General Terms and Conditions for Certification under MDR

1. Introduction

This document defines conditions, rights and duties, as well as the operating processes for the assessment and certification of medical devices according to Regulation (EU) 2017/745 (hereinafter MDR). The present terms and conditions outline also the conditions and processes for the surveillance of legacy devices certified under Directive 93/42/EEC according to Article 120 (3e) MDR. It further provides information on the issuance of a Notified Body opinion for drug-device combination products in accordance with MDR Article 117. Additionally, it provides 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.

Contracts are concluded directly between HTCert and the "Client", which refers to the entity requesting the services of the Notified Body and may be the manufacturer as defined in Article 2(30) of the MDR, the producer of systems or procedure packs as per Article 22(3) of the MDR, or the Market Authorization Holder for purposes of obtaining opinions under Article 117 of the MDR.

HTCert has the right to decide on the issuing, denial of issuing, maintaining, withdrawing, suspending and restricting of the certification based on available objective evidence.

Prerequisites for granting and maintenance of certification are:

- the seamless performance of all assessment activities as decided and planned by HTCert, including scheduled documentation assessments and onsite audits both at the manufacturer's site and other sites involved (e.g. the manufacturer's critical suppliers and subcontractors) and unannounced and short-notice audits
- the positive outcome of the aforementioned assessment activities carried out by HTCert
- payment of the amounts due to HTCert within the specified deadlines.

If HTCert, or the client, is unable to fulfil 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.

2. General principles of operation

2.1 Absence of discrimination

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

2.2 Independence, Impartiality

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

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.

2.3 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, and HTCert's Accreditation Body.

Information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates is not confidential. It has to be reported to EUDAMED and will be accessible to the public.

HTCert allows the competent authorities and the accreditation body of HTCert to have access in all relevant documents of the client within the scope of their monitoring obligations. The consent of the client to this is taken for granted by accepting the terms of this document. In any other case where 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 for personnel involved in the certification process.

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

2.4 Legal and regulatory framework

All assessment and certification activities are performed in accordance with:

- REGULATION (EU) 2017/745 on medical devices (MDR)
- Delegated and implementing acts within the framework of the MDR
- MDCG endorsed documents and other guidance
- ISO/IEC 17021-1:2015 "Conformity assessment - Requirements for bodies providing audit and certification of management systems"

Moreover, for the assessment and certification activities, HTCert uses Common Specifications and harmonised standards, as well as other standards of European or international consensus.

2.5 Reporting obligations

HTCert is required by REGULATION (EU) 2017/745 on medical devices (MDR) to report on:

- all issued and amended certificates
- all extensions and reductions of certificates' scope
- all suspended and reinstated certificates
- all withdrawn certificates
- all declined certifications
- Summary of Safety and Clinical Performance (SSCP)
- Periodic Safety Update Reports (PSUR)

2.6 HTCert notification

Information about HTCert notification status is available at the Nando website

3. Certification process

3.1 General

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

- Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation per Annex IX of the Regulation
- Conformity Assessment based on Product Conformity Verification per Annex XI (Part A) of the Regulation
- Issuance of Notified Body Opinion (NBOp) pursuant to Article 117 of the Regulation

HTCert is responsible for the 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. This means that

- QMS and Technical Documentation have to be submitted either in Greek or in English
- all communications regarding the project implementation will be in one of the above languages,
- for audits in facilities where other languages are used interpreter(s) will be required, resulting in additional assessment time and costs

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 Designating Authority and HTCert's Accreditation Body.

3.2 Process Steps

The major steps of the certification process are:

- Starting
  - request for certification
  - quotation
  - application
  - planning the assessment program
- Assessment
  - technical documentation assessment
  - quality management system audit
  - corrective actions
- 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

3.3 Starting the certification process

The applicant submits via the HTCert website https://htcert.com 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, after a preliminary verification of the qualification and classification presented by the manufacturer, provides a quotation for the completion of the process provided it has the competence and capability to perform all the activities required

In the event of acceptance, the manufacturer submits a formal, legally signed, application. The application and accompanying documentation to be submitted should include the following:

- details of the legal manufacturer, including legal and trade name, address of its registered place of business and any additional manufacturing site covered by the quality management system

- details of the authorized representative, including name and registered place of business (where applicable)
- details of any subcontractors
- all relevant information on the device or group of devices covered by the quality management system including name, classification and rationale, accessories, description, intended use and market history (if available)
- a draft of an EU declaration of conformity in accordance with Article 19 and Annex IV of the MDR for the device model covered by the conformity assessment procedure
- a declaration that the same application has not been submitted to any other notified body, or information about any previous Applications for the same conformity assessment that have been rejected by another notified body or withdrawn by the applicant before the final decision of such other notified body
- the documentation on the manufacturer's quality management system
- a description of the procedures in place to fulfil the obligations arising from the quality management system and required under the MDR and the undertaking by the manufacturer to apply those procedures
- a description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures.
- the documentation on the manufacturer's post-market surveillance system (PMS) and, where applicable, on the PMCF plan
- a description of the procedures in place to ensure that the manufacturer will meet any vigilance requirements
- a description of the procedures in place to keep up to date the PMS, the PMCF plan and the procedures on vigilance, as well as the undertaking by the manufacturer to apply those procedures
- documentation on the clinical evaluation plan and the description of the procedures in place to keep the plan up to date, taking into account the state of the art
- for all devices included in the requested scope, the complete technical documentation in line with HTCert's Technical Documentation Submission Guidance.

Specifically for legacy devices according to Article 120 (3e) MDR:
Notwithstanding the requirements described above, the manufacturer may, instead of providing the complete technical documentation submit

- for each device included in the requested scope, the sections of the technical documentation that cover
  - device description and specifications
  - all related sites of the manufacturer, the critical subcontractors and crucial suppliers
- a declaration that the technical documentations in line with HTCert's Technical Documentation Submission Guidance are at a stage of preparation
- a time schedule for their submission, to be agreed with HTCert

The following deadlines are set for the submission of the legacy devices' technical documentation:

- 31 December 2025 for devices in class III and IIb implantable
- 31 December 2026 for devices in class IIb non-implantable, IIa and Is/Im/Ir

After the submission of all aforementioned documents, HTCert carries out a thorough review which includes the following aspects:

- that the application is complete with respect to the requirements of the chosen conformity assessment procedure
- the qualification and classification of the devices included in the scope. In case of a disagreement between the manufacturer and HTCert about the classification the matter will be referred for a decision to the competent authority of the member state in which the manufacturer (or the authorized representative) has its registered place of business
- that the conformity assessment procedures chosen by the client are applicable
- that HTCert has the competence and that there are sufficient and suitable resources
- and, as regards the technical documentation,
  - that the technical documentation of the devices is complete and in line with HTCert Technical Documentation Submission Guidance

  or,
  - accepts the time schedule proposed by the manufacturer, if applicable.

All required documents must be submitted within 6 months after submission of the application. An additional period of 3 months maximum may be granted by HTCert after justified request of the manufacturer. During the review, clarifications and additional information may be requested. These must be answered within 30 days at the maximum. If the documents are not submitted within the time limits specified above, HTCert reserves the right to reject the application.

Specifically for legacy devices according to Article 120 (3e) MDR, the client is required to submit the full technical documentation of the devices as per the time schedule agreed. HTCert reserves the right to cancel the project if the technical documentation is not submitted within the deadlines established.

Acceptance of the application depends on a positive outcome of the review carried out by HTCert. In the

absence of a response from the applicant or after a negative outcome of the review the application is rejected.

If the application is rejected, the applicant will be informed in detail and the rejection will be reported to EUDAMED.

Likewise, HTCert will report to EUDAMED if the manufacturer decides to withdraw its application.

Upon acceptance of the application HTCert proceeds to the signing of the binding contract and the detailed scheduling of the assessment. This schedule includes the appointment of the assessment team, the technical documentation assessment and the QMS audit. The client is informed on the methods and the timing of the activities that will be carried out, the names of the assessment group and any specific requests to be agreed. 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.

HTCert does not guarantee positive assessment results and granting of certificates.

3.4 Assessment

HTCert examines and assesses the technical documentation of the product(s) and the Quality System implemented to determine if the provisions of the MDR are satisfied. If necessary, HTCert may also require having 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. Prior to the assessment, HTCert informs the client on the individuals appointed. The client has the right to object this assignment in case conflicts of interest can be documented. HTCert, at its sole discretion, reserves the right to confirm or substitute the person(s) in question, depending on the evaluation of the client's claims. HTCert reserves the right to terminate the contract if, as a result, it no longer has the capability to perform all the activities required.

3.4.1 technical documentation assessment

- The assessment of technical documentation for class III devices and certain class IIb devices (devices falling under Rule 12 and implantable devices other than those referred to in Article 52(4) of the MDR)-are not subject to sampling. A full assessment of the technical documentation is conducted for every device to be certified.
- The assessment of technical documentation for products in class IIa and all products of class IIb except those referred in the first paragraph may be subject to sampling. The decision on sampling and the sampling plan are the sole decision of HTCert.

  If sampling is applied
  - The sampling plan ensures that an adequate number of technical files are assessed for compliance.
  - The assessments of representative samples are conducted throughout the certification period.
  - The Sampling plan is not shared with the manufacturer.
- All information about manufacturing and design activities performed by suppliers and/or subcontractors has to be submitted directly by the manufacturer and cannot be provided to HTCert by the supplier or subcontractor directly, bypassing the manufacturer.
- HTCert aims to perform the technical documentation review, within 6-8 weeks after receiving the required documentation from the manufacturer.
- Assessment of certain devices (e.g. class III implantable devices or devices with medicinal substances) requires consultation with relevant parties (e.g. Medicinal Product Competent Authority). In these cases, the assessment cannot be completed before the consultation is closed. The time required for these activities is additional to the normal review time.
- The first step of the assessment process is a completeness check of the submitted documents. If the completeness check fails, a new submission and a new completeness check will be required adding time and cost to the review and delay the overall assessment.
- The technical documentation assessment against the MDR requirements (Annexes I, II and III) starts when all the required documentation is made available to HTCert in the structure provided.
- No classification between major or minor is made for technical documentation findings. All deficiencies identified need to be addressed before issuance of certificate, regardless of the device classification.
- The technical documentation review process is limited to three rounds of assessment and these have to be completed in one calendar year at the maximum. If deficiencies remain unaddressed at the end of the three rounds, this will lead to refusal of the application for the subject device(s) and notification of the refusal to EUDAMED.

3.4.2 quality management system audit

- The initial certification audit must start within one year after signing the contract, otherwise HTCert reserves the right to cancel the conformity assessment procedure and to refuse certification.
- The initial certification audit is conducted in two stages.

3.4.2.1 Stage 1 audit

- Stage 1 audit consists of a review of the QMS documentation and either an on-site visit or a remote audit to
  - verify that the information upon which HTCert has planned the audit is correct,
  - acquire sufficient knowledge of the system and the activities carried out at each site to proceed with Stage 2 planning
  - determine the readiness of the manufacturer for the stage 2 audit and identify any weaknesses that would be classified as major non-conformities at this stage
  - conclude on the need for supplier audits
  - agree all the details with the client and verify the suitability of the allocated resources.
- At the end of the stage 1, the audit team identifies the critical areas that must be solved before continuing with the stage 2 audit.
- If, during the stage 1 activities, information acquired about the client (e.g. number of employees, sites, suppliers, processes) is different than that provided with the application, it may be necessary to proceed to a new review and HTCert reserves the right to amend its quotation or even cancel the agreement.
- A repetition of stage 1 is necessary if the conclusion of the stage 1 audit is negative or if there is a period longer than 6 months from the end of stage 1 to the beginning of stage 2.

3.4.2.2 Stage 2 audit

- Stage 2 consists of an on-site audit of the manufacturer's QMS and it may also include audit on the premises of critical suppliers or subcontractors. The main goals are as follows:
  - to verify that the client's QMS complies with the requirements of the MDR
  - to evaluate the implementation, including effectiveness, of the client's QMS.
- Stage 2 audit can be initiated after the resolution of findings identified during Stage 1 and provided that the results of the technical documentation assessment do not indicate any fundamental deficiencies in the QMS.
- The audit team draws up an audit report which summarizes the results of the audit as gathered during both stages and includes the audit conclusions and the recommendation to issue or non-issue of a certificate.
- Ownership of the audit report is maintained by HTCert.
- 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, when they do not affect safety of the devices and the integrity of the Quality Management System
  - Observations when they indicate a weakness but do not fail to satisfy the mandatory requirements

3.4.3 corrective actions

- The client must undertake to eliminate all the non-conformities eventually found during the audit by implementing adequate corrections and corrective actions.
- The certification cannot be granted before all major nonconformities identified during stage 2 audit have been successfully closed out and a plan for implementation of corrections and corrective actions for minor nonconformities is accepted.
- For major and minor nonconformities, the client shall submit its response including the root cause analysis and the plan for implementation of corrections and corrective actions within 30 days from the audit closure date.
- HTCert will respond within 30 days, either accepting or rejecting the CAPA plan. In case of rejection, the client has the right to submit a new plan. CAPA plan submission is limited to three rounds in total, each with a maximum of 30 days.
- Major nonconformities identified shall be closed out within 90 days. An extension period may be granted by HTCert after justified request of the manufacturer. For minor nonconformities the actions taken by the client will normally be confirmed at the next scheduled audit.
- For the observations, there is no requirement for an action plan. During the next audit, the client is requested either to provide evidence that these have been taken into consideration, or to justify its decision not to take any action.
- Additional audits may be required to verify the effectiveness and implementation of the actions taken, depending on the nature and quantity of nonconformities.
- If the client does not respond within the established timeframes, or if no adequate evidence of the implementation and the effectiveness of the corrections and corrective actions is provided, HTCert is entitled to terminate the assessment process.

3.4.4 Consultation procedures

3.4.4.1 Medical devices containing medicinal substances

If a device incorporates, as an integral part, a medicinal substance that has an action ancillary to that of the device, HTCert conducts a consultation procedure with a competent authority as per Directive 2001/83/EC or the European Medicines Agency (EMA).

Having verified the usefulness of the substance as part of the device and taking account of the intended purpose of the device, HTCert seeks a scientific opinion from a Medicinal Products Authority or from the EMA on the quality and safety of the substance including the benefit or risk of the incorporation of the substance into the device. The manufacturer is asked to provide the required data in the scope and format stipulated by the respective authority.

The scientific opinion is issued within 210 days after receipt of the documents. HTCert gives due consideration to this opinion and does not grant certification if the scientific opinion is unfavourable. The final decision is conveyed to the medicinal products authority.

3.4.4.2 Devices composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body

For devices, or their products of metabolism, that are systemically absorbed by the human body in order to achieve their intended purpose, HTCert conducts a consultation procedure with a competent authority as per Directive 2001/83/EC or the European Medicines Agency (EMA).

In this procedure, a scientific opinion is issued as to whether the applicable requirements specified in Annex I of Directive 2001/83/EC are adhered to with the product. The manufacturer is asked to provide the required data in the scope and format stipulated by the respective authority.

The scientific opinion is issued within 150 days after receipt of the documents. HTCert gives due consideration to this opinion and does not grant certification if the scientific opinion is unfavourable. The final decision is conveyed to the medicinal products authority.

3.4.4.3 Implantable Class III devices and active Class IIb devices which are intended to administer and/or remove a medicinal product

In the case of these products, a Clinical evaluation consultation procedure is conducted. HTCert sends its clinical evaluation assessment report along with the manufacturer's clinical evaluation documentation to the European Commission. The documentation is reviewed by an expert panel which decides whether it will issue a scientific opinion, or the process may be continued without one within 21 days after receipt. The scientific opinion is issued within 60 days after receipt of the documents and HTCert gives due consideration to this opinion regarding its decision for granting certification. If necessary based on the views expressed in the scientific opinion of the expert panel, HTCert will advise the manufacturer to restrict the intended purpose of the device to certain groups of patients or certain medical indications and/or to impose a limit on the duration of validity of the certificate, to undertake specific PMCF studies, to adapt the instructions for use or the summary of safety and performance, or to impose other restrictions in its conformity assessment report, as appropriate.

3.4.5 Class Is, Im, Ir Devices

For class I sterile devices, class I measurement devices and class I reusable surgical instruments, the assessment procedure is respectively related only to:

- aspects relating to establishing, securing and maintaining sterile conditions
- aspects relating to the conformity of the device with the metrological requirements
- aspects relating to the reuse of the device (cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use).

3.4.6 Systems and procedure packs

For systems or procedure packs as referred to in Art. 22 (3) of the MDR, the assessment procedure is limited to the aspects relating to ensuring sterility until the sterile packaging is opened or damaged.

3.5 Certification decision

Upon 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.

If the certification is approved, HTCert grants the certificates to the client. HTCert may impose restrictions or require the client to undertake specific PMCF studies. HTCert will report to EUDAMED all information regarding certificates issued and any restrictions imposed on certificates.

The period of validity of certifications according to the MDR is five years maximum. All certificates granted remain the property of HTCert.

If the certification is not approved, HTCert informs the client of this decision in writing, giving the reasons and the minimum conditions to restart the certification process. All decisions regarding refused certificates are reported by HTCert to EUDAMED according to the requirements of the MDR.

3.6 Maintaining certification

During the validity period of the certification, the manufacturer has to comply with all applicable MDR requirements.

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

Surveillance activities include among others

- On-site audits, both scheduled and unannounced
- Sampling and testing of devices
- Assessment of Periodic Safety Update Reports (PSUR)
- Validation of the Summary of Safety and Clinical Performance (SSCP) where applicable
- Assessment of technical documentations on a random sample basis
- Screening relevant sources of scientific and clinical data and post-market information
- Review of certified client's statements (e.g. promotional material, website)

3.6.1 Surveillance audits

Surveillance audits are performed at least every 12 months, to ascertain that the client maintains and applies the approved Quality System. The first surveillance audit is conducted within 12 months after certification granting, unless HTCert considers a shorter period more appropriate. 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.

For class III devices, the surveillance also includes a test of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices.

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.

Normally, unannounced audits are performed at least once every five years for low-risk devices and once every three years for high-risk devices, last at least one day, are performed by at least two auditors and are conducted at the manufacturer's premises or at the premises of subcontractors and critical suppliers if this is deemed more effective. To ensure the smooth conduct of these audits, the client is obliged to inform HTCert on the periods of the year in which the devices covered by the certification are not in production, as for example periods of company closures, holidays, etc. If a visa is required to visit the country in which the manufacturer or the critical suppliers and subcontractors are located, a relevant invitation must be provided by the client, with the signature date and visit date left open. Costs for unannounced audits are at the client's expense and this also applies in the cases where HTCert could not conduct an unannounced audit due to client not providing the information described above.

During surveillance audits, both scheduled and unannounced, samples for product tests may be taken. If it is not possible to perform these tests as witness tests at the audited premises, or if there is any special reason for this, then HTCert is entitled to send samples to laboratories of its choice. The manufacturer bears the costs for performance of the tests, test samples, transport and disposal. Instead of, or in addition to the above-described sampling, HTCert is entitled to take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation. In these cases, the manufacturer bears all the costs.

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.

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. For the elimination of major nonconformities, a time limit of 90 days maximum applies. 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.

3.6.2 Periodic Safety Update Reports (PSUR)

Manufacturers of class IIa, class IIb and class III devices shall prepare a periodic safety update report (PSUR) for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered together with a rationale and description of any preventive and corrective actions taken.

Manufactures of class IIb and class III devices shall update the PSUR at least annually and manufacturers of class IIa devices at least every two years.

For class III devices and for implantable devices, manufacturers shall submit the PSURs to EUDAMED and HTCert will add its evaluation along with details of any action taken. For all other devices, the manufacturers shall make the PSURs available to HTCert. HTCert will verify the

reports on a representative basis during the annual surveillance audits.

All PSURs and HTCert assessments are available to competent authorities.

3.6.3 Assessment of technical documentations

In the cases that sampling is applied as per 3.4.1, an assessment of the technical documentation on the basis of further representative samples chosen in accordance with the established plan is performed annually throughout the validity period of the certificate.

All findings identified need to be addressed within 90 days at the maximum.

3.6.4 Change notifications

Throughout the validity period of the certificate the client is obliged to notify HTCert of any planned substantial changes to the certified management system or the certified products. These include but are not limited to:

- For all types of Certifications issued according to MDR:
  - changes to the legal, economic or organizational status or the ownership of the company
  - change of the Authorised Representative, if applicable
  - changes to the sites of the manufacturer or to manufacturing sites of critical subcontractors
  - changes in the contact person(s) and responsible persons (management representative, PRRC)
- For EU technical documentation assessment Certificates according to annex IX (chapter II) of MDR:
  - Any plan for change to the device approved, which may affect the safety and performance or the conditions of use of the device, including changes in its intended purpose.
  - Any plan for extension of the device range, as for instance approval of a new device with the same intended use as the already approved ones or approval of new trade name(s).
- For EU quality management system Certificate according to annex IX (chapters I and III) or EU quality assurance Certificate according to annex XI (part A) of MDR:
  - changes to the device design which may affect compliance of the device with the general safety and performance requirements set out in Annex I of the MDR (e.g. design specifications, software, materials/components, labelling, packaging, change of terminal sterilization method)
  - changes in the device(s) intended purpose
  - changes to the manufacturing process which may affect the compliance of the QMS and/or the devices with the MDR applicable requirements (e.g. changes in the sterilization process, the clean room, etc.)
  - changes to the outsourced activities, such as internalising or outsourcing a process, removing or adding critical suppliers and subcontractors
  - any plan for an extension or a limitation of the device range covered by the QMS approved

HTCert assesses the significance of changes, decides whether an additional assessment is required and notifies the client of its decision. The client is entitled to implement the notified change only after receiving approval from HTCert.

For medical devices containing medicinal substances, the manufacturer shall inform HTCert of any planned changes with respect to the ancillary substance. HTCert shall seek the opinion of the medicinal products authority consulted, in order to confirm that the quality and safety of the ancillary substance remain unchanged. The authority will provide its opinion within 60 days after receipt of all the necessary documentation regarding the changes. HTCert will not approve any changes if the scientific opinion provided by the medicinal products authority consulted is unfavourable.

3.6.5 Scope extension

Should changes occur during the validity period of the certification, such as new sites, lines of production and activities, the scope can be extended, if applied for by the client. HTCert reviews the application and provides a new quotation to the client. The provisions set forth in section 3.2.2 apply.

3.7 Recertification

For renewal of the certification the client must submit a request no later than 9 months before the certificate expiry date and submit the formal application at least 6 months before the certification expiry date. If the client does not lodge an application in the above specified limits, the contract is considered as terminated on the certificate expiry date and a new assessment cycle has to be initiated. This deadline also applies in the case of suspended certification.

For request, quotation, application and contract, section 3.3 applies.

Renewal activities are planned and carried out upon submission of the application.

The assessment activities are as for the initial certification except that a stage 1 audit will not be required unless there are substantial changes of the QMS.

The recertification audit is carried out at the client's premises and, if required, at its critical suppliers and subcontractors. The main goals of the recertification audit are as follows:

- to verify that the QMS continues to conform to the requirements of the MDR
- to verify the effectiveness of the QMS in the light of internal and external changes and its continued relevance and applicability to the scope of certification

The technical documentation has to be submitted as updated and including all changes to the originally approved device. In addition, for renewal of EU technical documentation assessment certificates, the manufacturer is required to submit

- all changes to the originally approved Device
- experience gained from post-market surveillance
- experience from risk management
- experience from updating the proof of compliance with the general safety and performance requirements set out in Annex I
- experience from reviews of the clinical evaluation, including the results of any clinical investigations and PMCF
- changes to the requirements, to components of the device or to the scientific or regulatory environment
- changes to applied or new harmonised standards, CS or equivalent documents
- changes in medical, scientific and technical knowledge, such as:
  - new treatments,
  - changes in test methods,
  - new scientific findings on materials and components, including findings on their biocompatibility,
  - experience from studies on comparable devices,
  - data from registers and registries,
  - experience from clinical investigations with comparable devices.

For the decision on re-certification the same methods and principles apply as for the initial certification decision.

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.

3.8 Issuance of Notified Body Opinion pursuant to MDR Article 117

According to Article 117 of MDR, manufacturers intending to place drug-device combination products on the market as integral devices marketed as medicinal products are required to obtain a Notified Body Opinion (NBOp). The Notified Body assesses the compliance of the device component with the applicable General Safety and Performance Requirements (GSPRs) as specified in Annex I of the MDR. Upon confirmation of compliance, the Notified Body issues an NBOp report, which the manufacturer must include in the Market Authorisation Application (MAA) for submission to the Competent Authority.

The major steps of the process for issuing a Notified Body Opinion are:

- Starting
  - The applicant submits its request providing information on the integral product.
  - Upon receipt of the request, HTCert conducts an initial review and provides a quotation.
  - In the event of acceptance, the manufacturer submits a formal, legally signed, application together with the required documentation.
  - HTCert reviews the application and the supporting documents to
    - verify that assessment according to MDR Article 117 is applicable to the device(s) in question
    - confirm the availability of sufficient and appropriate resources
    - evaluate the completeness of the technical documentation in line with the provisions of "Documentation Requirements for Drug Device Combination Products Falling in the Scope of Article 117 of MDR". If the completeness check fails, a new submission and a new completeness check will be required.

    Upon acceptance of the application HTCert proceeds to the signing of the binding contract.
- Assessment
  - HTCert carries out a thorough review of the submitted documentation to determine compliance with the GSPRs.
  - No classification between major or minor is made for technical documentation findings. All deficiencies identified need to be addressed before issuance of certificate, regardless of the device classification.
  - The assessment is limited to three rounds which have to be completed in one calendar year at the maximum. If deficiencies remain unaddressed at the end of the three rounds, this will lead to termination of the process.
- Final review and issuance of NBOp

- Upon satisfactory completion of the assessment, a final review of all the information gathered is conducted by personnel not involved in the assessment.
- Based on this assessment HTCert decides to issue a Notified Body Opinion (NBOp) on compliance with the GSPRs.

The process is completed upon the issuance of the opinion. There are no surveillance requirements.

4. 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".

5. Suspension, Withdrawal, Restriction of Certification

5.1 General

Certification may be suspended, withdrawn or restricted upon decision of HTCert.
Information related to granted, restricted, suspended and withdrawn certificates is publicly accessible and is not considered confidential.

5.2 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, including the unannounced audits
- a negative outcome of the surveillance audits, including the unannounced audits
- failure to address non-conformities
- misleading or unauthorized use of certificate or certification mark
- Implementation of substantial changes to the device and/or to the quality management system by the client without prior HTCert's approval
- divergence between the sample taken from the devices produced or from the market and the specifications laid down in the technical documentation or the approved design

If certification is suspended, HTCert communicates to the client the actions needed to end suspension and restore certification and the timeframe for their completion.

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.

The client is obliged to full payment of all surveillance fees during suspension period.

If the suspension is due to issues which can result to devices presenting an unacceptable risk to health and safety, HTCert reserves the right to require the client to withdraw or recall all relevant devices.

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.

All decisions regarding suspended and reinstated certificates are communicated according to the requirements of the MDR.

5.3 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, which 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 reserves the right to require the client to withdraw or recall all relevant devices.

All decisions regarding withdrawn certificates are communicated according to the requirements of the MDR

5.4 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.

All decisions regarding withdrawn certificates are communicated according to the requirements of the MDR

6. 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 general safety and performance requirements of the MDR
- 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.

7. Financial Terms and Conditions

7.1 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.

Cancelling 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, 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.

7.2 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.

8. 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, restricting, 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) to be certified, HTCert will inform the client and refer to the relevant (acc. to MDR, Art. 51, section 2) competent authority for decision.

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

9. Protection of personal data

Pursuant to Regulation (EU) No. 2016/679 on the protection of natural persons with regard to the processing of personal data ("General Data Protection Regulation") personal data provided directly by the client or via third parties are processed by HTCert in order to ensure proper execution of the contractual relations with the client.

The data will be processed for the time necessary to perform the contractual relations with the client, subject to a further storage period of 10 years (15 years for implantable devices) from completion of the last service provided, in order to comply with established legal and regulatory obligations.

HTCert may disclose the data to Accreditation Bodies and competent authorities and to all public and private entities to which notification is required by law or necessary for the performance of the services provided by HTCert.

10. 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 or claim in writing as soon as the client becomes or should have become aware of errors and deficiencies in the services provided by HTCert. Any complaint or claim for damages against HTCert must be brought by the client, on pain of forfeiture, within six (6) months of the event which gave rise to the claim or complaint, at the latest.

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.

11. 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.