEC 17021-1:2015 "Conformity assessment - Requirements for bodies providing audit and certification of management systems"
- Commission Implementing Regulation (EU) No 920/2013
- Council Directive 93/42/EEC concerning medical devices
- Commission Recommendation 2013/473/EU on the audits and assessments performed by notified bodies in the field of medical devices

Certification process

General

The certification processes followed by HTCert according to the various options of the MDD, are:

- Full Quality System Certification per Annex II of the MDD;
- Production Quality System Certification per Annex V of the MDD;

HTCert is responsible for issuing, modification, suspension and withdrawal of certificates and all other documents issued as part of the certification process. All these documents remain property of HTCert.

Greek and English are the only acceptable languages for communication with HTCert.

The client authorizes HTCert to have access to all premises, buildings, areas and information necessary to perform the assessment and is committed to allow the possible presence of auditors in training, observers

appointed by HTCert for internal evaluation purposes, assessors of HTCert's Accreditation Body.

Process Steps

The major steps of the certification process are:

- Starting
  - request for certification
  - quotation
  - application
  - planning the assessment program
- Assessment
  - documentation review
  - on-site audits
  - non-conformities follow-up
- Certification decision
  - reviewing the assessment results
  - decision on granting certification
  - settlement of financial obligations
  - granting of certification
- Maintaining Certification
  - surveillance activities
  - notification of changes
  - unannounced audits
  - settlement of financial obligations
- Recertification

Starting the certification process

The applicant submits its request for the certification, specifying the device(s) intended to be certified and the option chosen for the conformity assessment.

Upon receipt of the request, HTCert conducts a review and, where it has the competence and capability to perform all the activities required, provides a quotation including a time schedule for the completion of the process. In the event of acceptance, a contract describing the rights and obligations of HTCert and the client is signed by both parties.

Unless otherwise stipulated unambiguously in the contract, schedules, deadlines, etc. specified by HTCert are always estimates. HTCert cannot be held liable in the event of delays, if eventually the project proves to be more complicated or more time-consuming than anticipated.

The certification process includes the assessment of the technical documentation for the product(s) and the assessment of the quality system of the client. For the initiation of the process, the client must submit the following documents:

- Management System documentation
- Technical File(s)
- List of production units

Transfer from another notified body

If the application concerns transfer of certification issued by another Notified Body, the applicant shall inform HTCert in detail and provide authorization for communication with the other notified body. Prerequisites for this process are the following:

- The current certificate is issued by a Notified Body whose notification is not expired, suspended or withdrawn
- The current certificate is valid and has at least six months until the expiration date
- The certification scope and the manufacturing sites remain identical

Initial assessment

HTCert examines and assesses the technical documentation of the product(s) and the Quality System implemented to determine if the provisions of the MDD are satisfied. If necessary, HTCert may also require to have some tests carried out as part of the assessment.

The assignment of appropriately qualified and authorized personnel for conducting the audits and the documentation assessment is the sole responsibility of HTCert. If part of the evaluation is to be conducted by external expert(s), HTCert informs the client in advance and, upon request, submits a short CV of the experts to the client. The client has the right to object this assignment in case conflicts of interest can be documented. HTCert reserves the right to terminate the contract if, as a result, it no longer has the capability to perform all the activities required.

The first part of the assessment is the review of the Technical File(s) and the client's Management System Documentation. The Technical File(s) should contain all necessary documentation to demonstrate the compliance of the device(s) with the requirements of the MDD and be structured according to Guidance for Technical Documentation of Medical Devices.

The initial assessment always includes an on-site audit of the client's quality management system and it may also include audit on the premises of the client's suppliers and subcontractors. The audit is conducted in such a way to examine all requirements of MDD and products to be certified.

The initial certification audit is conducted in two stages.

Stage 1 consists of a review of the client's management system documented information and either an on-site visit or a remote audit to obtain necessary information and assess the readiness for stage 2.

Stage 2 consists of an on-site audit of the client's quality management system and it may also include audit on the premises of client's subcontractors. The assessment team evaluates the effectiveness of all functional areas

and management system processes, based upon observations, inspections, interviews, review of pertinent records, and other assessment techniques.

No more than 6 months may pass between the end of stage 1 and the beginning of stage 2. If it is not possible to comply with this six month deadline, a repetition of stage 1 is necessary. The client will receive a separate offer for this work.

The assessment team draws up an audit report summarizing the results of the audit, including expression of conformity or non-conformity of the client's management system with the requirements and the recommendation to issue or non-issue of a certificate.

Audit findings are classified as

- Major Nonconformities, when there is a significant breakdown of the system, as indicated by the specific failure or the frequency of occurrence
- Minor Nonconformities, regarding issues unlikely to have a significant impact
- Observations when they indicate a weakness but there is no requirement or objective evidence to cite

For each nonconformity identified, the client has to submit appropriate corrective actions. Additional audits may be required to verify the effectiveness and implementation of the actions taken.

The initial certification audit must start within one year after signing the contract, otherwise the contract is considered terminated.

Certification decision

Upon satisfactory completion of all the assessment activities, a final review of all the information gathered is conducted by personnel not involved in the assessment.

On the basis of this assessment HTCert decides to grant or not certification and informs the applicant of its decision.

If the technical documentation and the Quality System comply with the requirements, certification is granted. The certificate has a validity of 5 years from the date of issue.

If, on the other hand, the result of the review is negative, HTCert informs the client on the findings and asks for appropriate corrective actions to be submitted within a specified timeframe.

If the certification for a particular scope is refused three consecutive times or if the client does not submit the required data within the agreed timeframe, the contract will be considered invalid. HTCert will communicate this to the competent Authority according to the requirements of the MDD.

The applicant may lodge a new application. A new assessment and certification process will start.

Maintaining certification

During the validity period of the certification, HTCert performs surveillance activities to verify the uninterrupted conformity of the client to the requirements and assess any modifications to the processes or products.

To this purpose, HTCert periodically carries out surveillance audits, at least once a year, to ascertain that the client maintains and applies the approved Quality System. In addition to on-site auditing and assessment of technical documentation, surveillance activities may also include sampling and testing of devices.

The client ensures that HTCert has access to all necessary information and the requisite facilities to perform the audit tasks. The client commits to provide to HTCert, in a timely manner upon request, accurate and complete information concerning all processes and records related to the certification, as well as all data relating to complaints and their corrective actions.

In addition to the regular audit cycle, unannounced audits, without prior notification, are performed in conformity with the Commission Recommendation 2013/473/EU. The audits may be conducted at the client's premises or at the premises of the client's major subcontractors or suppliers, especially when they undertake important part of the manufacturing process. In general, unannounced audits have a duration of at least one day, are carried out by at least two auditors and take place at least once per 3 year. The frequency is determined on the basis of the following criteria:

- If the devices bear a high risk
- If the devices are often non-compliant
- Specific reasons for suspicion of nonconformities of the devices or manufacturer

In addition to the audits referred above, short notice or unannounced special audits may also be conducted in order to investigate complaints, in response to changes, as follow up on suspended clients, as well as in any other case considered necessary by HTCert.

If the client refuses to allow a surveillance audit, either scheduled or without prior notice, to take place, the certification may be suspended or withdrawn. Moreover, HTCert reserves the right to terminate the contract in any refusal to access the premises of a critical subcontractor or a crucial supplier at any time.

For each nonconformity identified during surveillance audits, the client has to submit appropriate corrective actions. Additional audits may be required to verify the effectiveness and implementation of the actions taken. Failure to address the non-conformities leads to suspension or withdrawal of the certification.

Throughout the validity period of the certificate the client is obliged to notify HTCert of any plan for substantial changes to the quality system or the product-range

covered. HTCert assesses the significance of changes, decides whether an additional assessment is required and notifies the client of its decision.

If the client wishes to expand the scope of certification, an application specifying the devices to be certified and the option chosen for the conformity assessment, must be submitted. HTCert reviews the application, evaluates the next steps of the process (i.e. if it has the competence and capability to perform the activities required, if on-site audit is to be performed or not, …) and provides a quotation to the client.

Recertification

Six months before expiry of the certificates issued, HTCert provides a quotation for renewal of the certification to the client. Renewal activities are planned and carried out upon acceptance of the quotation.

If the client does not accept the quotation at least three months before the certification expiry date, the contract is considered as terminated on the certificate expiry date.

If recertification activities are completed prior to the expiry date of the existing certification, a new certificate is issued having a validity of 5 years from the expiry date of the existing certification.

If recertification activities are completed within 6 months after the expiry date of the existing certification, a new certificate is issued having a validity period starting on the recertification decision and ending 5 years from the expiry date of the existing certification.

If recertification activities are not completed within 6 months after the expiry date of the existing certification, a new assessment cycle has to be initiated.

Use of certification, certificate and CE marking

Use of certification, certificate and CE marking includes all statements in written, visual or oral ways about the fact of the certification; use of original certificates and copies of them; any use of HTCert certification mark; affixing of CE marking followed by the identification number of HTCert.

The client is obliged to comply with the provisions of “Rules for the use of Certification, Certificate and Certification Mark”.

Suspension, Withdrawal, Limitation of Certification

General

Certification may be suspended, withdrawn or reduced upon decision of HTCert.

Information related to granted, suspended and withdrawn certificates is publicly accessible and is not considered confidential.

Suspension

Reasons that may lead to suspension of granted certificates include, but are not limited to:

- non-fulfilment of the contractual obligations by the client
- provision of incomplete or incorrect information or withholding of information on changes
- refusal to surveillance audit, either on the client’s premises or at the premises of a critical subcontractor or a crucial supplier
- failure to address non-conformities
- misleading or unauthorized use of certificate or certification mark

If certification is suspended, HTCert communicates to the client the actions needed to end suspension and restore certification and the timeframe for their completion. Suspension is also communicated to the competent Authority and to the other Notified Bodies, as required by the MDD.

During the suspension period, which cannot last longer than 6 months, the client loses its right to use the CE marking and the certificate and must discontinue its use of all advertising matter that contains any reference thereto.

If during the suspension period the client implements appropriate actions and the issues that lead to suspension are resolved, the suspension is cancelled and the certification is restored. Otherwise, the certification will be withdrawn or, its scope will be reduced.

Withdrawal

Reasons that can lead to withdrawal include, but are not limited to:

- expiry of the suspension period without resolving the issues that lead to suspension
- use of certificate or certification mark during the suspension period
- non-fulfilment of the client’s financial obligations
- bankruptcy of the client
- voluntary request of the client for termination of the contract

The withdrawal of the certification is communicated in writing to the client, and also to the competent Authority and to the other Notified Bodies, as required by the MDD.

The client is required to immediately cease the use of the CE marking, the certificate and the certification mark and to discontinue its use of all advertising matter that contains any reference thereto.

If the withdrawal is due to issues which can result to devices presenting an unacceptable risk to health and safety, HTCert will require the client to withdraw or recall all relevant devices and properly inform the competent Authority and the other Notified Bodies.

Reducing the scope of certification

The certification field can be reduced if, regarding specific activity of the client, the requirements arising from certification aren't met or upon request by the client.
To this purpose, the old certificate is withdrawn and a new certificate is issued having the same expiry date.

Obligations of Clients

The clients shall

- comply with all the contractual terms
- comply with the obligations arising from the quality system approved
- maintain the compliance of the product(s) with the essential requirements of the MDD
- fulfil their obligations themselves, regardless of any partial or total outsourcing of the production via subcontractors or suppliers
- have at their disposal the full technical documentation and integrate the quality system of critical subcontractors and of crucial suppliers with their quality system - referring to the technical documentation of a subcontractor or supplier does not fulfil their obligation
- inform HTCert accurately, honestly, timely and in detail on all data relating to the company and on any plan for substantial changes to the quality system or the product-range covered
- inform HTCert upon changes regarding authorized representative
- inform HTCert about all periods during which the certified devices are not manufactured
- ensure that HTCert will have unrestricted access to all critical subcontractors and crucial suppliers and thus to all sites where the devices or crucial components are produced, regardless of the length of the contractual chain between the manufacturer and the subcontractor or supplier
- supply HTCert with vigilance reports & FSCA reports related to its certified products at the same time as the client informs the competent authority according to current legislation
- accept that HTCert can take samples from the market, if necessary with support by the competent authorities, and perform testing in independent laboratories, and, in such a case, clients will bear all costs for testing
- regularly inform HTCert on updated data regarding clinical evaluation, post-market surveillance, post-market clinical follow-up, complaints related to the certified products by supplying relevant reports
- acknowledge that all documents which are provided or made available by HTCert remain the property of HTCert, and that they must not be available to third parties or be used for purposes other than those agreed with HTCert. The obligation for strict confidentiality about any information revealed within the terms of cooperation applies also after termination of the contract.

Financial Terms and Conditions

General

The fees for the certification process are estimated by HTCert on the basis of the information provided by the client and are calculated according to the certification price list.

Fees for follow up visits, reviewing client's proposed corrective actions, repetition of actions on client's responsibility, as well as fees for unannounced or special audits are additional to the initially calculated and charged on a case basis.

Canceling or postponing confirmed audits without timely notice of HTCert will result in additional charges for the client.

Expenses relating to unannounced audit that could not be carried on in consequence to denial of the client or its subcontractor/supplier or due to a stopped production for which HTCert was not timely informed will be charged to the client.

Costs for purchasing the device and for tests carried out on it, if necessary according to the Commission Recommendation 2013/473/EU, are additional and are not included in the offer.

The client is required to correctly inform HTCert on all issues relating to the certification process (number of employees, number of locations, etc.) and to update timely in case of any changes. HTCert has the right to review the fees agreed based on the new data.

The client shall cover all costs related to the certification process as defined in the quotation and any additional fees as described above. Full payment of all charges and fees of the initial assessment is a prerequisite for granting certification and payment of all fees for surveillance activities is a prerequisite for certification maintenance.

HTCert is entitled to suspend or withdraw a certificate if client violates its financial obligations.

Payment

The client shall pay each valid invoice submitted to it by HTCert within thirty (30) days of the date of the invoice.

If the client fails to pay on the due date, HTCert sends a warning letter of impending withdrawal of certification. If, after a reminder and a reasonable extension, settlement of financial obligations is not made, HTCert is entitled to conduct measures like judicial collection proceedings, the withdrawal of the certificate and the cancellation of the contract.

In case of delayed payment, HTCert has the right to charge interest at the legal rate in addition to the amount due, calculated from the due date of the invoice to the date of receipt of the amount.

If the client cancels the contract, the client shall pay all the outstanding invoices.

Complaints and Appeals

The client can lodge a complaint regarding HTCert's certification services. HTcert will handle the complaint according to its procedures and will properly inform the complainant on the outcome within twenty (20) working days of receipt of the complaint. Where the client does not agree to the result of the investigation of the complaint, the case may be lodged as an appeal.

The client can lodge an appeal against HTCert's decisions relating to the results of the conformity assessment process, including refusing, reducing the scope of certification, suspending or withdrawing of certification within twenty (20) working days from the notification of the decision. HTCert will handle the appeal according to its procedures and will inform the client within thirty (30) working days of receipt of the appeal. If the outcome of the appeal is not accepted by the applicant, the dispute arising from it may be submitted to court.

In the event that the appeal is proved unjustified, HTCert has the right to charge the complainant with all costs regarding the examination of the appeal, including costs of technical experts involved.

HTCert's procedures for handling complaints and/or appeals are available upon request.

In the event of a dispute between the client and HTCert regarding the classification of device(s) intended to be certified, the matter will be brought before the Cyprus Competent Authority for final decision.

Submission of complaints and/or appeals does not result in any discriminatory actions against the client.

Liability

HTCert shall only be liable for damages caused by breaches of duty against the contract if intent or gross negligence can be laid to its charge. The liability of HTCert is conditional on the client lodging his/her complaint in writing as soon as the client becomes or should have become aware of errors and deficiencies in the services provided by HTCert.

HTCert shall have no liability for delays or loss owing to the weather, strikes, catastrophes of nature, fire or other force majeure circumstances.

HTCert shall have no liability for any indirect or consequential loss or damage, costs or expenses to the extent that loss arises out of the provision of false, misleading, or incomplete documentation or information by the client.

HTCert shall have no liability any deficiency resulting from services provided by any other party and having a bearing on the certification.

HTCert cannot be held liable for any direct or indirect loss suffered by the client as a result of HTCert's ceasing its operation as an accredited certification body or due to changes in regulatory requirements.

The total liability of HTCert to the client in respect of all losses arising under or in connection with the contract, whether in contract, tort (including negligence), breach of statutory duty, or otherwise, will not exceed an amount equal to the annual fees payable by the client under the contract in relation to the services giving rise to the liability. These terms of HTCert's liability will survive termination of the contract.

The client is liable according to the general legal requirements.

Disputes

Any disagreement, dispute or demand that occurs by, or is related to the certification agreement is governed by the laws of the Republic of Cyprus and shall fall under the jurisdiction of the Courts of the Republic of Cyprus.