GENERAL TERMS AND CONDITIONS

(GTC)

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I. Organisational Conditions of the Service

Service Provider Name: NEOEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft. (hereinafter: **NEOEMKI**)

Registered office: H-1097 Budapest, Albert Flórián út 3/A

Company reg. No. 01-09-357519

VAT No.: 27927616-2-43

Bank Account No. 10409015-50526970-68801014 (K&H Bank):

Represented by: Imre László, managing director

II. NEOEMKI Contact Details

Registered office: 1097 Budapest, Albert Flórián út 3/A

Website: https://emki.hu/

Phone No. +36 20 268 7595

E-mail: cert@emki.hu

Site for Customer service: 1148 Budapest, Nagy Lajos Király út 10.

Customer service hours: Tuesday and Thursday, 9:00–14:00

III. Definitions, Abbreviations and Information

GTC (General Terms and Conditions):
As an integral part of the Certification Contract or agreement between NEOEMKI and the Client for the conformity assessment of medical devices or certification of quality management systems.

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

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

The certification cycle is three years for the quality management system certification area (according to the standard EN ISO 13485), and five years for the conformity assessment area (Regulation (EU) 2017/745).

For certificates issued in the framework of conformity assessment under the Medical Devices Directive 93/42/EC, the certification cycle lasts until the deadlines set out in Regulation (EU) 2023/607.

As a condition for the validity of the certificate during the cycle, NEOEMKI will carry out a surveillance audit at least once every calendar year for the surveillance of the quality management system certification area and the conformity assessment certificates under Directive 93/42/EC, and once every 12 months for the conformity assessment area of Regulation (EU) 2017/745 MDR.

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

Conformity assessment:
The process of determining whether the requirements of Regulation EU 2017/745 are met for a particular device.

Conformity assessment body:
A body that performs third-party conformity assessment activities including calibration, testing, certification and inspection.

Certification body:
A body providing certification services as defined in the Certification Contract.

Accredited body:
An organisation with a valid accreditation certificate issued by the National Accreditation Authority (NAH) or another relevant authority.

Designated body (Directive 93/42/EEC):
A conformity assessment body designated in accordance with the Medical Devices Directive (Directive 93/42/EEC).

Notified Body (NB):
A conformity assessment body designated in accordance with Regulation (EU) 2017/745.

CE marking of conformity or CE marking:
A marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in Regulation 2017/745 and other applicable Union harmonisation legislation providing for its affixing.

Client:
The party that requests services described in this document from NEOEMKI.

Unannounced audit:
(Only for conformity assessment) In order to verify compliance with legal obligations on a daily basis, the NEOEMKI will carry out an unannounced audit of the Client in addition to the initial, surveillance and renewal audits. An unannounced audit to the Client's contracted site, critical subcontractor or key supplier may be carried out by the NEOEMK at least once per certification cycle.

Application:
A formal submission by a manufacturer or authorised representative in accordance with Annexes IX and XI of MDR for conformity assessment.

Certification Contract:
An agreement detailing the scope, deadlines, validity, and financial terms of services provided by NEOEMKI as a Notified Body or accredited organisation.

Harmonised standard:
A European standard as defined in point (1)(c) of Article 2 of Regulation (EU) No 1025/2012.

Common specifications (CS):
Technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system.

Legacy device:
Devices certified under Directive 93/42/EEC and placed on the market after the MDR date of application (26 May 2021) remain lawful if MDR Article 120 requirements are met.

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

Emergency procedure:
The NEOEMKI's emergency procedure. Its application will be declared by the Managing Director, taking into account the circumstances, and will be notified to Clients.

State of emergency:
A legally declared state by the national government. In Hungary: according to Article 53 of the Fundamental Law, in the event of an elementary disaster or industrial accident endangering 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 in a cardinal law.

Extraordinary situation:
Any situation (e.g. disaster, strike, epidemic) that obstructs the execution of an on-site audit.

ICT (Information and Communication Technology):
Covers software, hardware, smartphones, handheld devices, laptops, desktops, drones, video cameras, wearables, artificial intelligence, etc.

Remote assessment / audit:
Enabling NEOEMKI's system certification and/or conformity assessment activities through the use of 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. Accreditations, Designations and Insurance Required for the provision of the service

NEOEMKI complies with the requirements of MSZ **EN ISO/IEC 17021-1** "*Conformity assessment. Requirements for bodies performing auditing and certification of management systems*" and MSZ **ISO/IEC TS 17021-3:2019** and is registered in the category of management system certification body (for management systems according to MSZ EN ISO 9001:2015 and MSZ EN ISO 13485:2016) under the No. **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 NAH (National Accreditation Authority).

NEOEMKI is a **designated and notified body** under the NANDO (New Approach Notified and Designated Organisations) system, with the **Notified Body No. 1011**.

NEOEMKI holds **professional liability insurance** covering its certification activities.
However, the geographical coverage of this insurance does **not** extend worldwide; therefore, NEOEMKI does **not** perform certification activities in the **USA, Canada, Australia**, or **New Zealand**.

V. Supervisory (Designating and Accrediting) Authorities

For Quality Management System certification according to EN ISO 13485:2016:
National Accreditation Authority (NAH), address: H-1118 Budapest, Tétényi út 82.

For Conformity Assessment of Medical Devices under MDR:
National Public Health and Pharmaceutical Centre (NNGYK), address: H-1135 Budapest, Szabolcs u. 33.

VI. Scope of the GTC, Independence and Impartiality

1. These **General Terms and Conditions (GTC)** shall apply to all agreements concluded between NEOEMKI and the Client concerning:

   A. Conformity assessment of medical devices according to Regulation (EU) 2017/745 of the European Parliament and of the Council (hereinafter referred to as MDR), including:

   - Annex IX, Chapter I, **Quality management system**,
   - Annex IX, Chapter II, **Assessment of the technical documentation**,
   - Annex XI, Part A, **Production Quality Assurance.**

   B. Provision of **Notified Body Opinion** under Article 117 of Regulation (EU) 2017/745 (MDR).

   C. Surveillance of **EC Certificates** issued under Directive 93/42/EEC (MDD) as per Article 120(3) of the MDR,

   D. Certification of Quality Management Systems according to EN ISO 13485:2016 standard.

2. The GTC constitutes an inseparable part of any Certification Contract between the Client and NEOEMKI. The current valid version of the GTC shall apply to all existing contractual relationships.
3. These GTC shall govern the aforementioned contracts of NEOEMKI, unless the parties have expressly agreed otherwise in writing.
4. NEOEMKI reserves the right to unilaterally amend the GTC with future effect and undertakes to notify the Client in writing within 8 days about any such amendments. NEOEMKI also notify the Client that in case the Client does not respond within the provided deadline, the amendment shall be considered accepted.
5. The GTC and its amendments shall enter into force on the date determined by NEOEMKI. The content of the new GTC, effective date, and version number will be published on the NEOEMKI website, and the contracted Clients will be informed electronically.
6. The validity of the GTC shall continue until a new version enters into force or until NEOEMKI's authorisation to provide the services concerned is terminated.
7. To assure independency and impartiality of the services, the Client acknowledges and agrees that contracted certification activities are incompatible with consultancy services related to the subject of the Certification Contract.
8. NEOEMKI does not pursue consultancy activities. The Client may not demand that NEOEMKI resolve any non-conformities that may be discovered during the certification process.
9. The Client must immediately notify NEOEMKI if consultancy was provided by NEOEMKI or its affiliates.
10. Any risk to impartiality or independence of NEOEMKI resulting from consultancy may entitle to immediate termination of the Certification Contract by NEOEMKI.
11. As a Notified Body (NB 1011) designated under the MDR in the designated conformity assessment area, NEOEMKI performs conformity assessments in compliance with the requirements set out in the legislation prescribing conformity assessment activities for the product or in the directly applicable and general legal act of the European Union.

12. The Client acknowledges and agrees that NEOEMKI performs its services in accordance with Hungarian and EU legislation, Common Specifications (CS), MEDDEV and MDCG guidelines, IAF documents, harmonised standards, and approved procedures of the designation and accreditation authorities. NEOEMKI's procedures related to quality management system certification and conformity assessment activities are publicly available on its website.

VII. Scope, Performance, Amendment and Termination

1. The Certification Contract shall enter into force upon signature by both parties. Upon the conclusion of the contract, NEOEMKI accepts the assignment.
2. The **scope of services** is exclusively determined by the Certification Contract based on the accepted offer. The offer issued by NEOEMKI and accepted by the Client forms an annex to the Certification Contract.
3. The potential scope of services determined in the Chapter VI of the GTC.
4. 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, until the expiry of the certificate issued (the validity date indicated on the certificate) or until the certificate is revoked.
5. Satisfactory performance according to Contract considered the service in accordance with generally accepted professional rules and the applicable regulations in force at the time of performance.
6. Satisfactory performance of the contract is independent from favourable (e.g. certification issuance, maintenance, restoring) or unfavourable (e.g. certification suspension, withdrawal, limitation or refusal of certification) results of the certification process.
7. Due to the nature of the services, performance of the contract involves multiple locations, documentation is evaluated at NEOEMKI's premises before the on-site audit, on-site audits are conducted at the Client's registered office, production sites, critical subcontractors, and/or key suppliers.
8. Due to the nature of the services, NEOEMKI may also perform audits at critical subcontractors' facilities. The Client must ensure in contracts with subcontractors that they permit NEOEMKI's personnel to access their facilities and cooperates as required for the audits.
9. On-site audits can only be conducted if the documentation review confirms the Client's readiness.
10. On-site audits are carried out at locations listed in the Certification Contract. If new locations requiring audits emerge after the Contract is signed, parties shall amend the contract.
11. The Certification Contract may be amended in writing by mutual contract at any time. The amended contract must be attached to the original contract.
12. The Certification Contract must be amended in the following cases:
    - at all times, when the services outlined in the Contract are amended, further services involved. Modification must be mutually agreed.
    - when unexpected changes substantially affect the service costs. In this case, NEOEMKI is obliged to send an offer to the Client considering the real costs of the service and to initiate a modification of the Contract with reference to the increased costs. If the Client rejects the

offer within 15 (fifteen) days of its receipt and does not accept the modification of the agreement, NEOEMKI is entitled to refuse further services and terminate the Certification Contract,

- when there are changes affecting the subject matter of the Contract in the regulations, standards, guidelines or regulations of the designating and accrediting bodies,
- when significant changes are reported by the Client, or the conditions discovered during on-site visit or in other way, are significantly altered from the previously enlisted on the quotation,
- when activities scheduled for a given year cannot be completed on time, and rescheduling necessary,
- when the Certification Contract involving multiple certificates is partially terminated.

13. The Certification Contract shall terminate in the following cases:
    - in case of unsuccessful certification:

      at the date of the certification decision,
    - in case of successful certification:
      - at the certificate's expiry date unless renewal is requested by Client in due time prior to expiration,
      - upon withdrawal of the certificate: at the date of withdrawal,
      - when surveillance becomes impossible due to reasons attributable to the Client, at the 8th calendar day from receipt of NEOEMKI's notice,
    - upon the expiration or substantial amendment of the relevant legislative and/or regulatory framework resulting non-compliance of product or management systems with the regulations, at the entry in force date of the relevant regulation.
14. The Certification Contract shall terminate in all cases for each certificate if performance becomes unfeasible for a reason for which neither party is responsible (e.g. change in legislation, withdrawal of the designation/accreditation of NEOEMKI or restriction of the designation/accreditation in a way that makes performance impossible). The party that becomes aware of the unfeasibility of performance is obliged to notify the other party of this in a documented manner and without delay. The defaulter is liable for any damage resulting from failure to notify. Upon termination of the agreement, the contractual fee for the service already provided prior to the termination must be paid.
15. If the agreement is terminated before the end of the certification cycle, NEOEMKI shall withdraw the issued certificates. Client must return the issued certifications without any delay.

VIII. Termination of the Certification Contract

The Certification Contract may be terminated by either party during the certification cycle through a **justified termination notice** as detailed in this chapter.

1. Both parties have the right to terminate the Certification Contract with termination with notice upon the expiry date of the validity period of the current certificate, or with the following notice periods.

- For quality management system certification: three (3) months' notice prior to the next scheduled certification audit,
- for Conformity Assessment of medical devices (including QMS): three (3) months' notice before the end of the current calendar year,
- for Notified Body Opinion under Article 117 of the MDR: three (3) months' notice.

2. If the Certification Contract covers multiple certificates, it may be partially terminated with respect to individual certificates upon the expiry date of the validity period of the current certificate.

3. With the exception of paragraph 1, the Certification Contract may only be terminated with notice if:
   - NEOEMKI notifies the Client of a modification to the GTC, and the Client does not accept the amendment within the provided deadline, or
   - A modification of the Certification Contract becomes necessary, and the Client refuses NEOEMKI's offer for such amendment within the provided deadline.

In such cases, the Client has the right of termination with notice by the end of the subsequent month, which he may exercise in writing within fifteen (15) days of receiving the notification of the change in the GTC or the amended offer.

A change in the GTC that does not significantly affect the subject matter of the Contract (e.g. administrative changes in NEOEMKI data, expansion of the scope of changes to be reported, etc.) does not constitute a reason for termination for the Client.

In the event of exercising the right of termination with notice, the contractual relationship shall terminate at the end of the following month.

4. In all other cases, the Certification Contract may only be terminated through **extraordinary termination** by either party via a written statement.

   Extraordinary termination is justified only in case of material breach of Contract.

   The following acts on the part of the Client are considered material breaches of agreement, including, but not limited to:
   - the Client conceals material information or intentionally makes false statements in the request for quotation, Certification Contract or during the performance of the Certification Contract,
   - prior to the scheduled date, the Client fails to inform NEOEMKI of the temporary impediment to the on-site inspection including the planned inspection of subcontractors,
   - the Client prevents the implementation of the activities necessary for maintaining the certificate, including the refusal of conclusion of the surveillance agreement,
   - NEOEMKI is unable to perform the surveillance audit or the review of the technical documentation by the prescribed deadline due to the fault of the Client,
   - NEOEMKI is unable to conduct the unannounced audit due to the fault of the Client,
   - Client fails to settle due payments (e.g. for audits, assessment), and/or travel expenses by the specified deadline,
   - Client misuses the certificate for services not covered by the certificate,
   - Client misuses the certificate for non-certified product,

- Client markets the certified product for an intended use other than the approved,
- Client markets a certified product with technical documentation other than the approved, or the certified product is distributed after a significant change that has not been approved by NEOEMKI.

5. In case of material breach NEOEMKI shall notify the Client and grant a maximum of 8 calendar days to remedy the breach and if the Client fails to remedy within this period, NEOEMKI is entitled to terminate the Contract with immediate effect.
6. If bankruptcy, liquidation, forced cancellation or restructuring proceedings are initiated against the Client, or if the Client initiates such proceedings against itself, NEOEMKI is entitled to terminate the Certification Contract.
7. If termination occurs due to a breach by the Client, the Client may not reclaim the fee already paid and shall be obliged to pay NEOEMKI a compensation for damage caused by the breach of Contract.
8. If termination is due to a breach by NEOEMKI, the Client may act according to the applicable provisions of the Hungarian Civil Code.

IX. Request for Quotation, Application and Conclusion of the Agreement

1. NEOEMKI accepts requests for quotations using the procedures and templates/forms published on its website. Requests that are incomplete or non-compliant in form or content shall be rejected.
2. NEOEMKI reserves the right to reject requests on a case-by-case basis, particularly if they conflict with legal or regulatory requirements, they oppose NEOEMKI's legitimate business interests, they are contrary to NEOEMKI's internal policies, they violate the Ethical and Business Conduct Code, or they conflict with NEOEMKI's corporate branding.
3. By submitting a request for quotation, the Client accepts the current version of these GTC and acknowledges that, in case of Contract conclusion, the GTC shall govern the relationship.
4. In addition to the above, special quotation conditions apply to the conformity assessment of medical devices in accordance with (EU) 2017/745. The Client must confirm acceptance of the conditions by signing the published form and submitting it at the same time as the request for a quotation.
5. The quotation is valid for the period indicated therein. If no validity period is specified, the offer is valid for 90 calendar days.
6. A quotation sent by NEOEMKI only results in a binding contract for the services covered if the Client accepts it in writing within the validity period, and (if required by applicable regulation) a formal application is accepted by NEOEMKI.
7. Acceptance 'in writing' includes submission in certified electronic form (e.g., authenticated e-mail).
8. The scope of services is determined exclusively by the Certification Contract based on the accepted offer. The accepted offer forms an annex to the Certification Contract.
9. The services included in the offer are applicable as follows, in accordance with Chapter VI of the present General Terms and Conditions (GTC):
    - for services under point **1.A**: for the specific year(s);
    - for services under point **1.B**: for the preparation of the specific Notified Body Opinion;
    - for services under point **1.C**: for the specific year(s);
    - for services under point **1.D**: for the specific year(s).

10. If the quotation does not specify the relevant years, the service period covers 1 year from issuance.
11. In cases where the applicable legislation requires the submission of a formal application based on the accepted offer, the Client must submit a formal application to NEOEMKI. In this case, the Contract may be concluded only if the application is accepted. In all other cases, the Certification Contract may be concluded without further conditions after the Client accepts the quotation.
12. The Client may request a new quotation for the next contractual period before the services included in the offer are completed (in the year of the last service due). An exception to this is if the Client terminates the Certification Contract by termination with notice in accordance with Chapter VII.
13. If during the term of the Certification Contract it becomes necessary to request a new quotation or the Client requires a changed service, the content of the Certification Contract will be amended in accordance with the content of the new quotation based on the Client's change notification and accepted by the Client. The new, accepted quotation forms an annex to the Certification Contract.
14. Applications under MDR can only be submitted by the manufacturer of the device concerned or by the manufacturer's authorised representative.
15. The Client must submit the conformity assessment application together with the accepted quotation. Upon submission, the Client must also pay the application review fee according to NEOEMKI's published list of fees.
16. Upon receiving the application, NEOEMKI will issue an advance payment letter of the application review fee in e-mail. Review of the application will only start after payment of the application review fee, and submission of all required documents.
17. The list of templates and mandatory attachments required for application are available on the NEOEMKI website. Client's acceptance of the price quote issued by NEOEMKI is the prerequisite for application submission.
18. NEOEMKI shall review incoming applications within 60 calendar days in accordance with its documented procedures. If the application is incomplete or non-compliant, the Client will have one-time opportunity to correct it (remedy period).
19. If the application remains non-compliant after the remedy period, NEOEMKI shall reject it, and no Contract will be concluded.
20. NEOEMKI shall inform the Client about the result of the application review by sending a review report within 30 days after completion of the review.
21. In case of application acceptance, rejection or withdrawal, NEOEMKI will register the decision in the Eudamed database and notify the Client simultaneously.
22. The Contract between the Client and NEOEMKI is drafted by NEOEMKI according to the quotation prepared and accepted based on the price quote request form sent by the Client, and it contains the information and data taken into account when planning the certification procedure.
23. By signing the Contract, the Client accepts the offered certification service fees, and the provisions of the applicable GTC.

X. Service Fees

1. The service fees of NEOEMKI are based on the performance of assignments under normal circumstances.

2. The Client acknowledges that fees specified in the offer apply to the entire certification cycle and were exclusively determined for the sites, processes, critical subcontractors, key suppliers and products specified in the Contract. Fees for the initial and surveillance procedures, the fees arising on a case-by-case basis, the fee for unannounced audits, (applicable for conformity assessment only), are listed separately.
3. The annual breakdown of service fees in the Certification Contract is based on NEOEMKI's preliminary audit programme. If the due service of the audit programme cannot be completed within a given year, the Certification Contract must be amended.
4. By signing the Certification Contract, the Client accepts the fees offered for the relevant certification activities. Service fees are independent of the outcome of the certification process.
5. From the second year onward, the Client shall pay the fees specified in the contract increased by the average annual consumer price index published for the calendar year preceding the payment.
6. The applicable average consumer price index shall be the value published by the Hungarian Central Statistical Office (HCSO). The index shall be applied from the first day of the month following its publication.
7. NEOEMKI publishes the standard list of service fees on its website, in both HUF and EUR currencies. The fees expressed in different currencies are determined independently, based on distinct financial conditions; hence, currency conversion is not relevant.
8. If the Client in separate declaration specifies the preferred currency when submitting the quotation request, the quotation and Contract will be prepared in the requested currency (HUF or EUR). In the absence of such a specification HUF shall apply for Clients registered in Hungary, EUR shall apply otherwise. The chosen currency remains fixed for the entire term of the Contract.
9. Where applicable, the indicated fees may be increased with value added tax (VAT), or any other service-related taxes to be paid by NEOEMKI.
10. NEOEMKI is entitled to revise its standard fees once a year.
11. The Client acknowledges that NEOEMKI will issue an advance payment request letter within 8 days of signing the Certification Contract. The advance payment is 50% of the total annual fee in case of device conformity assessment (including QMS), and 100% in the case of quality management system certification and annual surveillance of any certificate.
12. Payments must be settled without deduction or offset by the deadline specified in the advance payment request letter. Any complaints regarding the advance payment must be submitted within this deadline, but this does not result in the suspension of the payment obligation.
13. The payment must be made by transfer to the account number of NEOEMKI specified in the Contract in the specified amount and currency. Payment in any other way or in any other currency is not possible.
14. NEOEMKI issues an invoice for the advance payment upon receipt of the Client's payment. NEOEMKI begins the service upon receipt of the advance payment.
15. Should the Client fail to settle the evaluation and/or travel expenses by the deadline NEOEMKI is entitled to cancel the procedure and refuse the issuance of certificates or suspend an issued certificate.

16. With 30 calendar days prior to a scheduled on-site audit, NEOEMKI sends a Pro-Forma invoice with payment notification. The Client must settle the payment within 8 calendar days following the notification.
17. The Client acknowledges that the on-site audit preparation suspends before the outstanding amounts are fully settled. If the audit cannot be performed at the scheduled time due to payment delays, the Client bears the consequences.
18. In case of payment default, the Client must pay for the outstanding amount from the first day of the delay a default interest as per the applicable legal rate for commercial contracts.
19. If NEOEMKI takes actions to recover outstanding debts, the Client must reimburse all incurred costs, including payments to third parties hired for collection, internal administrative costs reasonably attributable to the recovery efforts.
20. Before continuing services, NEOEMKI may request appropriate guarantees from the Client to secure its receivables.
21. The contractual fee covers only the services specified in the quotation and Contract. Services not detailed in the Certification Contract are charged based on NEOEMKI's published list of standard fees.
22. Travel and accommodation expenses related to on-site audits are **not** included in the contractual fee. The Client is responsible for arranging and covering these costs, travel includes journeys between hotels and audit sites, and between multiple sites.
23. In the event of travelling outside Europe, auditors can only be provided with business-class flights. In special cases, upon the Client's request, NEOEMKI will assist in organizing travel and accommodation. In this case, the administrative costs of the organization will be invoiced to the Client on an hourly basis in addition to the actual costs incurred (airfare, hotel bill, taxi, etc.).
24. If NEOEMKI identifies non-conformities during the assessment of the documentation or the on-site audit, the certification fee specified in the Certification Contract includes the assessment of the client's CAPA plan and corrections once. If further improvements and reassessments become necessary, NEOEMKI is entitled to charge an hourly fee for the time spent on the reassessment according to the published list of standard fees.
25. NEOEMKI reserves the right to charge an additional fee according to the published list of standard fees, if an additional on-site audit is necessary to properly verify the implementation of corrective and preventive measures related to the identified non-conformities.
26. In the event of changes occurring during the certification cycle require a partial or complete reassessment of the documentation or on-site audit at the client, NEOEMKI is entitled to charge an hourly rate for the time spent on the assessment of the changes according to the published list of standard fees.
27. In the event of a reassessment as a result of a deficiency or non-conformity identified by the original assessment or for any other reason, the cost of this shall be borne by the Client.
28. If an unannounced audit fails due to reasons attributable to the Client, an additional fee will be charged for rescheduling.
29. The Parties accept the technical documentation assessment report, and the audit closing meeting report prepared and submitted on site, as a proof of service completion**.** The proof of service completion is an annex to the issued invoice.

30. If the initial certification ends with a negative result (no certificate was issued), NEOEMKI will refund the certificate issuance fee from the fee already paid by the Client.

31. NEOEMKI may reclaim the discounts applied in the certification fee from the Client if the basis for the discount did not exist at the time of issuing the offer or has ceased in the meantime, or if the Certification Contract is terminated during the certification cycle by termination with or without notice for a reason arising in the Client's interest.

32. If the fee payer is different from the Client, the data of the payer must be indicated on the Contract. In this case, the payer is liable for payment obligations and entitled to any refunds.

XI. Client's Rights and Obligations

The Client is entitled to:

- conduct an impartial procedure on the part of NEOEMKI, which the personnel participating in the service must also ensure with a declaration of impartiality,
- raise a well-founded objection against the members of the audit team/conformity assessment team appointed by NEOEMKI. An objection may only be accepted for reasons of impartiality and independence. The objection must be justified. In the event of a justified objection, NEOEMKI is obliged to reorganize the group. This provision shall not apply in the case of an extraordinary and/or unannounced audit.
- view the documents related to the certification decision (with such access being logged).
- ask questions related to the certification procedure and receive factual and substantiated to them.
- file a complaint with the head of NEOEMKI regarding the certification procedure in accordance with the complaint handling process published on the NEOEMKI website (E97 Events violating organizational integrity, complaint handling, appeal procedure). NEOEMKI is obliged to investigate all complaints reported by Clients according to its relevant procedures
- appeal in writing against decisions related to the certification in accordance with the appeal process published on the NEOEMKI website (E97 Events violating organizational integrity, complaint handling, appeal procedure). NEOEMKI is obliged to handle all appeals notified by clients in accordance with its relevant procedure.
- to request restriction of public access to information related to the certification, if this is not contrary to the obligation to disclose data required by law or IAF mandatory documents (MD).

The Client is obliged to:

- cooperate with NEOEMKI in a timely and full manner in the performance of the Certification Contract, including with third parties acting on behalf of the Client,
- comply with the applicable legislation on the certification service specified in the Certification Contract (including, among others, Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR), standards, common specifications (CS), guidelines (e.g. MDCG documents), IAF documents, safety and accident prevention regulations,
- submit NEOEMKI the documentation required for certification in Hungarian and/or English in the manner and form requested by NEOEMKI, acknowledging that all documents and records related to the certification process will be retained in electronic or printed form for the duration of the certification cycle or for the period specified by law.

- reimburse the additional costs if the data provided by him is incomplete, late or incorrect; his participation is not regular or not in accordance with the agreement,
- in the case of a quality system certification procedure, to provide the documentation of the quality management system to NEOEMKI.
- in the case of a conformity assessment procedure, to provide the documentation of the quality management system, the Technical Documentation and/or the Design Dossier of all devices involved in the certification, the Summary of Safety and Clinical Performance (SSCP) in Hungarian or English according to Article 32 of the MDR, taking into account that all documents and records related to the certification process will be retained by the NEOEMKI in electronic or printed form for the duration of the certification cycle or for the period specified by law,
- provide NEOEMKI with the information, data and documents necessary for the procedure before and during the start of the certification procedure and to assume responsibility for their correctness,
- maintain and manage the technical documentation of the devices covered by the Certification Contract, and to take the necessary measures to keep it up to date,
- provide the up-to-date version of technical documentation and quality system documentation of the devices covered by the certification, prior to a surveillance, renewal or extraordinary audit, separately listing the changes that have occurred in the meantime,
- maintain and manage the quality management system, and to take measures to correct and further develop it in accordance with a documented procedure,
- perform or have performed the tasks necessary for the performance of NEOEMKI's services on time,
- appoint a responsible person (contact person) and ensure their continuous availability,
- to answer NEOEMKI's questions regarding the certification procedure, to provide competent personnel for the on-site audit,
- ensure that the conditions for conducting the on-site audit (if necessary, by ensuring the use of ICT) are in a state suitable for providing services during the relevant certification period, at all production sites, critical subcontractor sites and key supplier sites,
- ensure that NEOEMKI's employees have access to the production site, registered office, site and areas within the organization of the client, critical subcontractor and key supplier sites required for the performance of the activities stipulated in the agreement, by ensuring the relevant conditions regarding work safety.
- to ensure, within the framework of the conformity assessment procedure, the feasibility of conducting unannounced audits at the production site of the product covered by the contract, or at any critical subcontractor or key supplier involved in the production process, in accordance with the provisions set out in the contract between the Client and its subcontractor or supplier;
- if a non-conformity is identified during the procedure, submit a corrective and preventive action plan (CAPA plan) within 15 days,

- correct the non-conformities within the deadline agreed in the corrective and preventive action plan approved by NEOEMKI, but within a maximum of 150 days in the case of an initial procedure, and within a maximum of 60 days in the case of a surveillance procedure, submit the supporting documents to NEOEMKI, and pay a penalty for the delay in case of failure to meet the deadlines, In the absence of a corrective submission, the procedure shall be closed upon the expiry of the deadline undertaken in the corrective and preventive action (CAPA) plan.
- notify the changes related to devices, processes concerned by the Contract or changes related to the manufactured product in a timely manner according to Chapter XIII of these GTC,
- use the documents, reports and certification mark related to the certification only in their entirety, without abbreviations or extracts, and in a non-misleading manner,
- follow NEOEMKI's regulations regarding the use of certification marks and to act accordingly (e.g. in the media, in advertising),
- after the successful completion of the conformity assessment procedure, the CE 1011 marking may only be displayed on medical devices manufactured during the validity period of the certificate issued under the Contract and on the information materials issued for them. The declaration of conformity may be issued for these products only,
- after the termination of the Certification Contract, including the withdrawal or expiry of the certificate, the use of the CE 1011 marking shall be immediately discontinued, and in the event of suspension of the certificate, it shall be suspended,
- in the event of termination of the Certification Contract for any reason - including the revocation or expiry of the certificate - to inform NEOEMKI about the range of products that were placed on the market under the supervision of NEOEMKI during the term of the Agreement (by providing the date, unique device identifier (basic UDI-DI, UDI-DI, UDI-PI), serial number, production batch number, LOT number),
- in the event of termination of the Certification Contract for any reason - including the withdrawal or expiry of the certificate - to comply with NEOEMKI's requirements (cessation of advertising and logo use, return of certificates, issuance of a manufacturer's warning),
- refrain from qualifying the certification service in a way that brings NEOEMKI into disrepute,
- refrain from making misleading, unauthorized statements regarding the certification activity,
- claim certified status only in relation to products and activities to which certificate applies.
- pay the certification fee and costs regardless of the final outcome of the certification procedure,
- reimburse the cost of services used outside the scope of the Certification Contract,
- reimburse the additional costs if the data provided by it is incomplete, late or incorrect; its participation is not regular or in accordance with the agreement,
- fully cooperate when accreditation or (re)designation process of NEOEMKI requires third-party (authority) assessment,
- ensure that NEOEMKI and, if necessary, the personnel of the competent authorities and accreditation bodies (e.g. during a witness audit) can inspect the Client's production and

operation sites, as well as the sites of critical subcontractors identified (e.g. critical suppliers, importers) during normal working hours, even without prior notice, at the Client's expense

- in case of the assessment carried out in accordance with Annex XI Part A of MDR, Client obliged to provide a copy of the type examination certificates referred to in point 4 of Annex X of MDR and to notify changes to the certificates,
- provide up-to-date contact details (address, contact person, fax, e-mail) and to inform NEOEMKI of any changes thereto without undue delay,
- ensure contractual obligations in the field of medical devices in third party contracts (e.g. technical/quality agreements) and must provide proof to NEOEMKI upon request,
- in case visa is required for an unannounced audit, the certificate holder must provide NEOEMKI with an invitation letter to visit the Client premises, including critical subcontractors or suppliers (invitations with date of visit blank will be filled in by NEOEMKI later).
- notify NEOEMKI about the period during which Client does not manufacture the certified devices (for scheduling the unannounced audit). The notification must be made by January 31 of each year.
- comply with the requirements set out in Article 120(3) of Regulation (EU) 2017/745 and other relevant legislation with regard to legacy devices certified by NEOEMKI,
- after obtaining the certification document (certificate):
  - notify NEOEMKI of any unexpected events related to the manufactured products certified by NEOEMKI,
  - notify NEOEMKI of any application, Certification Contract initiated with a conformity assessment body other than NEOEMKI for the certification of the products that are the subject of the Certification Contract,
  - submit to surveillance activities (e.g. on-site audit) based on prior agreement in order to maintain the validity of the certificate,
  - ensure unannounced audits to be held at Client's own sites and, if relevant, at its subcontractors,
  - provide product variants and amended products with a clear identifier in order to ensure identification and distinction of changes.

XII. NEOEMKI's Rights and Obligations

1. NEOEMKI is entitled to:

- conduct a certification procedure in the areas specified in the accreditation document and/or designation document.
- decide on conformity and on the issuance, refusal, maintenance, withdrawal, suspension and restriction of the certificate based on the available objective evidence. The certificate may not be issued or maintained in force until the implementation of corrective measures related to severe non-conformities has been accepted by NEOEMKI with appropriate results within the deadline.
- use a subcontractor in justified cases, with prior notification to the Client.
- request any information or data from the Client that is necessary for the proper completion of the chosen certification procedure.

- conduct an unannounced audit of the Client and/or its subcontractors, suppliers in extraordinary case and/or in the frame of conformity assessment procedures, as required by the relevant regulations, in the frame of complaint investigation, or on request from any competent authority.
- initiate the suspension of the certificate by informing the Client in writing if the Client violates its obligations and does not fully comply despite the request of NEOEMKI (including but not limited to: the surveillance audit is not carried out by the prescribed deadline and no other agreement is reached with the Client),
- terminate the Certification Contract with extraordinary notice in cases prescribed in these GTC,
- initiate the revocation of the certificate in cases according to these GTC,
- initiate the revocation of the certificate after the suspension if the Client does not eliminate the reasons for the suspension within 6 months after the suspension,
- carry out assessments and audits necessary for the contracted services at the Client/subcontractor during the term of the Certification Contract,
- refuse the service until the Client fulfils its obligation, e.g. if the Client does not provide the place of performance at all, or in a condition not suitable for the provision of the service, or Client makes performance impossible in other ways,
- record non-conformities during the certification process,
- refuse issuance of the certificate, refuse restore the certificate, suspend or withdraw the certificate already issued if the Client does not correct the identified non-conformities by the deadline, or the corrections made are not acceptable,
- conduct a follow-up audit including the closure of the documentation upon decision of the on-site audit team, at the Client's expense, within 180 days from the on-site audit for an initial audit, and within 90 days for a surveillance audit,
- retain ownership of the reports and documents prepared by NEOEMKI in connection with the certification,
- get access to, and permission to work at the Client's (including relevant subcontractors) registered office, premises, and areas within its organization for NEOEMKI’s employees, assigned external experts/subcontractors, to the extent necessary for the performance of the agreement,
- check the up-to-datedness of the technical documentation of the certified devices,
- retain the documentation provided by the Client in electronic or printed form after the completion of the certification procedure for the duration of the certification cycle or for the period specified by relevant regulation,
- issue a certificate in English and/or Hungarian, if the certification process resulted satisfactory,
- initiate the suspension of the certificate,
- exercise appropriate control over the application and display of the certification symbol in accordance with these GTC,

- verify the conformity of certified medical devices, NEOEMKI is entitled to take random samples at the expense of the Client to the extent necessary for the audit or inspection. In the frame of supervision, NEOEMKI may examine, and test recently manufactured (preferably originated from a continuous production process) suitable samples at the expense of the Client. The Client shall arrange the transport, insurance, logistics, customs clearance, etc. of the samples at its own expense. The documentation required for the conformity assessment shall be provided in English and/or Hungarian.

2. NEOEMKI is obliged to:

- ensure the independent and impartial conduct of the certification procedure,
- conduct the certification procedure in accordance with the applicable regulations relating to the product (service) to be certified and its own manual, procedures and instructions,
- provide personnel with appropriate professional competence in the area to be certified (with the personal participation of an employee, an assigned contractor or a subcontractor),
- inform the client about the participants in the procedure and the involvement of a subcontractor,
- examine the client's complaint against the personnel and, if the objection is justified, appoint another competent person;
- process the information obtained during the certification procedure confidentially, this confidentiality obligation also extends to all employees of NEOEMKI and any external experts and subcontractors it may have commissioned,
- provide the personnel assigned to perform certification activities related to the Client with a written declaration on maintaining confidentiality,
- immediately notify the Client if there is a legal or other obstacle to the performance of the activities covered by the contract,
- immediately notify the Client of any facts or circumstances that have or may have an impact on the performance of the activities covered by the contract,
- issue the certificate in accordance with the draft if the Client does not confirm the sent draft certificate within 14 days after a successful certification procedure,
- organise the certification surveillance procedures in relation to the Client's valid certificate by determining the documents to be submitted,
- conduct a surveillance procedure, which includes an on-site audit at the Client's production site and/or premises (including relevant subcontractors) and the assessment of the technical documentation according to the specified certification program/sampling plan (only in the conformity assessment procedure according to Regulation (EU) 2017/745),
- initiate the suspension of the certificate if the Client refuses to organise the supervision procedure or surveillance audit or hinders its conduct, and for this reason NEOEMKI cannot complete the procedure or audit by the relevant deadline,
- examine the Client's possible complaint or appeal against the certification decision based on the relevant procedure,
- comply with the deadlines according to the certification procedure published on its website,

- report the issued, amended or withdrawn certificates to the supervisory body and/or record them in the relevant international database (e.g. Eudamed, CertSearch),
- act in accordance with the regulations in the event of well-founded doubts regarding product safety or performance,
- store the documents generated during the certification activity for the period specified in the law after the completion of the certification procedure.

XIII. Notification Obligations and Change Management

1. The Client must comply with notification obligations under the regulatory requirements applicable to the certification procedures for conformity assessment and quality management systems.
2. The Certification Contract concluded between NEOEMKI, and the Client is valid only provided that the circumstances remain unchanged. If a change occurs that may affect the maintenance of the service ordered by the Client, it must be reported to NEOEMKI without delay, but at least within 30 days, on the form designed for this purpose. NEOEMKI publishes the change notification form on its website.
3. The Client must declare the changes that have occurred since the previous audit by filling out the Change Notification form prior to surveillance, renewal and extraordinary audits. If there has been a significant change in relation to the product and/or the quality management system since the previous audit, a list of the changes must be attached to the notification. The minimum data content of the list: brief description of the change, classification of the change, date of notification to NEOEMKI (if relevant), date of closure/introduction.
4. NEOEMKI is not responsible for the consequences of the Client's failure to notify. If NEOEMKI notices changed but unreported circumstances during the initial, surveillance, renewal, extraordinary or unannounced audit, or in any other way, it is entitled to initiate the amendment of the Contract and the adjustment of the certification fee.
5. The Client is obliged to report any changes that may significantly affect the quality management system and/or product covered by the certification.
6. NEOEMKI shall assess all notified changes in advance in order to determine the further actions to be taken (e.g.: determining the need for an on-site audit and/or technical documentation assessment, etc.). NEOEMKI shall notify the Client of the results of both the preliminary and - if relevant - subsequent assessments.
7. When managing changes, in the case of conformity assessment according to Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR), the provisions listed in the first paragraph of point 4.9 of Annex VII to the MDR must be followed.
8. In the case of conformity assessment procedures, the NBOG BPG 2014-3 recommendation must be taken into account in all cases, and in the case of surveillance activities of certificates issued according to MDD (93/42/EEC), the provisions of Article 120(3) of the MDR and the MDCG 2020-3 recommendation must also be taken into account.
9. The obligation to notify changes includes in particular:

   Changes in company data, such as legal, commercial, organizational status or ownership; organization and management (e.g. key management, decision-making or technical personnel); contact address.

Changes affecting the quality management system, such as scope (extended/reduced), name, address, headquarters, site, manufacturing site, legal form, SRN, organizational structure, management, number of employees, quality manager/assignee, person responsible for regulatory compliance (PRRC), product range (list), technology used, quality management process, subcontractor, supplier, authorized representative (EC REP) etc.

Changes affecting the product-related: intended purpose of the device, indications, contra-indications, list of the product, 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 the material used, the semi-finished product and the finished product), packaging, sterilization, shelf life, instruction for use (IFU), label, software, pharmaceutical or raw material of animal origin, EU type-examination certificate referred to in the related Annex X, point 4, basic UDI-DI, etc.

10. The Client is obliged to immediately inform NEOEMKI of any ongoing Application, Certification Contract with another certification/accredited body for the certification of the products or quality management system that are the subject of the Contract.
11. Special provisions for conformity assessment procedures:
    A. In the event of planned changes to an approved medical device or changes to the quality management system, NEOEMKI must be notified immediately. Significant changes must not be implemented without the prior approval of NEOEMKI. All information submitted regarding planned changes must be relevant and specific.
    B. NEOEMKI may request additional information regarding these changes at any time.
    C. Planned changes to a certified device, if these changes may affect the safety and performance of the device or the conditions prescribed for use of the device, require the prior approval of NEOEMKI before implementation by the client (see e.g. Article 4.10 of Annex IX of the MDR). The product affected by the change may not be placed on the market until the change notification has been approved by the certification body.
    D. When planning to introduce a change, Client shall inform NEOEMKI thereof. NEOEMKI must evaluate the planned changes and decide whether a new conformity assessment is necessary or whether it is sufficient to grant approval by supplementing the report on the assessment of the technical documentation. NEOEMKI must notify the manufacturer of its decision and, if it approves the changes, it must provide the manufacturer with a report on the assessment of the technical documentation.
    E. When the assessment of the change by the certification body requires consultation with the authorities, experts or the Commission, NEOEMKI shall conduct it.
    F. During the term of the agreement, the Client shall inform NEOEMKI within 72 hours of the occurrence of any incident or serious incident affected the product certified by NEOEMKI and the results of their investigation.
    G. During the term of the agreement, the Client is obliged to inform NEOEMKI within 72 hours of any procedure initiated by any Member State authority concerning the certified device.
    H. The Client shall inform NEOEMKI as a notified body without undue delay of all relevant vigilance information, in particular of all serious incidents, field safety corrective actions (FSCA), field

safety notices (FSN), periodic safety update reports (PSUR). In the event of a recall or other field safety corrective action, the Client shall submit a risk analysis to the notified body concurrently with the national competent authority. In addition, the Client shall submit a final vigilance report to NEOEMKI.

I. The Client shall immediately notify NEOEMKI of any relocation of the production site, transfer of the production site to another company or company owner, or any changes in the production process, including the management system that may affect the production of the certified product. In such a special case, in order to identify products from different production periods, NEOEMKI may request the product be identified with a specific marking or method in addition to the CE mark.

XIV. Subcontractors

NEOEMKI is entitled to engage third parties to pursue the agreed activities and assumes full responsibility therefor. NEOEMKI ensures that the obligations applicable to NEOEMKI also apply to the aforementioned third parties.

XV. Issuance, Expiration, Withdrawal, Suspension of Certificates

1. NEOEMKI is responsible for making a decision on conformity and issuing a certificate based on the available objective evidence.
2. NEOEMKI makes publicly available on its website the current documents describing its certification processes and the procedures for issuing, maintaining, renewing, extending, reducing, suspending or withdrawing 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 to these documents, of which it informs its Clients electronically.
3. The certificate becomes invalid if the indicated validity period has expired or the underlying main certificate has been terminated.
4. NEOEMKI may also withdraw the issued certificate at the request of the Client.
5. If NEOEMKI determines that the Client's product and/or quality management system do not comply with the requirements specified in the relevant legislation or in the directly applicable legal act of the European Union of general application, as well as in other technical regulations specified in Article 2, point 8 of Regulation 765/2008/EC, for which the Client requested the conformity assessment certificate, NEOEMKI shall not issue a certificate until the Client has taken the necessary measures to make the product and/or quality management system comply with the requirements.
6. If NEOEMKI determines after issuing the certificate that the certified product and/or quality management system no longer meets the requirements or there is a reasonable suspicion of this, in particular in the event of an official request, it shall notify the Client thereof by stating a deadline adapted to the specifics of the product. If the Client fails to take the necessary measures to bring the product and/or quality management system into compliance with the requirements within the specified deadline, or the product defect cannot be remedied, NEOEMKI, as a notified body, will restrict, suspend or withdraw the certificate. The period of suspension of the certificate may not exceed 6 months, after 6 months the certificate must be withdrawn.
7. If after issuing the conformity certificate, NEOEMKI becomes aware of that a serious risk to public health may arise in connection with the device, it is entitled to immediately suspend or withdraw the certificate.

8. If NEOEMKI experiences a violation of the provisions on the marketing of the product in the designated conformity assessment area, it shall inform other conformity assessment bodies operating in the designated conformity assessment area, including notified bodies in other states party to the Agreement on the European Economic Area (hereinafter: EEA States).
9. NEOEMKI shall, upon request, provide information on the results of the conformity assessment to other conformity assessment bodies operating in the designated conformity assessment area - including notified bodies in EEA States - and shall record the results of the assessment in the Eudamed system (according to Article 57(1) f), g), h) and i) of the MDR).
10. NEOEMKI may withdraw the certificate if there is a well-founded reason that makes it unacceptable for NEOEMKI to maintain the certificate, even considering the Client's legitimate concerns.
11. Well-founded reasons are the grounds for termination of the Agreement set out in these GTC, and such a breach of Contract shall be considered, in particular, if

a) the certification requirements are not met, including but not limited to, if

- the Client provides false information to NEOEMKI or conceals facts that are relevant for the conformity assessment or quality management system certification,
- the certified devices or the characteristics of the quality management system relevant for the certification do not or no longer meet the requirements,
- users, operators or third parties are exposed to significant risks, or the subject of certification must be withdrawn from the market by order of the authority,
- the requirements that underlying the certification change (e.g. the relevant normative documents, the state of the technology, the requirements specified by the authority, the accreditation body or the system owner), and the client does not substantiate this within a specified period by re-testing or re-auditing whether the subject of the certification complies with the new requirements,

b) the contractual basis for the use of the certificate ceases (for example, because the client permanently ceases its business activities without a legal successor),

c) in the event of a violation/failure to meet specific requirements or conditions, if the certificate was issued in this way,

d) the Client does not provide the necessary cooperation at all, not in a timely manner, or not to the extent necessary (for example, correcting non-conformities, providing documents and information, enabling audits, etc.); and therefore

- on-site audit is not possible,
- products or documents are not available within the specified deadline,

e) the Client conducts or tolerates abuse, deceptive use or otherwise misuse of NEOEMKI's reports, certificates, CE markings, declaration of conformity,

f) the Client fails to pay its due payment claim within the specified deadline despite a reminder,

g) the issued certificate is invalid if new facts or information emerge after the date of issue that necessitates the revision, suspension or withdrawal of the certificate,

h) NEOEMKI may withdraw the certificate in case of non-negligible breach of obligation at Client's side and the relevant normative documents require withdrawal, or upon the competent authority request.

12. In addition, NEOEMKI may limit the duration of certificates (i.e. reduce their validity period), restrict or temporarily suspend them.
13. As a temporary measure, suspension may be applied simultaneously with a notice to the Client, if this is proportionate to the extent of the breach of Contract.
14. NEOEMKI may charge the Client with all costs and expenses arising in connection with the termination, restriction or suspension caused by the Client, including those charged to NEOEMKI by authorized bodies (e.g. authorities, accreditation bodies).
15. NEOEMKI is obliged to publish the withdrawal, restriction or suspension of a certificate.
16. Withdrawn certificates must be returned to NEOEMKI immediately. Any further reference to the certificate or any other use thereof, including the use of the certification mark, is prohibited.
17. NEOEMKI disclaims liability for any disadvantages suffered by the Client or third parties as a result of lawful termination, reduction or suspension.

XVI. Delay in the Provision of Services, Penalties

1. In the event of a delay in the provision of services under the Certification Contract due to a reason attributable to the Client or a third party acting in its interest, NEOEMKI is entitled to charge the additional costs incurred and to demand a late payment penalty from the Client.
2. No penalty for delay may be demanded if the Client's delay was due to a reason attributable to NEOEMKI's employees or any party participating in the service on NEOEMKI's order. This provision shall also apply if the assessment is conducted with the involvement of an authority or an expert panel and this third party requires one or more additional assessments and/or examinations.
3. The Client's delay excludes the simultaneous delay of NEOEMKI. NEOEMKI is not liable for the failure to meet deadlines if the delay is due to the intermediary actions of the Client or another third party.
4. The penalty for delay applies to the days of delay, and its amount per day is the daily portion of net annual fee valid on the first day of delay (daily rate=net annual fee/365 days), but a maximum of HUF 800k (€2,000).
5. In cases where the Client's delay causes significant disruption to the planned certification or surveillance activities, NEOEMKI may initiate an extraordinary review of the certification status, suspend or withdraw the issued certificate, charge default penalties as described above.
6. If any delays or failures result in additional costs for NEOEMKI (e.g., rescheduled audits, repeated document evaluations, missed witness audits), the Client must compensate NEOEMKI for these costs based on actual expenses.

   The parties acknowledge NEOEMKI's expense

   • for additional administration (modification of documents, extra organization due to rescheduling, repeated witness audit, etc.) a flat rate of 10% of the annual fee per occasion,

   • for repetition of procedural steps (repeated assessments, additional time spent, etc.) the labour fee for the time spent, based on the hourly rate published in the standard fee list.

7. The payment of the penalty does not release the Client from the obligation to perform corrective actions and is independent of the subsequent outcome of the certification process.
8. If delays lead to the termination of the Certification Contract or to the withdrawal of a certificate no refund of paid fees shall be granted.
9. NEOEMKI may demand a penalty for failure in the event of the Client's
   - material breach of contract/law,
   - culpable breach of contract, GTC or related regulatory documents,
   - misconduct that makes it NEOEMKI's performance unfeasible.
10. A material breach may occur in the event of a particularly intentional and repeated infringement if the product bearing the conformity marking is placed on the market before the certificate has been issued, if the certificate is falsified or if the subject of the conformity assessment is advertised with an alleged certificate to which it does not correspond.
11. The amount of the penalty for failure is equal to 50% of the contractual fee for the given year or 100% of the fee for the unannounced visit (if failure concerns only the unannounced visit), up to a maximum of HUF 10 million (€25,000).
12. Payment of the penalty does not affect NEOEMKI's right to terminate the Contract and does not exclude the possibility of asserting further claims for compensation.

XVII. Liability

1. NEOEMKI shall only be obliged to compensate the Client for damages resulting from the negligent failure of NEOEMKI to fulfil its contractual obligations towards the Client, only in the event and to the extent stipulated in these General Terms and Conditions.
2. NEOEMKI is liable for direct damages only, arising from the proven breach of its contractual obligations, provided that such damages are the direct consequence of its own fault or negligence. Certification by NEOEMKI only confirms compliance with the specified requirements at the time of evaluation. The ongoing compliance and performance of the certified products remain the full responsibility of the Client.
3. NEOEMKI's liability for the damages specified in the previous point is limited to the amount of the **certification fee** paid by the Client under the Certification Contract, with a maximum of to the amount of HUF 25 million (twenty-five million forints) per Client. If the Client owes an amount exceeding HUF 25 million (twenty-five million forints) for the services under the agreement, NEOEMKI's liability is limited to the amount that the Client owes for the services in question, with a maximum of HUF 30 million (thirty million forints).
4. The Client is liable for ensuring that its products and quality management systems comply with the applicable legal and regulatory requirements, for providing complete, truthful, and accurate information to NEOEMKI during the entire certification cycle and for lawful and non-misleading use of the issued certificates and certification marks.
5. If the Client's acts or omissions cause harm to NEOEMKI's accreditation status, NEOEMKI's designation as a Notified Body, legal liability or reputation, the Client shall fully compensate NEOEMKI for all resulting damages, including costs of legal defense, administrative penalties, or loss of business opportunities.

6. The Client shall indemnify and hold harmless NEOEMKI from any third-party claims, damages, or costs arising out of the Client's unlawful or improper activities related to certified products or use of certification.
7. NEOEMKI's liability limitations set out in these General Terms and Conditions do not apply to damage caused by NEOEMKI's intentional misconduct or gross negligence.
8. In no event shall NEOEMKI be liable to the Client or any third party for any consequential damages, including, but not limited to, damages resulting from delays in the performance of the agreed services, loss of Client information, business interruption, loss of sales, loss of profits, loss of goodwill or damage to the brand name.
9. NEOEMKI's liability for damages shall cease if the Client has not notified NEOEMKI in writing of the damage within eight (8) days of the date on which the damage was discovered, or when it should have been reasonably discovered. NEOEMKI's liability shall cease in any case if the Client has not initiated legal action for compensation for the damage within 12 months of the date on which the service causing the damage was provided.
10. The limitations of the liability for damages and the Client's liability for damages under these General Terms and Conditions also apply to the employees of NEOEMKI and third parties engaged by NEOEMKI to perform the Contract.
11. NEOEMKI shall not be liable for failure to perform its obligations if the failure was caused by circumstances beyond NEOEMKI's control (force majeure). In the event of force majeure, NEOEMKI shall be suspended from performing its obligations. In the event that force majeure makes it impossible for NEOEMKI to perform its contractual obligations for a period exceeding thirty days, both parties shall be entitled to terminate the agreement without judicial intervention and without any obligation to compensate the Client for any damage. Force majeure in any case means a measure ordered by the government.
12. NEOEMKI excludes liability for damages arising from the Client's failure to comply with applicable laws, regulations, or contractual obligations, the Client's misuse of the certificate or certification mark.

XVIII. Retention Period of Documents

1. The Client shall retain all documents, records and test samples related to the certification and conformity assessment activities for a period of 10 years (for an implantable device 15 years) after the expiry, termination, suspension, or withdrawal of the certificate or after the last product covered by the certificate has been placed on the market, whichever is the later.

2. The document retention period applies to, including but not limited to:
   - Technical documentation
   - Quality management system documentation
   - Certification Contracts,
   - Audit reports, non-conformity reports
   - Evaluation reports,
   - Certification decisions,
   - Correspondence related to the certification process,
   - Issued certificates and related documentation,
   - Records of complaints, appeals, and their resolutions.

3. The quality management system certification documentation shall be retained for the duration of the certificate and for at least 3 extra years from expiration.
4. Provisions of normative documents that go beyond these requirements shall apply in all cases. In the event of changes to normative documents, they shall apply after their entry into force.
5. NEOEMKI shall not be liable if the Client is unable to present the test sample or document returned or retained in an unchanged condition.
6. For conformity assessments performed under Regulation (EU) 2017/745 (MDR) NEOEMKI shall comply with the record retention requirements specified in Article 51 and Annex VII of the MDR, including maintaining records for at least **10 years** (or **15 years** for implantable devices) after the last product has been placed on the market.

XIX. Confidentiality of Information

1. NEOEMKI shall process as confidential all information and data obtained from or about the Client in the course of the certification and conformity assessment activities, unless:
   - Disclosure is required by law,
   - Disclosure is required by accreditation or designation authorities,
   - Disclosure is required under Regulation (EU) 2017/745 (MDR) or other applicable legal provisions, IAF or MDCG documents,
   - The Client consents in writing to the disclosure.

   Confidential information includes, but is not limited to:
   - Trade secrets,
   - Technical documentation,
   - Development, production and quality control information,
   - Audit findings,
   - Corrective action plans,
   - Internal quality management documentation.
2. NEOEMKI may at any time provide authorized bodies (e.g. authorities, accreditation bodies) with direct access to the relevant documentation. NEOEMKI shall notify the Client in advance (unless prohibited by law) and shall disclose only the minimum necessary information to comply with the legal obligation.
3. The Client also undertakes to process as confidential all information received from NEOEMKI regarding the certification process, audit methods, and internal procedures.
4. If the Client plans to mention NEOEMKI or its services in a press release, professional article or community post, NEOEMKI must be notified in a timely manner. In addition, it must obtain NEOEMKI's written consent before publication.
5. For consumer information purposes or if required by relevant normative documents, NEOEMKI may publish mandatory information, including, among others, the names of certified Clients, the subject of certification, and the validity period.
6. This confidentiality obligation applies to all employees and agents of NEOEMKI such as personnel of NEOEMKI involved in the certification process, subcontractors and third-party experts engaged by NEOEMKI, any other third parties accessing the information in connection with the certification activities. NEOEMKI ensures that all personnel and subcontractors are bound by written agreement.

7. In the event of termination of the Certification Contract confidentiality obligations shall remain in force for an indefinite period.

XX. Handling of Personal Data

1. NEOEMKI is considered a data processor within the meaning of Regulation (EU) 2016/679 (General Data Protection Regulation; GDPR) when NEOEMKI processes personal data during its operation.
2. NEOEMKI's processing of personal data is limited to the extent strictly necessary for the performance of the Agreement. NEOEMKI will only process the data based on the written confirmation of the Client or in accordance with legal requirements.
3. NEOEMKI shall erase the personal data as soon as possible after the completion of the work, unless a legal obligation requires its further retention.
4. Personal data is also considered confidential information, and the rules of confidential processing apply.
5. In the event of subcontracting, NEOEMKI will inform the Client in advance about the third party(ies) it intends to involve and provide the Client with the opportunity to file an objection against the party(ies) concerned.
6. NEOEMKI shall inform the Client of the personal data breach without undue delay and shall provide all relevant (additional) information in connection therewith, unless the personal data breach is unlikely to result in a risk to the rights and freedoms of natural persons. NEOEMKI shall document the breaches and all relevant facts and circumstances relating to the breach.
7. This data handling obligation applies to all employees and agents of NEOEMKI such as personnel of NEOEMKI involved in the certification process, subcontractors and external experts engaged by NEOEMKI, any other third parties accessing the information in connection with the certification activities. NEOEMKI ensures that all personnel and subcontractors are bound by written agreement.

XXI. Use of Certificates and Certification Marks

1. The Client is obliged to comply with the relevant legislation when using any certification symbol (in case of conformity assessment: CE mark).
2. NEOEMKI is entitled to exercise appropriate control over the application and display of the certification symbol (CE mark).
3. The Client may use the certificates and CE marks in commercial transactions exclusively within the certified scope and during the period of validity of the certificate, in accordance with the provisions of the Certification Contract and these GTC, provided that the conditions under which the certificate was granted remain unchanged. The certificate may be used for marketing and promotional purposes, to demonstrate compliance to authorities, partners, and Clients, on the Client's official documents, websites, and in correspondence.
4. Client must use the certificate in its entirety, without partial citation, modification, or misrepresentation. It is prohibited to misuse the certificates and the certification symbol or use them in a misleading or other way that may endanger public confidence in NEOEMKI's certificates and the CE mark.
5. A certificate or certification symbol (CE mark) may only be used to advertise the specific subject of the certification. The use of the certification symbol may not create the impression that the certification also applies to subjects that are outside the scope of the certificate.

6. If the certificate or certification symbol refers only to specific aspects of the subject of certification, the advertisement may not give the impression that the subject of certification has been certified in its entirety.
7. CE marks associated with the NEOEMKI number may only be used for products that comply with the requirements of the certificate.
8. The CE mark stands alone and may not be associated with any other element (e.g. the Client's company logo, statement or graphic).
9. Advertising of a product bearing the CE mark is not permitted if only a management system certificate or a Declaration of Conformity has been issued. The certificate holder may only use the certification marks for the specific models listed on the certificate.
10. The certificate holder is responsible for supervising the use of the certification symbols. The certificate holder may not transfer the rights to the certificate to a third party.
11. Once a product certificate is invalid, the products covered by the certificate may no longer be placed on the market with the CE mark or the CE mark linked to the number of the notified body.
12. Holders of withdrawn certificates are furthermore obliged to either remove the CE mark from all accessible products, or make the CE mark permanently unrecognizable, or destroy the products and must allow NEOEMKI to verify these measures at the expense of the certificate holder.
13. In the case of certificates that do not constitute a legal obligation (voluntary certification), reference must be made to the voluntariness of the certification, the requirements of the certification system, and the normative basis or the owner of the system.
14. The role of NEOEMKI as an independent third party shall not be affected by the presentation of the certification marks. The Client may not use the NEOEMKI logo or any reference to NEOEMKI under any circumstances.
15. If NEOEMKI is subject to claims by third parties due to the Client’s use of the certificate, the declaration of conformity or the CE mark for breach of agreement, the Client shall, upon first request, indemnify NEOEMKI against all claims by third parties.
16. The same shall apply in the event that third parties make claims against NEOEMKI based on the Client’s advertising statements.
17. The Client is fully responsible for having the authorization to use the issued certificate or certification mark and to make any statements.
18. When conformity assessment under Regulation (EU) 2017/745 (MDR) is involved, the CE mark must be affixed on the product as required by Articles 20 and Annex V of the MDR, together with the identification number of NEOEMKI (NB 1011), in accordance with the CE marking guidelines and Eudamed registration obligations.
19. In case of misuse of the certificate or certification mark NEOEMKI shall take appropriate actions, including requiring immediate cessation of misuse, requiring withdrawal or correction of marketing materials, publishing a statement on the misuse (if necessary). If corrective action is not taken NEOEMKI may suspend, withdraw, or terminate the certificate, or take legal actions to protect its interests and reputation.

XXII. Certification/Conformity Assessment Procedure

1. Principles

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

Specific principles applicable in the case of conformity assessment pursuant to Regulation (EU) 2017/745:

- NEOEMKI, as a notified body (NB 1011), shall pursue conformity assessment activities in accordance with the provisions set out in the legislation prescribing conformity assessment activities for the product or in a directly applicable legal act of the European Union of general application in the designated conformity assessment area.
- The Client acknowledges that NEOEMKI recognises the common specifications (CS) and guidelines (MDCG) as mandatory.
- During the conformity assessment procedure for medical devices pursuant to Regulation (EU) 2017/745, NEOEMKI considers a high level of protection of the health of patients and users to be its primary objective, and to this end, it is entitled to require the Client to provide evidence specified by legislation, guidelines (MDCG), common specifications (CS), harmonized standards and science (in particular medicine) in order to ensure compliance.

2. Certification cycle planning

NEOEMKI prepares a program for the entire certification cycle in the case of certification and conformity assessment activities. In the case of preparing an expert opinion in accordance with Article 117 of Regulation (EU) 2017/745, due to the nature of the assessment activity (one-off event), certification cycle planning (preparation of a program) is not necessary.

The program includes the sites to be audited and, in the case of conformity assessment in accordance with Regulation (EU) 2017/745, the technical documentation to be assessed, and, if relevant, their sampling.

The first certification cycle always begins with the certification decision. Subsequent certification cycles begin with the re-certification decision. The certification cycle is three years for the quality management system certification area (according to EN ISO 13485:2016 standard), while the conformity assessment area is five years for the conformity assessment area of the Regulation (EU) 2017/745 (MDR).

In the case of conformity assessment of medical devices according to Directive 93/42/EC the certification cycle extends until the date specified in the relevant legislation.

Condition for maintaining the certificate: NEOEMKI must carry out surveillance audits in the field of system certification and Directive 93/42/EC conformity assessment at least once a calendar year, while in the field of conformity assessment of Regulation (EU) 2017/745 (MDR) once every 12 months and must document the validity of the certificate if the manufacturer meets the standard and/or legal requirements prescribed for it.

The date of the first surveillance audit following the initial certification cannot be later than 12 months from the date of the certification decision.

If the prescribed deadline cannot be met for reasons attributable to the client, the valid certificate must be temporarily suspended for a maximum of 6 months. Audits that can be conducted within this deadline

must be treated as extraordinary audits. If the 6-month deadline is exceeded, the certificate will be withdrawn. If the deadline was exceeded due to NEOEMKI's error, the above must be followed so that the client does not suffer any disadvantage from the error.

The renewal process should always be planned in such a way that it can be completed in sufficient time to allow for the certificate to be renewed in time before the certificate expiry date.

3. Conduct of certification procedures

The initial certification procedure always consists of two stages.

In the case of surveillance and renewal procedures, Stage 1 is only necessary if it is justified by changes indicated by the client or detected by NEOEMKI, or in the case of conformity assessment according to Regulation (EU) 2017/745, a review of technical documentation is required.

For certification according to MSZ EN ISO 13485:2016, for high-risk medical devices a partial Stage 1 procedure must be carried out on site.

In the case of preparing an expert opinion according to Article 117 of the MDR, only Stage 1 is necessary, which covers the assessment of the product documentation submitted by the client.

NEOEMKI appoints an assessment team for both stages. The Client has the right to raise a well-founded objection against the identity of the members of the audit team/conformity assessment team appointed by NEOEMKI. He must justify his objection. In case of a justified objection, NEOEMKI is obliged to reorganize the group. An objection can only be accepted for reasons of impartiality and independence. This provision does not apply in the case of extraordinary and/or unannounced audits due to the nature of the activity.

During the 1st stage of the initial procedure, NEOEMKI reviews the Client's quality management system documentation (quality manual and at least the list of procedures and the content of the key procedures), the management review and the internal audit documentation.

In the case of conformity assessment according to Regulation (EU) 2017/745, in Stage 1, the technical documentation(s) according to the sampling plan (if applicable) in the certification program must also be reviewed, if relevant, together with the relevant consultation procedures.

The assessment team designated by NEOEMKI will declare the result of Stage 1 within 6 months after the submission of all documentation, unless an authority or Expert Panel consultation is required due to the nature of the device, as their results have a significant impact on the outcome of the assessment.

If non-conformities are revealed in the documentation that do not allow the on-site audit to be conducted and do not prove the Client’s readiness for Stage 2, NEOEMKI is entitled to postpone Stage 2 of the initial procedure (on-site audit) until they are corrected.

The on-site audit to be conducted within the framework of Stage 2 may take place after the conclusion of Stage 1. The date of the on-site audit must be agreed with the Client in advance. The agreement is initiated by NEOEMKI. In justified cases, the Client may propose a date other than the proposed date on one occasion, so that it does not jeopardize compliance with the deadlines for the procedure. The tasks to be performed during the on-site audit are planned in the audit plan. After the date of the audit has been agreed, NEOEMKI will send the audit plan to the Client at least one week before the on-site audit.

The audit plan must be finalised with the client during the opening meeting of the on-site audit.

During the audit, the audit team systematically reviews the implementation, operation and documentation of the quality management system. The Client must ensure that the personnel required

to perform the audit are available to the auditors, and that the audit team members have access to the documents to be examined, access to the necessary plant areas and support the work of the auditors in order to conduct the audit in an appropriate manner.

The information subject to the audit includes design, development, production and quality control activities, the results of internal audits, management reviews, complaints and their handling, as well as the reporting of exceptional events, corrective actions and other regulatory reporting obligations. The audit also includes verification that the Client complies with its regulatory reporting obligations.

During the audit closing meeting, the assessment team states whether the audit objective has been met and records the audit conclusions, with particular regard to the detected non-conformities, which it prepares a report on and hands over to the client. If the audit objective has not been met, the team notifies the client in a documented manner during the final meeting and draws the client's attention to the fact that a follow-up audit may be necessary in this case, in addition to reviewing and amending the audit program for the cycle.

In the case of a conformity assessment area, if the client is unable to present the technical documentation during the on-site audit and/or it is determined that there is a discrepancy between the data in the technical documentation and what was experienced on-site, this must be documented as a major non-conformity.

The NEOEMKI on-site audit team is entitled to decide on the need for a follow-up audit. During an initial audit, the follow-up audit must be conducted within 180 days of the on-site audit, while in the case of a surveillance audit, it must be conducted within 90 days and the documentation must be closed (including the acceptance of the measures related to non-conformities by NEOEMKI). In the case of a follow-up audit, the applicable NEOEMKI audit standard fees shall apply.

The conclusions of the audit are recorded by the assessment team in a complete, concise and clear audit report, which must be made available to the client after the audit within 90 days of the conclusion of the audit.

NEOEMKI is entitled to check the up-to-datedness the technical documentation of the certified products at any time during the validity period of the certificate.

During the review conducted in both Stage 1 and Stage 2, NEOEMKI may identify non-conformities, either in the quality management system or in the technical documentation reviewed.

NEOEMKI records all detected non-conformities in a non-conformity report and hands them over to the client. In the case of non-conformities detected during the on-site audit, the handover takes place within the framework of the audit closing meeting, while in the case of non-conformities recorded off-site, it is done in a documented manner within 7 days of recording. The Client’s representative is entitled to make written comments on the non-conformity reports, and in justified cases, to express disagreement or raise objections to their contents. These possible comments and objections do not affect the conclusion of the on-site audit or technical documentation evaluation, and will be investigated in all cases, if necessary, in accordance with the NEOEMKI complaint handling procedure.

NEOEMKI classifies detected non-conformities into two categories:

- Major non-conformity: system error (complete lack of standard and/or legal requirements in the documents; repeated, regular deviation) and violation of regulations (MDR and/or IVDR).
- Minor non-conformity: non-conformities that occur in individual, sporadic cases, do not endanger safety, or can be corrected quickly are considered minor.

If a non-conformity is identified during the certification procedure, the Client must submit a corrective and preventive action plan (CAPA plan) to the NEOEMKI within 15 days. The CAPA plan must include at least the following: method of determining the roots causes, root causes, measures with a responsible person and deadline. The client is obliged to submit documents proving the correction of non-conformities to NEOEMKI by the deadline agreed in the accepted corrective and preventive action plan. In the absence of correction, the procedure will be closed upon expiry of the deadline agreed upon in the preventive action plan.

For minor non-conformities, it is sufficient to submit the necessary corrective and preventive action plan to NEOEMKI, and their implementation will be verified during the next on-site audit.

For major non-conformities, the implementation must be verified by checking the amended documentation or as part of a follow-up audit.

For initial procedures, 180 days (150 days for correction by the client + 30 days for verification by NEOEMKI) are available to correct the detected non-conformities, while in the case of surveillance, renewal or extraordinary procedures, 90 days (60 days for correction by the client + 30 days for verification by NEOEMKI) are available from the date of detection.

Additional non-conformities may be identified in the technical documentation sent by the Client as corrected.

The assessment team shall provide the decision-maker with the factual data and decision proposal necessary for making the certification decision.

NEOEMKI may make a certification decision on the issuance, maintenance of validity, or reinstatement of the certificate only after the Client has corrected the major non-conformities and their acceptance by NEOEMKI. For non-conformity of the technical documentation(s), a certificate may not be issued. If the corrections are not made or cannot be accepted, NEOEMKI shall refuse to issue or reinstate the certificate or suspend or withdraw the certificate already issued.

NEOEMKI shall in all cases inform the client in writing of the certification decision within 10 days of the decision being made. If the certification is subject to restrictions, NEOEMKI shall clearly record this on the certificate. NEOEMKI shall issue the certificate exclusively in Hungarian and/or English.

For an notified body opinion pursuant to Article 117 of the MDR, no certification decision shall be made, and no certificate shall be issued. The completed assessment shall in all cases be checked and approved by an expert with appropriate competence and appointed by a relevant assignment. In case the assessment is considered appropriate, approval shall be recorded on the notified body opinion template.

Surveillance procedure

The issued certificate validity is subject to carrying out surveillance audits at least once a calendar year in the case of system certification and Directive 93/42/EC conformity assessment, and once every 12 months in the case of MDR conformity assessment. The validity of the certificate must be documented if the manufacturer meets the standard and/or legal requirements.

The documents required for conducting the surveillance procedure (such as the valid quality manual and the list of possible changes) must be submitted to NEOEMKI by the deadline.

All regular surveillance procedures shall include:

- review of internal audits and management reviews;
- review of actions taken in response to non-conformities identified on the previous audit;
- review of complaint handling;

- an assessment of the effectiveness of the management system with regard to the certified client's objectives and the intended results of the respective system;
- a review of progress made with planned activities aimed at continual improvement;
- continuous operational monitoring;
- review of any changes;
- in the case of conformity assessment of medical devices, a review of the technical documentation;
- review of the use of certification marks and/or any other references to certification.

NEOEMKI shall provide the client with a report on the surveillance audit and the procedure.

Other surveillance activities

Surveillance activities may also include:

- inquiries from the certification body to certified Clients regarding certification aspects;
- evaluation of information related to Clients' operations (e.g. advertising materials, websites);
- requests for Client documents and records (on paper or electronic form);
- other means of monitoring Client performance.

Renewal of certification

The purpose of the recertification procedure is to review the continued conformity and effectiveness of the certified product and/or management system. During the recertification procedure, NEOEMKI reviews the technical documentation, the performance of the management system throughout the most recent certification cycle.

The recertification procedure must be completed before the expiry of the certificate in order to maintain the certificate. If such a recertification procedure is successful, NEOEMKI issues a new certificate

XXIII. Miscellaneous, Applicable Laws

1. In matters not regulated in these general terms and conditions, the provisions of Hungarian law in force always shall apply. The Parties shall primarily resolve their legal disputes through extra-judicial settlement. In the event of this failing, the Parties shall submit their legal disputes to the Hungarian court having jurisdiction at the registered office of NEOEMKI.
2. The provisions of Hungarian law shall apply to the GTC. With respect to matters not regulated hereunder, the Civil Code, Act CXXXIII of 2009 on the activities of conformity assessment bodies, and its implementing Government Decree 315/2009 (XII. 28.), as well as Regulation (EU) 2017/745 on medical devices (MDR) shall apply.
3. NEOEMKI publishes its current regulations on complaint handling and appeals on its website (E97 Incidents violating organizational integrity, complaint handling, appeal procedure). According to the regulations, the Client could file a complaint or appeal regarding NEOEMKI's procedure or certification decision, based on the relevant points of the E97 procedure.
4. The Client may only commission another certification body (Notified Body) for a conformity assessment procedure for medical devices covered by the Certification Contract if a prior written agreement has been reached with NEOEMKI.
5. By signing the Certification Contract, the Client declares that it qualifies as a transparent organization pursuant to Sec. 3 of Act CXCVI of 2011 on National Assets. The Client undertakes to inform NEOEMI immediately in the event of any change in its transparent organizational status. The Client acknowledges that if it qualifies as a non-transparent organization, NEOEMKI is entitled to terminate

the agreement with immediate effect, withdraw from it, and demand compensation for any other damage incurred, without compensating the Client.

6. The Client acknowledges that in the event of an emergency affecting the Client and/or NEOEMKI, the emergency procedure developed by NEOEMKI must be applied in order to ensure the sustainability of operations. Upon the declaration of an emergency, NEOEMKI shall act in accordance with its relevant procedure, and the procedure published on its website shall cease to be valid for the duration of the emergency.
7. The Client acknowledges that NEOEMKI has data provision obligations in the case of conformity assessment procedures carried out in accordance with Regulation (EU) 2017/745 (e.g.: recording information related to the certificate in the Eudamed system, recording the results of the application review, summary of safety and performance, consultation procedure applicable in the case of clinical evaluation of devices classified as class III or IIb, etc.) in accordance with Article 57(1)(f), (g), (h) and (i) of the MDR, which it fully complies with in accordance with the provisions of the relevant regulation.
8. The Client acknowledges that NEOEMKI is obliged to provide data and provide access to documents related to the given procedure (e.g. audit documentation, product review reports, etc.) within the framework of the inspection by the competent authorities.
9. The Client and NEOEMKI hereby declare that in the event of force majeure situations that prevent the fulfilment of these GTC, they will strive to amend the Agreement by mutual agreement, taking into account their mutual interests.

By signing the individual Certification Contract, the Client declares that he has read and accepted the content of NEOEMKI's General Terms and Conditions in force.

Budapest, 01.07.2025

Document changes

date	edition	version	modification	justification
09.10.2024.	01	01	Initial edition.	NEOEMKI has been designated as the notified body for conducting conformity assessment under MDR (Regulation (EU) 2017/745 on medical devices).
21.03.2025.	01	02	Recording NEOEMKI's site.	Establishment of the NEOEMKI's site.
01.07.2025.	01	03	Textual and structural modifications.	Complete review. Integration of M11 General Terms and Conditions (MDD, IVDD, ISO 9001 and 13485 certification) and M8903 General Terms and Conditions (MDR). Removal of M11, incorporation of relevant provisions into M8903.