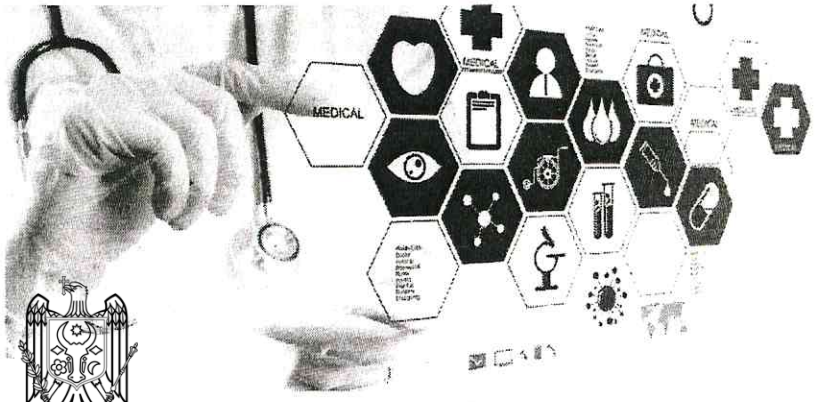
MDR COVER LETTER OF CONTRACT



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Location: Moldova

UDEM Adriatic d.o.o
NB:2696

Zhejiang Baitai Medical Technology Co., Ltd. - CN-MF-000033681

Medical Device Regulation
2017/745/EU

Offer date: : **19.7.2023**

Offer No : **MDR.2224.23.1**

Contract date : **31.7.2023**

Validity Date **29.10.2023**

Prepared by :

Aylin ARIYÖRÜK

Medical Device Technical Regulation Responsible

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The product information which issue the certification

Product Type :	Steam Sterilizers, Rule 16, Class IIa Models: BTD23-A, BTD17-A, BTD12-A, BTD8-A, BTS23-A, BTS17-A
Related Directive :	(EU) 2017/745
The Name of Subcontractor Laboratories :	

If you accept the offer, you have to sign the contact and send the following essential documents to us and so your application will be accepted.
If you have any opinion and suggestion about the offer, please contact with us via the following contact information.
The contract is an offer. Unless you sign and send us the contract, there is no provision in the contract.
Thank you for receiving the offer of UDEM Adriatic d.o.o ,we hope to work with you.

ESSENTIAL DOCUMENTS: After signed the contract, the following commitments should be sent by manufacturer with the signed contract.

- Trade Registry Gazette, Tax Board, Chamber Registration Certificate,
- List of authorized signatures belonging to the authority signing the contract,
- Contract of the Authorized Representative if the manufacturer's premises is not in the EU.
- The technical documentation set out in Annex II and Annex III of MDR,
- The name of the manufacturer and address of its registered place of business and any additional manufacturing site covered by the quality management system, and, if the manufacturer's application is lodged by its authorized representative, the name of the authorized representative and the address of the authorized representative's registered place of business,
- All relevant information on the device or group of devices covered by the quality management system,
- A written declaration that no application has been lodged with any other notified body for the same device- related quality management system, or information about any previous application for the same device- related quality management system,
- A draft of an EU declaration of conformity in accordance with Article 19 and Annex IV of MDR for the device model covered by the conformity assessment procedure,
- The documentation on the manufacturer's quality management system,
- A documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under this Regulation and the undertaking by the manufacturer in question to apply those procedures,
- A description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures,
- The documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92 of MDR,
- A description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92 of MDR, as well as the undertaking by the manufacturer to apply those procedures,
- Documentation on the clinical evaluation plan,

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- A description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art.
- A copy of the EU Quality Management system certificate or EU technical documentation assessment certificate for the application of Annex IX (I) or Annex IX (II), if any,
- A copy of the EU type-examination certificates referred to in Section 4 of Annex X of MDR for the application of Annex XI (Part A), except the Class II-a devices,
- Bank receipt or payment receipt which mentioned in Offer & Contract.

For the voluntary change of the NB according to article 58 of MDR

- Test reports, audit reports, non-conformities and corrective and preventive actions, required technical information shall be provided from the former Notified Body and presented to UDEM ADRIATIC.
- Transfer contracts between the Customer, Former Notified Body and UDEM ADRIATIC.

Annex :

- Certification Contract
- ANNEX 1 of Medical Device Product Certification Contract

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MEDICAL DEVICE PRODUCT CERTIFICATION CONTRACT

This offer will be used as a contract after signed. (MDR.2224.23.1 numbered and 31.07.2023 dated

EMPLOYER : Zhejiang Baitai Medical Technology Co., Ltd. - CN-MF-000033681

Address : NO.1, Longjing Road, Jinchuan Street Changshan Country, Quzhou, 324200 Zhejiang, P. R. China

(here and after referred to as **CUSTOMER** in this hereby contract)

Name of the Authorized Representative (if any) : Eunitor GmbH - DE-AR-000005081

Address : Kennedydamm 540476 Dusseldorf Germany

and

AUDITING COMPANY : UDEM Adriatic d.o.o.

Radnička cesta 54, R3, Green Gold Centar, IV. kat. 10000 Zagreb

Tel: +385 (1) 4819 601 Fax: +385 (1) 4819 434 (here and after referred to as **UDEM ADRIATIC** in this hereby contract)

This contract has been signed according to the scope defined below.

1. INTRODUCTION

This contract has been prepared in accordance with the requirements of accreditation bodies and related legislation (2017/745/EU) of which UDEM ADRIATIC is still connected.

2. THE SCOPE

UDEM ADRIATIC; will carry out the review of the technical documents of the product, make preparations before Conformity Assessment activities according to the national and international standards and legislation of the product, and realize the certification processes according to the results of Conformity Assessment, Sampling, Control of Test and Examinations and Reporting.

When the **CUSTOMER** of which conformity assessment has been conducted by **UDEM ADRIATIC,** has more than one site, no sampling process will be applied and all sites of the CUSTOMER are assessed. For the both announced and unannounced on-site assessments, UDEM ADRIATIC has right to enter THE CUSTOMER'S and if appropriate its supplier's and its subcontractor's premises.

3. CONFIDENTIALITY

UDEM ADRIATIC is responsible to ensure confidentiality for all information obtained during the Conformity Assessment process. With the confidentiality principle, necessary information will only be given to legal authorities and other bodies (e.g. accreditation body, agreement group of peer assessment scheme) within the information of **CUSTOMER** in written. **UDEM ADRIATIC** also keeps the confidentiality of the identity of the party who asks for the information.

4. GENERAL REQUIREMENTS

CUSTOMER shall obey following procedures and rules to obtain the certificate and keep it valid:

a. CUSTOMER accepts any change in the assessment duration, which was determined according to the application review, in consequence of preparation prior to Conformity Assessment.

b. The period between Preparation and Conformity Assessment, paying accommodation, food expense, transportation, etc. costs will also be accepted by **customer.**

c. CUSTOMER; will provide all necessary information requested by **UDEM ADRIATIC** for the completion of the conformity assessment process,

d. If all conditions necessary for the certification have not been fulfilled by the CUSTOMER, then **UDEM ADRIATIC** shall inform the **CUSTOMER** about incomplete parts of the application,

e. For the abovementioned cases and/or any deficiency according to the conformity assessment process; If the CUSTOMER has compensated and proved to meet all the necessary conditions within the time period defined by UDEM **ADRIATIC**; UDEM **ADRIATIC** provides to repeat only the necessary parts of the assessment process, with the condition that CUSTOMER will pay an additional cost.

f. If the CUSTOMER has not compensated within the time period defined by UDEM **ADRIATIC**, UDEM **ADRIATIC** may need to repeat the assessment completely with an additional cost,

g. Each certificate will be issued only for the product group which have been assessed and the scope will be indicated on the certificate.

h. The **CUSTOMER** will be responsible for any damage on the product during the tests outsourced/carried by **UDEM ADRIATIC** to control conformity of the product according to the regulation and standards and the **CUSTOMER** will be also responsible for the negative test results.

i. The **CUSTOMER** will accept the participation of the UDEM **ADRIATIC**'s assessment team as well as the observers/interpreters who will attend the audit.

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5.CONFORMITY ASSESSMENT APPLICATION

UDEM ADRIATIC will provide an offer to **CUSTOMER** to provide assessment scope and estimated costs according to the Application Form. Time and cost of the assessment can vary according to findings of project leader/site auditors/product reviewers and requirements related to the assessment time defined in the related instruction of UDEM ADRIATIC. With this contract **THE CUSTOMER** accepts and commits to obey the rules defined in **UDFRM.04-02 MDR Application Requirements Form.**

UDEM ADRIATIC has the right to refuse the application of **THE CUSTOMER.** If it is detected by **UDEM ADRIATIC** in the third application review that the application is not complete with respect to the requirements of the relevant conformity assessment procedure, as referred to in the corresponding Annex of MDR and if it is detected that the product is not qualified as a device according to MDR, then **UDEM ADRIATIC** will refuse the application. If any non-conformity detected by the assessments of **UDEM ADRIATIC** has not corrected by **the CUSTOMER** after the third evaluation of **UDEM ADRIATIC**, then the application will be refused by **UDEM ADRIATIC.** THE CUSTOMER has the right to withdraw its application from UDEM ADRIATIC in any time during the conformity assessment process.

UDEM ADRIATIC will, by means of electronic system referred in Article 57 of MDR, notify refusal or withdrawal of the application to other notified bodies according to Article 53 of MDR and Section 4.3 of the Annex VII of MDR.

6. INFORMATION SUBMITTED BY CUSTOMER

6.1 CUSTOMER shall have available within their organization at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices and declare the information of this person to UDEM in application process. (In accordance with MDR Article 15 clause 1).

6.2 CUSTOMER obliged to fulfil the commitments given to **UDEM ADRIATIC** at the application stage with the application form and to share all of the information and documents immediately upon request.

6.3 CUSTOMER shall provide all records about the product(s) in the scope of conformity assessment to **UDEM ADRIATIC** for the **assessment.** Also CUSTOMER has to declare UDEM **ADRIATIC**, all complaints related to the certified product in the latest 15 days as written.

6.4 CUSTOMER, who produces Class III or implantable device(s) shall submit PSURs by means of the electronic system referred to in Article 92 of MDR to **UDEM ADRIATIC. UDEM ADRIATIC** will review the report and add its evaluation to that electronic system with details of any action taken. Such PSURs and the evaluation by **UDEM ADRIATIC** will be made available to competent authorities through that electronic system. **The CUSTOMER**, who produces device(s) other than Class III and implantable device(s), shall make PSURs available to **UDEM ADRIATIC.**

6.5 CUSTOMER, who produces implantable device(s) and Class III device(s) other than custom-made, shall submit the draft of the summary of safety and clinical performance according to Article 32 of MDR to **UDEM ADRIATIC.** SSCP will be validated by **UDEM ADRIATIC.** After its validation, **UDEM ADRIATIC** will upload the summary to **EUDAMED. THE CUSTOMER** shall mention on the label or instructions for use where the summary is available.

6.6 If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, **CUSTOMER** shall implement the appropriate measures and inform the competent authorities concerned and, **UDEM ADRIATIC.** Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported in accordance with Article 87 of MDR.

6.7 Regarding to the analysis of serious incidents and field safety corrective actions, **CUSTOMER** shall co-operate with the competent authorities and **UDEM ADRIATIC** during the investigations referred to in the first subparagraph of Article 89 of MDR.

6.8 UDEM ADRIATIC has access to the information referred in paragraph 1 of Article 92 of MDR related to **THE CUSTOMER'S** devices covered in the scope of **UDEM ADRIATIC's** certificate(s) and the information referred to in paragraphs 5 to 8 of the Article 92 of MDR will be automatically transmitted, upon receipt, through the electronic system referred to in paragraph 1 of the Article 92 of MDR, to **UDEM ADRIATIC**

6.9 CUSTOMER accepts that the information referred to in paragraph 1 of the Article 100 of MDR shall be immediately transmitted through the electronic system to **UDEM ADRIATIC.**

6.10 As the result of the evaluation of the information supplied according to Article 92 of MDR and/or according to Article 100 of MDR, **UDEM ADRIATIC** has right to cancel the contract, which has been signed with **CUSTOMER.** For the assessment of that information, **UDEM ADRIATIC** may make additional assessments, on-site audits on the manufacturer's, it's supplier's and/or subcontractor's premises and take samples from the market and/or manufacturer's premises and conduct/be conducted test(s) to verify the conformity of the products to MDR. In this case, **CUSTOMER** admits paying possible additional charge for the assessments and product testing. As a result of this evaluation, UDEM ADRIATIC may decide to suspend, restrict or withdrawal of the certificate.

6.11 It's an obligatory for the **CUSTOMER**, to provide and declare the necessary information in latest 5 business days, asked by UDEM **ADRIATIC.**

6.12 THE CUSTOMER shall notify UDEM ADRIATIC about the planned significant change(s) of the assessed products and QMS according to principles set out in the clause 11 of this contract.

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7. CONFORMITY ASSESSMENT

When **UDEM ADRIATIC** determines that the **CUSTOMER** has fulfilled all the required conditions for Conformity Assessment (relevant provisions of MDR), **UDEM ADRIATIC** will inform the CUSTOMER and issue a certificate. The certificate is issued by **UDEM ADRIATIC** in Croatian and in English. The certificate will be valid for the period indicated on the certificate, unless the certificate is not restricted, suspended or withdrawn by **UDEM ADRIATIC** as a result of its announced and/or unannounced audits and/or assessments. Any supplement to a certificate will remain valid as long as the certificate which it supplements is valid. The certificate will stay as UDEM **ADRIATIC** property and can only be reproduced by a 3rd party carrying with "copy" title. **UDEM ADRIATIC** may impose restrictions to the intended purpose of a device to certain groups of patients or require **THE CUSTOMER** to undertake specific PMCF studies pursuant to Part B of Annex XIV of MDR. **UDEM ADRIATIC** will enter in the electronic system referred to in Article 57 of MDR (EUDAMED) any information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. Such information shall be accessible to the public according to the Article 56 of MDR.

For the medical devices incorporating medicinal substance, according to article 5.2 of the Annex IX of the medical device regulation, the opinion of one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC such as HALMED or EMA is necessary after the assessments of **UDEM ADRIATIC**. If the result of the evaluation of HALMED or EMA is negative and certification process is not completed due to this decision, conformity assessment costs are not repaid. **UDEM ADRIATIC** is not responsible for the long review period and uncompleted certification process. Any fee related to this evaluation of HALMED or EMA shall be paid by the **CUSTOMER.**

For the medical devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body, according to article 5.4 of the Annex IX of the MDR, the opinion of one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC (such as HALMED) or EMA is necessary after the assessments of UDEM ADRIATIC. If the result of the evaluation of one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or HALMED or EMA is negative and certification process is not completed due to this decision, conformity assessment costs are not repaid. **UDEM ADRIATIC** is not responsible for the long review period and uncompleted certification process. Any fee related to this evaluation of HALMED or EMA shall be paid by the CUSTOMER.

According to Article 54 of the MDR, for Class III implantable devices and for class IIb active devices intended to administer and/or remove a medicinal product as referred to in Section 6.4. of Annex VIII of MDR, after its clinical evaluation assessment UDEM ADRIATIC will submit THE CUSTOMER'S clinical evaluation documentation and its assessment report to the European Commission for the consultation of the Expert Panel, as specified in the section 5.1 of Annex IX of the MDR. **UDEM ADRIATIC** is not responsible for the long review period and uncompleted certification process. Any fee related to this consultation procedure shall be paid by the CUSTOMER.

7.1 If UDEM **ADRIATIC** detects that the documentation of the CUSTOMER has frauds or detects that the device is a falsified device, then UDEM **ADRIATIC** has right to cancel or early terminated of any assessment. According to the detecting stage of this situation, **UDEM ADRIATIC** will withdraw the application or the certificate of THE CUSTOMER. The notification will be made by UDEM ADRIATIC via EUDAMED. In these circumstances, **UDEM ADRIATIC** does not refund to the **CUSTOMER.**

7.1.1. Offer & Agreement condition is including preliminary verification step and verification step in frame of clause 4.2 & 4.3 of Annex VII.

a) Offer & agreement is prepared based on information which was specified by company on FRM.81 MDR Application Form.

b) (If appropriate) the second offer & updated agreement is prepared based on changing/ amended/ detailed information due to application review process, in frame of sharing the documents and technical information which was stated at section C of FRM 04-02 Application Requirements.

If preliminary application review condition and relevant offer and agreement are still valid, it will be specified at the end of FRM82-1 Application Review Form and it does not necessary preparing the new offer and the new agreement, but when the contract revision and / or is determined to be invalid, **the first offer and contract will be deemed void by both parties.**

Situations requiring offer and contract renewal and/ or refuse of the application:

Detection of different information from stated at FRM81. Application Form. E.g. medical device contains ancillary medicinal substance or and absorbable substance unlike the first application requirements, detecting more technical files and/ or product, if new suppliers are identified, if deciding that the product was not in scope of UDEM Adriatic d.o.o after detailed information sharing.

7.2 UDEM **ADRIATIC** has right to access CUSTOMER's suppliers/subcontractors premises if necessary during the conformity assessment process.

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7.3 UDEM ADRIATIC does not subcontract any activity other than those specified in UDTLM.01 Subcontracting Instruction which is available on UDEM ADRIATIC website. UDEM ADRIATIC may authorize external experts and external auditors for the conformity assessment activities and conducts testing activities in subcontracting laboratories according to the Annex IX Chapter 1 Section 3.4 of Medical Device Regulation (2017/745/EC) or Annex XI Part A Section 7 of MDR in accordance with UDTLM.01 Subcontracting Instruction.

7.4 UDEM Adriatic will retain full responsibility for being able to produce appropriate evidence of the competence of subcontractors and experts to fulfil their specific tasks, for making a decision based on a subcontractor's assessment and for the work conducted by subcontractors and experts on its behalf.

7.5 UDEM Adriatic will ensure that the subcontractor(s) meet the relevant requirements of the Annex VII of MDR and subcontractors and external experts do not further subcontract work to organizations or personnel.

8. SURVEILLANCE

UDEM **ADRIATIC** will carry out surveillance audits at least once every 12 months including specific parts of product features. Time and cost of on-site surveillance audits can differ according to requirements of legislations, standards and guidance documents.

When it's necessary UDEM **ADRIATIC** has right to enter site of the CUSTOMER, if appropriate its supplier and its subcontractor with surveillance purpose, UDEM **ADRIATIC** will keep the right to make short-term audits including unannounced visits when necessary. Customer will keep a registry covers all products, processes or services in the scope of the certificate and complaints and provide to UDEM **ADRIATIC** when requested. **CUSTOMER** will be informed results of each surveillance audit by **UDEM ADRIATIC.**

When it's necessary, UDEM **ADRIATIC** has right to enter site of the CUSTOMER and if appropriate, its critical suppliers and its subcontractor for surveillance and carry out short-term audits including unannounced visits.

CUSTOMER shall record complaints of all products, processes or services in the scope of the certificate and provide them to UDEM **ADRIATIC** upon request. **CUSTOMER** will be informed about results of each surveillance audit.

CUSTOMER shall give authorization to the **UDEM ADRIATIC** to carry out all the necessary audits, including on- site audits, and supply it with all relevant information, in particular:

— the documentation on its quality management system,

— documentation on any findings and conclusions resulting from the application of the post-market surveillance plan, including the PMCF plan, for a representative sample of devices, and of the provisions on vigilance set out in Articles 87 to 92 of MDR

— the data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests and the solutions adopted regarding the risk-management as referred to in Section 4 of Annex I of MDR, and (This intent is not applied for the application according PART A of Annex XI of MDR)

— the data stipulated in the part of the quality management system relating to manufacture, such as quality control reports and test data, calibration data, and records on the qualifications of the personnel concerned.

At the time of such on-site audits, **UDEM ADRIATIC** will, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It will provide the **CUSTOMER** with a surveillance audit report and, if a test has been carried out, with a test report.

In the case of class III devices, the surveillance assessment will also include a test of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices.

In the case of class IIa and class IIb devices, the surveillance assessment will also include an assessment of the technical documentation as referred to related provisions of MDR for the device or devices concerned on the basis of further representative samples chosen in accordance with the rationale documented by **UDEM ADRIATIC.**

UDEM ADRIATIC randomly performs unannounced audits on the site of the manufacturer and, where appropriate, of the manufacturer's suppliers and/or subcontractors, to verify the continuity of compliance with legal requirements. These audits are carried out MINIMUM once every five years or once in the certification period, at least one day and with at least two auditors.

If suspicious situation for manufacturer and device occurs and/or the device contains high risk the frequency of unannounced audits may be increased.

Within the context of such unannounced on-site audits, **UDEM ADRIATIC** will test an adequate sample of the devices produced or an adequate sample from the manufacturing process to verify that the manufactured device is in conformity with the technical documentation, Instead of, or in addition to, this sampling, **UDEM ADRIATIC** will take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation. **THE CUSTOMER** accepts to pay all the fees related to the testing and buying the device from the market.

The **CUSTOMER** shall inform **UDEM ADRIATIC** when the manufacturing of the products within the scope of the certificate is stopped. Outsourced manufacturing processes are also subjected to unannounced audits.

Critical suppliers and subcontractors / contractors can also be included unannounced audits when it is required.

The customer must provide a letter of invitation of the relevant country with the signing of this contract to **UDEM ADRIATIC** for realizing the visits to critical suppliers or subcontractors located abroad, where a visa is required for the personnel of UDEM ADRIATIC.

Ministry of Health has right to conduct unannounced audits to UDEM **ADRIATIC** and its customers.

9. RECERTIFICATION

At the end of each certification period, **THE CUSTOMER** shall submit an application to **UDEM ADRIATIC** at the latest 6 months prior to the end of the validity of its certificate with the Application Form. **UDEM ADRIATIC** will prepare a new offer for the re-certification and a new contract shall be signed mutually.

CUSTOMER will be informed about the conditions of recertification which is the final surveillance of the certification period.

CUSTOMER, who has EU Technical Documentation Assessment Certificate, shall submit with the application form a summary to **UDEM ADRIATIC** of changes and scientific findings for the device, including the followings:

a) all changes to the originally approved device, including changes not yet notified,

b) experience gained from post-market surveillance,

c) experience from risk management,

d) experience from updating the proof of compliance with the general safety and performance requirements set out in Annex I of MDR,

e) experience from reviews of the clinical evaluation, including the results of any clinical investigations and PMCF,

f) changes to the requirements, to components of the device or to the scientific or regulatory environment,

g) changes to applied or new harmonized standards, CS or equivalent documents, and

h) changes in medical, scientific and technical knowledge, such as:

- new treatments,
- changes in test methods,
- new scientific findings on materials and components, including findings on their biocompatibility,
- experience from studies on comparable devices,
- data from registers and registries,
- experience from clinical investigations with comparable devices.

According to the result of the application review and review of the abovementioned summary, UDEM ADRIATIC has right to refuse the re-certification application. In that case UDEM ADRIATIC will notify the other notified bodies via the electronic system mentioned in Article 57 of MDR. According to the review result of the summary report, UDEM ADRIATIC has right to restrict, suspend or withdraw the certificate.

10. EXPANSION OF THE CERTIFICATION SCOPE

To expand the scope of the certificate of a CUSTOMER to include additional sites, products, processes or services, a new application form shall be filled by the CUSTOMER. The areas which will be added to the scope will be assessed by UDEM **ADRIATIC.** The additional cost of the expansion of certification scope will be occurred and this cost can be varied according to content of the work. Clause 11 has the details about the evaluation of planned changes.

Although the current certificate is valid, in some cases it may be necessary to issue a new certificate.

In such cases, **CUSTOMER** shall return the previous certificate to UDEM **ADRIATIC.**

11. CHANGES ON CUSTOMER SPECIFICATIONS

CUSTOMER shall inform UDEM **ADRIATIC** at the latest within 15 business days in written regarding any planned change(s) that may affect compliance with relevant legislation(s), standards, product, process, service carried out. UDEM **ADRIATIC** will determine whether the planned changes require an additional audit or not. If CUSTOMER does not inform UDEM **ADRIATIC,** the certificate may be suspended and/or withdrawn.

CUSTOMER commits to declare following planned changes to **UDEM ADRIATIC:**

a) Legal, commercial, organizational status or ownership,

b) Organization and management (personnel responsible for regulatory compliance, key management, decision-maker and technical staff, etc.),

c) Communication addresses and the addresses of the manufacturer, if appropriate its supplier(s) and its subcontractor(s)

d) The scope of process regarding to the product group(s) certificated

e) Significant changes on the management system and processes.

f) Certified product specifications

g) The approved quality management system or systems or to the product-range covered,

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h) The approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device.

i) The intended use of or claims made for the device,

j) The approved type of a device, and

k) Any substance incorporated in or utilized for the manufacturing of a device and being subject to the specific procedures in accordance with 2017/745 regulation section 4.5.6.

l) CUSTOMER shall inform UDEM **ADRIATIC** in written 1 month before the change of production place and address(es) of the manufacturer, if appropriate its supplier(s) and/or its subcontractor(s). After the change of production area, CLIENT shall guarantee that any production will not be done until a successful assessment will be completed by UDEM **ADRIATIC.**

m) Management system and significant changes on the processes.

n) If there is any planned changes are made on additional articles related to a device included medicinal substance and especially in production process, **CUSTOMER** shall inform **UDEM ADRIATIC** about these planned changes. **UDEM ADRIATIC** makes application to **HALMED or EMA**, whose opinion **UDEM ADRIATIC** previously has taken, on the purpose to confirm whether the situation of these articles are safe and qualified or not. If the HALMED or EMA makes a negative decision, **CUSTOMER** is obliged to pay all possible costs. Certification and audit costs are not repaid to the **CUSTOMER**. The same procedure shall also be applied with the same conditions the products which are referred in the section 7 of this contract.

If the **CUSTOMER** has the EU QMS Certificate, then the **CUSTOMER** shall inform **UDEM ADRIATIC** any plan for substantial changes to the quality management system, or the device-range covered. **UDEM ADRIATIC** will determine the need for additional audits and verify whether after those changes the quality management system still meets the relevant requirements of MDR. **UDEM ADRIATIC** will notify the manufacturer of its decision which will contain the conclusions of the assessment, and where applicable, conclusions of additional audits. The approval of any substantial change to the quality management system or the device-range covered will take the form of a supplement to the EU quality management system certificate.

If **THE CUSTOMER** has EU Technical Documentation Certificate, then **THE CUSTOMER** shall notify planned changes to the approved device where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device to **UDEM ADRIATIC. UDEM ADRIATIC** will assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 52, in that case UDEM ADRIATIC will prepare a new offer for the certification and a new contract shall be signed mutually or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, UDEM ADRIATIC will assess the changes, notify the manufacturer of its decision and, where the changes are approved, provide it with a supplement to the EU technical documentation assessment certificate.

12. CUSTOMER RIGHTS

UDEM ADRIATIC will inform the CUSTOMER about any change on conformity assessment process, certification rules, structure on company partnership, national and international legislations and accreditation standards or logos via contact information (phone, fax, e-mail etc.) of customer defined on the application form in 15 days.

CUSTOMER has right to cancel the certificate, expand the scope, reduce the scope, and use the identification number of UDEM **ADRIATIC** according to the related provisions of MDR with CE mark as of the date of certification decision in the certification period in accordance with the applicable legislation.

CUSTOMER has right to learn site auditors and product reviewers in the audit team of **UDEM ADRIATIC** at least 2 days before the audit.

They also have right to object to site auditors or product reviewers in the team. This article is not applied for unannounced audits.

CUSTOMER has right to object any decision taken by UDEM **ADRIATIC** during the certification process. **CUSTOMER** has right to complain **UDEM ADRIATIC** in any subject. **CUSTOMER** may notice that kind of appeals according to PD.09 Procedure for handling complaints and appeals, which is published in the web site of **UDEM ADRIATIC.**

CUSTOMER has the right to object any decision taken by **UDEM ADRIATIC** during the Conformity Assessment process.

In accordance with Article 46 Cl.5 of MDR; Where **UDEM ADRIATIC**'s designation has been suspended, restricted, or fully or partially withdrawn, **UDEM ADRIATIC** will inform the CUSTORMER at the latest within 10 days.

If **UDEM ADRIATIC** ends its services, bankrupts, suspended/cancelled its accreditation/ authorization, will not return any payment or rights to the **CUSTOMER.**

Although the information of **CUSTOMER** on the Application Form is correct, if **UDEM ADRIATIC** personnel assign wrong audit team and if this situation detected by Impartiality Committee, Accreditation Agency, Ministry of Health, Joint assessment team or UDEM personnel, the costs of the repeated audit will be paid by **UDEM ADRIATIC.**

However, if this situation caused of wrong information given by **CUSTOMER** on the Application Form, any costs will be paid by the **CUSTOMER. UDEM ADRIATIC,** has the right to delegate the activities related to Conformity Assessment to an external organization. At this situation, a written approval will be taken from the **CUSTOMER**. UDEM **ADRIATIC** is responsible for the confidentiality of all information of customer and any conflict of interest. If any mistake is made by **UDEM ADRIATIC** on the CERTIFICATE that has been prepared as a result of the Conformity Assessment processes, **CUSTOMER** approves that the processes defined in UDEM **ADRIATIC** procedures will be immediately applied. These processes can include restriction of the scope, suspension, withdrawn or cancellation of the certificate. At this situation, the **CUSTOMER**'s right to object to the decisions taken by **UDEM ADRIATIC**.

13. USAGE OF LOGO, MARK and CERTIFICATE

CUSTOMER can refer on a communication media that their products, process or service has been assessed and can apply conformity mark on company documents and advertisement material related to the scope of certification as described in the TLM.02-01 Logo and Certificate Usage Instruction. Furthermore, **CUSTOMER** cannot use conformity mark on uncertified product.

CUSTOMER shall ensure that there is no confusion between products, processes and/or services in their publications and advertisements, whether they are certified or not.

CUSTOMER will not claim any declaration to 3rd parties about an uncertified product, process and/or service as it was certified.

CUSTOMER will follow the UDEM **ADRIATIC** instructions when using the CE marking and **UDEM ADRIATIC** Notified Body Number on its product.

Otherwise, CUSTOMER is responsible for any case of improper use.

During the certification cycle, **CUSTOMER** shall use logo, mark and certificate carefully according to rules below, otherwise **UDEM ADRIATIC** has right to suspend or withdraw certification of the **CUSTOMER** because of wrong usage and abuse of the certification. **UDEM ADRIATIC** also has right to take a legal action in cases like following;

a) Using certification status in a misleading manner,

b) Detecting any misleading statements during the certification cycle according to certification process in certificate,

c) Not correcting the advertising material according to the restriction of the scope of certification,

d) Using the Product Certificate to refer to certification of any other product / service or process which are not certified,

e) Meaning that the activities out of the scope of certification are also certified,

f) Using the certificate in a way to damage reputation and cause the loss of public confidence of UDEM **ADRIATIC**.

CUSTOMER commits that **CUSTOMER** is responsible for any damage arising from incorrect use and abuse logo, trademark and certificate. In the case of suspension or withdrawal of certificate for any reason, **CUSTOMER** will not make any reference to the status on advertising and communication materials, and stop using certification, logo, trademark and certificate.

UDEM ADRIATIC informs **CUSTOMER** with TLM.02 Logo, mark and certificate usage instruction which will be delivered in the certificate box about logo, mark and certificate usage.

After the certifications, CUSTOMER can trace the validity of the certificate on www.udemadriatic.com

14. SUSPENSION OF THE CERTIFICATE

UDEM ADRIATIC can suspend the certificate in the following situations for a limited time. During this period FRM.34-M Requirements for Suspension and Withdrawn Processes for Medical Devices will be applied;

a) If CUSTOMER continuously and seriously fails to meet the requirements of the certified product,

b) If CUSTOMER does not allow the surveillance or recertification audits to be carried out in necessary frequencies,

c) If CUSTOMER voluntarily asks for a temporary suspension.

d) If abuse using of certification as it was mentioned in Item 13, was not corrected with suitable retreats or with compensatory precautions by CUSTOMER;

e) If there is any violation for this contract. However, if this violation is related with an article which causes withdrawn of the certificate then article 15 shall be applied.

f) If the non-conformities detected in the assessments have not been closed within the specified periods, UDEM **ADRIATIC** suspends the certificate.

g) If UDEM **ADRIATIC** finds a divergence between the sample taken from the devices produced or from the market and the specifications laid down in the technical documentation or the approved design, UDEM **ADRIATIC** will suspend or withdrawn the relevant certificate or impose restrictions on it.

h) In accordance with Article 10 of MDR; If CUSTOMER fails to cooperate or the information and documentation provided is incomplete or incorrect, suspension process is applied until the CUSTOMER cooperates or provides complete and correct information.

i) In accordance with Article 32 of MDR; For implantable devices and for class III devices; If the summary of safety and clinical performance is not updated in Eudamed, location of the summary of safety and clinical performance is not defined in label/user manual or the summary of safety and clinical performance is not made available to the public via Eudamed, suspension process is applied.
j) In accordance with Article 86 of MDR; If CUSTOMER does not update or make available "PSUR"(Periodic safety update report) according to period given below for each device classes, suspension process is applied;
- Class IIb and Class III devices; CUSTOMER shall update the PSUR at least annually and shall make available for competent authorities.
- Class IIa devices; CUSTOMER shall update the PSUR when it is necessary and at least every two years and make available for competent authorities.
- Class III or implantable devices; CUSTOMER shall make available the PSUR to UDEM ADRIATIC and, upon request, to competent authorities via Electronic System.

CUSTOMER will not demonstrate any product, process or service as certified based on the suspended certificate. **UDEM ADRIATIC** will declare the suspension of certificate to the **CUSTOMER** in written.
Meanwhile, UDEM **ADRIATIC** will define the conditions that are necessary for ending the suspension period. The end of suspension period, if it is necessary, an audit will be conducted to determine that the conditions for the certificate to be valid again are fulfilled or not. If the conditions are fulfilled, suspension will be ended and CUSTOMER will be informed about the revalidation of the certificate.
If these conditions are not fulfilled, the certificate will be withdrawn. The costs of suspension and revalidation of the certificate will be paid by CUSTOMER. The suspension period is at most 6 months. If there is no application for the follow up audit within 6 months after the client's certificate has been suspended, the additional time can be given, or the certificate can be withdrawn by the Certification Committee's decision.
UDEM ADRIATIC will enter in the electronic system referred to in Article 57 of MDR (EUDAMED) any information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. Such information shall be accessible to the public according to the Article 56 of MDR.

15. WITHDRAWING OF THE CERTIFICATE

If the **CUSTOMER** does not get the precautions in the case of suspension or the violation of related articles of this contract, the certificate can be withdrawn. In the case of each situation above, UDEM **ADRIATIC** will inform the CUSTOMER in written and can withdraw the certificate. In the case of withdrawing, audit costs will not be repaid.
The **CUSTOMER** shall remove UDEM **ADRIATIC**'s logo and identification number from all kind of writings and presentation materials following the withdrawing of the certificate.
UDEM ADRIATIC will enter in the electronic system referred to in Article 57 of MDR (EUDAMED) any information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. Such information shall be accessible to the public according to the Article 56 of MDR.

16. CANCELLATION OF THE CERTIFICATE

If the CUSTOMER informs UDEM **ADRIATIC** in writing that he does not want to renew the certificate, if he does not continue to provide the product, process or service, then the certificate is cancelled. CUSTOMER shall deliver the certificate, document and other information to UDEM **ADRIATIC**.
UDEM ADRIATIC will enter in the electronic system referred to in Article 57 of MDR (EUDAMED) any information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. Such information shall be accessible to the public according to the Article 56 of MDR.

In the case of cancellation;

i. **UDEM ADRIATIC**, will not pay audit costs back.

ii. CUSTOMER, is responsible to pay whole of annual surveillance assessments

iii. CUSTOMER shall remove UDEM **ADRIATIC**'s logo and the identification number from all kind of publications and presentation materials following the cancellation of the certificate.

17. SHORT TERM AUDITS

UDEM **ADRIATIC** can organize short term audits to investigate complaints of CUSTOMERS, to examine changes of CUSTOMER, as the result of the evaluation of the information supplied according to Article 92 of MDR and/or according to Article 100 of MDR or to follow actions of suspended CUSTOMER or to follow-up on site audits. These audits can be organized with informing customer with a prior notice. CUSTOMER accepts all costs of these types of audits.

18. FEES AND PAYMENTS

Since the costs are based on the rate valid at the date of the offer, UDEM **ADRIATIC** reserves the right to raise the fees during the period of conformity assessment. **CUSTOMER** will be informed about any raise in fees. Transportation, accommodation, living etc. costs of the auditors will be paid by **CUSTOMER.**

The additional fees for services which are not included in the offer or contract and for additional surveillance/short term assessment arising from the non-conformities in the product are paid by the CUSTOMER.

These costs will be included from the following:

a. Repeating the audit program in whole or in part due to the failure to meet the initial certification requirements,

b. Additional work caused by suspension, withdrawing and-or reissuing of certification,

c. Reassessment of planned changes

d. Any charges associated with the cancelled visits recently notified and previously agreed, determined by cost and the cost of travel will be kept separate. All additional fees and charges are subjected to taxes.

e. The validity of the certificates are 3 years for Class III devices, 4 years for IIb devices, 4 years for the Novelty devices; 5 years for other devices. Third and Fourth Surveillance prices does not include Class III devices. Fourth Surveillance price does not include Class IIb and Novelty devices.

f. Fee for the certification service of UDEM **ADRIATIC**; The fee of the conformity assessment service is enclosed on annex 1 of this contract.

19. DOCUMENTS REQUIRED FOR THE INITIATION OF CONFORMITY ASSESSMENT

Customer shall submit the signed contact with the relevant documents and comments which are requested on the cover page of this contract.

20. VALIDITY

This contract consists of 9 (nine) pages and 20(clauses), Cover Pages and Annex 1 prepared as 2 copies. It's entering into force after signing by both parties. When the initial certification and the re-certification decision is taken, the certificate is valid until the expiry date written on the issued certificate.

Where the CUSTOMER who signed this contract benefits from the extended transition period set out in Article 120 of MDR amended by Regulation (EU) 2023/607 and also Article 2(3) of Regulation (EU) 2022/2346 amended by Regulation (EU) 2023/1194 and appropriate surveillance is applicable in accordance with Article 120(3e) of MDR, Annex 2 of this contract shall be also mutually signed for appropriate surveillance activities which will be conducted by UDEM ADRIATIC.

When the initial certification and the re-certification decision is taken, the certificate is valid until the expiry date written on the issued certificate.

This contract will be valid if the following three conditions are fulfilled within 3 (three) months from the contract date on the cover page.

-- mutually signed by the parties

-- Making the first payment in the payment schedule specified in ANNEX 1 Note 10 of the Medical Device Product Certification Contract

-- Sending the technical file, documents and commitments specified on the cover page

The rights obtained by the contract will be valid during to the contract term. CUSTOMER is obliged to fulfil the terms of this mutually signed contract.

In case of non-compliance with the provisions of this contract or in extraordinary conditions, both parties reserve the right to cancel this contract and the CUSTOMER; is obliged to pay the price of the services performed until that date.

In case of disputes relating to this contract or any additional protocol will take place in the context, laws of the Croatia shall be applied and Zagreb Courts and Enforcement Offices are fully authorized.

Dear Sir / Madam, please note that the contract must be wet-signed. Non-wet-signed contracts will not be considered. Please also add the date of signature at the sections of name, signature and your initials.

On behalf of the Customer	On behalf of UDEM Adriatic d.o.o.
Seal, Name, Signature, Date	Seal, Name, Signature, Date

ZAGREB, 31.7.2023,

BANK ACCOUNT NUMBER (EURO ACCOUNT)	
Account Name	UDEM Adriatic d.o.o.
Address	Radnicka Cesta 54/R3, 10000, Zagreb, Croatia
Bank	Raiffeisenbank Austria d.d. OIB: 53056966535
City	Zagreb
IBAN Number	HR7324840081135298384
SWIFT Number	RZBHHR2X

ANNEX 1 of MEDICAL DEVICE PRODUCT CERTIFICATION CONTRACT

31.07.2023 dated and **MDR.2224.23.1** numbered
ANNEX 1 of Medical Device Product Certification Contract

The fee determined by UDEM Adriatic d.o.o. for the certification service:

2017/745/EU Medical Devices Regulation Service Fee of Conformity Assesment: 28.400 €

Offer Detail:		Stage2	Surveillance1	Surveillance2
Number of **Is/Im/Ir** product groups in the scope of certification	:	**0**	**0**	**0**
Number of **IIa** product groups in the scope of certification	:	**1**	**0**	**0**
Number of **IIb** product groups in the scope of certification	:	**0**	**0**	**0**
Number of **III** product groups in the scope of certification	:	**0**	**0**	**0**

Technical File Preliminary Review	:	**1,00**	man / day	**3.200 €**	**3.200 €**
QMS Preliminary Review	:	**1,00**	man / day	**2.000 €**	**2.000 €**
CE Conformity Assessment (TD)	:	**1,50**	man / day	**3.200 €**	**4.800 €**
CE Conformity Assessment (QMS)	:	**3,50**	man / day	**2.000 €**	**7.000 €**
Clinical Review	:	**1,00**	man / day	**5.000 €**	**5.000 €**
Microbiological Assessment	:	**1,00**	man / day	**2.000 €**	**2.000 €**
Medicinal Substance Assesment	:	**0,00**	man / day	**0 €**	**0 €**
Absorbable Substance Assessment:	:	**0,00**	man / day	**0 €**	**0 €**
Nano Material Assessment:	:	**0,00**	man / day	**0 €**	**0 €**
In Vitro Diagnostic Device Assessment:	:	**0,00**	man / day	**0 €**	**0 €**
Software Validation Assessment	:	**1,00**	man / day	**3.200 €**	**3.200 €**
Reporting, Certificating, Annual Usage	:				**1.200 €**

For the products defined above which have already been initially certified in the scope of 2017/745/EU Medical Devices Regulation;

First Surveillance Audit Fee	:	**12.600 €**
Second Surveillance Audit Fee	:	**16.700 €**
Third Surveillance Audit Fee	:	**12.600 €**
Fourth Surveillance Audit Fee	:	**16.700 €**
Unannounced Audit Handling Fee	:	**6.200 €**
Application Review Fee	:	**2.840 €**

Note-1: Auditors expenses is not included in the Conformity Assesment Fee.
These expences will be invoiced according to UDTLM.17-1 MDR-Conformity Assessment Charging Instruction

Note-2: Test and all related costs about the testing of the product are paid by the **CUSTOMER.** Offered prices are valid for 3 days.
Even if the contract is signed; if the conformity assessment is not initiated because of the reasons arising from the CUSTOMER within 2 months after the date of signing of the contract, the offered amount may need to be updated by UDEM ADRIATIC.

Note-3: The termination periods of UDEM **ADRIATIC**'s services are defined in Adriatic UDFRM.229 Medical Devices Product Certification Service Standard form.

Note-4: The above fees do not include VAT.

Note-5: One of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or HALMED or EMA EMA and Expert Panel fees for the related medical devices belong to the CUSTOMER.

Note-6: For Surveillance audits the man / day audit fee published in January and June every year by UDEM **ADRIATIC** is applied.
The man / day calculation may vary according to the information received by Surveillance Audit Information Form before the audit.

Note-7: The clinical review fee will be charged in surveillance audits if the clinical evaluation is updated by CUSTOMER. It is applied annually for Class III devices.

Note-8: The application review fee is not refunded under any circumstances after the contract is signed.

Note-9: PSUR and SSCP review fees are applied for the related medical devices.

UDEM Adriatic d.o.o.
www.udemadriatic.com

UDEM Adriatic d.o.o.
UDEM OIB:50[illegible]79784
Radnička cesta [illegible] Green Gold Centar,IV.kat,Zagreb
[illegible]48 19601 Fax: (1)4813434
www.udemadriatic.com

Note-10: At least 50% of the initial certification fees shall be paid by **CUSTOMER** to UDEM **ADRIATIC** to initiate the conformity assessment process. Surveillance audit fees shall be paid 15 days prior to audit and **CUSTOMER** shall contact with UDEM **ADRIATIC.**

Note-11: **Offer & Agreement condition is including preliminary verification step and verification step in frame of clause 4.2 & 4.3 of Annex VII.**

a) Offer & agreement is prepared based on information which was specified by company on FRM.81 MDR Application Form.

b) (If appropriate) the second offer & updated agreement is prepared based on changing/ amended/ detailed information due to application review process, in frame of sharing the documents and technical information which was stated at section C of FRM 04-02 Application Requirements.

If preliminary application review condition and relevant offer and agreement are still valid, it will be specified at the end of FRM82-1 Application Review Form and it does not necessary preparing the new offer and the new agreement, but when the contract revision and / or is determined to be invalid, **the first offer and contract will be deemed void by both parties.**

Situations requiring offer and contract renewal and/ or refuse of the application:

Detection of different information from stated at FRM81. Application Form. E.g. medical device contains ancillary medicinal substance or and absorbable substance unlike the first application requirements, detecting more technical files and/ or product, if new suppliers are identified, if deciding that the product was not in scope of UDEM Adriatic d.o.o after detailed information sharing.

UDEM Adriatic d.o.o.
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