(EU) 2017/745 MDR

Application Requirements

This document has been prepared to inform medical device manufacturers about the conformity assessment activities to be carried out by UDEM A.Ş. within the scope of MDR.

UDEM A.Ş.
www.udem.com.tr

CONTENTS

This document has been prepared on the basis of MDRPD.01 Medical Device Certification Procedure and other related procedures to inform the application process for certification services within the scope of (EU) 2017/745 Medical Device Regulation (MDR) and conformity assessment activities within the scope of the whole cycle, including post-certification processes carried out by UDEM A.Ş.

MDR SCOPE OF ACTIVITY of UDEM A.Ş.

UDEM A.Ş. provides services for medical device conformity assessment activities in accordance with Annex IX and Annex XI Chapter A under MDR Article 52, taking into account MDCG guidelines and related harmonised standards and common specifications. The scope of authorisation of UDEM A.Ş. can be checked from the NANDO database given in the link below.

https://webgate.ec.europa.eu/single-market-compliance-space/#/notified-bodies/notifications?organizationRefeCd=NANDO_INPUT_185821&filter=notificationStatusId:1

UDEM A.Ş. accepts applications only in Turkish and English

PRE-APPLICATION ACTIVITIES

Medical device manufacturers that want to apply to UDEM A.Ş. within the scope of MDR must first ensure that their products are considered as medical devices according to the definition of medical device specified in Article 2(1) of MDR.

If the products to be applied are medical devices, it is necessary to determine the risk class (Class I-sterile, I-measurement function, I-reusable, IIa, IIb, III) within the scope of MDR Annex VIII. When determining the class of the device, the manufacturer is based on the most risky class according to the rules and sub-rules specified in the related annex, especially for products with more than one intended use. In addition, the manufacturer can also make use of the related guidance documents (MDCG 2021-24, MDCG 2022-5, MDCG 2019-11, Borderline Manual) when deciding on the classification.

After determining the risk class of the device, the manufacturer chooses an appropriate conformity assessment path according to Article 52 of the MDR.

Customers who can apply for conformity assessment according to Annex IX under Article 52 of the MDR:

- Customers of **class III devices** other than custom-made or investigational devices may be subject to a conformity assessment in Annex IX of the MDR.
- Customers of **class IIb devices** other than custom-made or investigational devices may be subject to conformity assessment as set out in Chapters I and III of Annex IX of the MDR, which includes an assessment of the technical documentation of at least one representative device of each generic device group as set out in Article 4 of Annex IX of the MDRHowever, for class IIb implantable devices other than sutures, staples, dental fillings, braces, dental crowns, screws, wedges, plates, wires, pins, clips and connectors, the assessment of the technical documentation referred to in Article 4 of Annex IX shall apply to each device.
- Customers of **class IIa devices**, other than custom-made or investigational devices, may be subject to conformity assessment as set out in I and III of Annex IX and including an assessment of the technical documentation of at least one representative device for each device category as set out in Article 4 of Annex IX of the MDR. The assessment of the technical documentation shall apply to at least one representative device for each device category.
- **In the case of class I devices placed on the market in sterile condition, having a measuring function or being reusable surgical instruments,** the customer may follow the procedures set out in Annex IX, Chapter I and III. However, UDEM A.Ş. is limited to the following in these procedures:
    - in the case of devices placed on the market in a sterile condition, matters relating to the establishment, securing and maintenance of sterile conditions;
    - in the case of devices with a measuring function, matters relating to the conformity of the devices with metrological requirements;
    - in the case of reusable surgical instruments, considerations relating to the reuse of the device, in particular cleaning, disinfection, sterilisation, maintenance and functional testing and related instructions for use.
- Customers of **Class III custom-made implantable devices** may carry out a conformity assessment as set out in Article 1 of Annex IX.

Customers who can apply for conformity assessment in accordance with Annex XI Chapter A under Article 52 of the MDR:

- Customers of **class IIa devices**, other than custom-made or investigational devices, may prepare the technical documentation specified in Annex II and III together with a conformity assessment as specified in Article 10 of Chapter A of Annex XI of the MDR.
- Customers of **class I devices placed on the market in sterile condition, having a measuring function or being reusable surgical instruments** may follow the procedures set out in Annex XI Chapter A. However, UDEM A.Ş. is limited to the following in these procedures:
    - in the case of devices placed on the market in a sterile condition, matters relating to the establishment, securing and maintenance of sterile conditions;
    - in the case of devices with a measuring function, matters relating to the conformity of the devices with metrological requirements;
    - in the case of reusable surgical instruments, considerations relating to the reuse of the device, in particular cleaning, disinfection, sterilisation, maintenance and functional testing and related instructions for use.
- Customers of **Class III custom-made implantable devices** may carry out a conformity assessment as set out in Annex XI Chapter A.

- Customers of **Class III devices** may carry out a conformity assessment as set out in Chapter A of Annex XI of the MDR if the customer holds the EU Type Examination certificates referred to in Article 4 of Annex X of the MDR.
- If the manufacturer has the EU Type Examination certificates referred to in Article 4 of Annex X of the MDR, customers of **class IIb devices** other than custom-made or investigational devices may be subject to a conformity assessment as set out in Chapter A of Annex XI of the MDR.

  In the conformity assessment activities of the systems or packages of procedures referred to in paragraph 1 of Article 22 of the MDR, UDEM A.Ş.'s involvement shall be limited to those aspects of the procedure relating to the maintenance of sterility until the sterile packaging is opened or damaged. In this scope, when UDEM A.Ş. assesses the sterilisation process of systems or process packages according to Article 22(3) of the MDR, the principles applicable to the conformity assessment of class I sterile products are applied. If the system or procedure package contains devices that do not carry the CE marking, or if the selected combination of devices is not suitable for their original intended use, or if sterilisation is not carried out in accordance with the customer's instructions, the system or procedure package is treated as a device in its own right, classified according to the class of the most risky product within the set and subject to the related conformity assessment procedure in accordance with Article 52 of the MDR.In this scope, interoperability and compatibility data are examined, especially for devices that are used together.

The medical device conformity assessment steps are summarized in the **flowchart** below for the initial certification process :

Pre-Application Process

- The purpose of the pre-application process is to verify whether the device covered by the customer's application is within the scope of UDEM A.Ş. authorisation, its class, etc. and to prepare the appropriate offer.
- The customer completes the pre-application form in full. (MDRFRM.01 and Annex-1)
- UDEM A.Ş. reviews the pre-application. If necessary, UDEM A.Ş. may request corrections or additional information/documents regarding the deficiencies in the form.
- UDEM A.Ş. may reject the application if it is of the opinion that the product within the scope of the application is not a medical device, is not within the scope of authorisation or does not have appropriate technical expertise in the related field.

Offer Process

- Based on the information provided by the customer in the pre-application form, UDEM A.Ş. prepares an offer in accordance with MDRLST.06 MDR List of Standard Fees and MDRTLM.05 Charging Instruction, which are available on the UDEM A.Ş. website. (MDRFRM.03)
- The offer is submitted for customer approval.
- The customer approves the offer and forwards it to UDEM A.Ş.

Official Application Process

- After the offer is approved, the customer receives MDRFRM.186 MDR Official Application Notification Letter.
- The customer prepares the commitment attached in this form, signs it and submits it with current QMS documentation, and then the application becomes official.

Contract Process

- After the official application is accepted, UDEM A.Ş. submits a contract containing the duties, authorities and responsibilities of the customer and UDEM A.Ş. (MDRFMR.04)
- The contract is submitted for customer approval.
- The customer signs the contract and submits it to UDEM A.Ş. in two copies with wet signature.

Application Review Process

- UDEM A.Ş. appoints a project leader for each project.
- The customer submits the application documents specified in the contract.
- The application is reviewed again in detail. (MDRFRM.06)

Audit Planning Process

- An audit programme is prepared by UDEM A.Ş. (MDRFRM.23)
- In this scope, the appropriate audit / evaluation team is determined, the sites / suppliers / subcontractors to be visited are determined and the files to be sampled for Class IIa and certain Class IIb devices are determined..
- Audit / assessment plans are prepared by the audit team in accordance with the scope of the application.(MDRFRM.11, MDRFRM.11-1, MDRFRM.11-2)
- Plans are submitted for customer approval 2 days before the audit/assessments.
- The customer has the right to object to the audit team by showing justification (taking into account the principles of impartiality, independence). In this case, UDEM A.Ş. determines a new team.

QMS Preliminary Review Process

- The customer's conformity assessment activity starts with the QMS pre-review process. The QMS pre-assessment can be conducted on-site, desk, remotely or hybrid.
- Within the scope of the QMS preliminary review, the customer's QMS documentation is assessed by the related site auditors. (MDRFRM.13)
- All minor and major non-conformities and observations identified within the scope of the QMS preliminary examination are recorded and shared with the customer. (MDRFRM.22)
- The customer conducts root cause analyses for the nonconformities and determines corrective and preventive action plans. All this information is submitted to UDEM A.Ş. via surveillance and non-conformity form within **30 days at the latest** after the examination. (MDRFMR.22)
- Site auditors review the related root cause analyses and CAPA plans and approve them if appropriate and sufficient. UDEM A.Ş. informs the customer on the same form about the analyses and plans that are not found appropriate, and the customer reviews and revises them according to the feedback of UDEM A.Ş. and submits them again. UDEM A.Ş. approves the related root cause analyses and CAPA plans when considered appropriate.
- The customer carries out the CAPA activities according to the CAPA plan approved by UDEM A.Ş. and submits the evidence documents within **3 months at the latest** after the CAPA plan is deemed appropriate.
- The related evidence documents are evaluated by UDEM A.Ş. If it is found to be inappropriate, UDEM A.Ş. transmits its evaluations on the non-conformity form and the customer is asked to carry out works by taking these evaluations into consideration. UDEM A.Ş. approves the necessary works when it finds them sufficient.

Technical Documentation Assessment Process

- After the QMS preliminary review process is completed, the customer's technical documentation is reviewed by the Project Leader within the scope of the completeness check. (MDRFRM.191). If any deficiencies are detected during the completeness check, it is expected to be corrected within 3 months.
- If no deficiencies are detected after the completeness check, the technical documentation is evaluated by the relevant product reviewers. (MDRFRM.19)
- Specific aspects of the device (sterilisation, software, nanomaterials, etc.) within the scope of the technical documentation are also assessed by the related product reviewers.
- All minor and major non-conformities and inspections identified within the scope of technical documentation assessment are recorded and shared with the customer. (MDRFRM.22)
- In case of missing data showing product safety and performance within the scope of technical documentation assessment, the assessment shall be repeated within **6 months at the latest**. However, if the customer has a justified justification, this period can be extended up to 1 year with the decision of the committee. If the assessment cannot be repeated within 1 year, the application is **REJECTED**.
- The customer conducts root cause analyses for the nonconformities and determines corrective and preventive action plans. All this information is submitted to UDEM A.Ş. via observation and non-conformity form within **15 days at the latest** after the assessment. (MDRFMR.22)
- Product reviewers review the related root cause analyses and CAPA plans and approve them if appropriate and sufficient. UDEM A.Ş. informs the customer on the same form about the analyses and plans that are not deemed appropriate. The customer reviews and revises them according to the feedback of UDEM A.Ş. and submits them again. UDEM A.Ş. approves the related root cause analyses and CAPA plans when considered appropriate.
- The customer carries out the CAPA activities according to the CAPA plan approved by UDEM A.Ş. and submits the evidence documents within **3 months at the latest** after the assessment.
- The related evidence documents are assessed by UDEM A.Ş. If it is found to be inappropriate, UDEM A.Ş. transmits its assessments on the non-conformity form and the customer is asked to carry out works by taking these assessments into consideration. UDEM A.Ş. approves the necessary works when it finds them sufficient.

Clinical Assessment Process

- The customer's clinical documentation is assessed by the related clinical experts. (MDRFRM.15)
- In addition, the customer's PSUR, PMCF and SSCP documents, if any, are also assessed by clinical experts on the related forms. (MDRFRM.28-1, MDRFRM.48-1, MDRFRM.15-1)
- All minor and major non-conformities and observations identified within the scope of clinical documentation assessment are recorded and shared with the customer. (MDRFRM.15)
- The customer conducts root cause analyses for the nonconformities and determines corrective and preventive action plans. All this information is submitted to UDEM A.Ş. via surveillance and non-conformity form within **30 days at the latest**.
- The customer carries out the CAPA activities according to the CAPA plan approved by UDEM A.Ş. and submits the evidence documents of the CAPA activities within **3 months at the latest** after the CAPA plan is deemed appropriate.
- The related evidence documents are evaluated by UDEM A.Ş. If it is found to be inappropriate, UDEM A.Ş. transmits its assessments on the non-conformity form and the customer is asked to carry out works by taking these assessments into consideration. UDEM A.Ş. approves the necessary works when it finds them sufficient.

QMS Site Audit

- All minor and major non-conformities and observations identified during the site audit are recorded and shared with the customer. (MDRFRM.22)
- The customer conducts root cause analyses for the nonconformities and determines corrective and preventive action plans. Transmits all this information to UDEM A.Ş. via observation and non-conformity form within **30 days at the latest** after the examination. (MDRFRM.22)
- Site auditors review the related root cause analyses and CAPA plans and approve them if appropriate and sufficient. UDEM A.Ş. informs the customer on the same form about the analyses and plans that are not found appropriate, and the customer reviews and revises them according to the feedback of UDEM A.Ş. and submits them again. UDEM A.Ş. approves the related root cause analyses and CAPA plans when considered appropriate.
- The customer carries out the CAPA activities according to the CAPA plan approved by UDEM A.Ş. and submits the evidence documents within **3 months at the latest after** the CAPA plan is deemed appropriate.
- The related evidence documents are assessed by UDEM A.Ş. UDEM A.Ş. approves the necessary works when it finds them sufficient. If it is concluded to be inappropriate, UDEM A.Ş. transmits its assessments on the non-conformity form and the customer is asked to carry out works by taking these assessments into consideration. This period is expected not to pass 6 months in any way. In some cases (outsourced processes, tests, infrastructure requirements, etc.), the committee may grant additional time up to 1 year as of the audit date. If the customer fails to close major/minor non-conformities within 6 months, the on-site audit is repeated. If the customer fails to close major/minor non-conformities within 6 months, the on-site audit is repeated.

Follow-up Audit

- In the case of non-conformity of the customer or critical supplier requiring on-site verification within the scope of QMS field audit, a follow-up audit is carried out within **6 months at the latest** after the audit.
- In the case that non-conformities persist or are not found to be effective within the scope of the follow-up audit, a follow-up audit is carried out within 3 months at the latest after the audit.
- If the follow-up audit is also unsuccessful, the related application is **REJECTED.**.

Final Review Process

- After all non-conformities are closed, the customer submits the current QMS, technical and clinical documentation to UDEM A.Ş. to include all non-conformity closure activities before the final review.
- All customer file, CAPA evidence are examined by the final reviewers by taking into consideration the legal requirements and procedure. If deficiencies are detected, UDEM A.Ş. may carry out additional assessment and request additional information / documents. (MDRFRM.36)
- Likewise, the internal clinical expert for the clinical assessment process reviews the clinical documentation and the assessments carried out. If deficiencies are detected, UDEM A.Ş. may carry out additional assessment, request additional information / documents. (MDRFRM.36-1)

Decision Making Process

- After the final review process is completed, the decision-making process is started for the application in question.
- Decision makers review all customer satisfaction and CAPA evidence and record their decision. If deficiencies are detected, UDEM A.Ş. may conduct additional assessment, request additional information / documents. (MDRFRM.35)
- If the deficiencies (if any) are completed, a decision is taken for certification.

Consultation Process

- Authorities are consulted for medical devices containing medicinal substances. If the scientific opinion is positive, the certification process is carried out, in case of negative results, the related application is **REJECTED** and the certificate is not issued.
- For medical devices consisting of substances or combinations of substances that are absorbed by the human body or locally distributed in the human body, the consultation process with the authorities is carried out. If the scientific opinion is positive, the certification process is continued, in case of negative results, UDEM A.Ş. **may REJECT** the related application or continue the process with justification. It transmits its final decision to the medical products advisory authority.
- For class III implantable devices and certain class IIb active devices, a clinical advisory process is carried out to the expert panel. If the expert panel does not provide an opinion within **60 days**, UDEM A. Ş. continues the certification procedure of the device in question. When the expert panel is concerned about the clinical evidence, it can advise the customer for the device in question. UDEM A.Ş. gives due importance to the expert panel opinions. When UDEM A.Ş. does not comply with the expert panel recommendations, it provides a full justification for this situation through Eudamed by the Commission.

Certificate Printing

- After the certification decision is made, the draft document is prepared by UDEM A.Ş. according to the conditions determined by the committee and sent to the customer for control.
- After the customer approves the draft document, the related certificate is printed and forwarded to the customer.

INITIAL CERTIFICATION PROCESS

Pre-Application Process

Companies wishing to receive conformity assessment service in the scope of (EU) 2017/745 from UDEM A.Ş. can reach by phone, e-mail **(mdr@udem.com.tr)** or in person. Applicants are required to submit **the MDRFRM.01 Medical Device Certification Application Form and MDRFRM.01 Annex-1 Product Information**, which can be accessed from the web page, to UDEM A.Ş. by filling in completely and accurately. Irrelevant items can be indicated as N/A. All candidates can access the related application form on our website. By filling out the application form, the applicants will be informed about the company and its products so that UDEM A.Ş. will make an accurate offer to the applicant. The customer signs the **MDRFRM.01 Medical Device Certification Application Form** and accepts the commitments specified in the said form.

Depending on the conformity assessment pathway chosen by the applicant, the application should contain the information set out in chapter 2.1 of Annex IX of the MDR or chapter 6.1 of Annex XI of the MDR. A single MDA/MDN code and all applicable MDS and MDT codes must be specified for each of the devices within the scope of the application. The application form is signed only by the customer or his authorised representative under the MDR (signature circular must be submitted). In case of incomplete or incorrect information entry in the application form, UDEM A.Ş. contacts the customer and requests the necessary corrections. The information in the application form is reviewed during the pre-application review process with the assessment within the scope of MDRFRM.01 Medical Device Certification Application Form Chapter 2. In case the class and rule information specified by the customer for the devices within the scope of the application is determined differently by UDEM A.Ş., the customer is consulted and the reasons are stated. However, in the event that the customer does not accept UDEM A.Ş.'s justifications and there is a dispute regarding the classification, the opinion of the competent authority of the EU Member State where the customer's registered place of business is located shall be sought. In cases where the customer does not have a registered place of business in Turkey or an EU Member State and has not yet appointed an authorised representative, such disputes shall be referred to the Turkish Medicines and Medical Devices Authority or the competent authority of the EU Member State, as applicable if the authorised representative is registered in Turkey or an EU Member State. The conformity assessment process shall be continued according to the opinion of the related authority.

If the device within the scope of the application is not a medical device or is not within the scope of authorisation of UDEM A.Ş. or if UDEM A.Ş. does not have the appropriate resources, the application is REJECTED.

Offer Process

Following the examination of the application form, an offer is created based on the information provided by the applicant in the application form according to **MDRLST.06 MDR List of Standard Fees**, which is prepared on the basis of **MDRTLM.05 Medical Device Charging Instruction** and is publicly available at UDEM A.Ş.'s web site, and communicated to the customer.

The related offer may be revised if the information within the scope of the application changes at any stage of the project.

Official Application Process

If the applicant approves **MDRFRM.03 MDR Offer Form**, **MDRFRM.186 MDR Official Application Notification Letter** is sent to the applicant by the planning responsible to inform the applicant that the application has

become official. After the commitment document specified in the related letter is prepared and signed by the applicant and submitted to UDEM A.Ş. with current QMS documentation, official application process starts. The commitments to be obtained from the applicant with the official application are as follows:

- ✓ A documented description of the procedures that operate to fulfill the obligations arising from the quality management system and required under the MDR and the commitment of the manufacturer in question to implement these 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,
- ✓ Description of the procedures operating to keep the post-market surveillance system and, where applicable, the PMCF plan up to date; procedures to ensure compliance with the obligations arising from the vigilance provisions set out in Articles 87 to 92 and the relevant acts adopted by the Commission; the manufacturer's commitment to implement these procedures,
- ✓ A commitment that no formal application has been made to another notified body for the QMS for the product and products mentioned in the application form within the scope of the same conformity assessment annex,
- ✓ In case of an official application to another notified body or a certificate issued by another notified body within the scope of the MDR for the products covered by the application, a commitment to provide all documentation requested by UDEM A.Ş. during the transfer process.

Official Application Transfer Process

The manufacturer that wants to transfer its official application shall apply to UDEM A.Ş. with **MDRFRM.01 Medical Device Certification Application Form** and **MDRFRM.01 Annex-1 Product Information.** Within the scope of the application, the reason for the withdrawal / rejection of the application made to the previous notified body is also stated in the application form. The process of receiving pre-applications, the pre-application review, offer process, official application process and the application review process are carried out as in the initial certification process. After the customer accepts the offer and the aplication becomes official, **MDRFRM.188 MDR Application Transfer Contract** is signed between the former notified body, UDEM A.Ş. and the manufacturer. At this stage the project leader requests from the previous notified body the customer's documentation (documentation of previous assessments if available, objective evidence of completion of non-conformities, assessment programme). After **MDRFRM.188 MDR Application Transfer Contract** is signed by the parties, the MDRFRM.04 MDR Certification Contract is mutually signed with the manufacturer.

After signature of the contract, the manufacturer is expected to submit its technical documentation. If the previous notified body has not yet carried out an audit/assessment after the contract, the process of appointing the project leader, preparing the audit programme and planning the audit is carried out as specified in the initial certification process.

If any audit/assessment activity was carried out by the previous notified body, the assessment programme, inspection reports and nonconformity reports, if any, are requested from the previous notified body and checked by the project leader and the assessments to be carried out are decided.

Contract Process

When the official application is accepted by UDEM A.Ş., a contract is signed in two copies between the applicant and UDEM A.Ş., which includes mutual legal responsibilities, commitments, compensation and confidentiality requirements for the customer and UDEM A.Ş. The document showing the official validity of the signatory must be sent to UDEM A.Ş. together with a copy of the Trade Registry Gazette or equivalent official document showing the official structure of the customer.

In order for the contract to be valid, the following conditions must also be fulfilled:

- ✓ Making the first payment in the payment plan of the **MDRFRM.04 MDR Certification Contract** and within 3 (three) months and uploading the receipt to UDEM A.Ş.'s system or sending it to UDEM A.Ş. via e-mail,
- ✓ Submitting technical documentation specified in the **MDRFRM.04 MDR Certification Contract** to UDEM A.Ş.'s within 6 (six) months or sending it to UDEM A.Ş. via e-mail.

In order to initiate the conformity assessment process, the customer sends the following information and documents via e-mail or uploads them to the UDEM A.Ş. system.

- Signature circular,
- Trade Registry Gazette,
- A draft EU declaration of conformity in accordance with Article 19 and Annex IV of the MDR for the device model covered by the conformity assessment procedure,
- Technical documentation referred to in Annex II and Annex III of the MDR,
- Documentation of clinical assessment and PMCF in accordance with MDR Annex XIV,
- Documentation of the manufacturer's post-market surveillance system and where applicable, the PMCF plan and procedures established to ensure compliance with the obligations arising from the provisions on vigilance laid down in Articles 87 to 92 and the related acts adopted by the Commission,
- Documentation of the clinical evaluation plan,
- Description of the procedures available to keep the clinical assessment plan up to date, taking into account the state of the art,
- If available, 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),
- For Class III and class IIb devices, a copy of the EU Type Examination certificates referred to in Article 4 of Annex X to the MDR for the application of Annex XI (Part A),
- Visa invitation letter if required,
- Bank receipt or payment receipt specified in the Offer and Contract.

In addition, an additional protocol between the customer and UDEM A.Ş., which regulates the conditions for the submission and review of the technical documentation referred to in Annex II and Annex III of the (EU) 2017/745 Medical Device Regulation, and which is prepared as an annex to the relevant contract, is sent to the medical device manufacturers who have signed the certification contract.

Application Review Process

UDEM A.Ş. assigns a project leader for each project to carry out the related activities in accordance with UDEM A.Ş. procedures (relevant legislation, guidance documents, CS and/or harmonised standards).

The project leader reviews the application through the customer's documentation before preparing the audit programme, in particular whether the device covered by the application is a medical device, whether it contains a specific substance and whether it is an innovative device, and may request additional information to ensure the appointment of qualified experts for each conformity assessment task. Even if a contract is

concluded at this stage, if the device within the scope of the application is not a medical device or is not within the scope of authorisation of UDEM A.Ş. or UDEM A.Ş. does not have the appropriate resources according to the additional documents submitted, the application in question may be REJECTED.

The application review process is completed after the information/documents required to be provided by the customer are received in full.

All applications and test results must be in English or Turkish. UDEM A.Ş. can make evaluations with personnel with the desired qualifications and language skills. After signing the contract, all correspondence with the customer will be in English or Turkish. If the certificates are delivered in a language other than these languages, the customer will be asked to translate them into one of these languages.

Documents will be submitted via the UDEM A.Ş. Software at or by electronic mail. The preferred document format is a paginated, bookmarked PDF using Optical Character Recognition (OCR, searchable format).

Audit Programming Process

The project leader prepares the evaluation programme based on the information in the application form and the customer documentation. Within the scope of the evaluation programme, the conformity assessment activities to be carried out within the scope of a full certification cycle for the related project of the customer, their duration, the sites to be visited, the files to be sampled, if any, and the audit / evaluation teams are determined.

The sampling process is carried out by reviewing the technical documentation of at least one representative device per generic device group (Level 4 EMDN) for **Class IIb devices** and at least one representative device per device category (MDA/MDN code) for **Class IIa devices**. The sampling system is carried out according to the MDCG 2019-13 guideline. For sampling risk classes, at least 15% of the devices in each device category and each generic group are sampled according to the related guideline. For initial certification, this rate can be reduced to 5%.

The following criteria are taken into account when selecting at least one device per group:

- Technology/production method/innovation of design/complexity
- Equivalence information
- Sterilisation methods
- Purpose of use of the device/place of use/indication
- The result of previous related assessments, such as physical, chemical, biological or clinical features
- PMS/Vigilance information

The devices excluded from the sampling process are as follows:

- ✓ Class III devices
- ✓ Class IIb implantable devices (excluding sutures, staples, dental fillings, braces, dental crowns, screws, wedges, plates, wires, pins, clips and connectors)
- ✓ Class IIb active devices intended to administer and/or remove from the body a medicinal product covered by Rule 12

The depth and scope of the technical documentation assessment of Class IIa and IIb devices is the same as the depth of assessment performed for Class III and Class IIb implantable devices.

In addition, the Project Leader performs a completeness check in order to assess whether the technical documentation provided by the applicant within the specified deadlines is of a quality that can be reviewed by product reviewers. If deficiencies are detected after the completeness check, these deficiencies are expected to be submitted to UDEM A.Ş. within 3 months.

Audit Process

The evaluations made within the scope of the conformity assessment process within the scope of the application start with the QMS preliminary examination and technical documentation assessment and then continue with the site audit. Non-conformities related to all audit and evaluation processes are communicated to the customer.

QMS Preliminary Review Process

The evaluation of the applicant's quality management system will be carried out through a two-stage assessment: Stage 1 QMS preliminary review will review the completeness of the applicant's QMS and Stage 2 QMS site audit will review the effective implementation of the applicant's QMS and its compliance with the MDR.

The planning phase of the QMS Preliminary Review Process is carried out by UDEM A.Ş. with different methods depending on the documentation and product / process status of the manufacturer, including desk / on-site / remotely / hybrid. If the manufacturer has an accredited ISO 13485:2016 certificate or EC/EU Certificates according to MDD/MDR, the auditor(s) will review the QMS documentation at the desk; in the absence of related certificates, the audit team will review the QMS documentation at the manufacturer's premises and, if applicable, at the premises of the manufacturer's suppliers and/or subcontractors to verify production and other related processes. If the manufacturer has an accredited ISO 13485:2016 certificate or EC/EU Certificates according to MDD/MDR, but in case of product / process complexity or technology innovation, etc., the pre-examination can be planned remotely or in combination, as an enquiry process with the manufacturer will be required. Within the scope of the hybrid examination, part of the enquiry can be carried out remotely by connecting to the manufacturer and part at the desk or part on-site and part at the desk.

Within the scope of the QMS pre-examination, the availability of the organisation's documentation for the requirements is checked and it is evaluated whether there is any situation that may prevent the site audit. In case of inconsistencies and/or deficiencies in the production processes / supplier information or documentation of the products within the scope of the application and / or uncertainty in the processes, the site audit cannot proceed and the organisation is expected to complete this deficiency.

If it is confirmed during the QMS documentation review that the requirements of the related procedure are fulfilled, on-site QMS audit planning can be started. The time interval between the preliminary examination and on-site audits is reasonably expected not to exceed 6 months. At the end of the six-month period, it is decided whether to carry out additional assessment or on-site audit according to the success of non-conformity closure activities and process change information. This period may be extended if there is no change in the production process / facilities.

Major nonconformities or uncertainties in the processes identified during the preliminary examination constitute an obstacle to the on-site audit. Therefore, it is not possible to continue the on-site audit without closing these nonconformities.

If the evaluation does not achieve its objectives (quality management system documentation is largely insufficient, the majority of data regarding production, quality control stages are missing or inconsistent, etc.), the evaluation may be interrupted and a repeat review may be requested by the evaluation teamThe repetition of the audit is carried out within 6 months at the latest from the date of the incomplete / ineffective audit, but if the manufacturer has justified reasons (outsourced processes, long-term test / validation origin, etc.), this period can be extended up to 1 year with the decision of the certification committee. Within 1 year, if the repeat audit cannot be planned for any reason, the application of the related project is rejected.

Technical Documentation Assessment

For all devices except class I devices and custom-made class III implantable devices, product reviewers are responsible for reviewing the applicant's technical documentation. UDEM A.Ş. can carry out the technical documentation assessment at the office desk / remotely / hybrid. Depending on the product / process complexity or technology innovation, the assessment can also be carried out remotely / hybrid. Within the scope of the hybrid assessment, queries can be made with the remote manufacturer for certain parts of the technical documentation.

At the initial certification stage, if SSCP and PSUR examination is required for the devices assessed, these reports are also evaluated by the relevant product examiners.

It also advises the audit team, and in particular the audit team leader, on aspects of the applicant's design or manufacturing processes that may be particularly related for the on-site audit. Within the scope of technical documentation assessment, the availability of the organisation's documentation for the requirements is checked and it is assessed whether there is any situation that may prevent the site audit. If inconsistencies and/or deficiencies in the production processes / supplier information or documentation of the products within the scope of the application and / or uncertainty in the products / processes are detected, the site audit cannot proceed and the organisation is expected to complete this deficiency.

In the event that the majority of the data indicating product safety and performance are missing, especially within the scope of the technical file assessment (absence of test reports, validation reports, inconsistency in production methodology, inconsistency in quality control processes, lack of product characteristics to prevent examination, etc.), the assessment is repeated. In case of evaluation / audit repetition, an offer is sent to the customer organisation for the related special process according to **MDRTLM.05 Medical Device Charging Instruction**. The repetition of the technical documentation assessment is carried out within 6 months at the latest from the date of incomplete / ineffective assessment, but if the manufacturer has justified reasons (outsourced processes, long-term testing / validation, etc.), this period can be extended up to 1 year with the decision of the certification committee. Within 1 year, if the re-evaluation cannot be planned for any reason, the application of the related project is rejected.

Clinical Assessment Process

Clinical experts are responsible for reviewing the customer's clinical documentation in accordance with UDEM A.Ş.'s procedures for all devices except class I devices and custom-made class III implantable devices.

In the initial certification stage, if SSCP, PMCF evaluation report and PSUR are required by the customer for the evaluated devices, these reports are evaluated by clinical experts.

UDEM A.Ş. uploads the summary of safety and clinical performance prepared by the customer to Eudamed after the validation phase in accordance with MDR Article 32. The SSCP file uploaded to Eudamed must be in PDF format. The PDF file must be downloadable, printable and searchable with the search function in the programme used to view the file. For Class IIa implantable devices and IIb implantable devices referred to in Article 52(4) of the MDR, UDEM A.Ş. shall upload the SSCPs for all devices covered by the issued certificate at the same time as it uploads the issued certificate, even if some SSCPs have not yet been validated and will be validated within the validity period of the certificate. In the revision history in the SSCP document, the manufacturer indicates whether this revision has been validated by UDEM A.Ş. The manufacturer is responsible for translations of the SSCP into other languages as soon as the "main" SSCP is uploaded by the notified body. If the "main" SSCP is in a language other than English, an English translation must be provided by the manufacturer within 90 days after the installation of the "main" SSCP. The manufacturer decides when to translate the first " main" SSCP into other languages in the Member States, depending on when it intends

to place the product on that market. UDEM A.Ş. does not validate translated SSCP documents. These translations are uploaded to Eudamed within 15 days of receipt.

In the event that the safety and performance data regarding the use of the product in the clinic within the scope of clinical documentation assessment are not of sufficient quality and quantity (lack of clinical research / PMCF studies or insufficient at large, etc.), the clinical documentation assessment process may be interrupted by clinical experts and a repeat assessment may be requested. According to Article 54 of the MDR, for class IIb active devices (Rule 12) and class III implantable devices used to administer and/or remove a medicinal product referred to in Article 6.4 of Annex VIII of the MDR, a clinical assessment consultation process may be carried out if necessary and UDEM A.Ş. shall take this opinion into account in the certification process.

Site Audit Process

QMS audit is carried out by site auditors at the organisation's premises and / if applicable, at the premises of the supplier / subcontractor. All audit reports are submitted to the manufacturer via system or e-mail during or after the assessments.

If the audit fails to achieve its objectives (the customer organisation does not allow a site visit, security weaknesses occur, lack of equipment/processes on site, etc.), the audit may be interrupted and a repeat audit may be requested by the audit team. In addition, if a situation that needs to be verified on-site (equipment, process deficiency / non-conformity, test activity non-conformity, site does not meet cleaning / contamination conditions, etc.), a follow-up audit is requested by the audit team. In case of assessment / audit repetition, an offer is sent to the customer organisation for the related special process according to **MDRTLM.05 Medical Device Charging Instruction**.

Follow-up Audit Process

Follow-up audits are planned within **6 months at the latest** after the initial certification audit. In some cases (outsourced processes, tests, infrastructure requirements, etc.) the committee may grant additional time up to 1 year from the audit date. In the event that nonconformities are not closed or new nonconformities are observed during the follow-up audit or the corrective actions applied are not found effective by the lead auditor, a follow-up audit is carried out **within 3 months**. If it is determined that the non-conformities are not eliminated in this follow-up audit, the application is REJECTED.

CAPA Assessment Process

All audit reports are provided to the customer via the system or e-mail during or after the assessments. UDEM A.Ş. may detect non-conformities during conformity assessment activities. The audit team's findings may include major and minor nonconformities categorised by the audit team according to the following principles. In MDR audits, if the same minor non-conformity is detected for two consecutive years, the non-conformity becomes a major non-conformity.

The applicant has to submit the root cause analysis and the remedial action plan for all non-conformities within **30 days**. The period for UDEM A.Ş. to evaluate the correction or corrective and preventive action plan received from the customer **is** also **30 days.** If the plan is deemed inappropriate, the customer is given another 30 days to prepare an appropriate plan. This process is repeated up to 3 times (maximum 90 days) until the plan is found appropriate. For both minor and major nonconformities, the time allowed for the submission of evidence of the implementation of these activities is a **maximum of 3 months** from the acceptance of the corrective action plan. If the objective evidence of corrective actions from the customer is found insufficient by the audit team, the organisation is notified in writing and additional work is requested. This period is reasonably expected not to **exceed 6 months**. In some cases (outsourced processes, tests, infrastructure requirements, the need to

carry out corrective action in case of a large number of devices affected by nonconformity, etc.), the committee may grant additional time up to 1 year as of the audit date. If the customer fails to close major/minor non-conformities within 6 months, the on-site audit is repeated.

The periods within the scope of the CAPA process are operated in the same way in all audits, including surveillance and recertification.

Certification Committee Process

After the QMS and Technical documentation Evaluations are approved for compliance with the relevant requirements, the entire customer file is reviewed by the relevant project leader and forwarded to the certification committee for the final review and decision-making process. UDEM A.Ş.'s certification committee reviews the reports and supporting documentation (including the quality management system and technical documentation provided by the applicant) and may request additional information/documentation or additional evaluation from the client if necessary. The Certification Committee does not make a certification decision without ensuring that all minor and major nonconformities identified are completely closed. If the reviewed documents are complete and sufficient in accordance with MDR Annex VII section 4.7, the MDR decides on the issuance of the certificate and the determination of the certification period, if necessary under certain conditions in accordance with section 4.8 of Annex VII.

When the decision for initial certification and recertification is made, the customer certificate is valid for the specified period from the registration of the certificate. The validity period of the certificates cannot exceed 5 years. The certification committee may restrict certification periods depending on the maturity of the organization's system, its success in nonconformity management, the innovativeness of the device, and the saturation of clinical evidence.

UDEM A.Ş. decides whether the following specific conditions or provisions need to be defined for certification,

- Need for additional clinical research
- Need for additional clinical follow-up
- Indication restriction requirement
- Requirement for patient population restriction
- User restriction requirement

Issuing of Certificate

According to the conformity assessment method chosen according to the decision of the certification committee, the following certificates are prepared as drafts by UDEM A.Ş. and forwarded to the customer for verification. After customer approval, the certificate is printed, checked and sent to the customer in both Turkish and English.

- EU Quality Management System Certificate according to MDR Annex IX Part I and Part III
- EU Technical Documentation Certificate according to MDR Annex IX Part II and Part III
- EU Quality Assurance Certificate according to MDR Annex XI Part A

Certificate Notification Process

UDEM A.Ş. enters into the electronic system referred to in Article 57 of the MDR (EUDAMED) information about certificates issued, including amendments and additions, and certificates suspended, reinstated, withdrawn, cancelled or rejected, and restrictions imposed on certificates. Such information shall be publicly available in accordance with Article 56 of the MDR.

Special processes within MDR

For medical devices containing medicinal substances, after the evaluations of UDEM A.Ş., the opinion of one of the authorities determined by the Member States in accordance with Directive 2001/83/EC, such as TITCK, other EU competent authorities or EMA, is obtained as required according to Article 5.2 of Annex IX of the medical device regulation. If the scientific opinion is positive, certification is carried out; in case of negative results, the relevant application is REJECTED.

For medical devices consisting of substances or combinations of substances that are absorbed by or locally dispersed in the human body according to Article 5.4 of Annex IX of the MDR, TITCK determined by the Member States in accordance with Directive 2001/83/EC, after evaluations by UDEM A.Ş., other EU competent authorities or the opinion of one of the authorities such as EMA is required. If the scientific opinion is positive, the certification process continues; in case of negative results, the relevant application may be REJECTED or the process may be continued with justification. UDEM A.Ş. forwards its final decision to the medical products advisory authority.

According to Article 54 of the MDR, for Class III implantable devices and class IIb active devices intended for administering and/or extracting a medicinal product referred to in Chapter 6.4 of Annex VIII of the MDR, after clinical evaluation evaluation as set out in section 5.1 of Annex IX of MDR, UDEM A.Ş. submits the applicant's clinical evaluation documentation and the evaluation report prepared by the UDEM A.Ş. clinical expert to the European Commission for consultation with the Expert Panel. UDEM A.Ş. shall forward to the Commission the evaluation report of the clinical evaluation, together with the manufacturer's clinical evaluation documentation referred to in points (c) and (d) of Article 6.1 of Annex II of the MDR, as follows:

- clinical evaluation report,
- clinical evaluation updates,
- clinical evaluation plan,
- PMCF plan,
- PMCF evaluation report or a justification for why a PMCF is not applicable.

A consultation procedure is not required in the following cases:

(a) In case of renewal of a certificate issued under MDR,

(b) Where the device has been designed by modifying a device already marketed by the same manufacturer for the same intended use, the manufacturer has demonstrated to the satisfaction of UDEM A.Ş. that the modifications do not adversely affect the benefit/risk ratio of the device, or,

(c) If the principles of clinical evaluation of the device type or category are addressed in the common specifications and UDEM A.Ş. confirms that the clinical evaluation of the manufacturer of this device complies with the common specifications for the clinical evaluation of such device.

If the expert panel, under the supervision of the Commission, decides not to give a scientific opinion based on the criteria (Annex IX, 5.1 (c)) or if no opinion is expressed within 60 days, UDEM A.Ş. continues the certification procedure of the device in question. UDEM A.Ş. gives due importance to the opinions expressed in the scientific opinion of the expert panel.

When the expert panel finds that the level of clinical evidence is insufficient or that this evidence raises serious concerns regarding the benefit-risk determination and the intended use, including the medical indication(s) and consistency with the PMCF plan, UDEM A.Ş. will advise the manufacturer, if necessary, on the following:

- too restrict the intended use of the device to certain patient groups or certain medical indications, and/or,
- to restrict the validity period of the certificate,
- to carry out certain PMCF studies,
- to adapt user manuals or safety and performance briefs, or
- where appropriate, to impose further restrictions on the conformity assessment report.

UDEM A.Ş. provides full justification in cases where the Commission, through Eudamed, does not follow the recommendations of its expert panel.

If, in addition to the clinical evaluation consultation procedure, one of the specific procedures specified in Article 5 of MDR Annex IX is also applicable for the device under conformity assessment, other specific procedures shall be applied before the clinical evaluation consultation procedure is carried out.

POST-CERTIFICATION ACTIVITIES

Once the applicant is eligible for certification, UDEM A.Ş. will continue to evaluate the applicant through regular audits, including:

- Surveillance assessments at least every 12 months in accordance with MDR Annex IX part 3 or MDR Annex XI part 7 (The frequency of surveillance audits may be increased in cases such as the adequacy of the organization within the scope of previous conformity assessment activities, vigilance information, etc.)
- Unannounced on-site audits in accordance with MDR Annex IX part 3 or MDR Annex XI part 7
- Short-notice audits (upon notifications such as vigilance, complaints, etc.)

Surveillance Audit Process

Surveillance audits also include QMS site audits and technical documentation evaluation. Within the scope of surveillance audits, technical documentation evaluations are carried out as follows:

- Evaluation of post-market data and their impact on technical documentation (clinical evaluation, risk analysis, design, user manual, etc.) for device groups not included in the sampling scope
- Full evaluation of a non-sampled technical documentation for devices included in the sampling scope
- In case there are very few devices included in the scope of sampling but within the scope of the certificate, evaluation of post-market data and their effects on technical documentation (clinical evaluation, risk analysis, design, user manual, etc.), even if they have been sampled before
- Partial evaluation of the technical documentation, if it is within the scope of sampling and has been evaluated in previous audits, but there is additional information such as vigilance for the device
- Evaluation of changes, if any

Before the surveillance audits, the customer informs UDEM A.Ş. about the changes regarding the processes within the scope of the certificate via the information form. In this context, the areas to be audited are determined by checking whether there is a change in the scope of the relevant surveillance audit, whether there are changes in the factors affecting the audit period (number of employees of the organization, sites, complexity of processes, products, etc.), the audit period and the personnel to be assigned in the audits / evaluations are determined.

Within the scope of surveillance audits, the customer's processes and subsystems are reviewed and planned, especially for the following:

- Design and development,
- Production and process controls,
- Product documents,
- Purchasing checks including verification of purchased devices,
- corrective and preventive actions, including post-market surveillance, vigilance, and
- PMCF,

and the requirements and provisions adopted by the customer, including those related to the fulfillment of the general safety and performance requirements specified in Annex I, are reviewed and audited.

Within the scope of surveillance audit, UDEM A.Ş. carries out tests or requests tests when deemed necessary to check whether the quality management system is working properly. During on-site audits, the audit team may accompany the manufacturer during any quality control testing and make and sign a copy of the test report to prove this accompaniment. In addition, in case of a suspicious situation within the scope of the audit (use of different raw materials than declared, product safety tests being deemed ineffective, inadequate qualification of the personnel performing input quality control, in-process control or final control tests, device, equipment, machine fluctuations, IQ, OQ and/or or realizing that PQs are used without making them, change in the validation of the sterilization method, change of supplier, addition/removal of external processes, etc.) the audir team can take samples from the site or the market and send them for testing. In the case of Class III devices, the audit team performs a test on approved parts and/or materials necessary for the integrity of the device, including, if appropriate, checking that the quantities of parts and/or materials manufactured or purchased are in accordance with the quantity of finished devices.

UDEM A.Ş. evaluates current SSCP, PMCF and PSURs within the scope of surveillance audits. PSUR reports are updated annually for class III and IIb devices. Accordingly, SSCP documents should also be updated. UDEM A.Ş. uploads the updated SSCP according to the relevant documentation in the technical documnetation each time it is validated, thus replacing the SSCP uploaded in the first certification with the current validated revision. When UDEM A.Ş. receives an updated SSCP document together with PSUR; it must upload the updated SSCP document within 15 days after validation or within 15 days after considering the postponement of validation until a validation is planned according to the relevant documents in the technical documentation during the validity period of the certificate. For Class III devices or implantable devices, UDEM A.Ş. uploads

the PSUR evaluation report to Eudamed after the review phase, with details of all actions taken. For class IIa implantable devices and some class IIb implantable devices specified in Article 52(4), the loading process is limited only to the devices sampled by UDEM A.Ş. within the scope of the relevant inspection.

Especially within the scope of the technical documentation evaluation, if the majority of the data showing product safety and performance is missing, the evaluation is repeated within 1 month. In case of repeat evaluation / audit, an offer is forwarded to the customer organization for the relevant special process in accordance with the **MDRTLM.05 Medical Device Charging Instruction.**

After surveillance audits, follow-up audits are carried out within **3 months** at the latest. If the follow-up decision is written due to a significant non-conformity regarding the safety of the product, the certification committee may decide to suspend the certificate if it is determined that the non-conformity has been demonstrably demonstrated.

If the follow-up audit reveals that non-conformities are not resolved or new non-conformities occur, the customer's certificate is suspended. The suspension period is a **maximum of 6 months** after the certificate is suspended. If the activities are not effective within the given time, the certificate is withdrawn.

If a follow-up audit is required for two consecutive years and is due to different issues, it may be decided to reduce the surveillance audit period from 1 year to 6 months by committee decision, or an audit may be carried out at the customer site. However, if a follow-up audit is required on the same issues for two consecutive years, a decision to suspend the document may be made.

While minor nonconformities detected only within the scope of surveillance audits are closed with a corrective action plan and verification of its effectiveness within the scope of the next surveillance audit; the period required to notify our organization of objective evidence regarding the implementation of corrective actions for major nonconformities is a **maximum of 3 months** after approval of the corrective action plans. UDEM A.Ş. audit team reviews corrective actions from the client and provides feedback on the evaluation to the client organization. If the objective evidence of corrective actions received from the customer is found insufficient by the audit team, the organization is notified in writing and additional work is requested. This period cannot **exceed 6 months** after the approval of corrective action plans. If the manufacturer cannot close major nonconformities within 6 months, the certificate will be suspended.

Recertification Process:

The customer must submit its certificate renewal request along with the Application Form to UDEM at least 6 months before the certificate expires. The manufacturer who is granted the EU Technical Documentation Evaluation Certificate shall submit the **MDRFRM.29 EU Technical Documentation Recertification Form** in addition to the application form. In this context, the customer submits to UDEM A.Ş. a summary of the changes and scientific findings regarding the device before recertification;

a) Any changes to the originally approved device, including changes that have not yet been notified,
b) Experience gained from post-market surveillance,
c) Experience of risk management,
d) Experience gained from updating evidence of compliance with the general safety and performance requirements specified in MDR Annex I,
e) Experience from clinical evaluation reviews, including the results of any clinical trials and PMCF,
f) Changes in the requirements of the device, its components or the scientific or regulatory environment,
g) Implemented or new harmonized standards, changes to OS or equivalent documents and changes to medical, scientific and technical information, e.g.:
   - new treatments,
   - changes in testing methods,

- new scientific findings about materials and ingredients, including findings on their biocompatibility,
- experience gained from studies on comparable devices,
- data from records and logbooks,
- experience gained from clinical studies with comparable devices

Evaluations and re-certification audits carried out within the scope of the re-certification process are planned, implemented and completed in accordance with the flow of the initial certification process, excluding the QMS preliminary audit process. If there are devices that were not sampled in the previous certification cycle, these devices are sampled in the re-certification cycle.

Within the scope of recertification processes, in the last sections of the audit reports, in case the audit objectives cannot be achieved, information on whether a repeat audit is required is provided along with the justification. Especially within the scope of technical documentation evaluation, if the majority of data indicating product safety and performance is missing, the evaluation is repeated. In case of repeat evaluation / audit, an offer is forwarded to the customer organization for the relevant special process in accordance with the **MDRTLM.05 Medical Device Pricing Instruction.**

During the certificate renewal process, UDEM A.Ş. uploads the updated SSCPs of all devices covered by the reissued certificate as soon as it installs the reissued certificate. The manufacturer must provide updated translations to UDEM A.Ş. within 90 days of uploading the updated “master” SSCP. UDEM A.Ş. uploads the translations within 15 days of receiving these translations from the customer. During the recertification process, the evaluation of nonconformities is carried out as in the initial certification process. All minor and major nonconformities must be closed with evidence. The decision for re-certification is made in the same way as for the first certification.

A new certificate is issued after the re-certification decision is taken by the Certification Committee. The date of issue of the first certificate is also stated in the new certificate. The validity period of this new certificate cannot exceed 5 years from the date of the recertification decision. The certification committee may make restrictions based on the data in the document cycle according to the validity period of the previous certification.

If recertification evaluations are not completed prior to the certificate validity date or if it cannot be verified that corrective actions have been implemented for any nonconformances, recertification will not be recommended and the validity of the certificate will not be extended. The customer is informed about this and the results are announced.

Unannounced Audit Process

Announced and unannounced on-site inspections are carried out at the facilities of the applicant and, where appropriate, its suppliers and/or subcontractors. These audits are carried out at least one day and with at least two site auditors, at least one of whom has the required MDT code(s) for medical device technology. This duration is increased according to the number of suppliers and / or subcontractors.

The frequency of unannounced audits is determined according to the customer's certification period. At least 1 unannounced audit is performed in each document cycle. The frequency of unannounced audits is being increased as a result of the information transmitted to UDEM A.Ş. from EUDAMED in accordance with MDR Article 92 (vigilance) and MDR Article 100 (market surveillance). The high risk of the device in question, the observation of a high number of non-conforming products during surveillance audits, unusually high frequency of negative feedback such as post-market vigilance, high number of complaints for the products in question compared

to industry norms, and the presence of information about the manufacturer/devices received through authorities or media organs are the processes that increase the frequency of unannounced audits.

Within the scope of unannounced audits, the compliance of critical components and materials, preferably recently produced and used from ongoing production, with traceability records and the conditions specified in the QMS documentation is verified.

During unannounced audits, at least 2 critical processes (exp: sterilization, packaging, input control, design control, etc.) are reviewed in detail, taking into account product safety and customer non-conformities.

As part of these unannounced on-site audits, site auditors may test a sample of manufactured devices or a sufficient sample from the manufacturing process to verify that the manufactured device complies with the technical documentation, except for individual Class III implantable devices. If there are not sufficient samples at customer facilities, samples can be taken from the market.

If a significant nonconformity regarding the safety or performance of the product is noted within the scope of the unannounced audit, the Lead Auditor notifies the manufacturer of the recommendation to stop production. Additionally, in such cases, if the Certification Committee determines that non-conformity has been demonstrated in a demonstrable manner, the certificate may be suspended.

Certificate Transfer Process

If the manufacturer requests to transfer the certificate issued by another notified body to UDEM A.Ş., UDEM A.Ş. signs a tripartite contract with the old notified body and the customer after the application evaluation and bidding processes.

A transfer agreement is signed between the customer, the former notified body and UDEM A.Ş., containing the following information;

a) the date on which certificates issued by the old notified body become invalid;
b) the last date by which the identification number of the old notified body may be stated in the information provided by the customer, including in any promotional material;
c) transfer of documents, including confidentiality issues and property rights;
d) the date on which the conformity assessment tasks of the old notified body are assigned to the new notified body;
e) last serial number or batch number for which the old notified body is responsible.

After the transfer agreement, the customer submits to UDEM A.Ş. the following documentation regarding the conformity assessment activities regarding the certificate issued by the former notified body:

1. Customer documentation (documentation of previous assessments, objective evidence of completion of nonconformities, etc.) and technical information
2. Information that the customer has not made an agreement with the old notified body for the continuation of certification and cancellation of the contract,
3. Mutual agreement on when the certificate will be cancelled by the old notified body and when the new notified body will issue the certificate,
4. The last serial number or batch number for which the old notified body was responsible,
5. Validity date and certificate number of the current certificate

UDEM A.Ş. evaluates the incoming documentation and decides on the conformity assessment activities to be carried out and their scope. The old notified body shall withdraw the certificates issued for the relevant device provided by the Voluntary Transfer Agreement on the date they become invalid. After the transfer audit / evaluations, the certification decision is carried out as in the first certification process.

If there is a medicinal product scientific opinion or clinical consultation result previously received from the competent authority or EMA and there is no change in the medical device, no additional opinion process will be carried out. UDEM A.Ş. review the opinions of the competent authority and, if necessary, may restrict the certificate to be transferred or reject the transfer application.

Change Notification Process:

Plans for changes and modifications related to the documentation and/or processes evaluated during the certification process (planned changes regarding the QMS system and planned changes regarding the approved device) are notified by the customer organization to UDEM A.Ş. in accordance with the **MDRFRM.04 MDR Certification Contract** signed at the beginning of the conformity assessment, and UDEM A.Ş. evaluates the change within the scope of this notification.

The client organization informs UDEM A.Ş. before making any changes to any of the following:

- ✓ Approved quality management system or systems or product groups within the scope,
- ✓ Approved design of a device,
- ✓ Intended use of the device or claims made for the device,
- ✓ Any substance used or integrated in the manufacture of a device and subject to special procedures in accordance with Article 4.5.6 of MDR Annex VII.

When necessary, UDEM A.Ş. may plan additional short-notice audit/evaluation within the scope of evaluating whether the relevant change continues to meet the legislative requirements. UDEM A.Ş.'s relevant change may indicate non-compliance after evaluation. If the customer organization completes the non-conformities, the relevant change is considered approved by UDEM A.Ş. and an additional certificate is issued if necessary.

Expansion of the scope of the certificate is handled by UDEM A.Ş. within the framework of the evaluation of the changes. To extent the scope of a customer's certification to include additional sites, products, processes or services, a new application form will be completed by the customer. The areas to be included in the scope are evaluated by UDEM A.Ş. as in the initial application process, according to the applicable procedure.

Vigilance Process:

When UDEM A.Ş. receives information on the vigilance status of the customer organization from the customer or the competent authorities or from the market surveillance reports required to be provided from EUDAMED according to Article 92 of the MDR and/or Article 100 of the MDR, it decides which of the following options will be applied;

- ➢ Not taking action on the grounds that the vigilance status is not related to the certificate issued,
- ➢ observe the activities of the customer and the competent authority and the results of the customer investigation to determine whether the issued certificate is at risk or whether sufficient corrective action has been taken,
- ➢ take extraordinary surveillance measures, such as document reviews, short-notice or unannounced audits and product testing, when the issued certificate is likely to be at risk,
- ➢ increase the frequency of surveillance audits,

- reviewing specific products or processes on the occasion of the client's next audit.

Reasons for Certificate Suspension, Withdrawal, Cancellation, Scope Reduction:

Decisions such as suspension, withdrawal, scope reduction or cancellation of the customer's certificate may be taken for the following reasons.

Suspension Requirements

UDEM A.Ş. suspends its customers' certificates in the following cases:

- If the customer consistently and seriously fails to fulfill the certification conditions for certified products,
- If the customer does not allow surveillance and recertification audits to be carried out as frequently as required by the contractual terms,
- If the customer voluntarily requests temporary suspension,
- If, after the audits, the customer has not completed its corrective and preventive actions within the periods specified in the observation and nonconformity form submitted to the organization,
- If it is proven that there is a clinical safety problem in the product as a result of the competent authority and UDEM A.Ş. evaluations carried out in case of a negative event within the scope of vigilance notifications,
- If UDEM A.Ş. determines a difference between the samples taken from the manufactured devices or the market and the features specified in the technical documentation or the approved design, and if this change may cause a negative event, UDEM A.Ş. suspends the relevant certificate.
- In accordance with MDR Article 10, if the organization does not cooperate or the information and documents provided are incomplete or incorrect, suspension is applied until the organization cooperates or provides complete and accurate information.
- According to Article 32 of the MDR, for implantable devices and class III devices; if the summary of safety and clinical performance is not updated in Eudamed, the location of the summary of safety and clinical performance is not identified on the label/instruction for use, or the safety and clinical performance summary is not made publicly available through Eudamed, suspension will apply.
- According to Article 86 of MDR; If the customer does not update or make available the “PSUR” (Periodic security update report) according to the period given below for each device class, suspension will be applied;
  - Class IIb and Class III devices; customer will update the PSUR at least once a year and make it available to the competent authorities.
  - Class IIa devices; customer updates the PSUR when necessary and every two years and makes it available to the competent authorities.
  - Class III or implantable devices; customer will submit the PSUR to UDEM A.Ş. and, upon request, it will be forwarded to the competent authorities via the Electronic System.
- If there is a significant nonconformity regarding product safety that emerges during surveillance audits and requires follow-up audit and there are situations that threaten the health of the user (such as unsafe sterilization process, use of suspicious raw materials), the audit team submits the relevant nonconformities to the committee within 3 business days after they are reported, may decide to suspend the relevant EU Certificate depending on its criticality. (Critical situation: It is required to decide to stop the production of the product on the grounds that it threatens the patient's health.)
- If it is seen that the non-conformities are not resolved or new non-conformities occur during the follow-up audit, the customers certificate will be suspended.

- If a follow-up audit is required for two consecutive years and the reason for the follow-up is due to the same items; relevant EU certificates may be suspended with the approval of the committee. In case of suspension, unannounced audits may be carried out.

In case of suspension conditions, planning responsible UDEM A.Ş. registers it in the Customer Portal and reports this customer to the project leader. The planning responsible is responsible for tracking the information and documents received from the customer during the suspension and unsuspension process. Relevant information, documents and documents are forwarded to the project leader, and the next processes are planned by the project leader.

UDEM A.Ş. informs the customer about the committee's suspension decision. The status of the customer whose certificate has been suspended can be accessed via EUDAMED. During the suspension, the customer's certificate is temporarily invalid. Therefore, the client should avoid any activity that may advertise the client certificate during this period. In case of suspension or withdrawal of certification, the organization must stop the use of logos and certificates. (See Logo and Certificate Usage Instructions).

* In cases where the reason for suspension does not allow the customer's surveillance and recertification audits to be carried out as frequently as required by the contract terms, the relevant certificate is suspended and the document remains suspended until the audit in question is scheduled. When an audit is planned, the relevant document is taken down and the audit is carried out.

The suspension period cannot exceed 6 months. If the customer does not apply for a follow-up audit within 6 months after the certificate is suspended, additional time may be granted or the certificate may be withdrawn by the decision of the Certification Committee. The suspension process is carried out by UDEM A.Ş. is tracked by software. After the suspension period, a follow-up audit is carried out for the relevant customer and it is evaluated whether the situation and/or non-conformities that caused the suspension of the document have been eliminated. If the result of the follow-up audit is negative, the scope of the document is narrowed, if appropriate, or the certification committee decides to withdraw the certificate.

Reinstating of Certificate

The planning responsible is responsible for tracking the information and documents received from the customer during the suspension process. Relevant information, documents and documents are forwarded to the project leader, and the next processes are planned by the project leader.

If the results of the evaluations for corrective actions and/or the follow-up audit, if necessary, are positive or if an audit that cannot be carried out with a reason for suspension is planned, the decision to suspend the certificate is taken by the certification committee based on the audit report prepared. After the committee decision, the EU certificate is re-issued with the revision number.

Withdrawal of Certificate

The certification of the customer whose certification is suspended and who does not complete the nonconformities or fulfill any of the certification conditions within the suspension period will be withdrawn. Withdrawal of the certificate means cancellation of the customer's document by UDEM A.Ş. and termination of the contract. UDEM A.Ş. informs the client about the committee's withdrawal decision. If the customer whose certificate has been cancelled wants to receive service from us, it must apply to our company again. The planning officer is responsible for tracking the information and documents coming to UDEM A.Ş. during the relevant process. Relevant information, documents and documents are forwarded to the project leader, and the next processes are planned by the project leader.

If the customer does not apply for a follow-up audit within 6 months after the certificate is suspended, additional time may be granted or the certificate may be withdrawn by the decision of the Certification Committee.

The certificate is withdrawn under the following conditions:

- Failure to fulfill the manufacturer's obligations regarding product safety and performance specified in the contract,
- Customer's failure to eliminate the reasons for suspension,
- The customer does not confirm that follow-up inspections, if necessary, have been carried out at the end of the suspension period,
- Failure to close the nonconformities revealed during follow-up audits to eliminate the suspension situation within the stipulated time,
- Deceptive and unfair use of the certificate in product or service areas other than those declared by the customer within the scope of the certificate,
- If UDEM A.Ş. detects differences between the samples taken from the manufactured devices or the market and the features specified in the technical documentation or the approved design, and if these changes may cause serious adverse events, UDEM A.Ş. withdraws the relevant products.
- There is no customer at the factory address declared in the certificate,
- Falsifying certificates, attachments and records,
- If it is proven that there is a serious clinical safety problem in the product as a result of the competent authority and UDEM A.Ş. evaluations carried out in case of a serious adverse event within the scope of vigilance notifications.,
- If the multi-site customer does not inform UDEM A.Ş. about the closure of any site or branch, the certificate will be withdrawn. If the head office or any of the sites fail to meet the requirements for maintaining certification, the certification will be completely cancelled.
- In the first audit conducted for a suspended company, if reasons for re-suspension are found, a decision to withdraw is taken.

If the certificate is withdrawn, the customer organization must fulfill the following obligations:

- To end the use of UDEM A.Ş.'s certificates and logos,
- To waive all rights under the withdrawn certificate,
- To pay outstanding fees for audits and evaluations previously carried out by UDEM A.Ş..

The client organization is expected to remove the UDEM A.Ş. logo from all correspondence and promotional materials within one month following the withdrawal of the certificate. Otherwise, UDEM A.Ş.;

- Informs the relevant competent authority and other notified bodies,
- The customer declares that the organization has used the certificate illegally by violating the terms of the contract in various broadcasting organizations,
- Takes legal action to eliminate the material and moral damages that may arise as a result.

In addition, customers whose certificates are withdrawn must stop all activities related to certification and advertising. Otherwise, UDEM A.Ş. will take legal action. After this period has passed, if the customer wishes to receive re-certification service, the first certification process is started.

If the customer does not apply for a follow-up audit within 6 months after the certificate is suspended, additional time may be granted or the certificate may be withdrawn by the decision of the Certification Committee.

Cancellation of Certificate

The planning responsible is responsible for tracking the information and documents coming to UDEM A.Ş. during the certificate cancellation process. Relevant information, documents and documents are forwarded to the project leader, and the next processes are planned by the project leader.

The certificate is cancelled under the following conditions:

- Failure to fulfill administrative and financial obligations in the contract,
- Upon customer's request,
- Bankruptcy of the customer and termination of activities within the scope of certification,
- Change in the legal entity of the customer.

If the certificate is cancelled, the customer organization must fulfill the following obligations:

- To end the use of UDEM'A.Ş.'s certificates and logos,
- To waive all rights under the cancelled certificate,
- To pay outstanding fees for audits and evaluations previously carried out by UDEM A.Ş.,

Customer organization UDEM A.Ş. It is expected to remove its logo from all correspondence and promotional materials within one month following the withdrawal of the certificate. Otherwise, UDEM A.Ş.;

- Informs the relevant competent authority and other notified bodies,
- The customer declares that the organization has used the certificate illegally by violating the terms of the contract in various broadcasting organizations.,
- Takes legal action to eliminate the material and moral damages that may arise as a result.

In addition, if the customer organization does not request re-certification, if the production/service within the scope of the certificate is terminated or if the company is closed, the certificate will be cancelled and announced to the public.

In addition, customers whose certificates have been cancelled are required to stop all activities related to certification and advertising. Otherwise, UDEM A.Ş. will take legal action. After this period has passed, if the customer wishes to receive re-certification service, the first certification process is started.

Reduction of Scope of Certificate

The planning responsible is responsible for tracking the information and documents coming to UDEM A.Ş. during the process of reduction the scope of the certificate. Relevant information, documents and documents are forwarded to the project leader, and the next processes are planned by the project leader.

The scope of the certificate is reduced under the following conditions:

- If the customer persistently and seriously fails to fulfill the certification requirements for a part of the product certification scope,
- If UDEM A.Ş. determines differences between the samples taken from the manufactured devices or the market and the features specified in the technical documentation or the approved design, if these changes may cause serious negative events, UDEM A.Ş. resduces the scope of the certificate by taking into account the relevant products.

UDEM A.Ş. reduces the scope of the customer's product certification to exclude the part that does not meet the requirements. When the scope of Product Certification is reduced, the customer must replace all advertising materials. CE Marking must be removed on products excluded from the scope.

- The scope of certification can also be reduced at the request of the customer.

EU Declaration of Conformity and UDEM A.Ş. product certificate are requested from the customer whose scope has been reduced. A new certificate with a new scope is issued and then sent to the customer.

- The need for scope reduction may arise during audits or if the customer does not comply with the required conditions.

Generally, audits are not carried out to reduce the scope. The status of the customer whose scope has been reduced is published on the website of UDEM A.Ş..

Use of logo, mark and certificate

The use of Logo, CE Mark and Certificate is defined as **TLM.02-01 Product Logo Mark and Certificate Usage Instruction**. This instruction is available at www.udem.com.tr.

Complaints and Appeals

The applicant may appeal or complain about any findings and decisions of UDEM A.Ş.. The relevant process is carried out in accordance with the **PD.09 Procedure for Handling Complaints and Appeals** available on UDEM A.Ş.'s website.

STRUCTURED DIALOGUE PROCESS

Structured dialogues may be organized between the manufacturer and UDEM A.Ş. in order to increase the efficiency and predictability of conformity assessment activities. Structured dialogues are conducted face-to-face by MDTRR and/or Project Leader in coordination with the Planning Reponsible. If needed, the Internal Clinical Expert/relevant Clinical Expert may also participate in the structured dialogues.

As part of the structured dialog, UDEM A.Ş. can provide the manufacturer with a comprehensive overview of;

- Information on the certification process, including pre-application and application process
- Project plans
- Delivery conditions (documents to be provided by the manufacturer, acceptable languages, etc.)
- Requirements for reporting the change
- Use of guidance, standards and common specifications
- Costs and timelines
- Exchange of views on the adequacy of clinical data
- Only a description of the requirements, without advice from the manufacturer on "how to do it".

Within the scope of structured dialogues between UDEM A.Ş. and the manufacturer, including the activities outlined below as general examples, any issue that may compromise impartiality, independence and objectivity should not be discussed.

- Gap analysis of the manufacturer,
- Checking the MDR readiness of the manufacturer,
- Review of demo files for MDR compliance,

- Review of the clinical development strategy,
- Providing technical solutions,
- Explanation of how the manufacturer must meet specific regulatory requirements.