National Medical Device Conformity Assessment and Certification LLC.

GENERAL TERMS AND CONDITIONS

(GTC)

v1.3

10.09.2020.

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I. Preambulum

NEOEMKI National Medical Device Conformity Assessment and Certification LLC. (hereinafter NEOEMKI) is the legal successor of the Directorate of Device Testing and Clinical Engineering of the National Institute of Pharmacy and Nutrition (OGYÉI). The legal succession and the establishment of NEOEMKI Kft. are regulated by 28/2015. (II. 25.) Government Decree amended by 164/2020. (IV.30.) Government Decree.

II. General Data of the Service Provider

II.1. Data of the Certifying Organization:

Name:	NEOEMKI National Medical Device Conformity Assessment and Certification LLC. (abbreviated as NEOEMKI, hereinafter Certification Organization)
Address:	1097 Budapest, Albert Flórián út 3/a
Name of Certification Body:	NEOEMKI
Company Registration No:	01-09-357519
Tax Identification No:	27927616-2-43
Bank Account No:	10409015-50526970-68801014 (K&H Bank)
Representative:	László Imre managing director

II.2. Contact Details of the Certifying Organization

Address:	1097 Budapest, Albert Flórián út 3/a
Website:	https://emki.hu
Phone Number:	+36 20 268 7595
E-mail address:	titkarsag@emki.hu, cert@emki.hu
Office Hours:	Monday-Thursday: 8:30 – 16:30
	Friday: 8:30 – 14:00

II.3. Availability of General Terms and Conditions

The valid version of the General Terms and Conditions is available at the Secretariat of the certification body and on its website. It is also available to its customers in printed form as an annex to the Certification Agreement. The certification body notifies customers of changes to the GTC.

II.4. Accreditation, Appointment and Other Conditions for Service Provision

NEOEMKI complies with MSZ EN ISO/IEC 17021-1 “Conformity assessment. Requirements for bodies performing audits and certification of management systems ”. NEOEMKI is accredited by the National Accreditation Authority for the conformity assessment of management systems, NAH-4-0009 / 2016

for management systems according to EN ISO 9001 and NAH-4-0096 / 2016 for management systems according to EN ISO 13485.

In the NANDO (New Approach Notified and Designated Organizations) system NEOEMKI is registered as a Notified Body under No. 1011. NEOEMKI has liability insurance for the provision of services under the Certification Contract.

II.5. Supervisory (appointing and accrediting) Bodies:

OGYÉI Department of Medical Devices 1051 Budapest, Zrínyi u. 3.

National Accreditation Authority of Hungary 1118 Budapest, Tétényi út 82.

III. General Terms and Definitions

III.1. Effective Date:

The date (day, month) of completion of the site audit (2nd phase) of the initial certification process. Additional annual surveillance audits should be scheduled based on the anniversary of the original certification audit.

III.2. Services:

Conformity assessment of medical devices according to Decree 4/2009 (III. 17) of the Ministry of Health, IVD medical devices according to Decree 8/2003 (III. 23) of the Ministry of Health, Social and Family Affairs and conformity assessment of management systems according to EN ISO 9001 and/or EN ISO 13481 standards.

III.3. Conformity Assessment (Certification)

- **Conformity assessment of the management system according to the ISO standard**

The process that includes the review of the quality management manual, procedures and regulations of the management system maintained by the Customer and the records generated in connection with its operation, as well as the on-site inspection (audit) of the manufacturing site. The conformity assessment procedure includes initial certification, surveillance visits and extraordinary visits.

- **Conformity assessment of medical devices on the basis of legislation**

The process that includes, in addition to quality system verification, the examination of the technical documentation of the manufactured medical device, with particular consideration to the clinical evaluation; laboratory testing if necessary, and on-site inspection (audit) of the manufacturer and its critical subcontractors. The conformity assessment procedure includes initial certification, surveillance visits, extraordinary visits and unannounced visits.

III.4. Certification Period:

For management systems according to EN ISO 9001 and EN ISO 13485, a certification cycle is a maximum of 3 years from the initial (renewal) certification. The issued certificate is valid until the end of the certification cycle, provided that the Certifying Organization carries out an annual surveillance visit and documents the validity of the certificate.

In the case of conformity assessment of medical devices and IVD medical devices, the certification cycle extends to the date specified in the relevant legislation. The issued certificate is valid until the end of the certification cycle, but no later than 26 May 2024, provided that the Certifying

Organization carries out an annual inspection visit, documents the validity of the certificate and the manufacturer meets the legal requirements.

III.5. Certifying Organization:

An organization that provides certification activities detailed in the Certification Agreement. NEOEMKI is an independent economic company, owned by the Hungarian state, with the rightsholder being the Ministry of Human Resources. The Certifying Organization has the designation and accreditation required to provide the service specified in the contract.

III.6. Client:

The organisation that requires and orders conformity assessment to be performed and whose management system, medical device product and/or IVD medical device product and their production is audited and assessed by the Certifying Organization.

III.7. Unannounced Visit (In case of CE certification):

In order to ensure continuous compliance with relevant legal requirements, besides the initial, surveillance and renewal audits, Certifying Organization makes unannounced visits at the Client organization. Unannounced visits can be performed at the Client's premises specified in the Agreement or at some of the Client's key suppliers or subcontractors at least once per certification cycle. When appropriate (production of high-risk devices, instability of the management system, etc.) the Certifying Organization may perform unannounced visits more frequently.

III.8.Certification Agreement

The Client and the Certifying Organization enter into an individual Certification Agreement for the service established between them. The individual Certification Agreement details the content, deadline, validity and financial conditions of the service.

III.9. Legacy device:

Devices that are lawfully continued to be placed on the market by the manufacturer with a directive certificate valid under the MDD Directive after the date of application of MDR (Regulation (EU) 2017/745) on 26 May 2021, complying with the requirements set out in the regulation.

III.10. Emergency Procedure:

Emergency procedure to be applied by NEOEMKI. Its application is ordered by the managing director of NEOEMKI, taking the circumstances into account, and notifying the clients.

III.11 Emergency

Cases of emergency may be: an unexpected, significant, unintentional event in the course of human activity that endangers human health or the environment and over which the certifying organization has no influence. This includes force majeure events such as war, strikes, riots, political instability, geopolitical tensions, terrorism, crime, epidemics, quarantine orders for other reasons, travel restrictions, natural disasters, other man-made disasters, and an emergency ordered by the government in the event of an elemental disaster or industrial accident endangering the safety of property.

The activities of the Certifying Organization related to the Client are regulated by the Certification Agreement, the GTC and the procedures published by the Certifying Organization on its website.

The service specified in the Certification Agreement concluded between the Client and the Certifying Organization is performed by the Certifying Organization on the basis of the procedure published on its website: it includes the basic concepts, the course of certification activities, deadlines, processes related to certification decision-making and requirements. The Certifying Organization may amend the published procedures provided that they are published on its website and that its customers are notified of any significant changes.

IV. Scope of Effect of GTC

IV.1. The scope of effect of the present General Terms and Conditions (GTC) is the Agreement (hereinafter Certification Agreement) between the Certifying Organization and the Client ordering conformity assessment of its medical device, IVD medical device and/or management system (hereinafter Client).

IV.2. This GTC shall be governed, construed, and enforced in accordance with the laws of Hungary. In case of matters not covered the Civil Code, the Act CXXXIII of 2009 on activity of organisations performing conformity assessment activity and the related 315/2009 (XII. 28.) Decree of the Government, 18/2010 (IV. 20.) Decree of the Minister of Health; the 4/2009 (III. 17.) Decree of the Minister of Health on medical devices and 8/2003 (III. 13) Decree of the Minister of Health, Social and Family Affairs on in vitro diagnostic medical devices are to be applied.

IV.3. GTC and its modifications are in effect from the date set by the Certifying Organization. Certifying Organization publishes the starting date of effect and the current version number of the GTC on NEOEMKI's website and notifies clients of the change via e-mail.

IV.4. GTC is in effect until the modified version is put in effect or until the Certifying Organization is entitled to provide the services.

IV.5. GTC is an inseparable attachment of the Certification Agreement.

V. Scope of Effect, Timeframe, and Termination of the Certification Agreement

V.1. Certification Agreement is in effect during the entire duration of the agreement.

V.2. Certification Agreement is in effect during the certification period, until the date of validity of the Certification Document issued. The length of validity is not identical with the date of effect in the actual year; in all cases it should be longer.

V.3. Certification Agreement can be modified in writing at any time by the consent of both parties.

V.4. Certification Agreement can be terminated without cause only when the Certifying Organization has informed the Client about significant modifications in the GTC, which the Client does not accept and informs the Certifying Organization about nonacceptance in writing in 15 days after receiving the notification. Minor modifications of the GTC do not entitle the Client to terminate the Agreement without cause.

V.5. In any other case either party can terminate the Certification Agreement with termination for cause in the form of a written statement. Termination for cause can only be justified if one side fails to act up to the terms of the Agreement which hinders or restricts the other party to meet the requirements set in the Agreement. In such cases the non-default party is required to notify and warn the default party to act according to the terms of the agreement and make rectifications within 8 days upon receipt the notice, or when it is not possible a longer time frame may be determined. In case such warning is ineffectual the Agreement can be terminated for cause (f.e. significant delay in the date of the surveillance audit without proper reasoning, breaching the terms of the GTC or the Certification Agreement).

Breach of agreement includes among others if the Certifying Organization is unable to perform the surveillance audit by the date of effect by the Client's fault, if the unannounced visit cannot be performed during the regular working hours previously declared by the Client and the Client

fails to inform the Certifying Organization during an initial, surveillance or renewal audit or in a written notice about any temporary obstructions or other conditions in the given period.

V.6. If termination for cause occurs due to the Client's failure to fulfil the duties under the Agreement terms the fees already paid cannot be claimed back and Client is obliged to pay for the damages caused for the Certifying Organization by breach of agreement.

V.7. If termination for cause occurs due to the breach of contract of the Certifying Organization, the Client may act in accordance with the relevant rules of the Civil Code.

V.8. In case Agreement terms cannot be fulfilled for reasons that neither party is responsible for (f.e. changes in relevant legislation) the Certification Agreement terminates. The party that obtains information about the changes in circumstances that effect the agreement terms in such way is obliged to notify the other party forthwith. The default party is responsible for any damages caused by failure to inform the other party. When the Certification Agreement is terminated the fees for the services provided before termination of the agreement must be paid by the Client.

V.9. In case the Certification Agreement is terminated before the certification period expires, the Certifying Organization withdraws the given certificate.

V.10. In case the on-site visit for the initial audit does not take place within one year from the expected date specified in the Certification Agreement the Agreement is repealed.

VI. Subject and Contents of the Certification Agreement

VI.1. Certification Agreement is made between the Certifying Organization and the Client; the Client assigns the Certifying Organization, as an appointed and accredited body, to perform the initial audit and the related surveillance audits under the conditions and with the contents determined in the Certification Agreement. The Client acknowledges and agrees that the Certifying Organization will provide the service in accordance with the relevant Hungarian and EU legislation, MEDDEV guidelines and standards, and the procedures approved by the designating and accrediting authorities.

VI.2. Subject of the Agreement may be:

- conformity assessment of medical devices according to 4/2009 (III. 17.) Decree of the Minister of Health on medical devices, transposing Council Directive 90/385 / EC on active implantable medical devices and Directive 93/42 / EEC on medical devices;
- conformity assessment of in vitro medical devices according to 8/2003 (III. 13) Decree of the Minister of Health, Social and Family Affairs on in vitro diagnostic medical devices, transposing Directive 98/79 / EC of the European Parliament and of the Council
- conformity assessment of general management systems according to EN ISO 9001:2015 standard;
- conformity assessment of management systems of producers of medical devices according to EN ISO 13485:2016 standard.

VI.3. By signing the Certification Agreement the Certifying Organization accepts the assignment.

VI.4. The specific Certification Agreement made between the Certifying Organization and the Client is prepared by the Certifying Organization according to the Quotation Request Form provided by the Client. The Certifying Organization includes the data and information relevant for the Client and used for planning the certification process.

VI.5. The Certification Agreement must be modified in case the circumstances and conditions revealed during the on-site visit are significantly different from the information provided in the Quotation Request Form (size of the organization, scope of production, involvement of subcontractors, products for certification), or the Client announces major changes that affect the certification process or the quality management system does not operate properly (on the subsequent audits more that 5 non-conformity issues have been recorded or unexpected events in relation to the medical devices have repeatedly occurred).

VI.6. The Certification Agreement specifies the time frame for the services ordered by the Client and the expected date of starting the audit.

VI.7. By signing the Certification Agreement, the Client agrees that the legacy devices placed on the market by him after 26 May 2021 must comply with the requirements set out in Article 120 (3) of Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices.

VII. Process of Making the Certification Agreement, Invoicing and Payment

VII.1. Client is bound to pay the fees and charges specified in the Certification Agreement to the Certifying Organization prior to the commencement of the activities included in the Agreement (documentation analysis, initial audit, surveillance audit, laboratory tests, etc.) according to the invoice issued by the Certifying Organization by bank transfer, following the payment terms. Az Client acknowledges that organization of the audit (in case of audit in a foreign country organization of the journey) will not begin until the payment for the services has been settled. All consequences of delays originating from Client's meeting payment terms are to be borne by the Client.

VII.2. In case the initial audit is unsuccessful and the certificate cannot be issued, Certifying Organization reimburses the costs of issuing the certificate as specified in the Certification Agreement from the amount paid by the Client.

VII.3. Client acknowledges and accepts that the certification fees and charges quoted by the Certifying Organization cover the services related to the sites, processes, key subcontractors, suppliers and products specified in the Certification Agreement, for the whole length of the certification process. In the quote the charges for the initial and surveillance audits and other incidental fees are given separately. If the examination of the documentation reveals non-conformity (ies), the re-assessment of their one-time repair by the Customer is included in the certification fee specified in the contract. If further corrections and re-assessments become necessary, the Certifying Organization is entitled to charge an additional fee specified in the individual Certification Agreement. By signing the Certification Agreement Client accepts the fees and charges determined for the whole certification period.

Service fees not specified in the Certification Agreement are calculated on the basis of the valid price list published on the website of the Certifying Organization.

Upon completion of the on-site audit, the closing meeting report prepared and submitted on site shall be considered as a certificate of compliance.

VII.4. In case an unannounced visit cannot be completed due to reasons arising from the Client's side the Certifying Organization is entitled to charge the Client for the repeated visit.

VII.5. Certifying Organization reserves the right to charge additional fees for non-compliance cases recorded during the site audits. Such additional fees cannot exceed 20% of the charges for the given audit (travelling and subsistence expenses excluded). In case of rectification of non-compliance requires a supplementary audit on the site, travelling and subsistence expenses are also to be borne by the Client.

VII.6. Any discounts or reduction of the charges and fees can be claimed back by the Certifying Organization if the Certification Agreement is terminated with or without cause during the certification period.

VII.7. If the Client and the payer are not identical obligations described in sections VI.1.-VI.2. and VI.4. are to be borne by the payer. The details of the payer – in case it is not the Client – must be included in the Certification Contract.

VIII. Rights and Obligations of the Client

VIII.1. During the conformity assessment procedure the Client is obliged to:

- provide the Certifying Organization with all the data and documents required for the procedure prior to the commencement of the initial or the surveillance audit and take responsibility for their correctness;
- supply the Certifying Organization with the relevant technical documentation and/or Design Dossier(s) and acknowledge that the documents or parts of documents required by the Certifying Organization are retained by the Certifying Organization in printed or electronic format during the certification period or for a time period determined by relevant legislation;
- ensure and provide proper conditions for the Certifying Organization to perform site audits during the certification period on all the production premises of the Client, its key subcontractors and suppliers;
- answer the Certifying Organization's questions regarding the conformity assessment process;
- appoint and ensure continuous availability of the person in charge (contact person) who is responsible for organizing and providing proper conditions for the audits during the conformity assessment process;
- ensure that staff of the Certifying Organization are allowed to enter the premises, production areas, offices and all other areas within the premises of the Client to be able to perform the conformity assessment procedures in accordance with the relevant health and safety measures;
- announce changes specified in section X;
- pay the fees and costs of the conformity assessment procedure irrespective of its final result;;
- inform the Certifying Organization about any certification issues, ongoing or closed certification findings, results or agreements with any other Certifying Organization in relation to the products involved in the certification process.

VIII.2. During the conformity assessment procedure the Client has the right to:

- raise a firmly-established objection against the auditor appointed by the Certifying Organization in case impartiality and independence of the auditor is not guaranteed;
- ask questions and receive well-grounded, objective replies in relation to the conformity assessment procedure;
- give written objections to the decisions made during the conformity assessment process according to section X of the present GTC.

VIII. 3. After receiving the Certification document (Certificate), with regards to the efficiency period of the Certificate Client is obliged to:

- in case of conformity assessment based on quality management system take all measures for its sustainment, maintenance, development and corrections according to the documented procedures;
- undertake the annual surveillance audits in order to maintain the validity of the certificate as discussed and agreed with the Certifying Organization;
- ensure that unannounced visits can be performed on the Client's premises;
- ensure that unannounced visits can take place at the premises of the key supplier or subcontractor involved in manufacturing the product and specified in the Certification Agreement according to the agreement between the Client and its subcontractor or supplier in the form of a contract;
- notify the Certifying Organization about any certification process or agreement with any other Certifying Organization regarding the products specified in the Certification Agreement;
- notify the Certifying Organization forthwith in case of any significant changes or modifications in the quality management system, organizational structure, location of production, technology, the certified product, etc;
- in case the product has different versions or types they must be marked with some indentifier so that they can be clearly identified and distinguished;
- inform the Certifying Organization about any unexpected events regarding the product certified by the Certifying Organization;
- use the documentation of the conformity assessment process, the logo and notes of the Certifying Organization (f.e. audit report) in their full forms, without any excerpting or extracting in a clear and unambiguous way;
- take into account the NEOEMKI regulations on the use of certification marks published on its website (M13) and act accordingly (eg in the media, in advertising);
- refrain from referring to the conformity assessment process in a way that may discredit or damage the reputation of the Certifying Organization;
- refrain from any derogatory, misleading or deceptive comments on the conformity assessment process;
- refer to activities and products as certified that the certification actually covers and entails;
- provide the Certifying Organization with the current documentation of the quality management system prior to the renewal audit with a separate listing of the modifications and changes taking place in the meantime;
- inform the Certifying Organization on the products (with their reference number, production sequence number, LOT number, product categoty, etc.) that were launched under the scope of the Certification Agreement during the period of the effect of the Certification Agreement in case the Certification Agreement is terminated for any reason and the Client has not made a new agreement with the Certifying Organization for the related product(s). The Client is required to specify the date when the last product of such kind was launched. The CE1011 mark can be used only on the medical devices and related information material that are under the effect of the Certification Agreement made with the Certifying Organization and EC conformity certificate is allowed to be issued only for such products.
- follow instructions of the Certifying Organization (ceasing using the logo and related advertisements, sending back the certificate, issuing producer's warning) in case the Certifying Organization suspends or withdraws the certificate.

IX. Rights and Obligations of the Certifying Organization

IX.1. The Certifying Organization is obliged to:

- perform the conformity assessment of the given product or system according to its own conformity assessment rules and procedures and the relevant legislative background;
- delegate an auditor with the necessary professional competences for the conformity assessment of the given product or system;
- examine any possible objections against the auditor and in case the objections are firmly grounded and justifiable, delegate another competent auditor;;
- treat all information revealed during the conformity assessment process confidentially; confidentiality rules and regulations apply to all the employees and contracted advisors of the Certifying Organization;
- initiate organizing the annual surveillance audits for the Client before the expiry of the certification period by specifying the documents required and sending the invoice for the supervisory audit fees;
- supervise its certification process annually on the Client's premises and/or production site by reviewing the (technical) documentation according to the certification plan specified by the auditor;
- initiate suspension of the certificate in case the Client refuses to organize the surveillance audit or hinders its organization and therefore the Certifying Organization is unable to register the date of the audit until the date of expiry of the certificate;
- examine the Client's objections, complaints or appeal against the certification decision according to Procedure E03 on appeal and complaint handling;
- meet deadlines in accordance with the certification procedures published on its website;
- keep its obligations and duties as described in the relevant legislation; notify the supervisory bodies about issued, modified or withdrawn certificates;
- in case there is any firmly established doubt or uncertainty regarding the production, safety or effectiveness of the given product, the Certifying Organization is required to take the steps described in section XI;
- file and store the documentation of the conformity assessment after its conclusion for the time period determined in relevant regulations.

IX.2. The Certifying Organization is entitled to:

- initiate suspension of the certificate by sending written notification to the Client and terminate the Certification Agreement with cause if surveillance audit is not performed until the expiry date of the certificate and no other agreement has been made with the Client;
- initiate withdrawal of the certificate if the Client fails to order a special audit within 6 months after suspension of the certificate;
- perform all necessary inspection and supervision for the activity specified in the Certification Agreement at the Client's premises [Sections 4. § (3)-(4) of Government Decree 315/2009 (XII. 28.)] and make unannounced visits at the Clients' or its key subcontractor's or supplier's premises;

- the Certifying Organization reserves the ownership rights related to the reports and documents prepared by the Certifying Organization in connection with the certification;
- employees and contracted advisors or experts of the Certifying Organization are entitled to enter and stay at the Client's premises, offices and all other production areas as it is required to perform the activities related to conformity assessment;
- return the documentation provided by the Client after completing the conformity assessment procedure;
- to initiate the suspension of the certificate if - in case of breach of its obligations - the Client fails to fully comply with the requirements despite the warning of Certifying Organization.

X. Changes in Client's Details, Notifications

X.1. The Certification Agreement made between the Certifying Organization and the Client is valid during the certification period with no amendments in its contents. In case there are any changes in the Client's data, circumstances of production, other activities or in the range of products manufactured Client is obliged to notify the Certifying Organization on the given form within 30 days. The Change Notification Form is available on the Certifying Organization's website. The Certifying Organization takes no responsibility for any consequences arising from Client's failure to announce such changes. In case the Certifying Organization takes notes of such unannounced changes during an initial, surveillance or renewal audit, the Certifying Organization is entitled to initiate to make modifications in the fees and charges of the certification process.

XI. Complaints and Appeals against the Certification Decision

XI.1. The Certifying Organization publishes its Procedure on handling complaints and appeals (Procedure E03) on its website. According to the regulations the Client has the right to make a complaint or an appeal against the procedures or the certification decision of the Certifying Organization following the instructions of the relevant sections of Procedure E03. The Certifying Organization publishes the form for making complaints and appeals on its website to provide guidance to the Client in the process.

XII. Other Provisions

XII.1. In case the Certifying Organization finds that the product the conformity assessment of which the Client ordered does not meet the requirements set by relevant legislation, general regulations of the European Union to be applied directly or technical requirements according to point 8 of section 2 of Directive 765/2008/EC, the Certifying Organization does not issue the certificate until the Client takes the necessary measures to adjust the product and ensure that it meets the requirements set above [Section 6. § (1) of 315/2009 (XII. 28.) Government Decree].

XII.2. In case the Certifying Organization states that the product does not meet the requirements set by the Directive referring to the product, after issuing the certificate, it notifies the Client specifying a deadline that is applicable for the given product. If the Client does not take the necessary measures for compliance with the relevant legislation and requirements or the product cannot be modified accordingly, the Certifying Organization restricts, suspends or withdraws the certificate following the procedural descriptions of the Quality Management Manual and

Procedures of the Certifying Organization [Section 6. § (2) of 315/2009 (XII. 28.) Government Decree].

XII.3. During the term of the agreement the Client is allowed to make any further agreement or give commission to another Certifying Organization (Notified Body) for the products under the scope of the Certification Agreement only by the prior written consent of the Certifying Organization.

XII.4. By signing the Certification Contract the Client declares that it is a transparent organization with regards to Section 50. § (1a) of the 368/2011 (XII. 31.) Government Decree on the Implementation of the Act on Public Finances and according to Paragraph 3 of the Act CXCV of 2011 on Public Finance. Client undertakes to notify the Certifying Organization in case of any changes in its transparent organization status. Client acknowledges that in case it ceases to be a transparent organization the Certifying Organization is entitled to terminate the agreement and claim for all damages, losses and expenses without any reimbursement to the Client.

XII.5. The Client acknowledges that, if justified, the Certifying Organization may order an emergency situation regarding the operation of the Client (several clients) or the Certifying Organization. In order to ensure the sustainability of the operation in the event of an emergency, the Certifying Organization has developed an emergency procedure. Simultaneously with the declaration of the emergency, the Certifying Organization 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.

XII.6. Client acknowledges that the Certifying Organization provides information to third parties on request about certificates in effect including the certified Client's name, registration number of the certification and areas of application.

XII.7. Client acknowledges that the Certifying Organization is obliged to ensure inspection of audit documentation and to disclose data to supervisory bodies having authority to perform such inspection and supervision.

XII.8. The parties shall attempt to resolve any dispute arising out of or relating to the agreement through negotiations; if the matter has not been resolved the dispute may be referred to jurisdiction by any party. In cases where the parties submit themselves to judicial way the court having jurisdiction is to be chosen according to the Certifying Organization's location.

XII.9. By signing the Certification Agreement Client declares that it acknowledges and accepts the contents of the current version of the General Terms and Conditions of NEOEMKI