



# Policy for Conformity Assessment, Granting, Suspension, Withdrawal and Reduction of the scope of Certification

## Introduction

This document describes the policy and procedures established for the certification activities. It outlines how HTCert plans and conducts assessments and is applicable to all applicant and certified clients.

Assessment of the conformity of a client is performed using a range of assessment techniques, which include, but is not limited to: document review, on-site audits and follow-up activities as well as post-certification monitoring. The purpose of the assessment is to determine whether the client has established and effectively implements a quality system that meets the requirements of the legislation or standards upon which he is seeking certification and as to whether product requirements have been fulfilled where applicable.

HTCert employs Project Managers who are responsible for the management of the assessment, certification, surveillance and recertification processes. They may act as lead assessors responsible for leading the assessment team or appoint suitably competent assessment teams, ensuring in each case that the appropriate resources/personnel are utilized for individual tasks of the assessment.

Each applicant and certified client provides information to HTCert on its activities, organization and staff. All information obtained before, during and after assessment, will be treated as strictly confidential by HTCert except when the disclosure of information is required by law.

The certification services are available to all interested parties with the exception of other certification bodies and are applied without any discrimination of commercial or financial nature or due to membership to any association.

## Assessment and Certification activities

### 1. Application and Contracting

A formal application signed by the client's legal representative and accompanied by all the information required has to be submitted. Applications submitted without the required documentation will not be accepted.

Each applicant is assigned to a Project Manager who conducts a review of the application and supplementary information to

- confirm the scope of certification sought
- ensure that HTCert has the competence and capability to perform all the activities required
- ensure the sufficiency of the provided data

A contract, having clear terms and conditions and describing the rights and obligations of HTCert and the client is signed by both parties.

## 2. Planning the assessment

Each client is unique; therefore, an individualized assessment program is drawn up in each case.

The Project Manager determines the overall program for the full certification cycle and is responsible for the selection and assignment of appropriately qualified and authorized personnel for conducting the audits and the documentation assessment. At this stage, the objectives, criteria and scope of the audit for each audit identified in the audit program are defined and a sampling plan for the assessment of technical documentation of medical devices is established where applicable.

The plan is subject to review and potential revision following the completion of each step of the assessment program and any extension to scope. The plan will be communicated to the client upon creation and subsequent revision.

## 3. Initial assessment

The first part of the assessment is the review of the client's management system documentation.

In the case of medical devices certification, the review includes also the technical documentation of the products as well as the documentation relating to pre-clinical and clinical aspects.

At this stage sufficient understanding of the client's management system and site operations is obtained and the appropriateness of the assessment program developed is confirmed or any required modification is made.

The initial assessment always includes an on-site audit of the client's quality management system and according to the audit program established, it may also include audits on the premises of the client's suppliers and subcontractors.

Audit findings are appropriately and consistently classified and communicated to the client. Nonconformities are classified as

- major, when there is a significant breakdown of the system, as indicated by the specific failure or the frequency of occurrence
- minor, regarding issues unlikely to have a significant impact

Findings that indicate a weakness but there is no requirement or objective evidence to cite are classified as Observations.

For each nonconformity identified, the client has to submit evidence to demonstrate the root cause investigation, the implementation of suitable corrective actions and any actions to prevent recurrence. Additional audits may be required to verify the effectiveness and implementation of the actions taken.

A detailed report providing a discernible audit trail, documenting the outcome of the assessment and drawing clear conclusions on the verification of the client's conformity to the requirements is provided.

## 4. Certification decision

Upon satisfactory completion of all of the identified assessment activities, the Project Manager reviews all of the information gathered and submits his recommendation on certification for independent decision.

An independent decision maker decides, based on the assessment documentation and additional information available, whether the requirements are fulfilled and certification can be granted.

If all the required criteria are satisfactorily met a certificate is issued. Certification is granted for

- a period of 5 years from the date of granting regarding certificates issued under Directive 93/42/EEC
- a period of 3 years from the date of granting regarding ISO certificates

If the final decision is not to grant certification, the client is properly informed.

## 5. Maintaining certification

The continuous and uninterrupted conformity of the client to the requirements is a prerequisite for the maintenance of the certification.

HTCert performs surveillance activities that include on-site auditing of the certified client's management system and, for clients certified according to directive 93/42/EEC, sampling and testing of devices and technical documentations.

Surveillance audits of the client are conducted on at least an annual basis and may be scheduled or non-scheduled. Increasing the frequency of surveillance audits may occur in various circumstances, like vigilance cases, findings of previous audits, or information indicating inadequate implementation of the approved quality system.

Following submission of appropriate correction and corrective actions for all major nonconformities and plan for correction and corrective action for any minor nonconformities raised at the surveillance visit, the Project Manager will confirm on-going maintenance of certification.

For clients certified according to directive 93/42/EEC, unannounced audits, without prior notification, are performed at a minimum of once per three years, either 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 addition to the surveillance audits referred above, short notice or unannounced audits may be conducted to certified clients. Such audits can 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.

## 6. Changes and modifications

Throughout the validity period of the certificate the client is obliged to notify HTCert of any modification to the applied quality system, or devices manufactured.

Project Manager assesses the significance of changes, decides whether an additional assessment is required and notifies the client of its decision. If a supplementary assessment/audit is required, a report containing the justified conclusions of the assessment/audit is provided.

In response to an application for expanding the scope of a certification already granted, Project Manager reviews the application and determines any assessment activities necessary to decide whether or not the extension may be granted. The client is properly informed.

## 7. Recertification

Reassessment involves the same methods and principles as the initial assessment.

A comprehensive re-examination of the client's management system, and regarding re-certification of medical devices a re-assessment of the technical documentation and clinical data has to be conducted.

The client has to submit correction and corrective actions for any major nonconformity and a suitable plan for correction and corrective action for any minor nonconformities in due time to enable for timely renewal before the certificate expiry date.

Upon completion of the reassessment activities, the Project Manager reviews all of the information gathered and submits his recommendation on renewal of certification for independent decision.

An independent decision maker decides, based on the reassessment documentation, whether the requirements are fulfilled and certification can be renewed.

## 8. Use of certificates and certification marks

Use of certificates and certification marks is explicitly described in "Rules for the use of Certification, Certificate and Certification Mark".

HTCert will take any appropriate action, as for example requests for correction and corrective action, suspension, withdrawal of certification, publication of the transgression and, if necessary, legal action, to deal with incorrect references to certification status or misleading use of certification documents, marks or audit reports.

## 9. Suspending, withdrawing or reducing the scope of certification

HTCert has the right to suspend, restrict or withdraw certificates issued if the client is not in compliance with the certification requirements or upon request by the client.

Reasons that can lead to suspension or withdrawal may arise as a result of an audit, or on received information. Examples of issues that may lead to suspension or withdrawal can be: improper use of certificates and certification marks, bankruptcy of the client, seriously failure to meet certification requirements, denial of the client to accept surveillance audit, voluntary request of a suspension, etc.

If certification is suspended, HTCert communicates to the client the actions needed to end suspension and restore certification and the timeframe for their completion. Upon resolving the issue that has resulted in the suspension, HTCert restores the suspended certification. Failure to resolve the issues that have resulted in the suspension results in withdrawal or reduction of the scope of certification.

The certification field can be reduced if found through the surveillance process that, regarding specific activity of the client, the requirements arising from certification aren't met or upon request by the client.

Upon suspension, withdrawal, or termination of certification, the client has to discontinue its use of all advertising matter that contains any reference thereto and take any other measure as required by the contractual agreement and the General Terms and Conditions of HTCert.