GENERAL TERMS AND CONDITIONS

(GTC)

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I. Preambulum

NEOEMKI National Medical Device Conformity Assessment and Certification LLC. (hereinafter referred to as NEOEMKI) is the legal successor of the National Institute of Pharmacy and Food Safety's Device Assessment and Hospital Technology Directorate. The legal succession and the establishment of NEOEMKI LLC. are regulated by Government Decree No. 28/2015 (II. 25.) as amended by Government Decree No. 164/2020 (IV.30.).

II. Organizational and supervisory conditions of the service

II.1. Organizational data:

Service provider name:	NEOEMKI National Medical Device Conformity Assessment and Certification LLC. (abbreviated as NEOEMKI, hereinafter referred to as the Certification Body)
Headquarters:	1097 Budapest, Albert Flórián út 3/A
Name of certification body:	NEOEMKI
Company registration number:	01-09-357519
Tax number:	27927616-2-43
Bank account number:	10409015-50526970-68801014 (K&H Bank)
Represented by:	Imre László, Managing director

II.2. Contact details of the Certification Body

address:	1097 Budapest, Albert Flórián út 3/a
website:	https://emki.hu/
phone number:	+36 20 268 7595
e-mail:	cert@emki.hu
customer reception:	Tuesdays and Thursdays: 9:00 - 14:00

II.3. Availability of the General Terms and Conditions (GTC)

The current General Terms and Conditions are available on the Certification body's website. The Certification Body shall notify its clients of any changes to the General Terms and Conditions by e-mail.

II.4. Accreditation, designation, and other conditions for the provision of the service

NEOEMKI complies with the requirements of EN ISO/IEC 17021-1 "Conformity assessment. Requirements for bodies performing auditing and certification of management systems" and EN ISO/IEC TS 17021-3:2019 and is accredited body to management system certification (for management systems according to MSZ EN ISO 9001:2015 and MSZ EN ISO 13485:2016) under the number NAH-4-0009/2021/K. The scope of accreditation is set out in the accreditation decision. The accreditation certificate is valid with the content of the current detailed document available on the website of the National Accreditation Authority.

NEOEMKI is a Notified Body with the identification number "1011" according to the NANDO (New Approach Notified and Designated Organizations) system.

NEOEMKI has liability insurance for the performance of services under the Certification Agreement. NEOEMKI's liability for damages is limited to the amount the liability insurance covers. The geographical scope of the policy does not cover the whole world, therefore NEOEMKI's certification activities exclude the USA, Canada, Australia, and New Zealand.

II. 5. Supervisory bodies (designating and accrediting):

OGYÉI Division for Medical Device Evaluation	1135 Budapest, Szabolcs utca 33.
National Accreditation Authority	1118 Budapest, Tétényi út 82.

III. Basic terms and definitions

III. 1. Certification services:

- **Certification of quality management systems** according to the requirements of **MSZ EN ISO 9001:2015.**
- **Certification of quality management systems** according to the requirements of **MSZ EN ISO 13485:2016.**
- **Conformity assessment:** Surveillance of the EC certificates issued for medical devices under the Directive 93/42/EC, according to Article 120 (3) of Regulation EU 2017/745.
  Surveillance activities according to the Regulation (EU) 2023/607.
- **Conformity assessment:** Surveillance of EC certificates for in vitro medical devices issued under Directive 98/79/EEC, according to Article 110(3) of Regulation EU 2017/746.

III. 2. Certification procedure (certification):

- **Quality management system certification according to MSZ EN ISO 9001 and 13485**

The certification process that includes the review of the documentation (e.g. QMS manual, procedures and policies), the records of the quality management system established, implemented and maintained by the Client, the records related to its operation, and the on-site inspection (audit) of the manufacturing site(s). The process includes initial, surveillance, recertification and, if necessary, extraordinary procedures (e.g. in case of significant change).

- **Surveillance of the EC certificates issued for medical devices under the Directive 93/42/EC, (MDD) according to Article 120 (3) of Regulation EU 2017/745**

The process that includes, in addition to the quality management system audit, the examination of the technical documentation of the medical device manufactured, with reference to the performance evaluation, and, if necessary, the on-site inspection (audit) of the manufacturer and its critical subcontractor sites. The conformity assessment process includes surveillance procedures, unannounced audits and, if necessary, extraordinary procedures (e.g. in case of change, nonconformity) and if can be implemented, the surveillance activities according to Regulation (EU) 2023/607 on Client's request.

- **Surveillance of EC certificates for in vitro medical devices issued under the Directive 98/79/EC; (IVDD) according to Article 110(3) of Regulation EU 2017/746**

The process that, in addition to the quality management system audit, includes the examination of the technical documentation of the manufactured IVD medical device, with particular reference to the performance evaluation, and, if necessary, the on-site inspection (audit) of the manufacturer and critical subcontractor sites. The conformity assessment process includes surveillance

procedures, unannounced audits and, if necessary, extraordinary procedures (e.g. change, nonconformity).

III. 3. Certification cycle:

The first certification cycle always starts with the certification decision. Subsequent certification cycles start with the recertification decision.

In case of a successful certification procedure the certification cycle lasts from the date of issue of the certificate until the expiry or revocation of the issued certificate. In case of an unsuccessful procedure the cycle ends with the certification decision.

The certification cycle duration is three years for the quality management system certification according to the standards MSZ EN ISO 9001 and 13485, and five years for the conformity assessment according to Directive 93/42/EC (MDD) and Directive 98/79/EEC (IVDD).

For conformity assessment of medical device under Directive 93/42/EC and in vitro diagnostic medical device under Directive 98/79/EEC the certification cycle shall extend until the date specified in the relevant legislation. The issued certificate is valid until the end of the certification cycle, but not later than 26 May 2024 in case of medical device or 26 May 2025 in case of in vitro diagnostic medical device, with the proviso that the Certification Body carries out its surveillance activities, such as annual surveillance audits and related technical documentation and other documentary examinations, as well as the assessment and surveillance of any changes notified by the manufacturer. The maintenance of the certificate shall be documented by the certification body as long as the manufacturer complies with the legal requirements imposed on it.

On Client's requests and on a contractual basis the Certification Body performs the supervision activities for the certificate issued by NEOEMKI in accordance with Regulation (EU) 2023/607. In this case the certificate may remain valid until the deadline specified in the table below, provided that the Client fulfills the conditions laid down in Article 1(1)(b)(3e) of Regulation (EU) 2023/607. According to Regulation (EU) 2023/607, the Certification Body undertakes the supervision of these certificates until September 26, 2024, at the latest, since from this date onwards, the notified body designated in accordance with Article 42 of Regulation (EU) 2017/745 is responsible for their supervision.

type of medical device, risk class	latest validity date
for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors	31 December 2027
for class IIb devices other than those not covered by above line, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function	31 December 2028

Condition for maintaining the certificate: the NEOEMKI must carry out surveillance audits at least once every calendar year for the system certification and conformity assessment areas and must document the maintenance of the certificate if the manufacturer meets the standard and/or legal requirements imposed on it.

The date of the first surveillance audit after the initial certification shall not be later than 12 months after the certification decision has been made.

If the deadline cannot be met for reasons attributable to the client, the valid certificate will be temporarily suspended for up to 6 months. Audits that can be carried out within this period shall

be treated as extraordinary audits. If the 6-month deadline is exceeded, the certificate will be revoked. If the deadline is exceeded due to the fault of NEOEMKI, the above procedure shall be followed so that the client does not suffer any disadvantage as a result.

In all cases, the recertification process must be designed to be completed in sufficient time to allow timely renewal of the certificate before its expiry date.

III.4. Certification Body:

The organization providing the certification service and carrying out the certification procedure detailed in the Certification Contract. NEOEMKI is an autonomous economic company owned by the Hungarian State, with the Ministry of the Interior as the legal owner. The Certification Body has the necessary designation and accreditation to provide the services specified in the contract.

III. 5. Client:

The organization ordering the certification service or procedure, whose quality management system and/or the medical device and/or in vitro diagnostic medical device and/or its production placed on the market is audited and assessed by the Certification Body.

III.6. Unannounced visit (only in case of CE certification, conformity assessment):

To verify compliance with legal obligations on a daily basis, the Certification Body will carry out an unannounced audit of the Client in addition to the initial, surveillance and recertification audits. An unannounced visit to the Client's contracted site, critical subcontractor or key supplier may be carried out by the Certification Body at least once per certification cycle.

III. 7. Certification Contract

The Client and the Certification Body will enter an individual Certification Contract for the service between them. The individual Certification Contract shall detail the content of the service, its deadline, validity, and financial terms.

III. 8. Legacy device:

Medical device and IVD medical device that have a valid certificate issued in accordance with Directive 93/42/EEC (MDD) or Directive 98/79/EC (IVDD) after the application date of Regulation (EU) 2017/745 (MDR) of 26 May 2021 and Regulation (EU) 2017/746 (IVDR) of 26 May 2022, respectively, may continue to be lawfully placed on the market, provided that the manufacturer complies with the requirements set out in Article 120 of Regulation (EU) 2017/745 and Article 110 of Regulation (EU) 2017/746 and continues to comply with the requirements of the Directive on which the original certification was based.

III.9 Emergency procedures:

The certification body's emergency procedure. Its application will be ordered by the head of the Certification Body, considering the circumstances, and will be notified to Clients.

III.10. State of emergency

The legal status declared by the government of a country. Hungary: according to Article 53 of the Fundamental Law, in the event of a natural disaster or industrial accident threatening the safety of life and property, and in order to avert the consequences thereof, a state of emergency may be declared and extraordinary measures may be introduced as provided for by a cardinal law.

III.11. Exceptional circumstances

Any situation (e.g. disaster, terrorist threat, strike, epidemic, etc.) that prevents an on-site audit from being carried out.

III.12. Rules of procedure

The Certification Body's activities in relation to the Client are governed by the Certification Contract, these Terms and Conditions and the procedures published by the Certification Body on its website. The services set out in the Certification Contract between the Client and the Certification Body shall be provided by the Certification Body in accordance with the procedures published on its website. The Certification Body may modify the published procedures on condition that they are published on its website and that the material changes are notified to its customers.

III.13. ICT

Information and communication technology. Includes: software, hardware, smartphones, handheld devices, laptops, desktops, drones, video cameras, wearables, artificial intelligence, etc.

III.14. Remote Evaluation / Remote Audit

Enabling NEOEMKI's system certification and/or conformity assessment activities using ICT, even when the audit team member(s) are not physically present on site, which includes off-site review of the necessary records/documentation.

IV. Scope of the GTC

IV.1. These General Terms and Conditions (GTC) apply to the Certification Contract between the Certification Body and the Client.

IV.2. The GTC shall be governed by the provisions of Hungarian law. In non-regulated matters, the Civil Code, the Act CXXXIII of 2009 on the Activities of Conformity Assessment Bodies, the government Decree 315/2009 (XII. 28.) on the implementation of the Act, as well as the Ministry of Health Decree 18/2010 (IV. 20.) and the Ministry of Health Decree 4/2009. (III.17.) on medical devices; the requirements of Regulation (EU) 2017/745 (MDR) and certain rules of Regulation (EU) 2017/746 (IVDR), as well as the requirements of Regulation (EU) 8/2003 (III.13.) of the Ministry of Health, Social Affairs and the Family on in vitro diagnostic medical devices, shall apply.

IV.3. The GTC and its amendments shall enter into force on the date determined by the Certification Body. The Certification Body shall publish the text, version number and effective date of the GTC in force on its website and shall notify its contracted Clients electronically of the change.

IV.4. The GTC shall remain in force until the entry into force of the amended GTC or until the date of the Certification Body's entitlement to provide the service.

IV.5. These GTC are an integral part of the Certification Contract concluded with the Client.

V. Subject and content of the Certification Contract

V.1 The Certification Contract is concluded between the Certification Body and the Client. In the Certification Contract, the Client mandates NEOEMKI to act as a Certification Body (designated and/or accredited body) to perform the services specified in the Certification Contract under the content and conditions specified therein.

V.2 The Client acknowledges and agrees that the Certification Body shall provide its services in accordance with the applicable Hungarian and EU legislation, common specifications, MEDDEV and MDCG guidelines and harmonized standards, and the procedures approved by the Designating and Accrediting Authorities. NEOEMKI makes its process for quality management system certification and conformity assessment activities publicly available on its website.

V.3 The Certification Contract shall include the cycle length of the service ordered by the Client.

V.4 The Certification Contract shall enter into force upon signature by both parties, and the Certification Body shall accept the assignment upon the conclusion of the Certification Contract.

V.5 The scope of the service is determined solely by the written Certification Contract based on the accepted offer. The quotation issued by the Certification Body and accepted by the Client shall be annexed to the Certification Contract.

V.6 If during the period of the certification contract the Client requires a change in the service, the content of the contract will be amended in accordance with the content of the new quotation prepared based on the Client's notification of change and accepted by the Client. The new accepted quotation shall be annexed to the contract.

V.7 The Certification Contract may be **subject to:**

- **Certification of quality management systems** according to the requirements of **MSZ EN ISO 9001:2015.**
- **Certification of quality management systems** according to the requirements of **MSZ EN ISO 13485:2016.**
- **Conformity assessment for medical devices:**
  - surveillance of EC certificates for medical device issued under the Directive 93/42/EEC on medical devices (MDD), for clients with a valid certificate issued by NEOEMKI, until the validity date indicated on the certificate, pursuant to Article 120 (3) of Regulation (EU) 2017/745;
  - surveillance of EC certificates for medical device issued under the Directive 93/42/EEC on medical devices (MDD), for clients with a valid certificate issued by NEOEMKI, during the validity period of the certificate, pursuant to Article 120 (3) of Regulation (EU) 2017/745; supplemented by the surveillance activities according to Regulation (EU) 2023/607.
- **Conformity assessment for in vitro diagnostic medical devices:**
  - surveillance of EC certificates issued for IVD medical device under the Directive 98/79/EC of the European Parliament and of the Council, for clients with a valid certificate issued by NEOEMKI, until the validity date indicated on the certificate, pursuant to Article 110 (3) of Regulation (EU) 2017/746.

V.8 Contractual performance is performance that is in accordance with the generally accepted rules and regulations of the service in question and in compliance with the regulations in force at the time of performance of the contract.

V.9 The performance under the contract is independent of whether the certification procedure leads to a favorable (e.g.: issuance, maintenance, reinstatement, etc.) or unfavorable (e.g.: suspension, revocation or limitation of the certificate, refusal to issue the certificate) result for the Client.

VI. Certification Contract duration, location, modification, termination

VI.1 The Certification Contract is valid for the entire duration of the contract (certification cycle). Duration of the Contract lasts:

- in case of an unsuccessful procedure, until the certification decision,
- in the case of a successful procedure
    - QMS certification according to MSZ EN ISO 9001:2015 and MSZ EN ISO 13485:2016 standards: until the validity date of the certificate (as stated on the certificate) or until revoking of the certificate,
    - conformity assessment according to Directive 93/42/EEC on medical devices (MDD): until the expiry of the issued certificate (the validity date indicated on the certificate), but not later than 26 September 2024 or until the withdrawal of the issued certificate,
    - conformity assessment according to Directive 98/79/EC on in vitro medical devices: until the expiry of the certificate issued (the expiry date indicated on the certificate), but not later than 26 May 2025 or until the certificate issued is withdrawn.

The Certification Body must carry out surveillance activities to maintain the certificate issued according to **GTC III.3. Certification cycle.**

NEOEMKI shall not be liable for any failure to meet the deadlines if the delay is caused by an intermediate action by the Client or another third party.

The Client's delay shall exclude the simultaneous delay of NEOEMKI.

VI.2 Due to the nature of the service, the performance will be split on-site, with one part, the evaluation of the documentation, taking place at the Certification Body prior to the on-site audit, and the other part, the on-site audit conducted by the Certification Body at the Client and its subcontractors and/or suppliers.

VI.3 The Certification Body shall carry out the on-site audit at the locations indicated in the quotation accepted by the Client. The on-site audit may be carried out if the Client's readiness is verified based on the documentation previously reviewed.

VI.4 Due to the nature of the service, the Certification Body has the possibility to carry out an on-site audit of the subcontractor that is critical to the procedure. The Client shall, in its contracts with its critical subcontractors, grant the staff of the Certification Body access to the subcontractor to the extent necessary for the audit to conduct the necessary audits.

VI.5 The Certification Contract may be amended at any time by mutual written agreement between the parties.

VI.6 Any modification to the services specified in the Certification Contract or the use of additional services shall require a written amendment to the Certification Contract. The amendment must be

accepted by both parties. The new agreement must always be attached to the original certification contract.

VI.7 The Certification Body may initiate a modification of the contract if unforeseen changes occur during the contract period that materially change the cost of the service provided. If the Client rejects the increased costs and the resulting contract modification, the Certification Organization is entitled to refuse further services.

VI.8 The Certification Body may initiate an amendment to the contract if there are changes in the legislation, standards, guidelines or regulations of the designating, accrediting bodies on which its activities are based that affect the subject matter of the contract.

VI.9 The Certification Contract shall be amended if the Client has notified a significant change affecting the certification, or if the on-site visit or other means reveal circumstances that differ significantly from the conditions communicated by the Client in the application form.

VI.10 Either party may terminate the contract by giving the other party notice of termination with good cause during the certification cycle.

VI.11 The Certification Contract may be terminated by ordinary notice only if the Certification Body has sent the Client a notification of a major amendment to the GTC (a change significantly affecting the subject matter of the contract, e.g.: a significant tightening of procedural deadlines for the Client, etc.), the Client does not accept the amendment and notifies the Certification Body in writing within 15 days of being informed. Minor modifications to the GTC (changes that do not significantly affect the subject matter of the contract, e.g. change of contact details of the Certification Body, extension of the scope of changes to be reported to the Certification Body, etc.) shall not constitute grounds for termination by the Client.

VI.12 In other cases, the Certification Contract may be terminated by either party by written notice to the other only by extraordinary termination. Extraordinary termination shall be possible only if the party giving cause for termination is in breach of contract in such a way as to make performance of the contract by the party at fault impossible.

VI.13 Breach of contract includes, but is not limited to, the Client's failure to inform the Certification Body prior to the scheduled date of the periodic obstruction of the on-site inspection, the Client's failure to allow the Certification Body to carry out the activities necessary to maintain the certificate, e.g.: the Certification Body is unable to carry out the surveillance audit or the assessment of the technical documentation within the prescribed time limit through the fault of the Client, the Certification Body is unable to carry out the unannounced audit (only possible in the case of a conformity assessment procedure) through the fault of the Client.

VI.14 It is considered as a breach of contract if the Client fails to pay the fees for the certification (e.g. assessment, audit, etc.) and/or the travel within the time limit.

VI.15 In the event of breach of contract, the party at fault shall be obliged to call upon the party in breach of contract to comply with the contract by setting a deadline of 8 days, or, if this is not possible, by setting a suitable deadline, and may use the extraordinary termination procedure if this call is unsuccessful.

VI.16 If the cause for the extraordinary termination is the Client's breach of contract, the Client may not claim back the commission fee already paid and shall pay the Certification Body for the damage caused by the breach of contract.

VI.17 If the cause of the extraordinary termination is the Certification Body's breach of contract, the Client may proceed according to the relevant provisions of the Civil Code.

VI.18 Termination of the contract with immediate effect is possible if the serious breach of contract or unlawful conduct cannot be remedied. Immediate termination will result, but not exclusively, from unauthorized use of the mark by the Client, for example:

- if they use their certificate for another activity for a non-certified activity,
- if they use another product's certificate for a non-certified product,
- if they market the certified product for a different use than that for which it has been approved,
- if they market the certified product following a significant change that has not been approved by the Certification Body,
- if they market a product which does not conform to the approved technical documentation.

VI.19 If fulfilment becomes impossible for reasons for which neither party is responsible (e.g. change in legislation) the Certification Contract will be terminated. The party which becomes aware of the impossibility of fulfilment shall immediately notify the other party thereof. The defaulting party shall be liable for any damage resulting from failure to notify. Upon termination of the Certification Contract, the contractual monetary consideration for the services already provided before termination shall be paid.

VI.20 In the event of termination of the Certification Contract before the end of the certification cycle, the valid certificates will be revoked by the Certification Body. In this case, the Client shall immediately return the certificates already issued to them.

VII. Procedure for concluding the Certification Contract, billing and payment of fees

VII.1 The Certification Contract between the Client and the Certification Body shall be drawn up by the Certification Body according to the price quote prepared on the basis of the quotation request form sent by the Client, and shall include the information and data taken into account in the planning of the certification procedure.

Accommodation and travel costs for on-site audits are not included in the quotation. Travel costs will be passed on to the Client. For travel outside Europe, only business class air travel is available for auditors.

VII.2 The service fees included in the certification contract are in no way dependent on the result of the certification.

VII.3 The Client acknowledges that the Certification Body has determined the certification fees set out in the Certification Contract considering the entire certification cycle, only for the sites, processes, critical subcontractors, key suppliers and products specified in the contract, separately indicating the fees for initial and surveillance procedures and ad hoc fees and, in the case of a conformity assessment area, the fees for unannounced audits.

VII.4 By signing the Certification Contract, the Client accepts the fees offered for the relevant certification activity.

VII.5 The client shall pay the calculated fees increased with the rate of the average annual consumer price index published for the relevant year.
The average consumer price index is the rate published annually by the Hungarian Central Statistical Office. The price index is applied from the first day of the month following the index publication.

Service fees not specified in the Certification Contract are calculated on the basis of the current fee schedule published on the website of the Certification Body.

VII.6 The Client is obliged to pay the fees and costs specified in the Certification Contract to the Certification Body before the commencement of the activities covered by the contract, based on a fee request letter issued by the Certification Body, by the deadline specified, by transfer to the bank account of the Certification Body. The Certification Body will issue an advance invoice for the payment. If the Client fails to pay the evaluation and/or the travel fee by the due date, the Certification Body shall be entitled to terminate the procedure and refuse to issue the certificate or, in the case of a certificate issued, to suspend it.

VII.7 The Client acknowledges that they are obliged to pay the full fee due under the contract at the time the evaluation of the technical documentation is started by the Certification Body.

The Client acknowledges that the organization of the site visit does not start before the transfer of the fee. If the on-site audit cannot take place as scheduled due to the delay in payment, the consequences of this shall be borne by the Client.

VII.8 The Certification Body shall, in return for the fee specified in the certification contract:

- in the case of the system certification area (certification of quality management systems according to the standards MSZ EN ISO 9001:2015 and/or MSZ EN ISO 13485:2016), examine the quality management documentation.
- for the conformity assessment domain (MDD, IVDD, MDR, IVDR), examine the quality management and technical documentation

VII.9 If during the examination of the documentation or during the on-site audit the Certification Body identifies a nonconformity, the certification fee set out in the Certification Contract includes an assessment of the correction by the Client on one occasion. If further corrections and re-assessments are required, the Certification Body shall be entitled to charge the hourly fee specified in the Certification Contract for the time spent on the re-assessment.

VII.10 The Certification Body reserves the right, if an on-site audit at the Client's premises or those of its subcontractors is necessary to verify the implementation of corrective and preventive actions related to the detected nonconformity in an appropriate manner, to set an additional fee in accordance with the activity performed. In this case, travel and accommodation costs shall also be borne by the Client.

VII.11 The final report of the on-site audit, prepared and delivered at the end of the on-site audit, shall be considered as a certificate of completion.

VII.12 If the initial certification is unsuccessful (and no certificate has been issued), the Certification Body will refund the fee for the issue of the certificate as specified in the quotation from the fee already paid by the client.

VII.13 If an unannounced audit fails due to reasons in the Client's interest, the Certification Body shall be entitled to charge the Client an additional fee for repeating the audit.

VII.14 In case of changes that occur during the certification cycle, if they require a partial or complete re-evaluation of the documentation or an on-site audit at the Client's premises, the Certification Body is entitled to charge the hourly rate specified in the certification contract for the time spent on the evaluation for the management of the changes. If the conditions of the contract change due to a change in the Client's requirements, NEOEMKI shall send the Client a proposal for an amendment to the quotation in relation to the changed conditions, which the Client shall be obliged to comment on in writing within 8 days. The accepted amended quotation shall become an annex to the contract.

VII.15 Where the change requires an extraordinary on-site audit, the Certification Body is entitled to charge the hourly rate specified in the Certification Contract based on the time required to assess the change.

VII.16 The discounts applied to the fee offered for the certification cycle may be reclaimed by the Certification Body from the Client if the Certification Contract is terminated during the certification cycle by ordinary or extraordinary termination for reasons in the Client's interest.

VII.17 The details of the Fee Payer, if different from the Client, must be indicated on the Certification Contract. If the Fee Payer is not the same as the Client, the Fee Payer shall be the party liable for payment and the beneficiary of any refunds.

VIII. Rights and obligations of the Client

VIII.1 The Client is entitled to:

- impartiality on the part of NEOEMKI, which must be guaranteed by a declaration of impartiality from the staff involved in the service.
- raise a justified objection to particular persons of the audit team/compliance assessment team appointed by the Certification Body. The reasons for the objection must be provided. In case of justified objections, NEOEMKI shall reorganize the team. Objections shall be admissible only on grounds of impartiality and independence. This provision shall not apply in the event of an extraordinary and/or unannounced audit.
- access the documents related to the certification decision, which will be logged.
- ask questions about the certification process and receive a reasoned, objective response.
- complain to the head of the Certification Body about the certification process in accordance with the complaints procedure published on the NEOEMKI website (E97 Handling events violating organizational integrity, complaints and appeals against a certification decision). NEOEMKI shall investigate any complaint reported by a Client in accordance with its applicable procedures.
- appeal in writing against certification decisions made in relation to the certification process in accordance with the appeals procedure published on the NEOEMKI website (E97 Handling events violating organizational integrity, complaints and appeals against a certification decision). NEOEMKI shall handle all appeals made by the Client in accordance with its relevant procedures.
- request that the public availability of information on certification be restricted, if this does not conflict with the obligation to disclose information which is required to be made public by law.

VIII.2 The Client shall:

- cooperate with the Certification Body in the fulfilment of the Certification Contract. This also applies to third parties acting on behalf of the Client.
- perform or cause to be performed, in a timely manner, the tasks necessary for the Certification Body to perform its services.
- comply with the applicable legislation (e.g. Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR), Regulation (EU) 2017/746 of the European Parliament and of the Council (IVDR), etc.), standards, common specifications, guidelines, safety and accident prevention regulations applicable to the certification service specified in the Certification Contract.
- provide the Certification Body with the information, data, and documents necessary for the certification procedure before and during the procedure and take responsibility for their accuracy.
- provide the Certification Body with the documentation to be submitted in Hungarian and/or English.

- reimburse the additional costs if the information provided is incomplete, late, or incorrect; or if its contribution is irregular or not in conformity with the contract.
- in the case of a system certification procedure (certification of quality management systems according to the standards MSZ EN ISO 9001:2015 and/or MSZ EN ISO 13485:2016), provide NEOEMKI with the quality management system documentation.
- in the case of conformity assessment procedures, provide the Certification Body with:

- the entire documentation of the quality management system,
- the Technical Files and/or Design Dossier of each device in the scope of certification,
- in case of medical device: all relevant data on post-market surveillance, vigilance, and registration of economical operators and products according to Article 120 (3) of (EU) 2017/745 regulation (MDR),

  in case of in-vitro medical device: all relevant data on post-market surveillance, vigilance, and registration of economical operators and products according to Article 110 (3) of (EU) 2017/746 regulation (IVDR),

  in Hungarian or in English, noting that all documents and records related to the certification process are stored in electronic or printed form by the Certification Body for the duration of the certification cycle or for the period specified by law.

- provide the Certification Body with the conditions for conducting an on-site audit (if necessary, by providing ICT) of all its manufacturing sites, critical subcontractor sites and key suppliers during the relevant certification period.
- answer questions from the Certification Body about the certification process.
- appoint a responsible person (contact person) and ensure their availability
- if the service is to be performed at a place designated by the Client, the Client is obliged to ensure that the place of performance is in a condition suitable for the provision of the service.
- ensure that the personnel of the Certification Body have the necessary access to the Client's production site, headquarters, premises, and areas within the Client's organization to carry out the activities specified in the Certification Contract, by ensuring the relevant safety conditions. This also applies to subcontractors used by the Client.
- report changes to its activities covered by the Certification Contract or to the manufactured product in a timely manner.
- pay the fees and costs of certification, regardless of the outcome of the certification procedure.
- notify the Certification Body of any ongoing or closed certification agreement with another certification body for the certification of the quality management system and products covered by the Certification Contract.
- submit a corrective and preventive action plan (CAPA plan) to the Certification Body within 15 days if nonconformity is identified during the procedure.
- submit to the Certification Body the documents justifying the correction of the nonconformities by the deadline agreed in the corrective and preventive action plan adopted by the Certification Body. In the absence of corrective action, the procedure will be closed at the end of the deadline set in the preventive action plan.

VIII.3 After obtaining the certificate, the Client shall, considering the scope of the certificate, also:

- maintain and service its quality management system and take measures to correct and improve it in accordance with documented procedures.
- in the case of conformity assessment, maintain the technical documentation of the equipment, keep it up to date / take the necessary measures to ensure that it is up to date.
- submit to surveillance activities (e.g. on-site audit), subject to prior agreement, in order to keep the certificate valid;
- in case of medical devices, apply the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR) on variations, post-market surveillance, vigilance, and registration of economic operators and devices, as set out in Article 120(3) of Regulation (EU) 2017/745;
- in case of in vitro diagnostic devices, apply the requirements of Regulation (EU) 2017/746 of the European Parliament and of the Council (IVDR) on variations, post-market surveillance, vigilance and registration of operators and devices, as set out in Article 110(3) of Regulation (EU) 2017/746;
- in the case of conformity assessment procedures according to directives MD or IVD: ensure that unannounced audits can be held at their own sites and, if relevant, at their subcontractors,
- in the case of conformity assessment procedures according to directives MD or IVD: ensure that unannounced audits can be held at their critical subcontractors, or key suppliers involved in the production of the product subject to the Certification Contract, as stipulated in the contract between manufacturer and their subcontractors,
- clearly identify product variants and modified products so that they can be identified and changes can be distinguished;
- use certification-related documents, marks or records of the Certification Body (e.g. audit reports) only in their entirety, without abbreviations or abstracts, and in a non-misleading manner;
- take into account the Certification Body's regulations on the use of certification marks published on its website and act accordingly (e.g. in the media, advertising). In case of conformity assessment: the Client may only affix the **CE 1011** marking to medical devices/in vitro diagnostic devices and information material issued for these products manufactured during the period of validity of the certificate issued under the Certification Contract and may issue a declaration of conformity for these products.
- comply with the requirements of the Certification Body (termination of advertising and logo use, return of certificates, issuance of a manufacturer's warning) if its certificate is suspended or revoked by the Certification Body.
- immediately terminate the use of the CE 1011 mark following the termination of the Certification Contract, including the revocation and expiry of the certificate, or pause the use of it if the certificate is suspended.
- refrain from qualifying the certification service in a way that would bring the Certification Body into disrepute.
- refrain from making misleading or inappropriate statements about certification activities.
- claim the fact that they have been certified only in relation to the activities or products to which the certificate relates.

- before the surveillance, recertification, or special audit, or for any other reason, provide the Certification Body with the documentation of its quality system in force at that time and the technical documentation of the devices covered by the certification, with a separate list of any changes that have occurred in the meantime.
- in the event of termination of the Certification Contract for any reason, including revocation or expiry of the certificate, inform the Certification Body, giving the range of the unique device identifier (basic UDI-DI, UDI-DI, UDI-PI), serial number, serial number, LOT number, etc., of the products that it has placed on the market under the supervision of the Certification Body during the period of the Certification Contract. The Client shall specify the date when the last product within this scope was placed on the market.
- comply with the requirements of Article 120(3) of Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices and other relevant legislation regarding the certification of inherited devices by the Certification Body.
- comply with the requirements of Article 110(3) of Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro medical devices and other relevant legislation regarding the certification of inherited devices by the Certification Body.

VIII.4 The Client shall notify the Certification Body after obtaining the certification document (certificate) about any:

- substantial change in its quality system, organizational structure, production site, technology, product manufactured, etc.; as described in **point XII of the GTC**.
- unexpected event related to products manufactured by it and certified by the Certification Body.
- certification agreement with a conformity assessment body other than the Certification Body for the certification of products covered by a Certification Contract.

IX. Rights and obligations of the Certification Body

IX.1 The Certification Body is entitled to:

- carry out certification procedures in the areas specified in its accreditation and/or designation document.
- decide, based on the available objective evidence, on the conformity and on the issuance, refusal, maintenance, revocation, suspension, and limitation of the certificate. Until the Certification Body accepts the implementation of corrective measures related to a major nonconformity with satisfactory results within the time limit, the certificate shall not be issued or cannot be held in force.
- use a subcontractor in justified cases, after informing the Client.
- request from the Client any information or data necessary for the proper performance of the certification procedure chosen.
- carry out an extraordinary and/or in the case of conformity assessment procedures unannounced audit at the Client's and/or its subcontractor's or supplier's premises.
- by informing the Client in writing, initiate the suspension of the certificate and terminate the Certification Contract by giving notice of termination if the surveillance audit is not carried out within the prescribed time limit (as specified in the applicable rules of the Certification Body) and no other agreement is reached with the Client.

- initiate the revocation of the certificate if the Client does not remove the reasons for the suspension within 6 months of the suspension.
- carry out the necessary inspections and checks at the Client's premises during the term of the Certification Contract for the activity covered by the Contract.
- if the service is to be performed at a location designated by the Client and the Client does not provide the location in a condition suitable for the provision of the service, refuse to provide the service until the Client has complied with its obligation. NEOEMKI may withdraw from the contract and claim damages beyond the time limit set by NEOEMKI.
- record nonconformities during the certification process. In the case of major nonconformity, 180 days in the initial procedure (150 days for the implementation of corrective action by the Client + 30 days for the assessment of the implementation and compliance of the corrective action by the Client by NEOEMKI), while in the surveillance procedure, a maximum of 90 days (60 days for the implementation of the corrective action by the Client + 30 days for the assessment of the implementation of the corrective action by the Client, including the post-audit, by NEOEMKI) are available for their correction and closure by NEOEMKI. If the corrections are not made or cannot be accepted, the Certification Body shall refuse to issue or reinstate the certificate or suspend or revoke the certificate already issued.
- task the Certified Organization's on-site audit team with deciding on whether a follow-up audit is necessary. In the case of an initial audit, the follow-up audit must be conducted, and the documentation closed by the Certification Body within 180 days of the on-site audit, and in the case of a surveillance audit within 90 days. In the case of a follow-up audit, the relevant NEOEMKI audit fees apply.
- retain ownership of the reports and documents prepared by the Certification Body in relation with the certification.
- to the extent necessary for the performance of the Certification Contract, allow its employees and external experts to enter and remain at the Client's headquarters, premises (including relevant subcontractors) and areas within its organization.
- keep the documentation provided by the Client in electronic or paper format at the Certification Body after the certification procedure has been completed, for the duration of the certification cycle or for the period specified by law.
- issue a certificate in English and/or Hungarian if the certification process has been completed with satisfactory results.
- initiate the suspension of the certificate if the Client fails to comply fully with its obligations in the event of nonconformity, despite a request from the Certification Body.
- exercise appropriate control over the use and display of its certification mark according to the **Chapter XI of the GTC!**

IX.2 The Certification Body shall:

- carry out the certification procedure in accordance with the legislation in force in the field (service) to be certified and with its own manual, procedures, instructions.
- provide personnel with the appropriate professional competence in the field to be certified (employee, contractor, or subcontractor with personal assistance) and inform the Client of the participants in the procedure,

- investigate a customer complaint against a member of staff and, if the complaint is justified, appoint another competent person.
- treat the information obtained during the certification procedure as confidential, this confidentiality obligation also extends to all employees of the Certification Body and any external experts or subcontractors it may engage.
- have the staff members designated to carry out certification activities related to the Client declare in writing that they will maintain confidentiality.
- ensure the independent and impartial conduct of the certification process, to which end NEOEMKI does not engage in consultancy activities. Under the Contract, the Client shall not be entitled to demand that NEOEMKI resolve any nonconformities that may be identified during the certification procedure.
- immediately notify the Client if there is any legal or other impediment to the performance of its activities covered by the Certification Contract.
- promptly notify the Client of any fact or circumstance that affects or may affect the performance of its activities covered by the Certification Contract.
- if the Client does not confirm the draft certificate sent within 14 days after a successful certification procedure, issue the certificate in accordance with the draft.
- organize the surveillance procedures in relation to the Client's valid certificate by specifying the documents to be submitted and sending the invoice for the surveillance fee.
- carry out a surveillance procedure, which includes an on-site audit at the Client's manufacturing site and/or premises (including relevant subcontractors) and, in the case of conformity assessment procedures (MDD, IVDD, MDR, IVDR), an assessment of the technical documentation according to the certification cycle plan (audit/certification program).
- initiate the suspension of the certificate if the Client refuses or hinders the organization of the surveillance procedure or audit, and the Certification Body is unable to carry out the procedure or audit by the relevant deadline.
- examine any complaint by the Client, including any appeal against the certification decision, in accordance with the relevant procedure.
- meet the deadlines set out in the certification procedures published on its website.
- fulfill its duties and obligations under the legislation, report issued, modified or revoked certificates to the supervisory body and/or to record them in the relevant international database (e.g. Eudamed, CertSearch).
- if there are reasonable doubts about the manufacture or the safety or efficacy of the product, must take action regarding the product in accordance with the regulations.
- store documents generated during the certification activity for the period specified in the legislation after the certification procedure has been completed.

X. Specific requirements for conformity assessment activities for medical devices under Directive 93/42/EC (MDD) and for in-vitro medical devices under Directive 98/79/EC (IVDD)

X.1. NEOEMKI, as a notified body (NB 1011), carries out conformity assessment activities in the designated conformity assessment area in accordance with the specifications laid down in the legislation or directly applicable EU legal act of general scope providing for conformity assessment activities for the product.

X.2 The Client acknowledges that NEOEMKI recognizes the Common Specifications (CS) and Guidelines (MDCG) as binding.

X.3 In the conformity assessment procedure of medical devices, NEOEMKI considers the high level of protection of the health of patients and users to be of primary importance, and to this end, it is entitled to require the Client to provide evidence defined by legislation, guidelines, common specifications, harmonized standards, and science, in particular medical science, in order to ensure conformity.

X.4 The Client may submit its request for conformity assessment to NEOEMKI together with its accepted quotation.

X.5 Following the submission of a request for conformity assessment, NEOEMKI will assess whether the request complies with the information previously provided in the request for quotation and the formal requirements for MDD, IVDD request. If the application is incomplete or does not comply with the specifications, the application will be rejected and no contract will be concluded. Contracts will only be concluded if the application is accepted.

X.6 The Certification Body currently only accepts applications to carry out surveillance activities under Regulation (EU) 2023/607 by accepting the relevant quotation issued by NEOEMKI.

X.7 Procedure for supervisory activities:

Procedure for conformity assessment surveillance according to Regulation (EU) 2023/607:

- In this special case, the certification contract may cover a maximum of 2 calendar years.
- In both calendar years, the Certification Body is obliged to conduct a surveillance procedure.
- In the case of the first calendar year, stages 1 and 2 must be completed in all cases.
- In the case of the second calendar year, the 1st stage is only necessary if changes or other reasons make this necessary.
- If the certification contract is for 1 calendar year, a two-stage surveillance procedure must be conducted, which in all cases includes the completion of both the 1st and 2nd stages.

Procedures for all conformity assessment surveillance procedures:

The surveillance procedure can consist of two stages (Stage 1 and 2). Stage 1 is only necessary if changes or other reasons make it necessary.

During the Stage 1 of the procedure, NEOEMKI shall review the Client's quality management documentation (quality manual and at least the list of procedures and the content of key procedures), the technical documentation(s) according to the sampling plan (if applicable), in addition to the management review and internal audit documentation. The conformity assessment team designated by NEOEMKI shall declare the result of Stage 1 within 3 months after the submission of all documentation. If deficiencies are identified in the documentation which do not allow for an on-site audit to be carried out, NEOEMKI shall be entitled to postpone the initial Stage 2 (on-site audit) until

they have been corrected. During the certification procedure, NEOEMKI shall be entitled to record nonconformities both in the quality management system and in the technical documentation(s) and/or production design(s). Further nonconformities may be identified for the production plan and/or technical documentation sent by the Client as a correction. NEOEMKI may take a certification decision on the issuance, maintenance, or reinstatement of the certificate only after the major nonconformities have been corrected by the Client and accepted by NEOEMKI.

In case of non-conformity of the technical documentation and/or design dossiers, the certificate can only be maintained if the corrections by the Client and their acceptance by NEOEMKI are concluded in an appropriate manner within the defined deadline.

X.8 The Certification Body is entitled to check the up-to-date status of the technical documentation of the certified products at any time during the term of the contract.

X.9 In the case of surveillance activities according to Regulation (EU) 2023/607, the Client must undertake the following:
- ensuring the fulfillment of the requirements laid down in point (3c) of Article 1 of Regulation (EU) 2023/607. Client must immediately notify the Certification Body in a documented manner when the conditions are not met.
- establishing a quality management system in accordance with Article 10 (9) of Regulation (EU) 2017/745 by May 26, 2024, at the latest.
- notifying NEOEMKI LLC. on the initiation (acceptance of application and conclusion of contract) and conclusion of any ongoing conformity assessment procedure for the relevant devices with a notified body designated according to Article 42 of the MDR within 8 days.

X.10 NEOEMKI shall conduct an annual surveillance audit at the Client's premises and/or at critical subcontractor, the cost of which shall be borne by the Client.

X.11 The Certification Body shall be entitled to carry out an extraordinary audit at the Client's premises, any of its sites, critical subcontractors, or suppliers, at the Client's expense, in particular in the event of a complaint investigation, a notified change or suspension of the certificate.

X.12 The Certified Body shall conduct an unannounced audit of the Client, any of its premises, critical subcontractors, or suppliers at the Client's expense in accordance with Recommendation 2013/473/EU. An unannounced audit shall be carried out in particular in the event of a legal requirement, investigation of a complaint or request by any competent authority.

X.13. If the manufacturer or its critical subcontractor is sited in a country that requires a visa, the Client must provide an appointment-free invitation letter for the visit to the manufacturer to allow an unannounced audit.

X.14. The Client shall inform the Certification Body of the periods during which it does not manufacture devices covered by the scope of the notified body's certificate to conduct an unannounced audit. The information shall be sent to cert@emki.hu by 31 January each year.

X.15 The Client shall cooperate in the conduct of the unannounced audit.

X.16 The Certification Body shall be entitled to carry out the necessary tests and inspections at the Client's premises during the term of the contract for the conformity assessment activities covered by the contract.

X.17 The Certification Body shall be entitled to take samples of the certified equipment or material used for the equipment and to have laboratory tests carried out during the contract period in order to verify conformity.

X.18 If NEOEMKI, as a designated organization, determines that the Client's product and/or quality management system does not comply with the requirements defined by the law, or by any directly applicable legal act of the European Union regarding the product, as well as with other technical specification as defined in Article 2 (8) of Regulation (EC) 765/2008, for which the certification was asked, the Certification Body is entitled to suspend the relevant certificate until the Client takes the necessary measures to bring the product and/or quality management system into compliance with the requirements.

X.19 The Certification Body is responsible for deciding on compliance, as well as suspension and revocation of the certificate, based on the available objective evidence.

X.20 The Client shall inform the Certification Body within 72 hours of any incident or accident affecting the product certified by NEOEMKI that occurs during the term of the contract and the results of the investigation.

X.21 The Client is obliged to inform the Certification Body within 72 hours of any proceedings initiated by a Member State authority concerning a product covered by certification during the term of the contract.

X.22 If NEOEMKI, as a notified body, establishes after the issue of the certificate of conformity that the certified product no longer meets the requirements or if it has reasonable grounds to suspect that it does not meet the requirements, particularly in the case of a request by a public authority, it shall notify the Client thereof within a period of time appropriate to the characteristics of the product. If the Client fails to take the necessary measures to bring the product into conformity within the time limit set, or if the defect in the product cannot be rectified, NEOEMKI as notified body shall limit or suspend the validity of the certificate or revoke the certificate. The period of suspension of the certificate shall not exceed 6 months, after 6 months the certificate shall be revoked.

X.23 If NEOEMKI, as a notified body, becomes aware after the issue of the certificate of conformity that the device may present a serious risk to public health, it is entitled to suspend or revoke the certificate immediately.

X.24 NEOEMKI shall make publicly available on its website the current documents describing its certification processes and the procedures for issuing, maintaining, renewing, extending, limiting, suspending, or revoking certificates, the certification activities, the designation areas it deals with and the geographical areas in which it operates, as well as the fact of any modification of these documents, which it shall inform its customers of electronically.

X.25 Where NEOEMKI, as a notified body, becomes aware of a nonconformity with the provisions concerning the making available on the market of a product in the designated conformity assessment area, it shall inform the other conformity assessment bodies operating in the designated conformity assessment area, including notified bodies of other States party to the Agreement on the European Economic Area (hereinafter referred to as "EEA States"), accordingly.

X.26 NEOEMKI, as a notified body, shall also provide information on the results of conformity assessment to other conformity assessment bodies, including notified bodies established in the EEA States, operating in the designated conformity assessment area, upon request.

X.27 The Client has the right to appeal to the designating authority against the activities of NEOEMKI as a notified body.

XI. Use of certification mark

XI.1 The Client shall comply with the applicable legislation when using the certification mark (CE mark in case of conformity assessment).

XI.2 NEOEMKI is entitled to exercise appropriate control over the use and display of the certification mark.

XI.3 Rules for claiming certified status:

- The certificate can be used to prove the certified status within the validity period.
- Misleading references to certified status are prohibited.
- The use of certification documents in a misleading way is prohibited.
- In the event of suspension or withdrawal of certification, all references to certification shall be removed.
- It is prohibited to create the impression that certification also applies to activities or products outside the scope of the application.
- If the scope of certification has been narrowed, all references should be amended accordingly.
- Any reference to the certification of a quality management system and/or product that could damage the reputation of NEOEMKI or the certification system and undermine public confidence is prohibited.
- NEOEMKI will exercise appropriate control and act if there is an impermissible reference to certified status or misleading use of certification documents, marks, or reports.

XII. Changes to Client Data, reporting changes

XII.1 The Certification Contract between the Certification Body and the Client shall remain valid for the duration of the certification cycle, without any changes to the terms of the Certification Contract. If there is a change that may affect the maintenance of the service ordered by the Client, he shall notify the Certification Body without delay, but at least within 30 days, using the form provided for that purpose. The change notification form will be published by the Certification Body on its website.

The Client is obliged to declare the changes that have been implemented since the previous audit prior to the supervisory, renewal and extraordinary audits by filling out the Change Notification form. If there have been significant changes to the product and/or the quality management system since the previous audit, the Client must include a list of the changes with the notification. The minimum data content of the list: short description of change, classification of change, date of notification to NEOEMKI (if relevant), date of closure/implementation.

XII.2 The Certification Body is not responsible for the consequences of any failure to notify the Client. If, during the initial, surveillance, recertification, extraordinary or unannounced audit or in any other way, the Certification Body observes changed but not reported circumstances, it is entitled to initiate a modification of the Certification Contract and the certification fee.

The Client shall report any changes that may have a significant impact on the quality management system and/or product covered by the certification.

The Certification Body shall carry out a preliminary assessment of all notified changes to determine the further actions to be taken (e.g.: on-site audit and/or technical documentation assessment, etc.). The Certification Body shall notify the Client of the results of both the preliminary and, if relevant, the subsequent assessment.

In case of conformity assessment procedures, the following documentation must be considered for the assessment of the change:

- the NBOG BPG 2014-3 guide in all cases,

- for surveillance activities for certificates issued under the MDD (93/42/EEC), the provisions of Article 120(3) of the MDR and the MDCG Recommendation 2020-3,

- while for surveillance activities for certificates issued under the IVDD (98/79/EC), the provisions of Article 110(3) of the IVDR and Recommendation MDCG 2022-6.

The obligation to notify changes includes in particular:

Changes to the quality management system: scope (extended/reduced), name, address, headquarters, SRN, site, manufacturing site, legal form, organization, management, number of employees, quality manager/assignee, person responsible for compliance (PRRC), product scope, technology used, quality management process, subcontractor, supplier, authorized representative (EC REP), etc.

Product changes: device intended purpose, indications, contra-indications, product listing, name, brand name, specification (technical description), approved device design, approved device type, materials incorporated in or used in the manufacture of the device and their suppliers, manufacturing technology, test method (for both input material, semi-finished product and finished product), packaging, sterilization, shelf life, instruction label, software, pharmaceutical or animal source material, basic UDI-DI, etc.

XII.3 Specific requirements for conformity assessment procedures:

- Until the change notification has been approved by the Certification Body, the product affected by the change may not be placed on the market.
- For changes to an already approved device, the approval of the Certification Body must be sought before the change is implemented if the changes may affect the safety or performance of the device or the conditions prescribed for its use.
- If the Client plans to introduce any of the above-mentioned changes, he must inform the Certification Body accordingly. The Certification Body must evaluate the planned changes and decide whether a new conformity assessment is necessary. The Certification Body must evaluate the changes and notify the manufacturer of its decision in any case.
- The Client is obliged to declare the changes that have been implemented since the previous audit prior to the supervisory, renewal and extraordinary audits by filling out the Change Notification form. If there have been significant changes to the product and/or the quality management system since the previous audit, the Client must include a list of the changes with the notification. The minimum data content of the list: short description of change, classification of change, date of notification to NEOEMKI (if relevant), date of closure/implementation.

  Changes in the list should be classified as follows:

  - In case of MDD:
    - According to NBOG BPG 2014-3 significant or NOT significant, or
    - According to Article 120 (3) of the MDR, significant or NOT significant,
  - In case of IVDD:
    - According to NBOG BPG 2014-3 significant or NOT significant, or

- According to Article 110 (3) of the IVDR, significant or NOT significant

- Based on the evaluation of the change by the certification body, when consultation with the competent authorities, experts or the Commission is required then it must be conducted by the Certification Body.

XIII. Complaints handling, appeals against certification decisions

XIII.1. The Certification Body publishes on its website its current regulations on complaints and appeals (E97 Handling events violating organizational integrity, complaints and appeals against a certification decision). The Client has the possibility to lodge a complaint or appeal against the Certification Body's procedures or certification decisions, in accordance with the relevant points of the E97 procedure. To facilitate the procedure for the Client, the Certification Body publishes on its website the forms for the submission of complaints and appeals.

XIV. Other provisions

XIV.1. If the Certification Body finds that the product or the quality management system does not comply with the requirements laid down for the product by law or by a directly applicable European Union act of general application as well as the requirements set out in the other technical specifications referred to in Article 2(8) of Regulation (EC) No 765/2008 for which the Client has requested conformity assessment, the Certification Body shall not issue a certificate of conformity until the Client has taken the necessary measures to bring the product into conformity with the requirements [Article 6(1) of Government Decree No. 315/2009 (XII. 28.), paragraph 6].

XIV.2. If, after the issue of the certificate of conformity, the Certification Body establishes that the certified product or quality management system no longer meets the requirements referred to in the directive applicable to the device, it shall notify the Client thereof, setting a time limit appropriate to the characteristics of the product. If the Client fails to take the necessary measures to bring the product into conformity within the given time limit or if the defect in the product cannot be remedied, the Certification Body shall limit the scope of the certificate, suspend it, or revoke it, as specified in its quality manual and its rules of operation and procedure [Article 6(2) of Government Decree No. 315/2009 (XII. 28.)]

XIV.3. The Client may only commission a conformity assessment procedure for medical devices covered by the Certification Contract to another certification body (Notified Body) during the period of validity of the Certification Contract if a prior written agreement to this effect has been made with the Certification Body signing this contract.

XIV.4. At the same time as signing the individual Certification Contract, the Client declares - also regarding Article 50 (1a) paragraph of Government Decree No.368/2011 (XII. 31.) on Public Finance - that it qualifies as a transparent organization pursuant to Article 3 of Act CXCVI of 2011 on National Property. The Client undertakes to inform the Certification Body without delay in the event of any change in its transparent organizational status. The Client acknowledges that if it is not a transparent organization, the Certification Body shall be entitled to terminate or withdraw from the contract with immediate effect and to claim compensation for any other damage incurred, without indemnifying the Client.

XIV.5. The Client acknowledges that in the event of an emergency affecting the Client and/or the Certification Body, the emergency procedure developed by the Certification Body shall be applied to ensure the sustainability of operations. At the time of the declaration of an emergency, the

Certification Body shall act in accordance with its relevant procedures, and the procedures published on its website shall be repealed for the duration of the emergency.

XIV.6. The Client acknowledges that the Certification Body will provide information on valid certificates, including the name of the certified Client, the certificate number and the scope of the certificate, upon request of a third party.

XIV.7. The Client acknowledges that the Certification Body has data reporting obligations for conformity assessment procedures carried out in accordance with Regulation (EU) 2017/745 and Regulation (EU) 2017/746 (e.g. MDR, IVDR Article 57(1) points (f), (g), (h) and (i) of the Regulation, recording of information related to the certificate, recording of the results of the application for a review, summary of safety and performance, consultation procedure for clinical evaluation of devices in Class III or IIb, etc.), which it fully complies with the requirements of the relevant Regulation.

XIV.8. The Client acknowledges that the Certification Body is obliged to provide data and access to documents related to the given procedure (e.g. audit documentation, product inspection reports, etc.) in the framework of the inspection by the competent authorities.

XIV.9. The parties shall attempt to settle any disputes by negotiation or out-of-court settlement, failing which either party may resort to legal proceedings. In the event of recourse to the courts, the parties submit to the jurisdiction of the courts of the place where the Certification Body is established.

XIV.10. The Contracting Parties shall act in accordance with the provisions of Act V of 2013 on the Civil Code in matters not regulated in these GTC.

XIV.11. The Client and the Certification Body agree that in the event of force majeure situations that prevent the performance of these GTC, they will endeavor to amend the contract by mutual agreement, considering their mutual interests.

XIV.12. By signing the individual Certification Contract, the Client declares that they have read and accepted the contents of the current General Terms and Conditions of NEOEMKI.