Agreement number of the notified body: 8802-SM-SP001-25-REQ202411-en

Implementation Contract for Conformity Assessment of Medical Devices

entered into pursuant to Section 2652 et seq. of Act No. 89/2012 Coll., the Civil Code, as amended, and Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
(hereinafter referred to as the "Agreement")

I. Parties

Manufacturer:
Name, company name: Magnosco
Legal form: GmbH
Reg. No.: HRB 191268 B VAT No.: DE293962617
Registered office: Justus-von-Liebig-Str. 2, Berlin Post code: 12489
(a) details of registration in the Public Register at the Registration Court: AG Charlottenburg
date of registration: 07.02.2024
Bank details:
Account number:
The manufacturer's statutory body or representative authorized to act and sign on behalf of the manufacturer:
Name: XXXXX Position: XXXXX

hereinafter referred to as the "**Manufacturer**"

Notified body:
Czech Metrology Institute
Registered office: Okružní 31, 638 00 Brno
Legal form: state contributory organization established by the Charter of the Ministry of Economy of the Czech Republic No. 521 385/92-44 of
21 December 1992, as amended by the Charter issued by Decision No. 72/2021 of the Minister of Industry and Trade,
file no.: MPO 628289/2021/21100/01000 of 9 December 2021;
Reg. No.: 00177016 VAT No.: CZ00177016
Bank details:
Account number:
XXXXX statutory body shall act on behalf of the notified body;

hereinafter referred to as the "**CMI**"

(hereinafter jointly referred to as the "**Parties**" and individually as a "**Party**")

Representations of the Parties

The Parties represent that the data specified in this Article of the Agreement are in accordance with the relevant entries in the Public Register (Section 25 et seq. of Act No. 304/2013 Coll., on Public Registers of

Legal and Natural Persons, as amended), or in the Trade Register (Section 60 of Act No. 455/1991 Coll., Trade Licensing Act, as amended), or in other records, and that the persons specified herein are their authorized representatives.

The Parties shall appoint persons authorized to act in relation to the subject matter of this Agreement:

a) for the Manufacturer:

- In contractual matters: XXXXX
- In matters of the certification process: XXXXX
- Person responsible for legal compliance: XXXXX

b) for the CMI:

- XXXXX

II. Subject matter and purpose of the Agreement

1. The Parties entered into the Framework Agreement on Medical Device Conformity Assessment and Related Services No. 1383-REQ-2024/11 on 10.03.2025 (hereinafter referred to as the "Framework Agreement"). In order to lay down the details of the specific certification, they conclude this Implementation Contract in accordance with Article II(2) of the Framework Agreement.

III. Place and time of performance of the Contract

1. The CMI undertakes to carry out the certification tasks within the time limits set by agreement between the Parties, provided that the CMI undertakes submit the assessment results to the Decision Making Committee (unless otherwise agreed) no later than **11.11.2025**. This term is valid only if the conditions for its extension specified below in Article III par. 2. are not met.

2. If, in the course of the certification tasks, the need to provide further necessary documents arises, or the documents already presented are incomplete, erroneous or there is a need to supplement them or to provide cooperation from the Manufacturer, the time limit referred to in the preceding paragraph shall be extended until the Manufacturer provides the required documents or the required cooperation to the CMI.

3. The CMI reserves the right of early performance.

IV. Price, billing and payment method

1. The Parties have agreed on the method of determining the prices for the conformity assessment services as follows:

    a. The specified estimated price for the certification of the medical devices listed in Annex 1, Specification of Medical Devices, to this Implementation Contract is **XXXXX EUR**. That price is determined on the basis of the rates specified in the CMI price list and the number of

hours calculated to perform the relevant tasks in the standard course of the conformity assessment process described in Article II(12) of the GTC. This price is a trade secret.

b. The price for other tasks of the CMI's notified body shall be determined on the basis of the CMI price list effective on the date of commencement of the task in question. In case that there is no item in the CMI price list for the given task, this task shall be charged on the basis of an agreement between the Parties prior to the commencement of the performance of the task in question.

c. Travel and accommodation costs and any bank, customs or other fees are calculated on the basis of the actual costs incurred. These costs shall be charged separately to the Manufacturer (not included in the project price) and the Manufacturer is obliged to pay them. The time spent on the journey, as well as the costs of receiving and handing over the medical device samples and the necessary documentation between the CMI and the Manufacturer, are calculated on the basis of the currently established rate specified in the CMI price list.

2. The Manufacturer acknowledges that the schedule of payments under the certification process, as well as other payment terms, are contained in the GTC and undertakes to comply with them.

3. The calculated price for the conformity assessment process referred to in paragraph 1(a) of this Article shall be 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 discrepancies. In case that during the certification process the CMI incurs additional costs, 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) of the GTC, 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 published CMI price list and the number of hours necessary to carry out the tasks in question.

4. In case that the CMI finds nonconformities that prevent the issuance of a certificate and decides to refuse the issuance of a certificate within the meaning of Article II(VI) of the Framework Agreement, the Manufacturer nevertheless undertakes to pay the full price for the certification referred to in Article IV(1)(a) of the Implementation Contract and all related costs.

5. If the inflation index reaches an increase of 3% or more compared to the situation in force for the previous calendar year, the CMI reserves the right to unilaterally increase the agreed prices by the same percentage increase, with effect from the calendar month after the Czech Statistical Office announces the inflation rate expressed as an increase in the average annual consumer price index. The Manufacturer undertakes to pay such increased prices.

V. Rights and obligations of the Parties

1. The rights and obligations of the Parties shall be governed by this Implementation Contract, the Framework Agreement, applicable law and the GTC.

2. The Manufacturer expressly represents that it has read and agrees with the GTC and accepts the rights and obligations contained therein, including the payment terms set out in Article V of the GTC, the

default interest, the contractual penalties and compensation set out in Article VI of the GTC and the Manufacturer's obligations set out in Article VIII of the GTC.

3. The Specifications of Medical Devices and the documentation sampling plan developed by the CMI are also annexed to this Contract.

VI. Term of Contract and its termination

1. This Contract shall come into force as of the date of signing by the Parties and into effect on the date of publication in the Register of Contracts.

2. Modifications and addenda to the Contract shall be made in writing, by numbered amendments.

3. The Contract may be terminated in the following ways:

   a) Automatically on the date on which the Post-Certification Monitoring Implementation Contract enters into force;
   b) For the reasons and in accordance with the procedure set out in Article V.4 of the Framework Agreement;
   c) By written agreement of the Parties;
   d) By notice of termination written and duly delivered by either of the Parties, including without reason, with a three-month notice period starting on the first day of the calendar month following its delivery to the other Party;
   e) By written and duly delivered notice of withdrawal in cases where the law so provides or in the event of a material breach of this Contract, the Framework Agreement or the GTC. A material breach of this Contract shall be understood to mean in particular:
      i. Delays by the CMI in performing a partial certification task longer than 120 days, unless the delay is caused by the Manufacturer's lack of cooperation or unless an extension of the time limits for performing the task in question has been agreed with the Manufacturer;
      ii. Failure to pay an outstanding invoice issued by the CMI on the basis of this Contract even within a reasonable additional period of time specified by the CMI in a written reminder.
      iii. If the Manufacturer fails to fulfil its obligations set out in the relevant legislation, this Implementation Contract, the GTC and, where applicable, the Framework Agreement necessary for the conformity assessment of medical devices in accordance with the MDR, thereby preventing the proper course of the certification process, because the CMI cannot carry out the required certification tasks or other activities of the notified body due to insufficient cooperation by the Manufacturer.

4. The Manufacturer also acknowledges that the withdrawal pursuant to Article VI(3)(e) hereof shall terminate the obligation of the Parties from the onset; consequently, the condition for the marketing of legacy devices set out in Article 120(3c)(e) of the MDR is not met. The Parties acknowledge that in case of termination pursuant to Article VII(3)(d) hereof, where the obligation of the Parties shall terminate upon the effective date of termination, the condition for the marketing of legacy devices set out in Article 120(3c)(e) of the MDR shall be maintained.

5. The Parties are obliged to settle all obligations arising from this Contract, the Framework Agreement and the GTC. The termination of the Agreement shall not affect the right to payment of a contractual penalty, compensation or default interest, if already incurred, the right to compensation for damages arising from the breach of a contractual obligation, or arrangements which, by their nature, are intended

to bind the Parties even after the termination of the Agreement, in particular the obligation to protect confidential information and confidentiality and the obligation relating to dispute resolution.

VII. Other and final arrangements

1. This Contract and the relationships arising from it shall be governed by the laws of the Czech Republic, without giving effect to any conflict of laws or choice of law rules. The legal relationships of the Parties not governed by the Contract shall be governed Framework Agreement, the GTC, the valid legal regulations, in particular the MDR, Act No. 89/2012 Coll., the Civil Code, as amended (hereinafter also referred to as 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 General Terms and Conditions of the Czech Metrology Institute for the Certification of Medical Devices (GTC) form an integral part of this Contract and the Manufacturer has already agreed to them as confirmed in the MEDECA software. The Parties hereby expressly exclude the application of any terms and conditions other than the CMI's GTC within the framework of the concluded obligation.

3. If a conflict arises between the wording of this Contract and the wording of the GTC, the provisions of the Contract shall prevail over the provisions of the GTC.

4. In accordance with Section 504 of the Civil Code, the Parties consider the entire contents of this Agreement to be trade secret and confidential information pursuant to Sections 1728 to 1730 of the Civil Code. In particular, information on the contractual partners, the subject matter of the offer, the request, the prices, the terms of delivery, the scope of performance, the timing, and any negotiations preceding or relating to the conclusion of the Contract are considered confidential (and trade secret). The Parties also undertake to protect and not to violate the trade secret of the other Party that they discover in the course of the execution of this Agreement in accordance with Sections 504 and 2985 of the Civil Code. Any confidential information and trade secret shall not be disclosed to a third party without the prior written consent of the other Party; the obligation of confidentiality and protection of confidential information shall survive the settlement of mutual obligations. A situation where information is disclosed to public authorities in order to comply with a legal obligation shall not be considered a breach. The Parties similarly undertake to protect and respect the other Party's other proprietary rights and to maintain the confidentiality of the information provided.

5. The CMI shall only be liable to the Manufacturer for damage caused to samples of medical devices entrusted to it if the damage has been caused by improper handling, whether negligent or intentional. In such cases, the CMI is obliged to compensate the Manufacturer for the damage caused, up to a maximum of the amount of the insurance benefit provided by the insurance company.

6. 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 Contract or its individual provisions or the quality and timing of the performance of the obligations under this Contract. In such a case, the Party concerned shall be obliged to initiate negotiations between the authorized representatives of the Parties.

7. If any provision of this Contract is or becomes invalid or ineffective, the remaining provisions of this 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.

8. The Parties agree that any disputes concerning the performance of the Contract shall be resolved primarily by mutual negotiations between representatives or statutory bodies, as a rule within 14 calendar days of a written notice or reminder 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.

9. 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.

10. The Parties have entered into this Contract voluntarily, seriously, understandably and definitely, after prior negotiation of the contractual obligations, in witness whereof they attach their signatures.

11. The Contract has been drawn up in two counterparts, each with the validity of an original, one counterpart to be given to the Manufacturer and one to the CMI.

In …… on ……..……	In …… on……..……
……	……
Manufacturer	CMI

Annexes:

- Annex 1: Specifications of Medical Devices
- Annex 2: Documentation Sampling Plan

Annex 1

Specifications of Medical Devices

Name of medical device	Basic UDI - DI	Intended purpose of medical device
XXXXX	XXXXX	XXXXX

In …… on ……..…… In …… on……..……

…… ……

Manufacturer CMI

Annex 2

Documentation Sampling Plan

Total number of TDs assessed: 1
Total number of categories/generic groups: 1/1

Name of medical device	Basic UDI - DI	Models	Class	Identificator
XXXXX	XXXXX	XXXXX	XXXXX	XXXXX

In …… on ……..…… In …… on……..……

…… ……

Manufacturer CMI