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1. PURPOSE

The purpose of this procedure is to define the methods and responsibilities regarding the classification, evaluation, recording, and resolution of all feedback by UDEM A.Ş. (appeals, complaints, and requests for information).

2. RESPONSIBILITIES

- General Manager
- Coordinator
- Quality Unit
- Complaint and Appeal Evaluation Committee
- Relevant Department Manager
- Technical Regulation Responsible
- Laboratory Manager
- Laboratory Responsible
- Administrative and Financial Affairs Unit
- Legal Advisory Office (Company Attorney)

3. DEFINITIONS

Complaint: An expression of dissatisfaction received from any individual or organization regarding the activities of UDEM A.Ş., with the expectation of a response.

Appeal: A request made by a customer to UDEM A.Ş., the relevant competent authority, or the accreditation body for the reconsideration of a decision regarding the certification of their management system and/or product, or the test results reported by the laboratory.

Request for Information: Official correspondence sent legal channels, accreditation bodies, competent authorities, and other parties regarding UDEM A.Ş.'s activities, specifically in processes where UDEM A.Ş. is directly involved or where its information is sought as a third party.

4. IMPLEMENTATION

UDEM A.Ş. makes this document, which defines how it handles complaints, appeals, and information requests submitted to it, available to the public on its website.

Complaints and appeals received verbally or in writing by UDEM A.Ş. personnel are recorded using **the FRM.38 Complaint and Appeal Evaluation Form** by the relevant personnel and forwarded to the Quality Unit for evaluation.

Information requests submitted to UDEM A.Ş. are evaluated by the Quality Unit and/or the Technical Regulation Responsible or Laboratory Manager/Laboratory Responsible of the relevant department based on their content. As a result of this evaluation, it is determined whether the information request is solely intended to provide information or documents, or whether it constitutes a complaint.

The evaluation and decision criteria for classifying information requests as complaints are defined in Section 4.3.3. For notifications determined to be complaints under Section 4.3.3, the **FRM.38 Complaint and Appeal Evaluation Form** is completed, and the process is conducted as a complaint under Section 4.1.

Notifications assessed as not constituting a complaint are treated as information requests, and in such cases, the **FRM.38 Complaint and Appeal Evaluation Form** is not completed.

The Quality Unit records all complaints, appeals, and information requests received by UDEM A.Ş. in the **FRM.220 Feedback Tracking Table** and ensures that the process is carried out in accordance with the steps defined in this procedure, depending on the type of feedback.

The matter subject to the request for information addressed within the scope of the complaint or appeal is evaluated by a committee formed by selecting members from the Complaints and Appeals Evaluation Committee who possess the necessary expertise to assess the relevant field. The evaluation results, the activities carried out, the date of resolution of the complaint/appeal/information request, the reasons for its occurrence, and any processes affected, if any, are recorded by the Quality Unit in the relevant sections of the **FRM.220 Feedback Tracking Table**.

During periodic management review meetings, the Quality Unit informs Top Management regarding complaints, appeals, and information requests received by UDEM A.Ş. during the relevant year and recorded in the **FRM.220 Feedback Tracking Table**.

All individuals whose opinions are sought at every stage of the process—from the receipt of a complaint, appeal, or information request through to its resolution—are obligated to act in accordance with the principles of impartiality, independence, and confidentiality. The process is safeguarded by the contracts and commitments defined in the **PD.04 Provision Of Resources Procedure** and mutually signed by the committee members.

If the complainant does not accept the proposed resolution, the complaint is converted into an appeal, and the process is conducted as appeal under Section 4.2

When evaluating complaints, appeals, and requests for information, the outcomes of previous similar complaints and appeals are taken into account.

The committee evaluating the complaint and/or appeal determines the necessity of sharing the subject of the complaint and appeal, the resolution method, and the results with the public, as well as the scope of such sharing if applicable.

Information regarding the customer obtained from sources other than the customer (such as the parties filing the complaint, appeal, or information request, accreditation bodies, competent authorities, etc.) is handled confidentially in accordance with UDEM A.Ş.'s principles.

4.1 Evaluation of Complaints:

Complaints received by UDEM A.Ş.;

1. Notifications received from UDEM A.Ş.'s customers or other relevant parties (competent authorities, the European Commission, accreditation bodies, market surveillance authorities, industry representatives, and the Turkish Republic's CİMER-Presidential Communication Center, Judicial Authorities, etc.) regarding UDEM A.Ş.'s product, system certification, and laboratory activities,
2. Notifications regarding other processes affecting the services provided by UDEM A.Ş.,
3. Court decisions, information requests, and summonses legally served to UDEM A.Ş.,
4. Negative situations mentioned in customer satisfaction surveys may also be included.

UDEM A.Ş. personnel who receive complaints verbally or in writing submit the **FRM.38 Complaint and Appeal Evaluation Form** to the Quality Unit. When the Quality Unit reviews the complaint, it must first confirm whether the complaint relates to UDEM A.Ş.'s operations and, if so, address it.

The Management Representative forms a committee by selecting appropriate members from the **LST.10 Complaint And Appeal Evaluation Committee List**, depending on the subject of the complaint.

If the complaint concerns the Quality Unit, the General Manager is responsible for evaluating the complaint and forming the committee, and appoints the Industry Department Manager or Coordinator as the committee chair. Industry Department Manager/Coordinator, selected as the committee chair, forms a committee by identifying two additional members from the **LST.10 Complaint And Appeal Evaluation Committee List** who are qualified to evaluate the matter.

If the complaint concerns one of the committee chairs, one of the other committee chairs listed in the **LST.10 Complaint And Appeal Evaluation Committee List** forms the complaint committee.

In cases where the complaint concerns all committee chairs, the General Manager designates an appropriate committee chair from among the members listed in the **LST.10 Complaint And Appeal Evaluation Committee List** and the designated committee chairperson forms a committee by

selecting two additional members from the **LST.10 Complaint And Appeal Evaluation Committee List** who are qualified to evaluate the matter.

The committee tasked with investigating the complaint shall be composed of individuals who possess the necessary expertise to evaluate the matter and can demonstrate their competence. If the complaint has been submitted through legal channels and involves a legal process, the committee must include the company's legal counsel. Additionally, these individuals must be distinct from those involved in the suitability assessment processes and must have no connection to the circumstances giving rise to the complaint. When forming the committee, family relationships are taken into account to ensure that no relatives, friends, or associates of the employee subject to the complaint are included. If the employee subject to the complaint holds a higher hierarchical position than the committee members, the assessment is presented to the Safeguarding Impartiality and Advice Committee members at the next meeting of the Safeguarding Impartiality and Advice Committee.

At least one chairperson and two members must be present for the committee to convene. The committee makes decisions by unanimous consent. In cases where unanimous consent cannot be reached, a new meeting is held within one week at the latest, with the participation of alternate members who possess the necessary expertise to evaluate the relevant matters.

Committee members report their findings, along with any additional actions, information, documents, or records they deem necessary, to the Management Representative. If the evaluation conducted by the committee determines that the incident subject to the complaint stems from a non-conformity originating from UDEM A.Ş., the Management Representative initiates corrective/preventive and improvement actions.

The Complaint Evaluation Committee must convene within 5 business days of the date the complaint is officially received by UDEM A.Ş. and report the evaluation results to the Quality Unit using the **FRM.35 Committee Meeting** Report.

The acceptance, investigation, and resolution of complaints are handled in a manner that does not result in discriminatory treatment against the party submitting the complaint. The final decision made is the responsibility of the committee members and therefore UDEM A.Ş.'s.

The Quality Unit notifies the complainant in writing, of the actions to be taken regarding the complaint and the responsible parties within one week at the latest. The Quality Unit notifies the complainant in writing of the results of the actions taken within one month at the latest from the date the complaint was received.

When a review, evaluation, and/or testing activity is deemed necessary to investigate a complaint, the relevant activities are planned and carried out.. All activities carried out within this scope are performed in accordance with the documented requirements of the relevant activity.

Depending on the nature of the complaint, activities such as conducting a short/unannounced on-site audit, partially or completely re-assessment the relevant parts of the activities or processes in question, thoroughly reviewing all records related to testing activities (raw data, device outputs, environmental conditions, personnel competence, equipment used, etc.), and verifying the compliance of the relevant process with documented methods and standards may be implemented if deemed necessary.

The method and scope to be applied will be determined by considering the content of the complaint, the risk level, and the sufficiency of the available evidence, and all activities performed will be recorded.

The Quality Unit is responsible for monitoring the process, which includes stages such as the evaluation of the complaint, the actions to be taken, the initiation of corrective/preventive and improvement actions if deemed necessary, the closure of the case, and the results of implementation.

If the complainant does not receive any response within 6 months as a result of the activities conducted by UDEM A.Ş. regarding the complaint, the complaint process is considered closed.

4.1.1 If the Complaint/Appeal Concerns Test Results and Methods, the Following Steps Are Followed:

Within the scope of laboratory activities, the following are defined as complaints: failure to deliver the test report by the specified time; incorrect entry of information such as customer details, standard name/number, or date in the report despite the test result being correct; late, inappropriate, or incorrect communication by personnel contacting the customer; and feedback regarding test fees. Feedback classified as appeals, on the other hand, refers to instances where the customer states that the relevant test result is incorrect and/or incomplete.

When a complaint is received, an evaluation is conducted by individuals independent of the situation in question, and necessary actions are initiated. If an appeal is received, the test is repeated. If the repeated test yields the same result as the initial test, the cost of the test is borne by the customer. If the customer is found to be justified in their complaint based on the result of the repeated test, no additional fee is charged to the customer.

However, in cases where only one Test Expert competent in the relevant test activity is present within the laboratory, or if a witness sample/device is not available, objections and complaints are handled using the following alternative evaluation methods:

- All records related to the relevant test process (raw data, device outputs, environmental conditions, calibration status of equipment used, method steps, etc.) are reviewed in detail,
- The accuracy and conformity of the applied test method to the standard are verified through documentation,
- Measurement uncertainty related to the test process is analyzed comparatively with validation/verification records and previous similar test results,
- If deemed necessary, in order to ensure impartiality, the opinion of a competent technical expert from outside the laboratory is obtained, or the verification of the relevant test in a suitable external laboratory is evaluated,
- The entire evaluation process is recorded and a decision is made together with its technical justifications.

For both complaints and appeals, in addition to the activities planned during the evaluation, the need to initiate corrective and/or improvement actions is assessed by the Management Representative and, if deemed necessary, initiated.

Complaints and appeals are accepted and recorded without any preconditions, and are evaluated impartially, accessibly, and fairly based on available information, documents, and records. Even if a witness sample or device cannot be provided, the application will not be rejected; the evaluation will be carried out using available data and alternative examination methods.

The Quality Department informs the customer in writing via email within one week at the latest that the complaint and/or appeal has been received by UDEM A.Ş. and will be evaluated in accordance with this procedure. Based on the decision resulting from the initial evaluation of the complaint/appeal, the Quality Unit will notify the complainant/appeal holder in writing via email, within one week of the date the complaint/appeal was accepted, regarding the actions to be taken and the responsible parties. Within one month of the date the complaint/appeal is received, the Quality Unit will notify the complainant/appeal holder in writing via email of the results of the actions taken. This timeframe may vary depending on the duration of the test in question, provided that the reasons for any extension are documented.

If UDEM A.Ş. does not receive a response from the complainant/appeal holder within 6 months as a result of the activities it carries out within the scope of the complaint/appeal, the complaint/appeal in question will be considered closed.

4.2 Evaluation of Appeals:

Appeals received by UDEM A.Ş.;

1. Notifications received from UDEM A.Ş.'s customers or other relevant parties (competent authorities, the European Commission, accreditation bodies, market surveillance authorities, industry representatives, and the Turkish Republic's CİMER-Presidential Communication Center, judicial authorities, etc.) regarding UDEM A.Ş.'s product, system certification, and laboratory activities,
2. Notifications regarding other processes affecting the services provided by UDEM A.Ş.
3. Court decisions, information requests, and summonses communicated to UDEM A.Ş. through legal channels,
4. Cases where the complainant does not accept the proposed solutions.

The personnel who receives the appeal at UDEM A.Ş., fills out the **FRM.38 Complaint and Appeal Evaluation Form** and forwards it to the Quality Unit. When reviewing the appeal, the Quality Unit must first confirm whether the complaint relates to UDEM A.Ş.'s operations or its customers, and if so, address it accordingly.

Depending on the subject of the appeal, the Management Representative forms a committee consisting of an appropriate chair and two members selected from the **LST.10 Complaint And Appeal Evaluation Committee List**. When determining this team, familial relationships are taken into account; thus, relatives, close associates, or friends of the employee subject to the appeal cannot be part of the team. The committee makes decisions by unanimous vote. In cases where consensus cannot be reached, a new meeting is convened within one week at the latest, with the participation of alternate members who possess the necessary expertise to evaluate the relevant areas.

The evaluation team reports its findings, along with any additional action or documentation requests deemed necessary, to the Management Representative. If the evaluation team determines, as a result of the investigation, that the incident subject to the appeal stems from a non-conformity originating from UDEM A.Ş., corrective/preventive or improvement actions are initiated by the Management Representative.

If a re-audit is required to investigate the appeal, a short-term audit process is conducted. Short-term audits are carried out in accordance with the documented requirements of the relevant activity.

When a review, evaluation, and/or testing activity is deemed necessary to investigate an appeal, the relevant activities are planned and carried out.. All activities carried out within this scope are performed in accordance with the documented requirements of the relevant activity.

Depending on the nature of the appeal, activities such as conducting a short/unannounced on-site audit, partially or completely re-assessment the relevant parts of the activities or processes in question, thoroughly reviewing all records related to testing activities (raw data, device outputs, environmental conditions, personnel competence, equipment used, etc.), and verifying the compliance of the relevant process with documented methods and standards may be implemented if deemed necessary.

The method and scope to be applied will be determined by considering the content of the appeal, the risk level, and the sufficiency of the available evidence, and all activities performed will be recorded.

The appeal evaluation committee must convene within 10 business days from the date the appeal is received by UDEM A.Ş. and report the evaluation results to the Quality Unit using the **FRM.35 Committee Meeting Report**.

The acceptance, investigation, and resolution of appeals are handled in a manner that does not result in discriminatory treatment against the appeal holder. The Committee must notify UDEM A.Ş. of its decision within one month at the latest. The Committee's decision is communicated to the appeal holder within one week by the Quality Unit using the **FRM.38 Complaint and Appeal Evaluation Form**.

If the appeal holders do not accept the committee's decision and/or if the committee exceeds the deadline for resolving the appeal, they may file a complaint with the Accreditation Agency and/or the relevant Ministry as part of the conformity assessment process.

If no response is received from the appeal holder within 6 months following the activities conducted by UDEM A.Ş. regarding the appeal, appeal process is considered closed.

4.3 Information Requests

4.3.1 Information Requests Submitted by Legal Authorities:

This includes situations where legal authorities (courts, official institutions requesting legal information, law firms, etc.) submit written notices, e-notices, e-mail, or similar means to UDEM A.Ş. requesting information, explanations, records, or opinions regarding its activities.

Personnel who receive a request for information addressed to UDEM A.Ş. forward the cover letter and other details regarding the matter to the Quality Unit. Following the evaluation defined in Section 4.3.3, the Quality Unit records the received request for information in the **FRM.220 Feedback Tracking Table**. The Quality Unit schedules a meeting to evaluate the information request



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with the General Manager and other relevant parties (such as the Coordinator, Technical Regulation Responsible, etc.). The meeting is recorded by using the **FRM.33 Meeting Minutes**.

If it is necessary to seek opinions based on the information requested in the evaluated request, consultations are held with competent individuals regarding the matter. If the information request involves evidence related to UDEM A.Ş.'s operations, the retention periods of relevant records and UDEM A.Ş.'s responsibility in this regard are reviewed. If UDEM A.Ş. is not a direct party to the requested information, the information and records to be provided are reviewed by UDEM A.Ş. and the Company's Legal Counsel under confidentiality guidelines. Information specific to UDEM A.Ş.'s operations and customers is not disclosed to third parties unless required by law.

In the actions to be taken by UDEM A.Ş. in response to a request and in the official correspondence to be sent to the requesting party, the deadlines specified in the document and within the framework of legal liabilities shall be taken as the basis.

The draft of the official statement prepared following the evaluation, along with any relevant records, is forwarded by the Quality Unit to the Company Attorney. The Company Attorney reviews the content of the information and records prepared as part of the process from a legal perspective and makes any necessary corrections. The final official letter is sent to the requesting institution by the Company Attorney through official channels.

Information requests received through legal channels may evolve into complaints or appeals during the process. If an information request becomes a complaint, the procedures outlined in Section 4.1 are applied; if it becomes an appeal, the procedures outlined in Section 4.2 are applied, and a new entry is added to the **FRM.220 Feedback Tracking** Table with a new number.

Activities related to the request, relevant deadlines, process owners, and closure statuses are maintained up-to-date by the Quality Unit in the **FRM.220 Feedback Tracking Table**.

4.3.2 Information Requests Communicated by the Accreditation Body/Competent Authorities:

This includes situations where the Accreditation Body/Authorized Authorities have submitted written requests for information, explanations, records, and opinions regarding the activities of UDEM A.Ş.

Personnel who receive a request for information addressed to UDEM A.Ş. forward the cover letter and other details regarding the matter to the Quality Unit. The Quality Unit records the received request for information in the **FRM.220 Feedback Tracking Table** and monitors the entire process through this table. The Coordinator/Technical Regulation Responsible provides an explanation regarding the activities conducted within the scope of the information request to the relevant institution via a cover letter/official correspondence or forwards it to the Quality Unit for such

notification. If the information request turns into a complaint, the processes specified in Section 4.1 are applied; if it turns into an appeal, the processes specified in Section 4.2 are applied, and a new entry is added to the **FRM.220 Feedback Tracking** Table with a new number.

4.3.3 Classification of Information Requests as Complaints:

Information requests submitted to UDEM A.Ş. are evaluated by the Quality Unit and/or the relevant technical regulation responsables based on their content and scope.

Information requests are classified as complaints in the following cases, and the process specified in Section 4.1 is carried out:

- Questioning the accuracy, adequacy, or appropriateness of UDEM A.Ş.'s conformity assessment activities,
- Situations that necessitate an investigation or re-evaluation regarding a specific product, certificate, evaluation decision, or conformity assessment process,
- Notifications containing claims of errors, deficiencies, or non-conformities regarding activities conducted by UDEM A.Ş.,
- Official notifications regarding circumstances that could affect the reliability of product performance, safety, or conformity assessment results,

In the following cases, the notification is considered a request for information, and the process is conducted as specified in Section 4.3.2.

- Requests made for the purpose of providing general information,
- Routine document sharing or verification requests,
- Requests that do not question the accuracy or compliance of UDEM A.Ş.'s activities,
- Official correspondence for administrative or informational purposes

The process for handling information requests that escalate into complaints is defined in Section 4.3.1.

4.4. Tracking of "Open" Status Feedback from the Previous Year:

UDEM A.Ş. is responsible for tracking complaints, appeals, and requests for information carried over from the previous year(s) and remaining in the "open" status in the **FRM.220 Feedback Tracking Table**.

In this context, the following steps are followed:

1. **Annual Review:** In January of each year, the Quality Unit reviews all feedback with an "open" status from the previous year.

2. **Status Assessment:** The current status of the feedback, actions taken, and any deficiencies are identified.
3. **Completion and Notification:** The necessary actions are completed, and the Quality Unit provides written notification to the party who submitted the feedback within 15 days at the latest.
4. **Updating Records:** As part of the activities carried out, the Quality Unit updates **the FRM.220 Feedback Tracking Table**.
5. **Reporting:** The Quality Unit reports these records to Senior Management during the Management Review meeting.

Complaints, appeals, and information requests submitted to UDEM A.Ş. in the fourth quarter of the year or near the end of the year, which cannot be resolved within the relevant year, are maintained in the “open” status in the **FRM.220 Feedback Tracking Table** and continue to be tracked in the following year in accordance with the steps defined in this procedure. All evaluation, monitoring, and resolution steps related to these communications are implemented in accordance with the requirements defined in the procedure, and the relevant records are tracked via **the FRM.220 Feedback Tracking Table**.

4.5. Customer Satisfaction:

Complaints and appeals may be submitted by customers on an annual basis and/or through the **FRM.39 Customer Satisfaction Survey**, which is available on the UDEM A.Ş. website and accessible to customers at all times. The Quality Unit accepts and evaluates the completed surveys.

UDEM A.Ş. customers can submit their complaints, appeals, and all feedback to UDEM A.Ş. through the **FRM.39 Customer Satisfaction Survey**, which is sent to them periodically via email at least once a year, automatically transmitted via software at certain stages of the certification process within the scope of medical device conformity assessment activities, and/or continuously accessible on the UDEM A.Ş. website. The Quality Unit accepts completed surveys without discrimination and evaluates them in accordance with its impartial requirements.

Additionally, to ensure that feedback regarding laboratory activities is communicated through an effective and direct method and is easily accessible to customers, a specific survey link has been included in the email signatures of personnel in the roles of Laboratory Manager and Test Specialist, and customers in contact have been informed about the relevant survey. The survey questions pertain solely to laboratory activities and are evaluated by the Quality Unit independently of laboratory personnel.

4.5.1 Evaluation of the Satisfaction Survey:

Among the 10 questions in the **FRM.39 Customer Satisfaction Survey** document, responses containing positive statements *such as “Very satisfied, I would definitely recommend, “Very successful,” “Very compatible,” “Very accessible and user-friendly,”* and similar positive statements are scored as “5,” while responses containing negative statements *such as “Not at all satisfied,” “I would definitely not recommend,” “Very unsuccessful,” “Definitely not compatible,”* and “Unsuccessful” are scored as “1” by the Quality Unit.

The evaluation of scores in the survey results is applied according to the scoring system outlined in the table below. Scored customers are grouped based on the evaluation results.

40–50	Extremely satisfied
30–40	Satisfied
20–30	Neutral
10–20	Not satisfied
0–10	Extremely dissatisfied

In addition to rating scores, customers may also submit complaints while providing suggestions, requests, and feedback in the comments section of the survey. The relevant section of the survey is initially reviewed by the Quality Department and then by the responsible department head.

Responses to the question identifying the processes customers were dissatisfied with in the “I Would Not Recommend at All” and “I Would Partially Recommend” groups are reviewed by the Quality Unit. Where necessary, actions are taken to implement improvements, and/or the relevant departments responsible for the process are ensured to take action. The relevant process is presented to Senior Management at the annual Management Review meeting.

In addition to the numerical ratings provided for the questions in the satisfaction survey, feedback submitted in the “Comments and Suggestions” section is also evaluated by the Quality Unit; if necessary, the responsible manager of the relevant department is requested to participate in the evaluation. If deemed necessary following the evaluation, the Quality Unit may send a separate email to the relevant individual who completed the survey on behalf of the client organization, providing additional information in line with the content of the submitted opinions and suggestions.

5. RELATED DOCUMENTS

- PD.04 Provision Of Resources Procedure
- FRM.35 Committee Meeting Report
- FRM.38 Complaint and Appeal Evaluation Form
- LST.10 Complaint And Appeal Evaluation Committee List



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- FRM.220 Feedback Tracking Table
- FRM.39 Customer Satisfaction Survey

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