General Terms and Conditions of the Czech Metrology Institute for the Certification of Medical Devices

I. Introductory provisions

1. These General Terms and Conditions (hereinafter referred to as the "**GTC**") govern certain rights and obligations of the notified body – the Czech Metrology Institute, Reg. No.: 00177016, with its registered office at Okružní 31, 638 00 Brno (hereinafter referred to as the "**CMI**"), and a natural or legal person (hereinafter referred to as the "**Manufacturer**") who, on the basis of a duly delivered request, has requested the CMI to perform the relevant conformity assessment and certification of medical devices in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices (hereinafter referred to as the "**MDR**").

2. These GTC have been issued in accordance with Section 1751 of Act No. 89/2012 Coll., the Civil Code, as amended (hereinafter referred to as the "**Civil Code**") and are an integral part of the Framework Agreement on Medical Device Conformity Assessment concluded with the Manufacturer (hereinafter also referred to as the "**Agreement**") and the Implementation Contract relating to the specific project (certification, post-certification monitoring, recertification or surveillance of legacy devices) (hereinafter also referred to as the "**Implementation Contract**"). The provisions of these GTC also govern certain rights and obligations of the CMI and the Manufacturer prior to the conclusion of the Agreement regarding the terms and conditions of the request and its review.

3. Terms and their definitions used in the GTC, the Agreement and the Implementation Contract:
   (a) Framework Agreement or Agreement refers to the agreement for medical device conformity assessment and related services entered into between the CMI and the Manufacturer, which is concluded for one or multiple medical devices to be subject to the CMI's services and which governs the terms and conditions, method of implementation, as well as the scope of procedures used in the process of certification, post-certification monitoring, recertification or surveillance of legacy devices related to medical devices specified in that Agreement.
   (b) Implementation Contract refers to a contract concluded in connection with the Framework Agreement, setting out the details of a specific project (certification, post-certification monitoring, recertification or surveillance of legacy devices).
   (c) Estimated price refers to a preliminary estimate of the total price for all of the CMI's services, calculated on the basis of a non-binding inquiry submitted by the Manufacturer and contained in the Agreement.
   (d) Detailed estimated price refers to the price for the CMI's services contained in the Implementation Contract.
   e) Final price refers to the price known only at the end of the project and corresponding to the actual scope of services provided by the CMI, which is the basis for the final invoice.
   (f) Advance refers to a payment of 50% of the estimated price for the CMI's services paid by the Manufacturer on the basis of an advance invoice, against which any regular invoices issued in accordance with the schedule set out in Part V of these GTC and any penalties and compensations pursuant to Part VI of these GTC shall be set off.
   (g) Legacy devices refer to medical devices referred to in Article 120(3a), (3b) and (3f) of the MDR.
   (h) Contractual compensation refers to a lump-sum compensation for costs reasonably incurred, including remuneration or a pro rata portion thereof, for the performance of the CMI's services,

allocation of the notified entity's capacity and human resources for scheduled services of the CMI, and compensation for lost profits due to the rejection of other customers.

II. Submission of inquiry, request and tasks of the CMI in the certification process

1. The CMI presents on its website the procedure for submitting a non-binding inquiry for the certification process of medical devices. The entire non-binding inquiry and review process is provided by the CMI free of charge. The data provided by the Manufacturer in the inquiry, which the CMI may have supplemented or clarified, form the basis for the creation of a non-binding offer, the content of which is primarily the range of time requirements for specific tasks of the CMI, multiplied by the appropriate rate on the basis of the CMI price list, and a preliminary estimate of the total price for the conformity assessment process (hereinafter referred to as the "Estimated Price"). The Manufacturer shall always submit a non-binding inquiry before the request is submitted, this process cannot be skipped.

2. In order to initiate tasks under the required medical device certification process, the Manufacturer is required to submit a request in accordance with the relevant procedure, which is available on the CMI website, and pay a flat fee for its review. In the request, the Manufacturer is obliged to duly indicate and provide all data, documents, system documentation and samples that are required for the conformity assessment procedure in accordance with the relevant provisions of the MDR. The completed request shall be electronically signed by the Manufacturer's authorized person and submitted by the Manufacturer via an electronic form on the CMI website. Once access to the MEDECA application software is granted, it shall attach all the necessary attachments to it. By submitting a request, the Manufacturer undertakes to pay a flat rate price (fee) for the review of the request in accordance with the CMI price list valid on the date of submission of the request, no later than 10 days from the date of submission of the request.

3. If electronic communication is not functional, the CMI shall allow the request to be submitted in paper form. In that case, the written form of communication shall be used on both sides until the electronic form of communication is put back into operation. All paper documents shall be duly digitized and attached to the communication in electronic form.

4. Upon receipt of the request and payment of the flat fee for the review of the request pursuant to Article II(2) of these GTC, the CMI undertakes to assess the request in accordance with the internal regulations for the review of requests. As part of the assessment, the CMI shall carry out a formal check of the completeness of the request and its attachments. Furthermore, a cursory review of the requirements that the MDR places on the Manufacturer, a cursory review of the qualification and classification of the medical device(s) to be subject to conformity assessment, and whether the medical device in question falls within the scope for which the CMI is designated as a notified body.

5. In case of any ambiguity, the CMI is entitled to ask the Manufacturer to clarify or supplement the data and documents provided in the request. The Manufacturer undertakes to provide the necessary cooperation for this.

6. In case the CMI has doubt about the correctness of the qualification or classification of a medical device, the Manufacturer is entitled, but always at its own expense, to submit a request for an opinion to the competent authority of the Member State in which the Manufacturer has its registered place of business, or to the competent authority of the Member State where the authorized representative is established if the Manufacturer is from a third country. If an authorized

representative is not appointed in the European Union, the competent authority shall be designated according to the location of the representative indicated in the technical documentation who has confirmed in writing their intention to accept the mandate of authorized representative of the Manufacturer concerned. Both the Manufacturer and the CMI agree that in the context of further contractual relationships (or in the continuation of an ongoing contractual relationship) concluded between these Parties, the Parties shall consider the opinion of the relevant competent authority as binding.

7. If the CMI finds, after the review, that the request and its necessary attachments do not meet the minimum requirements, but that the deficiencies can be clarified or supplemented, it shall invite the requester to clarify or substantiate these facts within a specified time limit. In case that the Manufacturer fails to comply with this obligation even after repeated requests from the CMI, or if the request contains irremediable deficiencies, the CMI shall reject the request, notify the Manufacturer thereof and, in accordance with the requirements of the MDR, publish information on the rejection of the request in the EUDAMED electronic system. Similarly, information on the rejection of a request due to failure to pay the request review fee or on the possible withdrawal of a request by the Manufacturer shall be published in the EUDAMED electronic system.

8. Upon completion of the request review and review of the necessary attachments, if the request review is positive, the CMI shall prepare a draft Agreement specifying the framework conditions and parameters of the required conformity assessment, including the Estimated Price. The draft Agreement shall then be submitted to the Manufacturer for its acceptance and signature. The Manufacturer acknowledges that the Agreement with the CMI may only be entered into with the Manufacturer. The conclusion of the Agreement is subject to the prior submission of the system documentation and the payment of an advance of 50% of the Estimated Price (hereinafter referred to as the "Advance") attributable to the certification. For the purpose of payment of the Advance, the CMI shall issue an advance invoice to the Manufacturer indicating the Advances for each specific medical device.

9. After the conclusion of the Agreement and before the expiration of the specified maximum time limit, the CMI shall invite the Manufacturer to complete all remaining attachments to the request, especially the technical documentation. Upon submission of the technical documentation, the CMI shall issue a proper invoice to the Manufacturer for a portion of the Estimated Price based on the schedule set forth in Article V of these GTC, payment of which is a condition for the commencement of the CMI's review of the technical documentation. In the Agreement, the CMI undertakes to perform all relevant tasks for the preparation of the conformity assessment of the medical device, in particular a detailed substantive review of the final documentation, the preparation of a detailed implementation plan and scope of specific conformity assessment procedures, the allocation of its resources, as well as the pricing of individual activities in the conformity assessment process and the estimation of the time frame.

10. If, based on the final documentation, the CMI has doubt about the correctness of the qualification or classification of the medical device, the Manufacturer is entitled to request an opinion from the competent authority, as in Article II(6) hereof. Both the Manufacturer and the CMI agree to treat the opinion of the relevant competent authority as binding in the context of the contractual relationship between them.

11. As part of the detailed substantive review, the CMI may ask the Manufacturer to add missing information to its request or attachments. The Manufacturer undertakes to provide all the necessary information within reasonable time limits set by the CMI.

12. On the basis of the substantive review, the CMI shall send the Manufacturer a draft Implementation Contract for signing, specifying the specific conditions and parameters of the required conformity assessment, in particular the scope of the procedures used, the method and schedule of implementation, the Detailed Estimated Price for all activities in the conformity assessment process (in the case of a smooth course of the assessment process, i.e. without the need to resolve nonconformities and undergo an additional iterations or iterations or additional work by the CMI) and the terms of performance of the Implementation Contract. The Manufacturer is obliged and bound to enter into that Implementation Contract within the time limit set by the CMI, and no later than within 30 days. After the signing of the Implementation Contract, the CMI shall issue a proper invoice to the Manufacturer for a part of the Estimated Price based on the schedule specified in Article V hereof. Payment of this invoice is a condition for starting the conformity assessment process.

13. If there are any obstacles preventing the conclusion of the Implementation Contract, the contractual relationship between the Manufacturer and the CMI as defined in the Agreement shall be terminated. The CMI shall then publish information on the rejection of the request in the EUDAMED electronic system in accordance with the MDR requirements.

14. Once signed by both Parties, the Implementation Contract shall be validly concluded. The Manufacturer undertakes to pay the price for the conformity assessment tasks in accordance with the rules set out in Article V of the GTC.

15. As part of the assessment of the Manufacturer's quality management system, which must already be in place when the request for conformity assessment is submitted, the CMI shall check whether the Manufacturer's quality system meets the requirements of the MDR. This assessment shall include an audit at the premises of the Manufacturer and, where appropriate and practical, at the premises of key suppliers and subcontractors. The results of this assessment shall be recorded by the CMI in the quality management system assessment report.

16. When assessing the technical documentation, the CMI shall verify compliance with all relevant safety and efficacy requirements of Annex I to the MDR, the technical documentation requirements of Annexes II and III to the MDR, as well as any specific requirements depending on the conformity assessment procedure of the medical device and the specification of the medical device. In case of doubt as to the conformity of a medical device, the CMI shall be entitled to require the Manufacturer to have additional tests and trials carried out in order to verify that the solutions adopted by the Manufacturer meet the general safety and efficacy requirements set out in Annex I to the MDR, or to propose that the CMI itself carry out such tests. In case that the Manufacturer agrees to have the CMI perform the tests, the Manufacturer agrees to pay the associated costs for performing these additional tests as part of the final price for the certification project based on the final invoice. In case that the tests or trials are not carried out directly by the CMI, the Manufacturer is obliged to agree with the CMI where and under what conditions these tests shall be carried out. As part of the assessment of the technical documentation, the CMI shall also conduct a review of the clinical evidence, considering the clinical evaluation and benefit-risk determination, and decide whether it shall set specific milestones for the Manufacturer to allow the CMI to review updates to the clinical evidence based on post-market surveillance and PMCF data. The CMI shall clearly document the conclusions of its clinical trial assessments in the Clinical Trial Assessment Report and provide a detailed report for each specific project based on a standard format containing a minimum set of elements specified by the Medical Device Coordination Group.

17. The CMI undertakes to ensure that the conformity assessment steps carried out under the Implementation Contract are properly documented in accordance with its internal procedures. The

CMI undertakes to provide the Manufacturer with reports of the relevant assessments made in accordance with internal procedures and the MDR.

18. The CMI shall issue the relevant certificate of conformity (hereinafter referred to as the "Certificate") if compliance with the relevant provisions of the MDR is sufficiently demonstrated, otherwise it shall decide to reject the Certificate.

19. If the CMI identifies nonconformities, the Manufacturer shall be asked to take corrective actions to eliminate the nonconformities. If the Manufacturer rectifies the nonconformities within the agreed period of time, the CMI shall issue the relevant Certificate. Otherwise, the Manufacturer shall repeatedly call for rectification of the nonconformities and shall set a reasonable time limit, which may be extended at the Manufacturer's request in justified cases. If the Manufacturer subsequently, within the specified (or extended) period of time does not eliminate the nonconformities, the CMI may decide to reject the relevant Certificate and terminate the conformity assessment process. The Manufacturer acknowledges that the price to be quoted in the Implementation Contract includes only one assessment of the items and documentation; any nonconformities or additional nonconformities and assessments shall be paid for in excess of this price.

20. In accordance with the requirements of the MDR, the CMI shall publish information on the issue or rejection of the certificate in the EUDAMED electronic system. In case of rejection, the contractual relationship between the Manufacturer and the CMI shall be terminated.

III. CMI's tasks in the framework of surveillance and other post-certification activities

1. After the relevant Certificate is granted, the CMI shall carry out surveillance, within the framework of which, in accordance with the relevant provisions of Annexes IX to XI to the MDR, it regularly carries out appropriate surveillance audits (planned, unannounced and emergency), assessments, sample testing and monitoring of updates to the relevant Manufacturer's documentation. Surveillance and emergency audits may be carried out at the Manufacturer as well as at its key suppliers and subcontractors.

2. As part of surveillance audits, the CMI is entitled to request the Manufacturer to submit samples of relevant documentation or to take samples of devices to assess their conformity.

3. In case that the CMI identifies a nonconformity, the Manufacturer shall immediately take the necessary corrective actions to remedy the nonconformity within the time limit set by the CMI, which may be extended in justified cases. If the Manufacturer fails to take corrective action within the specified (or extended) period of time, the CMI shall suspend, limit or revoke the validity of the relevant Certificate. In cases of major nonconformities, the CMI may suspend, limit or revoke the validity of the relevant Certificate without prior notice for remedy. If corrective actions are not resolved, the CMI shall publish the information in accordance with the MDR requirements in the EUDAMED electronic system.

4. The Manufacturer is obliged to contractually arrange, with its suppliers and subcontractors, the possibility of conducting announced and unannounced audits of these entities for the benefit of the CMI.

5. The Manufacturer acknowledges that in case any surveillance audit cannot be carried out due to non-performance by the Manufacturer or its suppliers or subcontractors, the CMI shall suspend,

limit or revoke the validity of the relevant Certificate and publish this information in the EUDAMED electronic system in accordance with the MDR requirements.

6. The Manufacturer is obliged to keep the CMI informed of the period of time when production of the medical device covered by the Certificate shall not take place. If failure to comply with this obligation results in an unannounced audit, the Manufacturer is be obliged to reimburse the CMI for all costs associated with the audit. In case of repeated inability to perform an unannounced audit due to failure to comply with the obligation under this paragraph, the CMI may proceed to suspend, limit or revoke the validity of the relevant Certificate and publish this information in the EUDAMED electronic system in accordance with the requirements of the MDR.

7. The Manufacturer agrees to allow the CMI to take photographic documentation of the medical devices, their markings, as well as any accompanying documentation and, where justified, work and production procedures, as part of surveillance audits.

8. The CMI is entitled to carry out an extraordinary on-site or remote audit of the Manufacturer or its suppliers or subcontractors in the following cases:
    a. due to external factors (e.g. when data from the evaluation of experience gained with the manufactured devices indicate possible deficiencies in the quality management system) or when the CMI becomes aware of substantial information concerning failure to comply with safety requirements;
    b. the Manufacturer's request for an assessment of change;
    c. complaint resulting in suspected non-compliance with certification requirements;
    d. inspection of corrective actions.

9. Within 30 days of the issuance of the Certificate, the CMI shall send to the Manufacturer a draft Implementation Contract concerning post-certification monitoring for signing, specifying the specific conditions and parameters of surveillance, in particular the scope of the procedures used, the method and plan of implementation, the Estimated Price for all activities during the post-certification monitoring (in case of a smooth course of surveillance, i.e. without the need to resolve nonconformities) and the time limits for the execution of that Implementation Contract. The Manufacturer is obliged and bound to enter into that Implementation Contract within the time limit set by the CMI, and no later than within 30 days. The Manufacturer acknowledges that failure to sign or terminate the Post-Certification Monitoring Implementation Contract shall terminate the Certificate issued under the Agreement and the Certification Implementation Contract.

10. The Manufacturer acknowledges that a condition for entering into this Implementation Contract is the payment of an advance of 50% of the Estimated Price attributable to post-certification monitoring. For the purpose of payment of the Advance, the CMI shall issue an advance invoice to the Manufacturer indicating the Advances for each specific medical device.

11. The provisions of this Article of the GTC shall also apply mutatis mutandis to the surveillance of legacy devices within the meaning of Article 120(3e) of the MDR, including the right of the CMI to issue an advance invoice for the surveillance of legacy devices indicating the advances for each specific medical device.

12. In relation to legacy devices and surveillance under Article 120(3e) of the MDR, the CMI is entitled to check compliance with the conditions set out in Article 120(3c) and (3d) of the MDR. In case of non-compliance with any or all of these conditions, the CMI is entitled to warn the Manufacturer of the breach of the conditions, to call upon the Manufacturer to remedy the breach and/or not to place the medical device on the market, to inform the competent surveillance authority thereof and,

taking into account the principle of proportionality, to suspend, revoke or otherwise limit the Certificate.

13. Pursuant to Regulation (EU) 2023/607 of the European Parliament and of the Council, in order to continue to place on the market or put into service its legacy devices referred to in paragraphs 3a and 3b of Article 120 of the MDR, the Manufacturer is required to implement a quality management system in accordance with Article 10(9) of the MDR by the dates referred to in those paragraphs, by 26 May 2024 at the latest. The CMI shall verify this condition before signing the Framework Agreement in one of the following three ways:
    a. the Manufacturer shall provide the CMI with a valid certificate of conformity of its quality management system to EN ISO 13485 and at the same time a GAP analysis between the requirements of this standard and the requirements of Article 10(9) of the MDR;
    b. an internal audit by a third party that demonstrates that it has qualified auditors for the quality management system in accordance with EN ISO 13485 and has experience in implementing or auditing a quality management system in accordance with Article 10(9) of the MDR; or
    c. a preliminary audit by the CMI to verify that a quality management system has been implemented by the Manufacturer in accordance with Article 10(9) of the MDR.

    For these activities, the CMI shall invoice the price in accordance with the CMI price list in effect on the date of commencement of the activity in question.

14. The Manufacturer acknowledges that if it fails to comply with its obligations set out in the applicable legislation, the Agreement, these GTC or the Conformity Assessment Implementation Contract, which are necessary for the conformity assessment of the medical device under the MDR (new device) intended to replace a device with a Certificate issued in accordance with Directive 93/42/EEC (legacy device), and thus if the Manufacturer prevents the proper process of certification of the new device and prevents the CMI from carrying out the required certification tasks due to the lack of cooperation of the Manufacturer, the CMI shall have the right to withdraw from the Agreement. The consequence of such withdrawal is the failure to comply with the condition for the use of the transitional period of the relevant legacy device, the termination of the CMI's surveillance of that device and the need to cease the placing of the relevant legacy device on the market.

IV. Re-certification

1. The Manufacturer is obliged to submit a request for recertification no later than 12 months before the expiry of the relevant Certificate. The Manufacturer is obliged to submit a non-binding inquiry and request in accordance with the established template and procedure as for the initial certification. If the Manufacturer does not submit the request for re-certification in that time frame, the CMI cannot guarantee that it will be able to complete the conformity assessment process before the expiry of the relevant Certificate.

2. The Manufacturer acknowledges that there is no legal entitlement to accept the submitted request for re-certification, even if the request meets all formal requirements. In particular, insufficient capacity of the CMI's resources may be a reason for not accepting a request.

3. If the re-certification process is successfully completed, the CMI shall issue a new Certificate.

4. Furthermore, the provisions of Article II of these GTC shall apply mutatis mutandis to the re-certification.

V. Payment terms

1. For the relevant tasks in the conformity assessment process carried out on the basis of the Manufacturer's request and in accordance with the concluded Implementation Contract, the prices calculated in accordance with the CMI price list effective at the time of initiation of the relevant tasks of conformity assessment of medical devices shall be charged. The CMI price list is published on the CMI website.

2. In accordance with Article II(2) of the GTC, the Manufacturer is obliged to pay a flat-rate price for the review of the request in accordance with the CMI price list.

3. After reviewing the request (in case of a positive outcome of the review), the CMI shall send a draft Agreement to the Manufacturer, including the Estimated Price. The Detailed Estimated Price shall be determined within the framework of the Implementation Contract after a detailed substantive review of the documentation based on the current rates listed in the CMI price list and the number of hours calculated to perform the relevant tasks in the standard course of the certification process described in Article II(12) hereof.

4. If, in the cases referred to in Article II hereof, it becomes necessary for the CMI to carry out additional activities within the scope of the required certification beyond the price specified in the Implementation Contract (e.g. additional tasks and assessments due to identified nonconformities), the Manufacturer undertakes to pay the related costs for the performance of these additional tasks as part of the final price for the project on the basis of the final invoice. The same procedure shall also be followed in case that during certification there is a need to subcontract any of the tasks or tests (e.g. carrying out tests in an external laboratory).

5. By signing the Implementation Contract, the Manufacturer undertakes to pay the prices for the relevant conformity assessment tasks and other activities of the CMI's notified body within the meaning of Article V of the GTC.

6. The VAT shall be added to the individual prices in accordance with Act No. 235/2004 Coll., on Value Added Tax, as amended.

7. The Manufacturer undertakes to pay the invoiced prices including other costs (costs of handing over samples and documentation, travel and accommodation costs, bank, customs and other fees) in cash on the basis of a current tax document issued, containing the details provided for in Section 29 et seq. of Act No. 235/2004 Coll., on Value Added Tax, as amended.

8. The maturity term of no more than 30 calendar days shall be indicated in the relevant tax document.

9. Payment of the invoiced amount shall be made by the Manufacturer by issuing a wire transfer order to the benefit of the CMI's account. This obligation shall be fulfilled on the day the amount is credited to the CMI's account.

10. The CMI reserves the right to require partial payment in advance in the form of an advance invoice. The CMI shall issue an advance invoice for 50% of the Estimated Price attributable to the specific

project. The payment of the advance for certification is a condition for the conclusion of the Contract.

11. The CMI shall issue proper invoices to the Manufacturer in accordance with the following schedule for the certification process:
    a) upon submission of the technical documentation, for 30% of a portion of the Estimated Price set out in the Agreement attributable to the certification process; payment of this invoice shall be a condition for the commencement of the CMI's review of the technical documentation.
    b) after the signing of the Implementation Contract, for 20% of a portion of the Estimated Price set out in the Agreement attributable to the certification process; failure to pay this invoice shall be grounds for withdrawal from the Implementation Contract.
    c) prior to the decision on certification, for 30% of a portion of the Estimated Price set out in the Agreement attributable to the certification process; payment of this invoice shall be a condition for the continuation of the certification process by the CMI.
    d) prior to the issuance of the Certificate, the CMI shall issue a final invoice for the Manufacturer for the final price, which shall take into account and consider the differences between the invoices already paid and the actual costs incurred for the certification, taking into account any additional nonconformities, re-assessments, iterations and other services performed beyond the scope of Article II(12) hereof; payment of this invoice shall be a condition for the issuance of the Certificate.

    The Manufacturer acknowledges that during the period of its default in the payment of any invoice, the CMI shall not be in default in the performance of its obligations.

12. The CMI shall issue a proper invoice for the Manufacturer for 20% of the Estimated Price of post-certification monitoring one year after the Certificate is issued. The invoices for post-certification monitoring shall be issued mutatis mutandis in the following years.

13. The CMI shall issue a proper invoice for the Manufacturer of the legacy devices for 20% of the Estimated Price for the surveillance of the legacy devices at the end of one year after the assumption of surveillance pursuant to Article 120(3e) of the MDR. The invoices for this surveillance shall be issued mutatis mutandis in subsequent years, with the last invoice being issued for the pro rata period ending at the time of expiry of the time limit under Article 120(3a), (3b) or (3f) of the MDR.

14. In case that the CMI is unable to perform the required certification tasks due to insufficient cooperation of the Manufacturer, the CMI is entitled to compensation for the costs reasonably incurred, including the remuneration (or its proportional part) that should have been due to the CMI for the certification task performed, by paying the contractual compensation specified in Part VI hereof.

15. Travel and accommodation costs shall be calculated in accordance with the published CMI price list. The time spent on the trip is calculated on the basis of the current rate specified in that price list and the expenses related to accommodation and transport according to the actual costs incurred.

16. The calculated Detailed Estimated Price for the conformity assessment process, which shall be specified in the Implementation Contract, is valid if the process is carried out in a standard form, the Manufacturer provides proper cooperation and has prepared documentation of adequate quality without any nonconformities. In case that during the certification process additional costs arise for the notified body, such as (but not limited to) the need to perform additional tasks due to any identified nonconformities, review of the settlement of these nonconformities and additional iterations beyond the scope specified in Article II(12) hereof, unexpected consultations with external authorities, the need to subcontract certain tasks or tests (e.g. performing tests in an external laboratory), etc., these costs shall be invoiced as part of the final price for the project on

the basis of the final invoice, based on the product of the relevant hourly rates specified in the current, valid and published CMI price list and the number of hours necessary to perform the tasks in question.

VI. Default interest, contractual penalties and compensation

1. In case of failure to comply with the contractual obligation to pay the invoiced price for the activities referred to in Article V hereof in a timely and proper manner, which is specified in more detail in the Agreement or the Implementation Contract, the Manufacturer shall be in default of the performance of the monetary obligation. As a result of this fact, the Manufacturer is obliged to pay to the CMI contractual default interest in the amount of 0.03% of the amount due for each day in default (State organizations are obliged, under the relevant provisions of Act No. 219/2000 Coll. (Section 14(5)) of the Act on the Property of the Czech Republic and its Representation in Legal Relations, as amended, to claim default interest and agreed contractual penalties).

2. The Manufacturer undertakes to inform the CMI without undue delay in writing or electronically via the MEDECA software of any changes that could affect the certification tasks in the period of time since the issue of the relevant Certificate, as well as of the changes referred to in Article VIII(14) of the GTC. If the Manufacturer breaches this obligation, it is obliged and undertakes to pay to the CMI a contractual penalty of EUR 3,000 for each individual case of breach.

3. In case that the Manufacturer decides to terminate the Agreement by written and duly delivered notice, even without a reason, before the submission of the technical documentation, the Manufacturer undertakes to pay to the CMI contractual compensation in the amount of 50% of a portion of the Estimated Price set out in the Agreement attributable to the specific project.

4. In case the Manufacturer fails to fulfil its obligation to submit the technical documentation to the CMI in accordance with the MDR by the date agreed in the Agreement, usually within 30 days of the CMI's written request, but no later than one year from the signing of the Framework Agreement (unless the CMI and the Manufacturer agree on a different individual schedule), the Manufacturer is obliged and undertakes to pay to the CMI a contractual compensation in the amount of 50% of a portion of the Estimated Price set out in the Agreement attributable to the specific project. In this case, the CMI also has the right to withdraw from the Agreement.

5. If the Manufacturer breaches its obligation to conclude the Implementation Contract within the meaning of Article II(12) of the GTC, the Manufacturer is obliged and undertakes to pay to the CMI a contractual compensation of 20% of a portion of the Estimated Price set out in the Agreement attributable to the specific project. In this case, the CMI also has the right to withdraw from the Agreement.

6. In case of withdrawal from the Agreement by the CMI due to the Manufacturer's failure to perform its obligations under the relevant legislation, these GTC, the Agreement or the Implementation Contract, preventing the proper course of the certification process because the CMI could not perform the required certification tasks or other activities of the notified body due to insufficient cooperation by the Manufacturer, the CMI is entitled to a contractual compensation of up to 50% of the Estimated Price attributable to the specific project, but no more than the amount that was not paid via proper invoices by the time of withdrawal from the Agreement in accordance with the schedule specified in Article V of the GTC or by payment of other contractual compensation within the meaning of this Article of the GTC.

7. The Manufacturer undertakes to cease using and referring to the Certificate issued by the CMI upon expiry, suspension or revocation of the Certificate in question and undertakes not to place the medical device in question on the market without a valid Certificate in countries where a valid Certificate is a condition for placing the medical device on the market. If the Manufacturer breaches any of the obligations referred to in this paragraph, it is obliged and undertakes to pay to the CMI a contractual penalty of EUR 10,000 for each individual case of breach.

8. The Manufacturer shall pay the contractual penalty or compensation to the CMI no later than 30 days after receipt of the contractual penalty statement. If the Manufacturer fails to pay the contractual penalty within this period of time, the CMI is entitled to charge interest on the overdue amount at the rate of 0.5% of the amount due per day in addition to the contractual penalty or compensation.

9. The arrangements set out in this Article are without prejudice to any claim for damages by the Parties arising from any failure to comply with the obligations under any contract concluded between the Manufacturer and the CMI, or the GTC.

VII. General rights and obligations of the CMI and its staff

1. The CMI and its staff undertake to carry out the required conformity assessment activities in accordance with the MDR, the approved internal procedures, at the highest level of competence, in the required technical and scientific competence in the specific field, and shall not be subject to any pressure or inducement, especially financial, which might influence their judgement or the results of their conformity assessment, especially from persons or groups of persons having an interest in the results of these activities.

2. The CMI represents that it is a third-party body independent of the Manufacturer for whom it carries out conformity assessment activities. The CMI also represents that it is independent of any other economic operator having an interest in the medical devices under consideration, as well as of any competitors of the Manufacturer. This shall not prevent the CMI from carrying out conformity assessment activities for competing manufacturers.

3. The CMI undertakes to take all necessary steps to ensure its independence, objectivity and impartiality in its activities. The CMI represents that it has a documented and established structure and procedures to ensure impartiality and to promote and apply the principles of impartiality throughout its organization, in all assessment activities and with all staff, including their family members. These procedures shall enable the identification, investigation and resolution of any case where a conflict of interest may arise. In case of an impending conflict of interest, the CMI shall take appropriate precautionary measures, if possible, or reject the Manufacturer's request for conformity assessment on the above grounds. The investigation, outcome and resolution of each such case shall be properly documented.

4. The CMI is authorized to carry out conformity assessment activities for medical devices within the scope of procedures and for the groups of types of medical devices for which it has been appointed. The scope of the appointment is available in the database of notified bodies created and maintained by the European Commission (Single Market Compliance Space database).

5. The CMI undertakes to inform the Manufacturer immediately if the scope of the appointment is reduced or cancelled. In case of planned closure, the CMI shall inform the Manufacturer at least one year before it ceases its activities. Upon termination, the CMI shall keep the Certificates issued temporarily valid for a period of nine months, provided that another notified body confirms in

writing that it will assume responsibility for the medical device covered by those Certificates. In case of involuntary suspension, limitation or partial or total revocation of the designation, the CMI shall inform the Manufacturer thereof within 14 days at the latest. In that case, the CMI shall keep the issued Certificates valid under the conditions set out in Article 46(8) and (9) of the MDR.

6. The CMI undertakes to perform the tasks for which it has been appointed in accordance with the MDR, to fulfil the organizational and general requirements and the quality management requirements, resources and procedures necessary for the performance of those tasks, in particular to comply with the provisions of Annex VII to the MDR.

7. The Manufacturer acknowledges that the conformity assessment activities may be subcontracted or performed by a branch and that the Manufacturer shall be informed thereof.

8. The CMI represents that it is not an insurer, warranty provider or guarantor and disclaims all liability in this capacity and a manufacturer seeking a warranty against loss, cost or damage should obtain adequate commercial insurance from an insurance provider.

9. The CMI shall not be liable for any delayed performance, partial or total non-performance of services resulting directly or indirectly from any event beyond the CMI's control, including failure of the Manufacturer to perform its obligations under the GTC, the Agreement, the Implementation Contract or any amendments thereto, the submitted request or related certification schemes.

10. Neither the CMI nor any of its employees, external staff or subcontractors shall be liable to the Manufacturer or any third party for any action taken or not taken on the basis of incorrect results resulting from unclear, erroneous, incomplete, misleading or false information provided by the Manufacturer or its authorized representative to the CMI.

11. The CMI shall not be liable for any indirect or consequential loss to the Manufacturer, including (without limitation) loss of profits, loss of business, loss of opportunity, loss of credibility, loss of goodwill, and the cost of removing medical devices from the market or circulation or for failure to issue, suspension or limitation of certification.

12. The Parties agree that the CMI's total liability for damages shall not exceed the amount for activities billed to the Manufacturer in the last calendar year or EUR 8,000.00, whichever is less.

13. The Manufacturer agrees to indemnify and hold the CMI harmless from and against any and all claims for damages arising out of the failure of its medical devices, their nonconformity or other occurrence with respect to medical devices certified by the CMI and marketed by the Manufacturer or arising out of the use of such medical devices.

14. The Manufacturer acknowledges that it is obliged to have at least one person within its organization responsible for compliance with the legislation in accordance with the provisions of Article 15 of the MDR. This person shall be kept by name by the Manufacturer throughout the period of the request for conformity assessment and validity of the Certificate and continuously and permanently updated within the MEDECA software with the CMI.

VIII. General rights and obligations of the Manufacturer

1. The Manufacturer undertakes to comply with the relevant requirements of the MDR and other applicable legislation on an ongoing and continuous basis. Only medical devices that have been

designed and manufactured in accordance with the requirements of the MDR shall be placed on the market or put into service by the Manufacturer.

2. The Manufacturer undertakes to provide the CMI, its employees and external personnel with the necessary cooperation for the activities within the scope of the required certification and post-certification activities resulting from the requirements of the relevant annexes to the MDR (announced, unannounced, extraordinary audits and other surveillance activities) and other tasks of the CMI's notified body, such as monitoring corrective actions in cases of identified nonconformities related to the fulfilment of the MDR requirements, tasks in relation to investigations launched by the competent authorities concerned, assessment of changes, or activities related to the transition of the Manufacturer to another notified body). With regard to the chosen certification procedure, the Manufacturer shall in particular enable:
   a. inspections, evaluations and surveillance, in particular the coordination of sample examination for technical documentation (including records) and sampling and testing of medical devices;
   b. access to the Manufacturer's premises as well as to all medical devices, manufacturing facilities, persons and, where applicable, to selected suppliers and subcontractors in connection with the CMI's conformity assessment and surveillance activities, both to the CMI's employees and to external personnel and invited observers;
   c. access to complete system and technical documentation;
   d. investigation of complaints and monitoring of vigilance cases.

3. The Manufacturer acknowledges and agrees that the conformity assessment process may result in a negative outcome, in which case the CMI may not issue any conformity assessment certificate. In case that the results of the conformity assessment do not demonstrate compliance with all relevant requirements, the CMI shall have the right or obligation (if applicable) to notify the relevant competent authority of such results.

4. Where required, the Manufacturer shall obtain and maintain all necessary licenses, certificates and approvals and comply with all applicable laws and regulations regarding certification services, use and maintenance of its premises, facilities or equipment.

5. The Manufacturer undertakes to submit only factually correct, complete and unaltered original documents or copies thereof. The Manufacturer acknowledges that in case of a breach of this obligation, the CMI may terminate the certification process without issuing the relevant Certificate, whereby the Manufacturer shall be obliged to pay to the CMI the proper invoices issued in accordance with the schedule contained in Article V hereof and any contractual compensation pursuant to Article VI hereof. If a breach of a given obligation is found during the validity of the Certificate, the CMI may revoke the validity of the respective Certificates without any compensation to the Manufacturer.

6. The Manufacturer represents that it will not use the Certificates issued by the CMI in a manner that would discredit the CMI, damage its good name or that could be considered misleading or unauthorized by the CMI, and will not make statements or representations that are misleading or false and that would or could lead to a misunderstanding of the certification granted.

7. During the term of the contractual relationship, the Manufacturer undertakes to inform the CMI of all risks related to the subject of certification, including aspects of the working environment of the production plants.

8. The Manufacturer shall not attempt to influence in any way the CMI's decision regarding certification except by providing evidence to demonstrate compliance with the MDR. The Manufacturer acknowledges that any attempts to influence the CMI's decision-making through

financial or other pressures or incentives shall result in the termination of the certification process, or the invalidation of already issued certification documents, the publication of information in the EUDAMED database and the charging of all CMI assessment costs.

9. The Manufacturer undertakes to reimburse the CMI for all prices and other costs incurred during the certification and other tasks of the CMI's notified body in accordance with the rules set out in these GTC, the Agreement and the Implementation Contract, regardless of the results of these tasks.

10. The Manufacturer is obliged to inform the CMI of any changes concerning the name, legal form, organizational structure and other material facts that could affect the validity and accuracy of the issued Certificates.

11. If the Manufacturer is not established in one of the EU Member States, it is obliged to submit to the CMI a copy of the written authorization of the authorized representative and the written consent of the authorized representative to this authorization. In the event of a change in the authorised representative, the Manufacturer is obliged to immediately send the Agreement with the new authorized representative and, if applicable, with the previous authorized representative to the CMI.

12. The Manufacturer shall represent that it has not lodged a request for conformity assessment of the medical devices concerned with another notified body, or that it has withdrawn a request previously lodged, or that it has been rejected. In case of rejection of a request by another notified body, the Manufacturer shall inform the CMI of the reasons for such rejection.

13. The Manufacturer shall, in view of the MDR requirements relating to the chosen certification procedure, establish, document, implement and maintain a quality management system, a risk management system and a unique device identification (UDI) system, as well as a post-market surveillance system, including information from the vigilance system, on a daily basis in accordance with the predefined plans. The Manufacturer is also obliged to keep the technical documentation and clinical evaluation up to date. The Manufacturer is obliged to keep the CMI informed of these activities via the MEDECA software, in particular, it is obliged to keep the documentation listed below up to date and to submit it to the CMI at the intervals specified (unless otherwise agreed as part of the conformity assessment process or surveillance activities):
    a. identification of the benefit-risk ratio and better risk management (Annex I, section I of the MDR) - updated at least annually;
    b. clinical trials - update at least once a year;
    c. clinical trial report - updated at least once a year for class III and implantable devices, for others as needed;
    d. summary of safety and clinical function data (Article 32 of the MDR - class III devices and implantable devices) - updated at least annually;
    e. post-mark clinical follow-up assessment report (Article 61(11) of the MDR - class III devices and implantable devices) - updated at least annually;
    f. preparation of a post-market surveillance report (Article 85 of the MDR - ZP Is and Im) - update at least once a year;
    g. regularly updated safety report (Article 86(1) of the MDR) - updated at least once a year for class IIb and III devices, at least once every two years for class IIa devices.

14. The Manufacturer is also obliged to inform the CMI via the MEDECA software:
    a. of each vigilance report (regardless of severity), i.e. in particular:
        - of any serious adverse event, within the same time limits as the relevant competent authorities (2-15 days depending on the nature of the adverse event - see Article 87 of the MDR);

- of all other adverse events not classified as serious by the Manufacturer; within 20 days;
- of each field safety corrective action (FSCA) identified, the Manufacturer shall submit the draft FSCA to the notified body for approval prior to implementation, unless there is a risk of delay (in which case the Manufacturer shall inform the CMI of the FSCA without undue delay);
- of a field safety notice (FSN) along with the report to the relevant competent authority;
- of trend report, along with the report to the competent authority;

b. of a change to the base UDI-DI of the certified medical device, without delay;
c. of the Manufacturer's intention to make changes to the quality management system or to the range of products covered by it or to make changes to the approved design of the device, its structure and its intended purpose; in such a case, the Manufacturer shall submit its intention to the CMI and await its approval or rejection, while the CMI has the right to carry out an extraordinary audit to verify whether the intended changes are significant or insignificant. The Manufacturer acknowledges that a significant change in the structure and intended purpose of the medical device may result in the medical device being viewed as a new device not covered by the original certificate of conformity. This obligation also applies to surveillance of legacy devices by the CMI on the basis of Article 120(3e) of the MDR;
d. where the competent authority of a Member State finds that a manufacturer's medical device may present an unacceptable risk to health and safety and imposes appropriate measures on the manufacturer without delay;
e. where the competent authority of a Member State finds that a manufacturer's medical device does not comply with the MDR but does not present an unacceptable risk to health and safety and requests the manufacturer to rectify the nonconformity without delay;
f. any other facts that could affect compliance with the certification requirements or that could affect the Manufacturer's ability to meet the relevant certification requirements (e.g. changes in legal personality or ownership, changes in key personnel, changes in the product, its production technology or critical service activities, changes in production location, changes in contact details, changes in key suppliers and subcontractors).

15. The Manufacturer acknowledges that in case of failure to comply with the information obligations with respect to the CMI pursuant to Article VIII(10), (13) or (14) of the GTC, the CMI may suspend, limit or revoke the validity of the issued Certificate, or limit its scope.

16. The Manufacturer agrees not to use the name "CMI" or "ČMI" and any of its trademarks, slogans, symbols or trade names for any reason in its promotional materials for advertising or other purposes without the express prior written consent of the CMI. Upon suspension, withdrawal or revocation of certification, the Manufacturer shall immediately cease (or discontinue) the use of any promotional materials that contain a reference to the certification. It is also obliged to cease using this Certificate, to cease affixing the CE marking with the CMI's notified body number to the medical devices concerned and to place these medical devices on the EU market. In case of a limitation of the scope of validity of an issued Certificate, the provisions of this paragraph shall apply mutatis mutandis to medical devices which have been excluded from the scope of validity of the Certificate. The provisions of this Article shall survive the termination of the Agreement, the Implementation Contract and any amendments thereto, and the termination of these contracts shall not affect the CMI's right to compensation for damages resulting from the breach of the obligation in question.

17. The Manufacturer undertakes to always use only the full texts of the documents as a whole when providing copies of certification documents to other persons.

18. The Manufacturer shall inform the CMI without undue delay of the termination of the use of the certification.

19. Upon termination or expiration of the contracts between the Manufacturer and the CMI, the Manufacturer shall promptly return to the CMI all confidential information received from the CMI.

20. The Manufacturer acknowledges that the termination or expiration of the contracts between the Manufacturer and the CMI shall terminate the Manufacturer's access to the affected MEDECA SW projects covered by the contracts.

21. The Manufacturer agrees not to seek financial or other compensation from the CMI in case of a limitation of scope or cancellation of the CMI's appointment as described in Article II(5) of the GTC.

22. After certification, the Manufacturer shall remain responsible to the authorities and any third parties concerned to comply with the relevant legal requirements regarding the safety and efficacy of its medical devices.

IX. Complaints and appeals

1. The Manufacturer is entitled to lodge a complaint or appeal against the CMI's certification procedure, which may be lodged in case of its disagreement with the CMI's decision concerning certification.

2. The time limit for lodging an appeal shall be 15 days from the date of delivery of the decision against which the appeal is directed. The CMI shall accept appeals sent in writing by registered mail to the address of the CMI's head office (or directly to the address of the CMI's Medical Certification Centre) or via data mailbox or the MEDECA software. In the appeal, the customer is obliged to give proper reasons for the decision in question and to provide evidence in support of these claims. The receipt of the appeal shall confirmed by the CMI to the customer electronically via data mailbox or via the MEDECA software.

3. By filing a complaint, the customer can draw attention to inappropriate behaviour of a CMI employee during the certification process, express disagreement with the conformity assessment procedure applied by the CMI or respond to other non-contractual deficiencies found during the implementation of the conformity assessment by the CMI. Complaints shall be submitted in writing to the address of the CMI head office (or directly to the address of the CMI's Medical Certification Centre) or via data mailbox or the MEDECA software. The receipt of a complaint or a claim by the CMI shall be confirmed to the customer via data mailbox or the MEDECA software.

4. Complaints by the Manufacturer against the CMI's certification procedure or appeals against a certification decision shall be investigated by the CMI in the manner described in the CMI's relevant internal regulations.

5. If the CMI finds the complaint or appeal to be justified, it shall amend the document in question, usually in the form of an amendment, or modify its decision. In this case, the costs of investigating the complaint and modifying the documents shall be borne by the CMI.

6. If the CMI finds the complaint to be unfounded, the original documents and decisions shall remain valid. In that case, the costs related to the investigation of the complaint shall be borne by the

Manufacturer. If the CMI finds the appeal against an issued decision to be unfounded, the CMI shall notify the Office for Technical Standardization, Metrology and Testing (hereinafter referred to as the "**Office**") of its official opinion and shall also send it the complete file with its opinion on the decision within 30 days of the date of receipt of the appeal. In case of an inadmissible or late appeal, the CMI shall forward the file to the Office within 10 days.

X. Force and effect of the GTC

1. These GTC shall be binding on the Manufacturer from the time of request until the termination of the concluded Agreement. In case that the Manufacturer has entered into more than one conformity assessment contract with the CMI, the Manufacturer shall be bound by these conditions until the end of the last of these contracts.

2. These GTC shall be in force and effect in their entirety, unless the Agreement, the Implementation Contract, mandatory provisions of the Civil Code and other legal regulations provide otherwise.

3. The Manufacturer acknowledges and agrees that the CMI is entitled to make changes to the GTC. The CMI is obliged to inform the Manufacturer (or the person designated by it in the Agreement to act in contractual matters) of changes to the GTC and the effective date of the new version of the GTC. If the Manufacturer does not send its disagreement to the CMI within 15 days of dispatch of the information on the change of the GTC, it shall be deemed to agree to the change of the GTC. In case the Manufacturer disagrees with the change of the GTC, the contractual relationship shall be terminated. In that case, the Manufacturer is obliged to pay the CMI the correct invoices and any penalties and compensation to which the CMI is entitled up to the time of termination of the contractual relationship.

XI. Data protection arrangements

1. The Manufacturer and the CMI (hereinafter also referred to as the "Parties") undertake to process personal data for the purpose of fulfilling the contractual relationship in accordance with Regulation (EU) No 2016/679 of the European Parliament and of the Council (GDPR) and Act No 110/2019 Coll., on Personal Data Processing, as amended.

2. Personal data shall only be processed by the Parties to the extent necessary for the fulfilment of the above purpose and only for the period of time necessary to achieve the above purposes, but no longer than the period of time specified by and in accordance with the relevant legal and internal regulations.

3. Each of the Parties shall be the controller within the meaning of the provisions of applicable law. Only the controller and persons who are in an employment relationship with the controller or the processor on the basis of a contractual relationship with the controller and only for the above-mentioned processing purposes shall have access to personal data. Access to and handling of personal data processed by each controller is subject to the internal rules of that controller.

4. The Parties are obliged to inform the data subjects (e.g. contact persons) that their personal data may be processed for the purpose of the performance of the contract in question. They are also obliged to inform data subjects of the possibility of exercising their rights with the controller, specifically for:

- the right to access, rectification or erasure of personal data, the right to restriction of processing and the right to object to unlawful processing;
- the right to lodge a complaint with the surveillance authority.

XII. Intellectual property rights

1. The Manufacturer acknowledges that the CMI is the owner or licensee of the copyright, know-how and other intellectual property rights with respect to the certification procedures, any documentation issued by the CMI and all associated forms and work environments of the MEDECA software.

2. All intellectual property rights belonging to a Party prior to the conclusion of the Agreement shall remain the property of that Party. Nothing in the GTC or the Agreement shall confer any right to transfer any intellectual property rights from either Party to the other Party or to any third party.

3. No licence to any intellectual property rights shall be given or granted in connection with the Agreement to either Party or any third party.

4. The CMI reserves the right to immediately terminate the respective contractual relationship as a result of any unauthorized use of the name "CMI", "ČMI" or any trademarks, slogans, symbols or marks of the CMI.

5. The Parties undertake mutatis mutandis to protect and respect the other Party's other proprietary rights and to maintain the confidentiality of the information provided.

XIII. Confidentiality obligation

1. The Parties undertake to keep confidential from third parties any information which they learn from the other Party in the performance of the Agreement or the Implementation Contract, including but not limited to any information relating to the other Party or its agents, affiliates, business, pricing policy or activities contemplated by the Agreement or the Implementation Contract, obtained or acquired by either Party under the Agreement or any Implementing Contract which is expressly marked as confidential or is of such a nature that, if disclosed, it may cause prejudice to the other Party, whether in the nature of personal, commercial or other information ("hereinafter referred to as "Confidential Information").

2. The Parties shall not disclose Confidential Information to any third party without the written consent of the other Party or use it contrary to the purpose of the Agreement, the Implementation Contract or for their own purposes, unless it concerns:
   a) information that is publicly available, or
   b) a case where disclosure is required by law or by a binding decision of an authorized authority.

3. The Party shall be obliged to bind all persons participating in the performance of the Agreement or the Implementation Contract to the confidentiality obligation referred to in the preceding paragraph.

4. For breach of the confidentiality obligation by persons participating in the performance under the Agreement or the Implementation Contract, the Party shall be liable as if it had breached the obligation itself.

5. The confidentiality obligation shall survive the termination of the Agreement or the Implementation Contract.

6. In case of termination of the Agreement, the Parties shall, if requested by the other Party, return or destroy all confidential information relating to the other Party, except for information that the Parties are required to retain under applicable law.

XIV. Other and final arrangements

1. These GTC, as well as the Agreement and the relationships arising from it, shall be governed by the laws of the Czech Republic, without any conflict of laws or choice of law rules. The legal relationships of the Parties not governed by these GTC, the Agreement or the Implementation Contract shall be governed by the applicable legal regulations, in particular the MDR, the Civil Code, Act No. 90/2016 Coll., on Conformity Assessment of Specified Products Made Available on the Market, as amended, and the relevant implementing regulations.

2. The Parties are obliged to inform each other actively and without undue delay of the occurrence of facts that could affect the validity of the Agreement, the Implementation Contract, the GTC or their individual provisions or the quality and timing of the performance of obligations arising from them. In such a case, the Party concerned shall be obliged to initiate negotiations between the authorized representatives of the Parties.

3. If any provision of these GTC, the Agreement or the Implementation Contract is or becomes invalid or ineffective, the remaining provisions of these GTC, the Agreement or the Implementation Contract shall remain valid and effective. Instead of the invalid or ineffective provision, the provisions of generally binding legal regulations governing the relationship between the Parties shall apply. The Parties then undertake to modify their relationship by adopting another provision which best corresponds in its result to the intention of the invalid or ineffective provision.

4. If a conflict arises between the wording of these GTC and the wording of the Agreement or the Implementation Contract, the provisions of the Agreement or the Implementation Contract shall prevail over the provisions of the GTC.

5. The Parties agree to resolve any disputes concerning the performance of the Agreement and other obligations arising from the certification procedure primarily by mutual negotiations between representatives or statutory bodies, generally within 14 calendar days of a written request or notice from one of the Parties. If the dispute is not resolved by agreement, the matter shall be resolved by the courts of the Czech Republic.

6. In accordance with the provisions of Section 89a of Act No 99/1963 Coll., the Civil Procedure Code, as amended, the Parties have concluded an agreement or have agreed on a different local jurisdiction of the court of first instance. The court with local jurisdiction is the court of first instance in whose district the CMI has its registered office.

7. The Manufacturer represents that it has read the contents of these GTC before submitting the relevant request and signing the Agreement.

8. These GTC have been approved by the senior management of the CMI and came into force and effec on.....