

INFORMATIVE

on Terms and Conditions of CE Certiso Ltd., Organisation for Certification and Testing on the Field of Medical and Hospital Engineering

The Informative on Terms and Conditions serve as preliminary information for the interested, all relevant provisions are incorporated into the contract

1. The creation of the mandate

1.1. Price offer

- 1.1.1. A preceding Price Offer is mandatory for the contracting of the Parties.
- 1.1.2. The request for price offer shall include all necessary information to specify the service parameters.
- 1.1.3. The Principal takes responsibility for the validity, accessibility and on-time availability of the information and data provided for the Price Offer.

1.2. Definition of the offer

- 1.2.1. The Service Provider complies the offer based on the information given by the Principal in accordance with the current laws, regulations and procedures.
- 1.2.2. The content of the offer - especially with regard to the scope, deadlines and consideration - may change in accordance with the agreement with the Principal until the conclusion of the contract.
- 1.2.3. The content of the offer covers the entire certification process, including the supervision period.
- 1.2.4. The consideration for the services specified in the offer is irrespective of whether the outcome of the services results in the issuance of a certification to the Principal or not.
- 1.2.5. The offer shall be binding exclusively in writing and CE Certiso Ltd. shall send such offer to the Customer by mail or by e-mail.
- 1.2.6. If the Customer accepts the offer beyond the deadline, CE Certiso Kft shall be entitled to amend the offer or refuse to conclude the contract.

1.3. Contracting

- 1.3.1. The Principal shall inform CE Certiso Ltd. about their choice and acceptance of the offer in a written response duly signed by the Principal.
- 1.3.2. If the terms of the contract change due to the changed demand of the Principal, CE Certiso Kft. shall send a proposal to the Principal regarding the change of the offer based on the changed conditions, of which the Principal shall declare in writing within 8 days.

2. The Subject Matter of the Contract

- 2.1. The services are defined exclusively by this Contract based on the accepted price offer ("Price Offer"). The Price Offer has been issued by the Service Provider and accepted by the Principal, hereby forms an Annex to the Contract.
- 2.2. The Service Provider is providing its service on the basis of the applicable legislations, standards, common specifications ("CS") and guidance documents, guidelines and procedures approved by the relevant authorities. The Service Provider's certification, conformity assessment and design examination procedures are available on its website.
- 2.3. If during the term of this Contract the Principal requires a change in the services, the services will be updated and a Price Offer, detailing the revised services as stipulated in the Principal's change-notification and approved by the Principal. The approved new Price Offer shall form an Annex to this Contract.
- 2.4. A completion of services shall be classified as a contractual completion, if it is completed in accordance with the generally approved rules relating to the actual service and by taking into consideration the specifications valid at the time of the completion of this Contract.
- 2.5. Contractual completion shall be irrespective of whether the outcome of the services results in the issuance of a certification to the Principal or not such as the certificate issuance is refused or the issued certificate is withdrawn, restricted or suspended.

3. The Location of the Service

- 3.1. The completion of services may take place at various locations, including but not limited to an on-site audit conducted at the sites where the Principal or its subcontractors and/or suppliers carry out their activities.
- 3.2. The Service Provider shall carry out the on-site audits at locations as specified in the Price Offer. The on-site audit can be conducted if the preparation of the Principal can be verified based on the previously evaluated documentations.
- 3.3. From the nature of the services, the Service Provider also has the opportunity to conduct on-site audits at the subcontractor's sites that are critical to the procedure. The Principal shall arrange access to the site of the critical subcontractors in order to conduct the necessary audit.

4. The Term of The Contract

- 4.1. The term of the contract is valid until the expiration or withdrawal of certificate or, , until certification-decision making.
- 4.2. The Service Provider shall carry out a supervisory audit within 12 months to maintain the issued certificate
- 4.3. Service Provider shall not be liable for the failure to meet deadlines, if the delay is due to the actions of the Principal or a third party.
- 4.4. The Principal shall not be liable for any delays caused by the Service Provider or any other party acting of its behalf.

5. Payment to the Service Provider for the Service

- 5.1. Due to the nature of the services provided by the Service Provider consists of procedures that are repeated periodically. Due to the diversity of the, the fees to be made by the Principal shall be paid in instalments in accordance with the accepted Price Offer.

- 5.2. The Principal shall pay the fees due to the Service Provider by bank transfer prior to the on-site audit.
- 5.3. If the price offer has been accepted by the Principal and the application has been submitted, the Principal is obliged to pay a 300€ request examination fee when applying for MDR certification. The request examination fee is included in the certification fee if the application complete and in accordance with point 2.1 of MDR annex IX.
- 5.4. If the Principal requests a dossier evaluation as part of the initial procedure, the Principal shall pay, by bank transfer, the fee for the evaluation in advance the pre-audit evaluation of the design dossier or the technical file. The Principal shall pay, by bank transfer, the remaining amount prior to the on-site audit.
- 5.5. The Service Provider shall review the quality management system documentation and technical file in return the payment based on the accepted Price Offer. If, due to non-conformity of this documentation, is to be carried out by the Service Provider due to revealed nonconformity or nonconformities, the Price Offer includes a one-time review. If further corrections and reviews are necessary, the Principal shall charge a fee of 250 €/hour by the Service Provider.
- 5.6. In the event of changes occurring the certification cycles, if reevaluation of the documentation is necessary in whole or part, the Service Provider shall be entitled to request 250 €/hour management fee.
- 5.7. In case the change requires a special on-site audit is necessary, the Service Provider shall perform the audit and charge a fee equal to a surveillance audit as specified in the Price Offer.
- 5.8. The Principal confirms that the services detailed specified in the Price Offer is not reliant, in any way, on the outcome of the certification service.
- 5.9. . If additional services are required but are not listed in the Price Offer, the Service Provider shall inform the Principal of the cost for said services.
- 5.10. Should, due to a change requested by the Principal, the terms of this Contract change the Service Provider shall submit a proposal, for the change, to the Principal to amend the Price Offer and the Principal will provide a written notice within 8 days confirming the requirement. The approved amended Price Offer shall become an Annex to this Contract.
- 5.11. All travel costs related to an on-site audit are not covered by the Price offer. All Travel costs will be invoiced to the Principal.
- 5.12. In case of travelling outside of Europe the auditors shall be provided with business class flights.
- 5.13. If the Principal fails to pay the assessment fee for travel expenses by the due date, the Service Provider shall be entitled to terminate the process and decline the issuance of the certificate, or suspend an already issued certificate.

6. Rights and Obligations of the Parties

6.1. The Rights of the Principal

- 6.1.1. The Principal is entitled to an impartial procedure conducted by Service Provider, which must also be guaranteed by a declaration of impartiality provided by the staff participating in the provision of the service.
- 6.1.2. The Principal shall have the right to object to the appointment of members of audit team. The Principal must, confirm in writing, their objection. In case of a valid

objection, Service Provider shall re-organise the audit team. An objection can only be accepted for reasons of impartiality and independence. This provision shall not be applicable to extraordinary and/or unannounced audits.

- 6.1.3. The Principal shall have the right to review the documents relating to the certification decision, which are filed in the Service Provider's archives.
- 6.1.4. The Principal shall have the right to submit a complaint to the General Manager of the Service Provider in respect of the procedure conducted by the Service Provider, and the Service Provider must investigate it in accordance with its complaint management procedure as specified on its website.
- 6.1.5. The Principal shall have the right to appeal against the certification decision of the Service Provider, and the Service Provider shall conduct an appeal in accordance with its appeal procedure as published on its website.
- 6.1.6. The Principal shall have the right to request the limitation of public access to information on the certification, in case the request is not contradictory of the mandatory public disclosure obligation by the regulations.

6.2. The Obligations of the Principal

- 6.2.1. The Principal and any other third party acting on its behalf shall co-operate with the Service Provider.
- 6.2.2. The Principal shall perform, or perform on its behalf, all the activities on time that are its responsibility and necessary for the performance of this Contract.
- 6.2.3. The Principal shall provide the Service Provider with the information, data and documentation required for the performance of this Contract. The change notification form, that may have an impact on the constant maintenance of the service ordered by the Principal.
- 6.2.4. The Principal hereby confirms that it shall report all changes, which can significantly affect the system and/or the device involved in the certification. The change reporting obligation applies to, in particular
 - 6.2.4.1. in the case of quality management system: scope, name, address, site (expanded/narrowed), organization form, organization structure, leadership, number of employees, quality manager/agent, person responsible for compliance insurance, responsible personnel, product range, applied technology, quality management process, subcontractor, supplier, European Representative (EC REP), new factory change, etc.
 - 6.2.4.2. in case of certified device: product list, name, brand name, specification (technical description), approved device design, approved device type, materials part of the device or used for its production and their suppliers, manufacturing technology, testing method (of raw material, semi-finished product and end product as well), packaging, sterilization, shelf life, instruction for use, label, software, indication, contraindication, medicinal material or of animal origin, change of related certificate of Conformity assessment based on type-examination mentioned in point 4 of Annex X, basic UDI-DI etc.
- 6.2.5. The product affected by the change cannot be put on the market until the submitted change is accepted by the Service Provider.
- 6.2.6. In case of changes regarding already approved device the Service Provider must approve the change prior to implementation if the changes can influence the safety of the device, or its performance or the conditions of its use.

- 6.2.7. If the Principal is planning to implement a change as described in the above sections, the Principal shall inform the Service Provider. The Service Provider shall review the planned changes and shall make a decision on whether it is necessary to perform a new conformity assessment or it is sufficient to approve by supplementing the certificate related to the technical documentation evaluation. In the latter case, the Service Provider must review the changes, inform the Principal of the decision and in case the changes were approved, must provide the Provider the EC-certificate supplement related to the technical file evaluation.
- 6.2.8. If, based on the review by the Service Provider, the change requires a consultation with the authority, an expert or with the Committee, then it must be conducted by the Service Provider.
- 6.2.9. During the co-operation, the Principal must comply with the relevant legislations, standards, CS and guidance documents, health and safety regulations.
- 6.2.10. The Principal shall reimburse any excess costs if the data it has provided was incomplete, late or incorrect; if its co-operation is not regular or if it is not in accordance with the Contract.
- 6.2.11. If the service has to be conducted at a place designated by the Principal, it is the Principal's obligation to ensure that the conditions are appropriate for the provision of the service at the place of completion.
- 6.2.12. Principal must submit the documentation in Hungarian or in English.
- 6.2.13. If during the procedure a non-conformity is established, the Principal is obligated to submit corrective and preventive action plan (CAPA plan) for the Service Provider within 15 days.
- 6.2.14. The Principal shall submit the documentation to the Service Provider which verifies the correction of non-conformities by the deadline set in the corrective and preventive action plan. In the absence of correction(s), the procedure shall be closed by the end of the deadline set in the action plan.

6.3. The Rights of the Service Provider

- 6.3.1. The Service Provider has the right to assign a competent assessment team to conduct the procedure.
- 6.3.2. For its activities the Service Provider has the right to use a subcontractor in justified cases. In case of subcontracting, the Service Provider shall inform the Principal prior to the use of said subcontractor.
- 6.3.3. The Service Provider has the right to make decision on the issuing or on the denial of issuing, maintaining, withdrawing, suspending and restricting of the certification based on available objective evidences. In the case of lack of closure of major nonconformity, the certificate cannot be issued.
- 6.3.4. The Service Provider, as Notified Body, has the right to request any information or data that it deems necessary for the appropriate performance of the chosen conformity assessment procedure.
- 6.3.5. In order to ensure an independent and impartial procedure the Service Provider shall not carry out any advisory activity. The Principal shall not require the Service Provider to resolve any discrepancies that may have been discovered the course of providing the services under this Contract.

- 6.3.6. If the services must be provided at a location designated by the Principal, and the Principal does not make the place of completion available in a condition appropriate for the provision of the service, the Service Provider may refuse the provision of the service until the Principal does fulfil its obligation. The Service Provider may withdraw from this Contract and demand a compensation beyond the deadline specified by the Service Provider.
- 6.3.7. The Service Provider has the right to conduct an extraordinary and/or unannounced audit at the Principal's location or the location of its subcontractor/ supplier, specifically in the case of an investigation of a complaint, a reported change or an earlier suspension of the Principal's certification, and, furthermore, in an event specified by law.
- 6.3.8. The Service Provider has the right to record nonconformities. In the case of a major nonconformity, during initial procedure, there are 180 days, during surveillance procedure, 90 days top for the corrections and closure of nonconformity by Service Provider, including follow-up audit in accordance with Point 5.3.8. In the lack of corrections or acceptance of corrections, the Service Provider is obligated to suspend the issued certificate.
- 6.3.9. Audit team of Service Provider, conducting on-site audit, has the right to make decision on the necessity of follow-up audit. In case of initial procedure, the follow-up audit must be conducted in 180 days from the on-site audit, in case of surveillance, 90 days from the on-site audit. In case of follow-up audit, the rate of fee of the relevant audit must be applied.
- 6.3.10. Service Provider has the right to exercise the correct verification procedure in respect of the certification logo, its application and display.

6.4. The Obligations of the Service Provider

- 6.4.1. The Service Provider must carry out the service specified in the Price Offer with the personal participation of an employee, a participant or sub-contractor, who is subject to a supplier contract and has the relevant competence for such services.
- 6.4.2. The Service Provider shall inform the Principal of the participants in the procedure.
- 6.4.3. The Service Provider shall keep confidential all data obtained during the provision of the services under this Contract.
- 6.4.4. The Service Provider employees and third-parties carry out the service in accordance this Contract shall sign a confidentiality agreement. prior to carry out and services.
- 6.4.5. The Service Provider hereby confirms that holds a valid liability insurance covering the scope of its activity, which has been issued by an insurance company based in the Republic of Hungary.
- 6.4.6. The Service Provider's liability for damages extends to the coverage of liability insurance.
- 6.4.7. The Service Provider hereby declares that there is no legal or other impediment to the performance of its services under this Contract and has the appropriate competence to perform its duties under this Contract. The Service Provider shall immediately notify the Principal of any fact or circumstances that may affect its ability to perform the services under this Contract.

6.4.8. In case of successful certification procedure, the Service Provider has the right to issue the certificate, in the lack of approval of the Principal, 14 days after the draft of certification has been sent to Principal via e-mail.

6.5. Obligation of Confidentiality

6.5.1. The Parties shall handle all information obtained and shared during the term of this Contractor as confidential business information.

6.5.2. The Parties shall handle all facts, data and information that became their possession in connection with this Contract and not make it available to a third-party who is not a party to this Contract.

6.5.3. If necessary, the Service Provider may make copies of the documents prepared during the service for its archives, and it must store the paper-based and electronic data in a manner that is not accessible by any third party.

6.5.4. In respect of the data, facts and information that became known to the Service Provider in connection with this Contract – including also the confidential business information specified in the Civil Code (hereinafter: Ptk.) – the Service Provider is bound by a confidentiality obligations which shall continue after the expiry or early termination of this Contract. This confidentiality obligation shall include but is not limited to –Principal’s clients, documentation and any other information that can be construed as needing to remain confidential. The Parties may seek written consent to share the other Party’s confidential information.

6.5.5. The Principal accepts that the Service Provider may forward information and documents to the relevant authorities on the basis of its authoritative and legislative obligations and upon the request of the accrediting body, competent authority, market supervisory or any other official organisation. The Service Provider must provide details to the Principal concerning the information and/or documents that have been forwarded to any authority.

7. Copyright

7.1. The copyright or co-authorship right derived from reports, minutes or expert opinions prepared by the Service Provider shall be owned by the Service Provider, the Principal may use the minutes, reports and expert opinions prepared during the scope of this Contract only for the purposes specified by this Contract.

8. Special terms and conditions concerning the quality management system certification

8.1. Service Provider obliged to perform surveillance audits on yearly period at the site(s) of Principal. Fee of surveillance audits are charged on the Principal.

8.2. The first surveillance audit must be performed in 12 months counting from the closure decision’s day of the initial procedure. If the prescribed deadline can not be hold, CE Certiso Ltd. must temporarily suspend, til 6 months maximum, the valid certificate. The audit performed in this 6 months is an extraordinary audit. In case of overrunning the 6 months of suspension, the certificate will be withdrawn.

8.3. On its website, Service Provider must make publicly accessible all those actual documents that describe its audit procedures, as well as the procedures to issue, maintain, renew, extend, limit, suspend or withdraw the certificates, the certification activity, as well as the types of management systems which it is working with and those geographical areas where it is operating.

- 8.4. CE Certiso Ltd. allows its clients the use of its certification logo, ensuring the traceability of the certification to the Notified Body.
- 8.5. The system certification logo can be used in advertisements, catalogues, on its own papers, in the media by the certified organization presented on the certificate for the verification that its quality management system owns a valid certificate.
- 8.6. For the request of Principal, Service Provider gives the system certification logo on electronic way.
- 8.7. In case the system certification logo has been awarded, Principal doesn't have the right to use it on product, on packaging of product well-seen for customer or any other way which may suggest that the logo means the conformance of the product. The use of system certification logo is not allowed on reports of laboratory examinations, calibrations or controls.
- 8.8. The certification may be used within the validity period to confirm the certified status.
- 8.9. Rules relating to make references to the certified status:
 - 8.9.1. It is prohibited to make misleading references to the certified status.
 - 8.9.2. It is prohibited to use the certification documents in a misleading way.
 - 8.9.3. If the certification is suspended or withdrawn, all references to the certification must be deleted.
 - 8.9.4. It is prohibited to create an image that the system certification relates to product, service or process of the certified organization.
 - 8.9.5. It is prohibited to create an image whereby the certification also relates to activities beyond the scope of the field of application.
 - 8.9.6. If the scope of the certification has been limited, all references must be modified accordingly.
 - 8.9.7. It is prohibited to make any references to the quality management system certification that would damage the good reputation of CE Certiso Ltd. and thus weaken the confidence of the public.
 - 8.9.8. CE Certiso Ltd. shall exercise a correct verification system and shall take steps if unauthorised references are made to the certified status, or if the certification documents, logos or audit reports are used in a misleading way.

9. Special terms and conditions concerning the conformity assessment activity

- 9.1. The Service Provider, as a Notified Body (NB 2409), shall carrying out a conformity assessment activity in accordance with the legislation specifying the product-related conformity assessment activity or in accordance with the provisions specified in a directly applicable EU legislation in force.
- 9.2. The Principal must accept that the Service Provider considers CS and guidance documents, guidelines obligatory applicable.
- 9.3. During the assessment of medical devices, the Service Provider considers the high-level protection of health of patients and users primary, and for this purpose, the Service Provider has the right to demand objective evidences from the Principal as determined by legislation, law, guidelines, CS and guidance documents, standards and science – especially medicine – for ensuring conformance.

- 9.4. After the submission of application the Service Provider shall examine whether the application complies with the formal requirements of the MDR/IVDR. If the application is incomplete or does not meet the requirements, the application shall be rejected and the contract shall become void.
- 9.5. During Stage 1 of initial procedure, the Service Provider reviews – besides the Quality management documentation (quality management manual and the list of processes at least), the management review and the internal audit report – the Technical File(s) according to the sampling plan or Design Dossier(s) of Principal. The Service Provider's assessment team shall submit its evaluation on the results of the Stage 1 review 3 months from the receipt of the documents. In case of revealed nonconformities inhibit the performance of on-site audit, the Stage 2 (on-site audit) of initial procedure cannot be performed until the nonconformities have been corrected, then the Service Provider has the right to postpone the on-site audit. During on-site audit, the Service Provider has the right to record nonconformities of quality management system and of Technical File(s) and/or Design Dossier(s). Further nonconformities can be determined on the Technical File(s) and/or Design Dossier(s) sent by Principal as correction. Certification decision on issuing, maintaining, reinstalling the certificate can be made by the Service Provider in case the correction of major nonconformities by the Principal and the acceptance of the corrections by the Service Provider. In case of nonconformity of the Technical File(s) and/or Design Dossier(s) the certificate cannot be issued.
- 9.6. The Service Provider has the right to examine up-to-date state of the technical documentation of the medical devices certified by it at any time during the validity of the certificate.
- 9.7. The Principal, in case of the Part A of Annex XI of MDR or Annex XI of IVDR: to make the copy of the EC type-examination certificates (number, version and validity-expiry) mentioned in point 4 of Annex X. available for the Service Provider and in case of any change related to the certificates the Service Provider shall be informed.
- 9.8. The Service Provider must carry out a surveillance audit every year at the site of the Principal and/or its critical subcontractors, and the Principal shall bear the cost of such audits. The first surveillance audit shall be performed within 365 days of the certification decision.
- 9.9. The Service Provider has the right to perform an extraordinary audit at the sites of the Principal, its critical subcontractors and/or suppliers, at the Principal's cost, especially in the case of an investigation of a complaint, a reported change or an earlier suspension of the Principal's conformity assessment.
- 9.10. The Service Provider is required to conduct an unannounced audit as per 2013/473/EU recommendation at the sites of the Principal, its critical subcontractors and/or suppliers, at the Principal's cost, Unannounced audits must be conducted especially in the case of a legislative order, investigation of a complaint or upon the request of a competent authority
- 9.11. To conduct an unannounced audit, the Principal is obligated to issue an open invitation to visit the Principal's site at any time in case a visa is required to visit the country where the Principal's sites and/or critical subcontractor is located.
- 9.12. To conduct an unannounced audit the Principal is obligated to inform the Service Provider on the interval where there is not any manufacturing activity regarding the medical devices covered by the certification. Information must be provided by 15th of January every year via e-mail to address info@cecertiso.hu.

- 9.13. The Principal must co-operate with all requests for an unannounced audit.
- 9.14. During the term of this contract, the Service Provider has the right to conduct the tests and verifications at the Principal's site that are necessary for the conformity assessment.
- 9.15. During the validity of this contract the Service Provider is entitled to take samples of the medical devices and/or of the raw materials, and to order laboratory testing in order to confirm the conformity.
- 9.16. If the Service Provider, as Notified Body, establishes that the Principal's medical device does not comply with the criteria specified in the product-related legislation or in a directly applicable EU legislation, or furthermore, that it does not comply with the other technical conditions specified in Point 8 of Article 2 of EU Directive 765/2008/EC, in respect of which the conformity assessment certificate was requested by the Principal, the Notified Body shall not issue a certificate until the Principal takes the necessary steps to make the medical device comply the criteria.
- 9.17. The Service Provider is responsible for all the decision making, based on the available objective evidences, on the issue of the certificate.
- 9.18. The Principal will inform the Service Provider within 72 hours of any adverse event, incident occurred during the validity of the contract, the obligation of providing information also includes the result of the internal investigation.
- 9.19. The Principal will inform the Service Provider within 72 hours of any procedure initiated by any Competent Authority of Member State in relation to any product within the scope of certification.
- 9.20. If following the issuance of the certificate, the Service Provider, as Notified Body, establishes or reasonably suspects – especially in case of request of authority - that the certified medical device no longer meets the criteria, it shall inform the Principal thereof and specify a deadline relevant to the characteristics of the medical device. If within the determined deadline the Principal does not take the necessary steps to make the medical device compliant with the criteria or it is not possible to remedy the fault of the medical device, the Service Provider, as Notified body, shall either restrict, suspend or withdraw. The term of suspension of certificate cannot be more than 6 months, after 6 months the certificate must be withdrawn.
- 9.21. If following the issue of the certificate, the Service Provider, as the Notified Body, shall have the right to either suspend or withdraw the certificate immediately if it becomes aware of any information that the medical device poses a possible major risk of public health.
- 9.22. On its website, the Service Provider must make publicly accessible all the documents that describe its audit procedures, as well as the procedures to issue, maintain, renew, extend, limit, suspend or withdraw the certificates, the certification activity, as well as the conformity assessment routes to which it is designated and those geographical areas where it is operating, and also the information when such documents are amended, and in this respect it shall send an electronic notification thereof to its clients.
- 9.23. If the Service Provider, as Notified body, experiences any breach of the rules concerning the distribution of the medical device within the field of the specified conformity assessment, it shall inform the other notified bodies operating within that field of conformity assessment, including also the nominated and registered organisations that are party to the European Economic Community Agreement (hereinafter: EEC Countries).

- 9.24. Upon the request of the other notified bodies operating within the field of conformity assessment – including the organisations registered in the EEC countries – the Service Provider, as Notified Body, shall also provide information on the positive conformity assessment results.
- 9.25. It is the obligation of the Service Provider to inform the competent authority of the result of the conformity assessment.
- 9.26. During the use of the conformity assessment logo (CE marking), the Principal must comply with the relevant legal regulations.
- 9.27. The Service Provider has the right to exercise the correct monitoring procedure to check the use and display of the conformity assessment logo (CE marking).
- 9.28. Rules relating to make references to the certified status:
- 9.28.1. The certification may be used within the validity period to confirm the certified status.
- 9.28.2. It is prohibited to make misleading references to the certified status.
- 9.28.3. It is prohibited to use the certification documents in a misleading way.
- 9.28.4. If the certification is suspended or withdrawn, all references to the certification must be deleted.
- 9.28.5. It is prohibited to create an image whereby the certification also relates to activities or products beyond the scope of the certificate.
- 9.28.6. If the scope of the certification has been limited, all references must be amended accordingly.
- 9.28.7. It is prohibited to make any references to the conformity assessment system and/or product certification that would damage the good reputation of the Service Provider or that of the certification system, and thus weaken the confidence of the public.
- 9.28.8. The Service Provider shall exercise a correct verification system and shall take steps if unauthorised references are made to the certified status, or if the certification documents, logos or audit reports are used in a misleading way.
- 9.28.9. The Principal has the right to turn to competent authority against activity of Service Provider, as Notified Body.

10. Amendment to the Contract

- 10.1. Any amendments to the services specified in this Contract, or the utilisation of subsequent services shall be required a written amendment signed by both Parties.
- 10.2. The Services Provider may initiate an amendment to this Contract if changes occur to the contractual conditions that would significantly modify the cost of the service provided. If the Principal rejects, without a justified explanation, the increased costs confirmed in detail and, consequently, the resulting amendment to the Contract, the Service provider shall have the right to refuse the provision of any further services.
- 10.3. The Service Provider may initiate an amendment to this Contract if significant changes occur to international regulations, standards, guidelines that form the basis of its activity, or to the regulations relating to designation and accrediting bodies, which then have an effect on the subject matter of this Contract.

11. Termination of the Contract

- 11.1. This Contract may be terminated by either Party upon not less than thirty days written notice to the other Party.
- 11.2. The Service Provider may terminate this Contract upon not less than 3 months written notice prior to the surveillance.
- 11.3. Either Party may immediately terminate this Contract due if the other Party breaches the terms of this Contract and does not rectify said breach within 8 days of being made aware of said breach
- 11.4. The immediate termination of the contract is possible if the other Party commits a major non-compliance with terms of this Contract or commits an unlawful act that cannot be remedied.
- 11.5. The unlawful use of certificate markings from the part of the Principal concludes to immediate termination of this Contract. With special attention to the following criteria:
 - 11.5.1. Using the certification marking of a certified medical device on another medical device.
 - 11.5.2. Using a certification marking of a medical product for a different scope than provided
 - 11.5.3. Distributing the certified medical device with a major change without the approval of the Service Provider
 - 11.5.4. Distributing a medical device that differs from the approved technical file.

12. Miscellaneous Provisions

- 12.1. The Parties state that should any vis maior situation occur that would hinder the completion of fulfilment of this Contract, they shall aim to amend this Contract by joint consent and by taking into consideration their mutual interest.
- 12.2. The Parties agree to settle any disputes arising from or in connection with this Contract primarily by out-of-court negotiations, but if such deems unsuccessful, either party may initiate a court proceeding.
- 12.3. The Parties shall specify the jurisdiction of the court relevant to the seat of the Service Provider to settle any legal disputes arising from or in connection with this Contract.
- 12.4. The Parties state that all issues not covered in this Contract shall be governed by the provisions of the Hungarian Civil Code (2013. évi V. törvény).