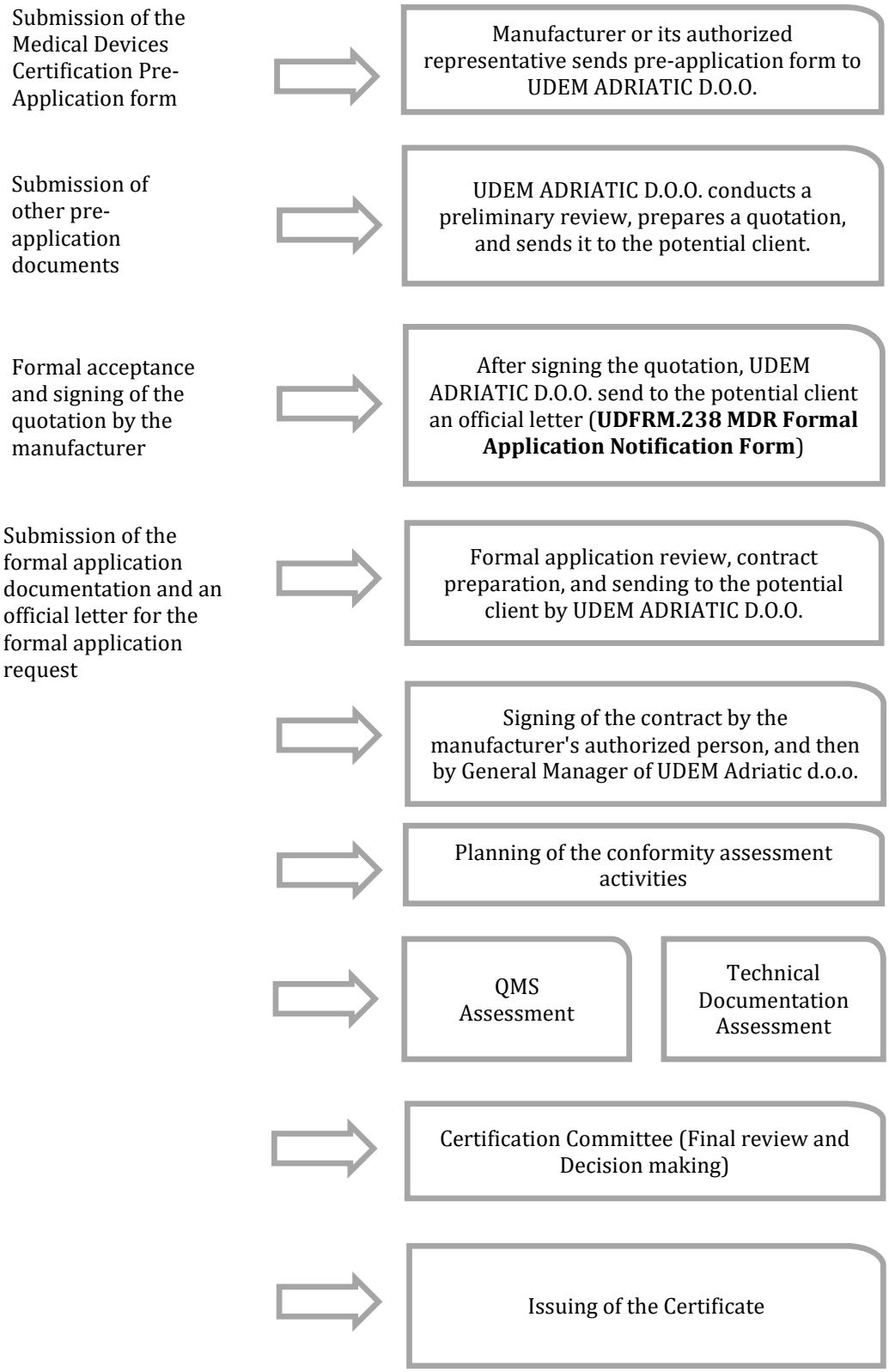
MDR APPLICATION REQUIREMENTS

UDEM ADRIATIC D.O.O. performs conformity assessment activities for medical devices in accordance with 2017/745/EU MDR Annex IX and Annex XI Part A. Information on the designation scope of UDEM ADRIATIC D.O.O. can be verified in the NANDO database.

Conformity assessment steps are summarized with the following flowchart:



The manufacturers with the following conditions can apply for a conformity assessment regarding Annex IX (Chapter I and III) and Annex IX (Chapter II).

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 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, 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. However, the involvement of UDEM ADRIATIC D.O.O. in these procedures is limited:
   (a) in the case of devices placed on the market in sterile condition, to the aspects relating to establishing, securing and maintaining sterile conditions;
   (b) in the case of devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements;
   (c) in the case of reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.
5- Manufacturers of custom-made devices shall follow the procedure set out in Annex XIII and draw up the statement set out in Section 1 of Annex XIII before placing such devices on the market. In addition to the procedure applicable pursuant to the first subparagraph, manufacturers of class III custom-made implantable devices can apply a conformity assessment as specified in Chapter I of Annex IX.

The manufacturers with the following conditions can apply for a conformity assessment regarding Annex XI (Part A);

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, 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. However, the involvement of UDEM ADRIATIC D.O.O. in those procedures is limited:

(a) in the case of devices placed on the market in sterile condition, to the aspects relating to establishing, securing and maintaining sterile conditions;

(b) in the case of devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements;

(c) in the case of reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

3- Manufacturers of custom-made devices shall follow the procedure set out in Annex XIII and draw up the statement set out in Section 1 of Annex XIII before placing such devices on the market. In addition to the procedure applicable pursuant to the first subparagraph, manufacturers of class III custom-made implantable devices can apply a conformity assessment as specified in Part A of Annex XI.

4- Manufacturers of class III 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 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.

In addition, according to Article 22(3) of MDR, any natural or legal person who sterilises systems or procedure packs referred in Article 22(1) of MDR for the purpose of placing them on the market shall, at their choice, apply one of the procedures set out in Annex IX or the procedure set out in Part A of Annex XI. The application of those procedures and the involvement of UDEM ADRIATIC D.O.O. shall be limited to the aspects of the procedure relating to ensuring sterility until the sterile packaging is opened or damaged. The natural or legal person shall draw up a statement declaring that sterilisation has been carried out in accordance with the manufacturer's instructions. Where the system or procedure pack incorporates devices which do not bear the CE marking or where the chosen combination of devices is not compatible in view of their original intended purpose, or where the sterilisation has not been carried out in accordance with the manufacturer's instructions, the system or procedure pack shall be treated as a device in its own right and shall be subject to the relevant conformity assessment procedure pursuant to Article 52 of MDR. The natural or legal person shall assume the obligations incumbent on manufacturers.

Applicants shall submit the **FRM.81 Medical Devices Certification Pre-Application Form** to UDEM ADRIATIC d.o.o. The applicant may be either the manufacturer or its authorised representative, and the pre-application form shall be submitted solely by the applicant company. The FRM.81 Medical Devices Certification Pre-Application Form is available through the **ONLINE APPLICATION** link on the UDEM ADRIATIC d.o.o website (www.udemadriatic.com).

By filling out the pre-application form, the applicants will provide the necessary information about their company and the devices so that UDEM ADRIATIC D.O.O. will provide an accurate quotation to the applicant. According to the applicant's selected conformity assessment route, the application should include the information specified in section 2.1 of Annex IX of MDR or

section 6.1 of Annex XI Part A of MDR. The pre-application form shall be signed by the manufacturer or the authorized representative within the scope of MDR 2017/745/EU.

PRE-APPLICATION PROCESS

The manufacturer or its authorised representative shall submit **FRM.81 Medical Devices Certification Pre-Application Form** together with the relevant information relating to the device(s) and the manufacturer.

The pre-application shall include the following documents and commitments:

- Informative documents relating to the device(s) included in the pre-application (e.g. brochures, catalogues, promotional materials, instructions for use and similar documents);
- Certificate of Activity / Business Licence of the manufacturer;
- Authorised Representative Agreement, where applicable;
- Copies of existing certificates, where applicable (e.g. EC/EU certificates, ISO 13485 certificates, MDSAP certificates, UKCA certificates);
- Copies of Quality Management System certificates of critical suppliers and subcontractors, where applicable.

At the pre-application stage, commitments may be submitted **through FRM.81 Medical Devices Certification Pre-Application Form**, which includes the relevant declarations.

Where certain supporting documents are not available during the pre-application stage (e.g. informative documents such as brochures, catalogues, promotional CDs or Certificate of Activity, existing certificates etc.), a quotation may still be prepared, provided that the justification is documented in FRM.82-2 MDR Pre-Application Review Form. However, all applicable documents shall be submitted during the Formal Application stage.

By signing **FRM.81 Medical Devices Certification Pre-Application Form**, the manufacturer or its authorised representative confirms and accepts that:

- the information provided is complete, accurate and valid;
- the applicant assumes responsibility for any incorrect or incomplete information;
- the information provided in FRM.81 may be used by UDEM ADRIATIC D.O.O. for preparation of a quotation;
- once the quotation is accepted, the information provided in FRM.81 becomes an integral part of the formal application;
- signing FRM.81 does not constitute a formal application under MDR Annex VII Section 4.3.

Only the manufacturer or its authorised representative may sign FRM.81 Medical Devices Certification Pre-Application Form.

LANGUAGE OF DOCUMENTATION

All MDR conformity assessment applications, including pre-application, as well as all Technical Documentation and Quality Management System documentation submitted to UDEM ADRIATIC D.O.O., shall be provided in English.

All correspondence relating to conformity assessment activities is conducted in English.

Documents submitted in other languages shall be translated into English by the manufacturer.

All formal application documentation shall be uploaded to the UDEM ADRIATIC D.O.O. MDR software by the manufacturer or its authorised representative.

The preferred document format is a paginated, bookmarked and searchable PDF (OCR format).

PRE-APPLICATION REVIEW

UDEM ADRIATIC D.O.O. reviews all pre-application form and documents to determine whether sufficient information has been provided to prepare a quotation. Where information is incomplete or incorrect, the manufacturer may be requested to provide additional information or clarification.

If the pre-application review result is positive, a quotation is prepared and submitted to the manufacturer.

If the pre-application review result is negative, the manufacturer is informed accordingly.

Where the manufacturer fails to provide requested information, does not submit required documentation in English, or does not respond within the specified timeframe, the pre-application may be rejected.

QUOTATION PROCESS

Following a positive pre-application review result, UDEM ADRIATIC D.O.O. prepares a quotation based on the information provided by the manufacturer in **FRM.81 Medical Devices Certification Pre-Application Form.**

The quotation is prepared in accordance with **UDTLM.17-1 MDR Conformity Assessment Charging Instruction** and **UDLST.10 MDR List of Standard Fees for Conformity Assessment Activities,** which is publicly available at www.udemadriatic.com.

All information obtained during the MDR conformity assessment process, including pre-application activities, is treated as confidential and is disclosed only where required by applicable legislation or competent authorities, notifying the client in writing. UDEM ADRIATIC D.O.O. also keeps the confidentiality of the identity of the party who asks for the information. These confidentiality principles are clearly specified in **UDFRM.179 MDR Quotation Form.**

UDFRM.179 MDR Quotation Form may only be signed and approved by the manufacturer, even if the pre-application was submitted to UDEM ADRIATIC D.O.O. by its authorised representative.

The validity period of the quotation is 15 working days. If the quotation is not accepted within this period, a new pre-application may be required.

Upon acceptance of the quotation by the manufacturer, UDEM ADRIATIC D.O.O. issues **UDFRM.238 MDR Formal Application Notification Form**, which provides information regarding the formal application requirements in accordance with MDR Annex VII Section 4.3.

FORMAL APPLICATION PROCESS

As specified in **UDFRM.238 MDR Formal Application Notification Form**, which is sent to the manufacturer after the approval of the quotation prepared by UDEM ADRIATIC D.O.O., a formal application process in accordance with Annex VII Section 4.3 of MDR may be initiated after the manufacturer signs and accepts the relevant quotation.

Since all information submitted during the pre-application stage through **FRM.81 Medical Devices Certification Pre-Application Form** is recognised by UDEM ADRIATIC D.O.O. as an integral part of the formal application for the applicable conformity assessment activities under MDR, the resubmission of FRM.81 or a separate application form is not required at the formal application stage.

For initiating the formal application process, all commitments and application documentation specified in Annex IX Section 2.1 and Annex XI Part A Section 6.1 of MDR shall be submitted together with an official letter requesting the formal application. In accordance with Annex VII Section 4.3 of MDR, the formal application may be lodged either by the manufacturer or by its authorised representative.

All application documentation shall be uploaded to the UDEM ADRIATIC D.O.O. MDR software by the manufacturer or its authorised representative.

After uploading all application documentation to the MDR software, the official letter for the formal application request is sent to UDEM ADRIATIC D.O.O. by e-mail by the applicant. The formal application is considered officially submitted when the manufacturer or its authorised representative has provided both the official application letter and all required application documentation.

The formal application shall include, as applicable:

- Trade Registry Gazette / Business Registration Certificate, Tax Board, Chamber Registration Certificate,
- List of authorised signatures belonging to the authority signing the quotation/contract,
- Authorised Representative Agreement, if the manufacturer is not established in an EU Member State.
- The technical documentation set out in Annex II and Annex III of MDR,

- A declaration as to whether the device covered by the application contains, as an integral part, a substance which may be considered to be a medicinal product within the scope of the 2001/83 EC Directive, if used separately, including a medicinal product derived from human blood or human plasma.
- If the device incorporates a medicinal product, a commitment must be given about the sharing of data which is needed to evaluate the test results, the usefulness, quality and safety of human blood/plasma derivative or medicinal substance.
- A declaration as to whether the device covered by the application is manufactured utilising tissues or cells of human or animal origin or their derivatives.
- 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 authorised representative, the name of the authorised representative and the address of the authorised 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 MDR 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,
- A copy of the EU Quality Management System Certificate or EU Technical Documentation Assessment Certificate for the application of Annex IX (Chapter I and III) or Annex IX (Chapter 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 for the Class I and IIa devices,
- Bank receipt or payment receipt for the application fee, which is mentioned in the Quotation.

For the voluntary change of the Notified Body according to Article 58 of MDR;

- If the company has a certificate from another notified body about the same devices, a commitment to share the certification date, information about the surveillance audits, past audit results and other necessary information with UDEM ADRIATIC D.O.O. during the transfer process.
- 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 d.o.o.
- Transfer contracts between the Manufacturer, Former Notified Body and UDEM Adriatic d.o.o.

FORMAL APPLICATION REVIEW

For each formal application, UDEM ADRIATIC D.O.O. appoints a Project Leader responsible for conducting the application review, coordinating assessment activities and ensuring that the conformity assessment is performed in accordance with applicable legislation, guidance documents, Common Specifications, harmonised standards and internal procedures.

The Project Leader may request additional information where necessary to ensure the assignment of competent personnel and the proper planning of conformity assessment activities.

Where technical documentation is incomplete, or where the manufacturer indicates that certain documentation will be submitted later, the manufacturer shall provide a documented submission plan including proposed deadlines. UDEM ADRIATIC D.O.O. reserves the right to accept, reject or require modification of the proposed plan.

In all cases, the agreed deadlines for submission of outstanding technical documentation shall not exceed three months from the date on which the MDR Certification Contract enters into force.

The formal application review confirms:

- that the application documentation is complete;
- that the device falls within the designation scope of UDEM ADRIATIC D.O.O.;
- that the product qualifies as a device under MDR;
- that appropriate resources are available for the conformity assessment activities.

Where the application review result is positive, the certification contract is prepared and submitted to the manufacturer.

UDEM ADRIATIC D.O.O. may refuse the application where:

- the device is outside the designation scope;
- the product does not qualify as a device under MDR;
- the application documentation is incomplete;
- required documentation is not submitted in English;
- missing information is not provided within the specified timeframe;
- suitable resources are not available.

Where the application is refused, the applicant is informed by e-mail.

UDEM ADRIATIC D.O.O. shall notify refusal or withdrawal of an application to other notified bodies in accordance with Article 53 and Annex VII Section 4.3 of MDR.

CONTRACT PROCESS

Following acceptance of the formal application, UDEM ADRIATIC D.O.O. prepares **UDFRM.07 M Medical Devices Regulation Certification Contract**, which defines the rights, obligations and responsibilities of both parties.

The certification contract shall be signed by the manufacturer, even where the formal application was submitted through an authorised representative.

The validity period of the contract is **three months**. Where the manufacturer does not sign the contract within this period, or signs it after expiry of the validity period, the contract becomes invalid and the application is considered withdrawn.

Following signature by the manufacturer, the contract is signed by the General Manager of UDEM ADRIATIC D.O.O. and enters into force.

The following conditions shall be fulfilled within three months from the contract effective date:

- payment of the first instalment specified in Annex 1 of the contract;
- submission of technical documentation in accordance with any agreed submission plan.

UDFRM.07 M Medical Devices Regulation Certification Contract, includes, as applicable:

- confidentiality requirements;
- complaint and appeal rights;
- withdrawal and certificate cancellation provisions;
- conditions for suspension, restriction and withdrawal of certificates;
- manufacturer notification obligations;
- certificate, mark and logo usage requirements;
- conformity assessment conditions;
- rights of UDEM ADRIATIC D.O.O. to perform surveillance, unannounced, supplier, subcontractor and other audits;
- contract validity provisions.

Where significant changes occur that affect the scope of certification activities after the contract enters into force, the contract shall be revised and re-signed by both parties.

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

The Product Reviewer(s) with the relevant device expertise are responsible for carrying out device related reviews. They are responsible for the review of the manufacturer's technical documentation for the entire documentation or for specific aspects of this documentation such as biological safety, clinical evaluation, software or sterilization validation. They should also advise the audit team, and in particular the audit team leader, on aspects of the manufacturer's design or production processes that could be of particular relevance for the on-site audit. The review of the technical documentation will cover all the details in the technical documentation.

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

Once the QMS, Technical Documentation Assessments and Clinical Evaluation Assessment 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 D.O.O. will review reports and supporting documentation (including quality management system and technical documentation provided by the manufacturer) if its complete and sufficient according to section 4.7 of Annex VII of MDR and will decide 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 manufacturer. UDEM ADRIATIC D.O.O. may impose restrictions on the intended purpose of a device to certain groups of patients or require the manufacturer to undertake specific PMCF studies pursuant to Part B of Annex XIV of MDR. UDEM ADRIATIC D.O.O. will enter into 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 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 D.O.O.

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 D.O.O.

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 D.O.O. will submit

manufacturer's clinical evaluation documentation and its assessment report to the EU 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 d.o.o. may identify nonconformities during conformity assessment activities. The manufacturer shall submit a CAPA plan no later than 30 days after being notified of the identified nonconformities and shall ensure that all nonconformities are adequately addressed and closed within a timeframe agreed with UDEM ADRIATIC d.o.o., in accordance with the applicable regulatory and certification 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 on the safety and performance of the medical device. If there is an indirect influence of the nonconformity on the safety and performance of the device, this is an indirect impact. If there is a direct influence of the nonconformity on the safety and performance of the device, this is a direct impact. When classifying the nonconformities, first, the auditor shall classify the nonconformity as a direct impact or as a non-direct impact.

Minor: Minor nonconformities 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 is no absence of 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 that resulted in the release of a nonconforming medical device to the market shall never be classified as a minor nonconformity.

Major: Major nonconformities are nonconformities that have a direct impact. Major nonconformity 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 nonconformity," 4) "release of non-conforming product". The absence of documented processes or procedures shall be yield as major nonconformities.

In addition, the audit and assessment findings may include not only major or minor nonconformities but also observations. **Observations** are findings that require attention and follow-up but do not involve a violation of legal requirements. Observations identified during audits and assessments conducted by UDEM ADRIATIC D.O.O. are reported to the manufacturer in the same manner as nonconformities. Manufacturers are not required to submit a root cause analysis, a CAPA plan or evidence of CAPAs implementation for observations to UDEM ADRIATIC D.O.O. However, it is expected that reported observations will be taken into consideration and followed up by manufacturers as part of an effective CAPA management process. This includes taking preventive actions to improve the current situation or to avoid similar issues in the future.

POST CERTIFICATION ACTIVITIES

After a certificate has been issued to the manufacturer, UDEM ADRIATIC d.o.o. shall continue to assess the manufacturer through ongoing activities, including:

- Surveillance audits of the manufacturer conducted at least annually which shall be planned and performed in accordance with the applicable requirements of MDR Annex VII, Section 4.5;
- Unannounced on-site audits according to section 3 of Annex IX of MDR or section 7 of Annex XI of MDR
- Short term on site audits
- Technical assessments for the certificate.

Announced and unannounced on-site audits shall be conducted at the premises of the manufacturer and, where appropriate, at the premises of its critical suppliers and/or subcontractors.

SURVEILLANCE ACTIVITIES:

The surveillance activities carried out by UDEM ADRIATIC D.O.O. shall include;

- the surveillance audits of the manufacturer on at least an annual basis which shall be planned and conducted in line with the relevant requirements in MDR Annex VII Section 4.5,
- the assessments of the manufacturer's documentation on, and application of the provisions on, vigilance, the post-market surveillance, and PMCF,
- sample and test devices and technical documentation, during audits, according to pre-defined sampling criteria and testing procedures to ensure that the manufacturer continuously applies the approved quality management system.

The surveillance audits shall be carried out at least every 12 months.

Taking into consideration the necessity for contingent scheduling adjustments, surveillance audits can be conducted **within a limited window of +/- 3 months from the due date** without particular concern. However, if the surveillance audits are conducted outside this time window (earlier or later), this will be exceptional and must be justified and documented in consideration of the possible impact on the certificate's validity. An accumulation of deviations over the years, e.g. changing the due date is not allowed.

As a general rule, if UDEM ADRIATIC D.O.O. cannot conduct the surveillance audit within this time period for any reason, then the certificate shall be suspended until the audit has been carried out by UDEM ADRIATIC D.O.O.

USE OF THE UDEM ADRIATIC D.O.O. LOGO, CE MARKING AND CERTIFICATES

The conditions for the use of the UDEM ADRIATIC D.O.O. logo, CE marking and certificates are defined in **TLM.02-01 MDR Product Logo and Certificate Usage Instruction**. The instruction is publicly available on the UDEM ADRIATIC D.O.O. website (www.udemadriatic.com).

COMPLAINTS AND APPEALS

Applicants have the right to submit complaints and appeals regarding any findings, decisions or activities of UDEM ADRIATIC D.O.O. related to conformity assessment activities. Complaints and appeals are handled in accordance with **PD.09 Procedure for Handling Complaints and Appeals**, which is publicly available on the UDEM ADRIATIC D.O.O. website..

RECERTIFICATION PROCESS

Based on an application by the manufacturer and according to Article 56(2) of the MDR and Section 4.11 of Annex VII of the MDR, UDEM ADRIATIC D.O.O. can extend the validity of QMS certificates (EU quality management system or EU quality assurance certificates) as well as product certificates (EU technical documentation assessment certificates) for further periods of a maximum five years.

At the end of each certification period, the applicant shall submit a pre-application to UDEM ADRIATIC D.O.O. at the latest 6 months prior to the end of the validity of its certificate with the **FRM.81 Medical Devices Certification Pre-Application Form**. UDEM ADRIATIC D.O.O. will prepare a new quotation for the re-certification and a new contract shall be signed mutually.

Manufacturer, who has EU Technical Documentation Assessment Certificate, shall submit to UDEM ADRIATIC D.O.O a summary of changes and scientific findings for the device according to section 4.11 of Annex VII of MDR together with the pre-application form.

MECHANISM OF STRUCTURED DIALOGUE

The structured dialogue mechanism is established in accordance with the principles set out in MDCG 2022-14 and is intended to facilitate an efficient, transparent and predictable conformity assessment process while preserving the independence, objectivity and impartiality of UDEM ADRIATIC D.O.O.

A structured dialogue may be initiated upon a written request from the manufacturer, including requests submitted by e-mail. UDEM ADRIATIC D.O.O. may also initiate a structured dialogue where considered necessary for the effective management of the conformity assessment process, particularly where additional information, clarification or documentation is required.

Requests for structured dialogue are reviewed by UDEM ADRIATIC D.O.O. to determine whether the proposed topics fall within the scope of structured dialogue activities. Where the request is accepted, a meeting is arranged with the manufacturer. Where the request is not accepted, the manufacturer is informed accordingly, including the reasons for the decision.

Structured dialogues may be conducted through face-to-face meetings or remote communication platforms (e.g. Microsoft Teams, Zoom or equivalent).

Structured dialogue activities may take place during both the pre-application and post-application phases of the conformity assessment process.

As part of the structured dialogue, UDEM ADRIATIC D.O.O. may provide information regarding:

- conformity assessment and certification procedures;
- pre-application and formal application requirements;
- contractual arrangements;
- required forms and documentation;
- applicable conformity assessment routes and special procedures;
- acceptable languages for submitted documentation;
- applicable timelines and deadlines;
- fees and financial conditions related to conformity assessment activities;
- other procedural and regulatory requirements relevant to the assessment process.

Structured dialogue activities are limited to explaining regulatory requirements and assessment expectations and are focused on **what needs to be fulfilled** rather than **how compliance should be achieved**. UDEM ADRIATIC D.O.O. does not provide consultancy services.

Where appropriate, UDEM ADRIATIC D.O.O. and the manufacturer may discuss the the possibility to leverage evidence stemming from previous assessments, including assessments performed under Regulation (EU) 2017/745 (MDR), Directive 93/42/EEC (MDD), or other regulatory jurisdictions, with the objective of improving the efficiency of the conformity assessment process.

During the post-application phase, structured dialogue may include discussions regarding the sufficiency of clinical evidence, the clinical evaluation strategy, the potential applicability of Article 61(10) of MDR, claims of equivalence, and the appropriateness of Post-Market Clinical Follow-up (PMCF) activities. Such discussions are intended to improve the predictability of the conformity assessment process and shall not compromise the independence, objectivity or impartiality of UDEM ADRIATIC D.O.O.

Any questions raised by the manufacturer within the framework of a structured dialogue shall respect the independence, objectivity and impartiality requirements applicable to notified bodies. Questions shall not seek advice on how to achieve compliance or request specific compliance solutions. Responsibility for demonstrating compliance with applicable regulatory requirements remains solely with the manufacturer.

Any fees associated with structured dialogue activities may be included in the fees charged for pre-application or conformity assessment activities, as applicable.