INFORMATION

on the Terms and Conditions of CE Certiso Kft.

This document on Terms and Conditions serves as preliminary information for the inquiring Party. All relevant provisions are incorporated into the contract

1. The Process of Assignment

1.1. Requesting an Offer

1.1.1. The contract between CE Certiso Kft. (Service Provider) and the Principal's is has to be preceded by a request for a price offer.

1.1.2. The request for Price Offer shall include all necessary and relevant information to identify the service parameters.

1.1.3. Requests for an Offer shall be made by filling out the form created for this purpose.

1.1.4. The Principal is responsible for the validity, accessibility and availability of the information and data provided for the Price Offer. The Principal is responsible for the accuracy of the necessary information and data arising during the quotation request, as well as for providing them in time.

1.2. Definition of the Price Offer

1.2.1.The Service Provider compiles the Price 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 Price Offer covers the entire certification process, including the surveillance period.

1.2.3. The fee of the services specified in the Price Offer is irrespective of whether the services result in a favourable outcome for the Principal or not.

1.2.4.The Price Offer shall be binding exclusively in writing. CE Certiso Kft. shall send such an Price Offer to the Customer by e-mail.

1.2.5. If the Principal accepts the Price Offer beyond the validity deadline, CE Certiso Kft shall be entitled to amend the Price Offer or refuse to conclude the contract.

1.3. Contracting

1.3.1.The Principal shall inform CE Certiso Kft. about the acceptance of the Price Offer in a written response with an authorized signature by the Principal.

1.3.2. If the terms of the contract change due to a change in the demands of the Principal, CE Certiso Kft. shall send a proposal to the Principal regarding the change of the Price Offer based on the changed conditions. The Principal shall provide feedback on the amended Price Offer in writing within 8 days.

2. The Subject Matter of the Contract and Services

2.1. The services are defined exclusively by the Contract, which is based on the accepted Price Offer. The Price Offer, having been issued by the Service Provider and accepted by the Principal, constitutes 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"), guidance documents, guidelines, MDCG documents and procedures approved by the relevant authorities. The Service Provider's certification and conformity assessment procedures are available for the public on its website.

2.3. If during the term of the initial Contract the Principal requires a change in the services, a new Price Offer will be issued, detailing the revised services based on the Principal's change-notification. The agreed new Price Offer shall form an Annex to the Contract. Also, the contents of the Contract will be updated on the basis of the accepted Price Offer.

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 provisions valid at the time of the completion of the Contract.

2.5. Contractual completion shall be irrespective of whether the services result in favourable outcome for the Principal, such as the issuance or maintenance of a certificate, or not favourable outcome such as certificate issuance is refused or the issued certificate is withdrawn, restricted or suspended.

3. The Location of the Service

3.1. By virtue of the service, 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. Besides, the technical documentation will be evaluated as well.

3.2. The Service Provider shall carry out the on-site audits at locations as specified in the accepted Price Offer. The on-site audit can be conducted if the preparedness of the Principal can be verified based on the previously evaluated documentation.

3.3. By virtue of the services, the Service Provider is also entitled to conduct on-site audits at the subcontractor's sites that are critical to the procedure. The Principal shall arrange access to the site(s) of the critical subcontractor(s) to enable the conduction of such an audit.

4. The Term of The Contract

4.1. The term of the contract is valid until the expiration or withdrawal of a certificate or, in case of a failed procedure, until the certification decision-making.

4.2. The Service Provider is obliged to conduct a surveillance 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, the services consist of procedures that are repeated periodically. Due to the possibility of separation of services, the fees to be paid by the Principal shall be paid in instalments in accordance with the accepted Price Offer.

5.2. The Principal shall pay the fees by bank transfer to the Service Provider according to the invoice issued by the Service Provider, prior to the due on-site audit.

5.3. 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 revealed nonconformity or nonconformities in this documentation, a subsequent review is to be carried out by the Service Provider, the Service Provider shall charge a fee on a hourly basis as defined in the Standard fee.

5.4. In the event of changes occurring during the certification cycles and if any changes make a re-evaluation of the documentation in whole or part necessary, the Service Provider shall be entitled to charge a management fee on a hourly basis as defined in the Standard fee.

5.5. If any vigilance case occurs, the Service Provider shall charge a fee on a hourly basis as defined in the standard fee for the handling of the vigilance case.

5.6. In case the change makes an extraordinary on-site audit necessary, the Service Provider shall perform the audit and charge a fee equal to a surveillance audit as specified in the Price Offer.

5.7. The fees defined in the Price Offer are irrespective of the outcome of the certification services.

5.8. If additional services are required that are not listed in the Price Offer, the Service Provider shall inform the Principal of the cost for the additional services and the Annex to the Contract might be modified.

5.9. If the terms of the contract change due to a change in the demands of the Principal, the Service Provider shall send a proposal to the Principal regarding the change of the Price Offer based on the changed conditions. The Principal shall provide feedback on the amended Price Price Offer in writing within 8 days. The accepted amended Price Price Offer will constitute an Annex to the Contract.

5.10. 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.

5.11. In case of traveling outside of Europe the auditors shall travel with business class flights.

5.12. If the Principal fails to pay the assessment fee or 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 confirmed by a declaration of impartiality provided by the staff participating in the service.

6.1.2.The Principal shall have the right to make an objection to the designation of members of the 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 related 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 obligations stipulated by the regulations in force.

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 have performed on its behalf, all the activities on due time that are its responsibility and necessary for the completion of the Contract.

6.2.3.The Principal shall provide the Service Provider all data, information and documentation required for the completion of the Contract. Changes that may have an impact on the constant maintenance of the service ordered by the Principal shall be communicated via the Change Notification Form to the Service Provider in order to maintain its ability to carry out its activites related to the service.

6.2.4.The Principal confirms that it shall report all changes, which may 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, responsible personnel, product range, applied technology, quality management process, subcontractor, supplier, European Representative (EC REP), new factory, etc.

6.2.4.2. in case of a certified device: product list, name, brand name, specification (technical description), approved device design, approved device type, materials that form part of the device or are used during its production and their suppliers, manufacturing technology, testing method (of raw material, semi-finished product and end product as well), packaging, sterilization method, shelf life, instruction for use, labelling, software, indication, contraindication, medicinal substance or any material of animal origin, any changes to the EU type-examination certificate 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 proposed change is approved 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 may have an impact on 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 Principle shall inform the Service Provider. The Service Provider shall review the planned changes and shall make a decision whether it is necessary to perform a new conformity assessment or it is sufficient to approve the change 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 its decision and in case the changes were approved, must issue the EC-certificate supplement related to the technical file evaluation. 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.

6.2.8. During the co-operation, the Principal must comply with the relevant legislations, standards, CS and guidance documents, MDCG documents, health and safety regulations.

6.2.9. 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.

6.2.10. If the service has to be conducted at a site determined by the Principal, it is the Principal's obligation to ensure that the conditions are appropriate for the completion of services at the site.

6.2.11. Principal must submit the documentation in Hungarian or in English language.

6.2.12. If a non-conformity is established during the procedure, the Principal is obligated to submit a corrective and preventive action plan (CAPA plan) for the Service Provider within 15 days.

6.2.13. The Principal shall submit to the Service Provider the documentation 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 the subcontractor.

6.3.3. Based on objective evidence made available to the Service Provider, it has the right to make a decision on conformity and on the issuing or on the denial of issuing, maintaining, withdrawing, suspending or restricting of the certificate. As long as a major nonconformity is not corrected and closed, a 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. Under the contract, the Principal shall not require the Service Provider to resolve any discrepancies that may have been discovered during the course of the services.

6.3.6. The Service Provider has the right to charge additional fees occurring due to additional reasonable and necessary services that are additional to the Price Offer in a delayed sequence if it has informed the Principal in advance to charging the fees and has justified the necessity of each service item.

6.3.7. If the services must be conducted at a location determined by the Principal, and the Principal does not make the site of completion in a condition appropriate for the services available, the Service Provider may refuse the provision of the service as long as the Principal does not fulfil its obligation. The Service Provider may withdraw from the Contract and demand compensation beyond the deadline specified by the Service Provider.

6.3.8. The Service Provider has the right to conduct an extraordinary and/or unannounced audit at the Principal's site or at the location of its subcontractor/ supplier, especially 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.

6.3.9. The Service Provider has the right to record nonconformities during audits. In the case of a major nonconformity revealed during an initial procedure there are 180 days, while during a surveillance procedure there are 90 days for the corrections by the Principal and for the closure of nonconformities by the Service Provider, including follow-up audit in accordance with 6.3.10 In case the Principal fails to correct the nonconformities or the corrections of those are not acceptable, the Service Provider is obligated to suspend the issued certificate.

6.3.10. The audit team assigned by the Service Provider conducting the audit has the right to make decision on the necessity of a follow-up audit. In case of an initial procedure, the follow-up audit must be conducted within 180 days from the initial audit, while in case of a surveillance, it shall be conducted by the Service Provider within 90 days from the on-site audit. In case of a follow-up audit, the fee of the relevant audit shall be applicable.

6.3.11. The Service Provider has the right to terminate the conformity assessment process and reject the application after two rounds of review of the documentation if nonconformity or nonconformities in the reviewed documentation persist.

6.3.12. Service Provider has the right to exert appropriate control over the use and display of the certification logo.

6.4. The Obligations of the Service Provider

6.4.1.The Service Provider must carry out the service specified in the Price 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 the Contract.

6.4.4.The Service Provider employees and third parties carrying out the service in accordance with the Contract shall sign a confidentiality agreement prior to performing the service.

6.4.5.The Service Provider hereby confirms that holds 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 impediments to the performance of its services under the Contract and has the appropriate competence to perform its duties under the Contract. The Service Provider shall immediately notify the Principal of any facts or circumstances that may affect its ability to perform the services under the Contract.

6.4.8.In case of a 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 the 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 the Contractor as confidential business information.

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

6.5.3. If necessary, the Service Provider may make copies of the documents prepared during the service for its archives, and 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 the Contract – including also the confidential business information specified in the Civil Code (hereinafter: Ptk.) – the Service Provider is bound by confidentiality obligations with an indefinite duration which shall continue after the expiry or early termination of the Contract. This confidentiality obligation shall especially be related to but is not limited to the Principal's clients. 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 authorities.

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 the Contract only for the purposes specified by the Contract.

8. Special terms and conditions regarding quality management system certification

8.1. Service Provider obliged to perform surveillance audits on a yearly period at the site(s) of Principal. The fee of surveillance audits is charged to the Principal.

8.2. The first surveillance audit must be performed within 12 months from the closure decision's day of the initial procedure. If the prescribed deadline cannot be adhered to, the Service Provider must temporarily suspend, for a maximum period of 6 months, the valid certificate. The audit performed in this 6-months period will be regarded as an extraordinary audit. In case of overrunning the 6 months of suspension, the certificate shall 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 Kft. 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 the Principal's own papers, in the media by the certified organization presented on the certificate for the verification that its quality management system holds a valid certificate.

8.6. For the request of the Principal, the Service Provider provides the system certification logo in an electronic way.

8.7. In case the system certification logo has been awarded, the Principal doesn't have the right to use it on the product, on the packaging of the product where it can be well-seen for the customer or any other way in which it may suggest that the logo means the conformance of the product. The use of the system certification logo is not allowed on reports of laboratory examinations, calibrations, or controls.

8.8. The certification logo may be used within the validity period to confirm the certified status.

8.9. Rules of making 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 the products, services, or processes 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 Kft. and thus weaken the confidence of the public.

8.9.8. CE Certiso Kft. shall exercise a appropriate control 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 carry out the 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 accepts that the Service Provider considers common specifications (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 as primary priority, and for this purpose, the Service Provider has the right to demand objective evidence from the Principal as determined by legislation, law, guidelines, CS and guidance documents, standards and science –especially medicine – for ensuring conformity.

9.4. After the submission of application the Service Provider shall examine whether the application complies with the formal requirements of the MDR. If the application is incomplete or does not meet the requirements, the application shall be returned for correction. In case a subsequent application fails due to deficiencies, the application might be rejected.

9.5. During Stage 1 of an initial procedure, the Service Provider reviews, in addition to the Quality management documentation (of which at least the quality manual and the list of operating procedures), the management review and the internal audit report of the Principal, the Technical File(s) or Design Dossier(s) according to the sampling plan (if applicable). The Service Provider's assessment team shall submit the results of its evaluation of the Stage 1 review within 3 months from the receipt of the documents. If revealed nonconformities preclude the performance of an on-site audit, the Stage 2 (on-site audit) of the initial procedure cannot be performed until the nonconformities have been corrected and in this case 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 related to both the quality management system and to the Technical File(s) and/or Design Dossier(s). Further nonconformities can be determined in the Technical File(s) and/or Design Dossier(s) that are submitted by the Principal as correction. Certification decision on issuing, maintaining, or reinstalling the certificate can only be made by the Service Provider if the correction of major nonconformities was completed by the Principal and the corrections were accepted by the Service Provider. In the presence of nonconformities in the Technical File(s) and/or Design Dossier(s) certificates cannot be issued.

9.6. The Service Provider has the right to examine the up-to-dateness of the technical documentation of the medical devices certified by it at any time during the validity of the certificate.

9.7. In case of Part A of Annex XI of MDR: the Prinicipal is obliged 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 after 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 frames of an investigation of a complaint, a reported change or a former suspension of the Principal's conformity assessment.

9.10. The Service Provider is required to conduct an unannounced audit as per the recommendation 2013/473/EU 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 enable the performing of an unannounced audit, the Principal is obligated to issue an open invitation (the invitation is not bound to a defined date) to allow the Service Provider 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 facilitate the performing of an unannounced audit, the Principal is obligated to inform the Service Provider of the time period(s) when manufacturing of the medical devices covered by the certification does not taking place. This information must be provided by 15th of January each year via e-mail to the address info@cecertiso.hu.

9.13. The Principal is obliged to co-operate with all requests for an unannounced audit.

9.14. During the term of the Contract, the Service Provider has the right to conduct tests and verifications at the Principal's site that are deemed necessary for the conformity assessment.

9.15. During the validity of the Contract the Service Provider is entitled to take samples of the medical devices and/or of the raw materials and to order laboratory tests 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, the medical device 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 implements necessary actions to make the medical device comply with the criteria.

9.17. The Service Provider is responsible for all the decision-making, based on the available objective evidence, on the conformity and on the issuing of the certificate.

9.18. The Principal is obliged to inform the Service Provider within 72 hours of any adverse events or incidents that occur during the validity of the Contract, and furthermore, the Principal must inform the Service Provider of the results of the internal investigation.

9.19. The Principal is obliged to inform the Service Provider within 72 hours of any procedure initiated by any Competent Authority of a 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 a Notified Body, establishes or reasonably suspects – especially in case of a request by an authority - that the certified medical device does not any longer meet the criteria, it shall inform the Principal thereof and specify a deadline relevant to the characteristics of the medical device to correct the deficiencies. If within the determined deadline the Principal does not implement the necessary actions 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 certificate. The term of suspension cannot be longer than 6 months, after 6 months the certificate must be withdrawn.

9.21. After the issuing of a 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 suggests that the medical device poses a major risk to 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 violation 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 organizations that are party to the European Economic Community Agreement (hereinafter: EEC Countries).

9.24. Upon the request of other notified bodies operating within the field of conformity assessment – including the organizations 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 on the result of the conformity assessment.

9.26. The Principal must comply with the relevant legal regulations concerning the use of the conformity assessment logo (CE marking).

9.27. The Service Provider has the right to exert appropriate monitoring in order to check the use and display of the conformity assessment logo (CE marking).

9.28. Rules of making 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 appropriate control and shall take steps if unauthorized references are made to the certified status, or if the certification documents, logos, or audit reports are used in a misleading way.

9.29. The Principal has the right to contact the competent authorities against the activities of the Service Provider as Notified Body.

10. Amendment to the Contract

10.1. Any amendments to the services specified in the Contract, or the ordering? of subsequent services require a written agreement signed by both Parties. Such an agreement shall be enclosed to the Contract.

10.2. The Services Provider may initiate an amendment to the Contract if changes occur to the contractual conditions that would significantly modify the costs 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 the 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 the Contract.

11. Termination of the Contract

11.1. The Contract may be terminated by either Party by indicating the reason for that in a notice.

11.2. The Service Provider may terminate the Contract upon not less than 3 months' written notice prior to the due surveillance of the certificate.

11.3. An extraordinary termination of the Contract is possible if one Party commits a major violation of the terms of the Contract that precludes the completion of the terms in the Contract by the other Party. In this case the other Party must call the attention of the violating Party to its acts and define an 8-day deadline, if that is not possible, then an appropriate deadline. If this warning action does not lead to a resolution, the innocent Party is entitled to terminate the Contract.

11.4 An extraordinary termination of the Contract with immediate effect is possible if a major violation of the terms of the Contract or an unlawful act cannot be remedied.

11.5. The unlawful use of certification logo by the Principal leads to extraordinary termination of the Contract with immediate effect. With special attention to the following criteria:

11.5.1. Using the certification logo of a certified medical device on another medical device.

11.5.2. Marketing of a certified medical device with a different intended use from that was approved by the certification

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 declare that should any vis maior situation occur that would hamper the completion of the Contract, they shall seek to amend the 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 the Contract primarily by out-of-court negotiations, but if it concludes unsuccessfully, either Party may initiate a court proceeding.

12.3. The Parties shall specify the jurisdiction of the court relevant to the registered place of business of the Service Provider to settle any legal disputes arising from or in connection with the Contract.

12.4. The Parties state that all issues not covered in the Contract shall be governed by the provisions of the Hungarian Civil Code (2013. évi V. törvény)

Contact information of CE Certiso Kft.:

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