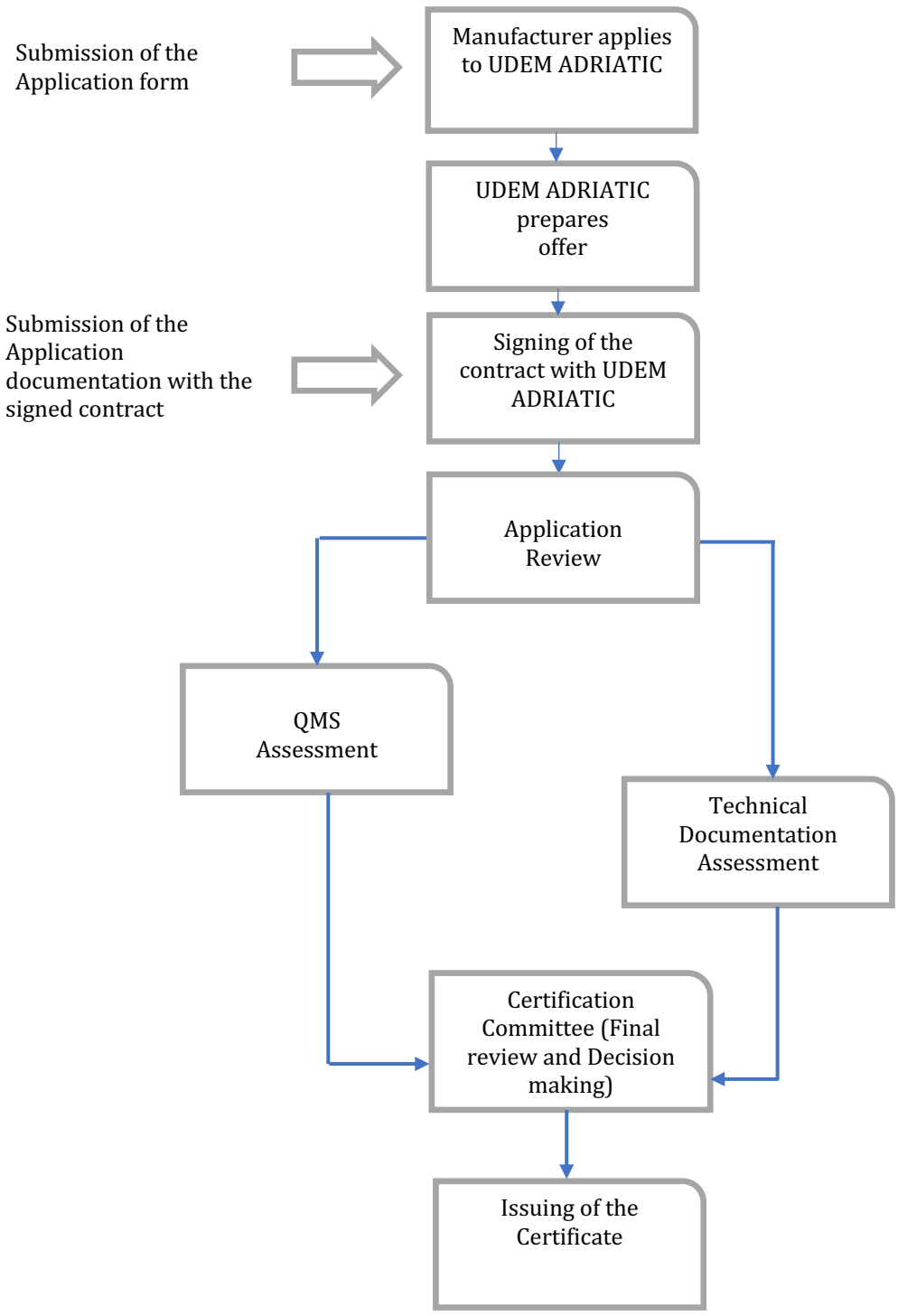
APPLICATION REQUIREMENTS FOR MDR CONFORMITY ASSESSMENT SERVICES

UDEM Adriatic d.o.o. provides services for the medical device conformity assessment activities in accordance with 2017/745/EU MDR Annex IX and Annex XI Part A. The designation scope of UDEM Adriatic d.o.o. can be checked from NANDO database.

Conformity assessment steps are summarized with the following flowchart:



APPLICATION REQUIREMENTS FOR MDR CONFORMITY ASSESSMENT SERVICES

Manufacturers who can apply for a conformity assessment according to Annex IX of MDR:

1- Manufacturers of class III devices, other than custom-made or investigational devices, can be subject to a conformity assessment in Annex IX of MDR.
2- Manufacturers of class IIb devices, other than custom-made or investigational devices, can be subject to a conformity assessment as specified in Chapters I and III of Annex IX of MDR, and including an assessment of the technical documentation as specified in Section 4 of Annex IX of MDR of at least one representative device per generic device group. However, for class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, the assessment of the technical documentation as specified in Section 4 of Annex IX of MDR shall apply for every device.
3- Manufacturers of class IIa devices, other than custom-made or investigational devices, can be subject to a conformity assessment as specified in Chapters I and III of Annex IX of MDR, and including an assessment of the technical documentation as specified in Section 4 of that Annex of at least one representative device for each category of devices. The assessment of the technical documentation shall apply for at least one representative device for each category of devices.
4- In the case of class I devices placed on the market in sterile condition, have a measuring function or are reusable surgical instruments, the manufacturer can apply the procedures set out in Chapters I and III of Annex IX.
5- Manufacturers of Class III custom-made implantable devices shall follow the procedure set out in Annex XIII of MDR and draw up the statement set out in Section 1 of that Annex and can apply to the conformity assessment as specified in Chapter 1 of Annex IX of MDR.

Manufacturers who can apply for a conformity assessment according to Annex XI Part A of MDR

1- Manufacturers of class IIa devices, other than custom-made or investigational devices, can draw up the technical documentation set out in Annexes II and III of MDR coupled with a conformity assessment as specified in Section 10 of Part A of Annex XI of MDR.
2- Manufacturers of class I devices placed on the market in sterile condition, have a measuring function or are reusable surgical instruments, can apply the procedures set out in Part A of Annex XI of MDR.
3- Manufacturers of Class III custom-made implantable devices shall follow the procedure set out in Annex XIII of MDR and draw up the statement set out in Section 1 of that Annex and can apply to the conformity assessment as specified in Part A of Annex XI of MDR.
4- Manufacturers of class III devices, if the manufacturer has EU type-examination certificates referred to in Section 4 of Annex X of MDR, can apply a conformity assessment as specified in Part A of Annex XI of MDR
5- Manufacturers of class IIb devices, other than custom-made or investigational devices, if the manufacturer has EU type-examination certificates referred to in Section 4 of Annex X of MDR, can be subject to a conformity assessment as specified in Part A of Annex XI of MDR.

The applicants will need to submit **FRM.81 Medical CE &13485 Application Form** to UDEM ADRIATIC. All applicants can reach related application form on our web site on **ONLINE APPLICATION** link.

By filling the application form, the applicants will provide the necessary information about its company and the products so that UDEM ADRIATIC will provide an accurate offer to the applicant. According to the applicant's selected conformity assessment route, the application should include the information specified in the section 2.1 of Annex IX of MDR or section 6.1 of Annex XI of MDR. The application form shall be signed with the manufacturer or the authorized representative within the scope of MDR 2017/745/EU.

After the review of the application form, UDEM ADRIATIC will generate an offer based on the information the applicant gives in the Application form according to **UDTLM.17-1 MDR-Conformity Assessment Charging Instruction** which is publicly available at www.udemadriatic.com.

When the offer is accepted by the applicant, the applicant will sign the offer and a contract between the applicant and UDEM Adriatic will be prepared and signed mutually.

UDEM Adriatic will assign a Project Leader for every individual application, who is responsible for ensuring that the assessment of an individual application is conducted properly, observing the UDEM ADRIATIC's procedures (in accordance with the relevant legislation, guidance documents, CS and/or harmonized standards). This person will ensure that the appropriate resources are utilized for each of the tasks of the assessment. The project leader is also responsible to coordinate the planning responsible who makes the communication with the applicant for all regulatory needs, which is limited with the information specified in the section 1.2.9 of Annex VII of MDR.

The project leader will review the application and may request additional information to ensure the appointment of qualified experts for each conformity assessment task.

Site auditors are responsible to carry out audits of the applicant's quality management system (QMS) and of its suppliers and/or subcontractors when appropriate and to draw up records and reports on the corresponding audits. The assessment of the quality management system of the applicant will be conducted through a two-stage assessment: Stage 1 will review the completeness of the applicant's QMS, and Stage 2 will review the effective implementation of the applicant's QMS and its compliance to the MDR.

The Product Reviewer(s) with the relevant product expertise are responsible for carrying out product related reviews. They are responsible for the review of the applicant's technical documentation for the entire documentation or for specific aspects of this documentation such as biological safety, clinical evaluation, software or sterilisation validation. They should also advise the audit team, and in particular the audit team leader, on aspects of the applicant's design or production processes which could be of particular relevance for the on-site audit. The review of the technical documentation will be conducted through a two-stage assessment: Stage 1 will review the completeness of the applicant's technical documentation and Stage 2 will review all the details in the technical documentation.

Clinical experts are responsible for the review of part or of all the clinical aspects of the technical documentation as required by the internal clinician of UDEM Adriatic in accordance with the UDEM Adriatic's procedures.

Once the QMS and Technical documentation Assessments have confirmed compliance to the applicable requirements, after the review of the project leader and the analysis of the conflict of interests, the certification committee of UDEM Adriatic will review reports and supporting documentation (including quality management system and technical documentation provided by the applicant) are complete and sufficient according to section 4.7 of Annex VII of MDR and will make decision on issuing the certificate and for defining the period of certification according to section 4.8 of Annex VII of MDR.

Once approved, the certificate will be issued to the applicant. UDEM ADRIATIC may impose restrictions to the intended purpose of a device to certain groups of patients or require the applicant 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.

Special processes within 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.

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.

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 applicant'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.

Assessment findings

UDEM Adriatic may detect non-conformities during the conformity assessment activities. The applicant should submit the CAPA plan in 15 days and shall close the nonconformities in an agreed time between UDEM Adriatic and in accordance with the requirements.

Findings of the audit team may involve major and minor nonconformities, which are classified by the audit team with the following principles.
It is essential that nonconformities are clearly worded with factual and precise language that enables the reader to comprehend the actual non-fulfillment that was detected during the audit. The information presented should be an accurate representation of the reviewed records, samples and procedures, as well as interviews conducted.
For the classification of the nonconformities, the auditor shall assess the influence of the nonconformity to the safety and performance of the medical device. If there is an indirect influence of the nonconformity to the safety and performance of the device, this an indirect impact. If there is a direct influence of the nonconformity to the safety and performance of the device, this a direct impact. When classifying the non-conformities, first the auditor shall classify the non-conformity as direct impact or in direct impact.

Minor: Minor non-conformities are a single lapse in the fulfillment of a requirement, which has an indirect influence on the safety and performance of the device (indirect impact). If a nonconformity is classified as minor, then there isn't any absence of the documentation for a requirement. Because the absence of a documented process or procedure will fundamentally affect consistency and effective implementation of any process. A nonconformity which resulted in the release of a nonconforming medical device to the market shall never be classified as a minor non-conformity.

Major: Major non-conformites are non-conformities that have a direct impact. Major non conformity is described as one of the following: 1) "a total absence in the fulfillment of a requirement," 2) "repetition of a previous nonconformity," 3) "failure to address a previously identified minor non-conformity" 4) "release of non-conforming product.". The absence of the documented processes or procedures shall be yield as major nonconformities.

APPLICATION PROCESS

A) PRE-APPLICATION: The application must include the following commitments which are taken from manufacturer with the **FRM.81 Medical CE &13485 Application Form** in the pre-application stage:

- Identity documents (brochures, catalogues, promotional CDs, etc.)
- Certificate of Activity,
- Commitment of the manufacturer to fulfil the requirements of the approved quality system.
- A written declaration about not be made any application to another notified body for the same medical devices.
-The commitment of the manufacturer about the approved quality system which will be continued effectively and completely.
-If the company has a certificate from another notified body about the same medical devices, the NB must give a commitment to share the certification date, information about the surveillance audits, past audits results with UDEM ADRIATIC D.O.O.
- According to the Medical Device Regulation and the medical device, as part of a whole human blood derivative or a declaration whether containing a substance or not and considering the intended purpose of the medical device, the commitment must be taken about the sharing of data which is needed to evaluate the test results, the usefulness, quality and reliability of human blood derivative or substance.
- In medical device manufacturing, a declaration on the use of animal-derivative tissue according to the regulations regarding animal-derivative tissue.

B) APPLICATION REVIEW PROCESS: UDEM ADRIATIC D.O.O. will send UDFRM.179 MDR Offer form to the potential client, after reviewing Application Form and supported Documents which was defined at chapter A.

C) CONTRACT PROCESS: If the Applicant approve the UDFRM.179 MDR Offer, UDEM ADRIATIC D.O.O. will send UDFRM.07 Medical Device Product Certification Contract. 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 manufacturers' 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,
- a description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art.
- 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.

Language of Technical and QMS documentation:

All submissions and test results should be in the English or Croatian language. UDEM Adriatic may accept some parts of the Technical Documentation in another EU language if UDEM Adriatic is able to assess with the personnel who have desired qualification and language capabilities. All correspondence with the client after the contract is signed will be in English or Croatian. If the documents are delivered on a different language than these languages, the customer is requested to translate them into one of these languages.
The documents shall be submitted via the software, which is available in the. UDEM Adriatic web site (www.udemadriatic.com) or via electronic mail. The preferred document format is paginated, bookmarked PDF utilizing Optical Character Recognition (OCR, searchable format).

UDEM Adriatic has the right to refuse or withdraw the application according to the conditions which are set in the contract and shall 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.

Post certification activities

Once the applicant has granted to have a certification, UDEM Adriatic will continue to assess the applicant through regular audits, including:

- Surveillance assessments at least once every 12 months according to section 3 of Annex IX of MDR or section 7 of Annex XI of MDR
- Unannounced on-site audits according to section 3 of Annex IX of MDR or section 7 of Annex XI of MDR
- Short notice on site audits
- Technical audits for the certificate

On-site audits both announced and unannounced will be realized in the premises of the applicant and of its suppliers and/or subcontractors when appropriate.

Logo, mark and usage of certificate: Using of Logo, CE Marking and Certificate is defined **TLM.02-01 Product Logo and Certificate Usage Instruction.** This instruction is available on www.udemadriatic.com

Complaints and appeals: The applicant can complaint and appeal to any finding and decision of UDEM Adriatic during the conformity assessment process according to PD.09 Procedures for Handling Complaints and Appeal which is available in UDEM Adriatic's web site.

Re-certification:

At the end of each certification period, the applicant may 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.

Applicant, 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 according section 4.11 of Annex VII of MDR.