PROCEDURE FOR HANDLING COMPLAINTS AND APPEALS

1. PURPOSE

The purpose of this procedure is to describe how the complaints and appeals of our customers regarding our EN ISO 17021-1:2015 system certification activities and EN ISO 17065:2012 and 2017/745/EU MDR conformity assessment activities are received and handled.

2. RESPONSIBILITY

- General Manager
- Complaints and Appeals Evaluation Committee
- Department Managers (MDTRR)
- Management Representative
- Planning Responsible

3. DEFINITIONS

Appeal: request by the person or organization that provides, or that is, the object of conformity assessment to a conformity assessment body or an accreditation body for reconsideration by that body of a decision it has made relating to that object.
Complaint: expression of dissatisfaction, other than appeal, by any person or organization to a conformity assessment body or accreditation body, relating to the activities of that body, where a response is expected.

Conformity assessment body: body that performs conformity assessment services.

Note 1 to entry: An accreditation body is not a conformity assessment body.

Accreditation body: authoritative body that performs accreditation.

Note 1 to entry: The authority of an accreditation body is generally derived from government.

(See: ISO/IEC 17000 Conformity assessment — Vocabulary and general principles" Pg. 32, Articles 6.4 and 6.5)

4. APPLICATION

UDEM Adriatic d.o.o offers public access to this document describing how the received complaints and appeals will be handled in its web site.
Persons who give their opinions during the process starting from the receipt of complaints and appeals until their conclusion are obliged to act based on the principle of neutrality and should not make any discrimination towards the person bringing that complaint or appeal. Persons who will be charged with tasks during this process should also maintain the principle of confidentiality.
At UDEM Adriatic d.o.o we are committed to the provision of high quality and fair and transparent admissions procedures for all our applicants. We recognise, however, that there may be occasions when an applicant will feel dissatisfied with the conduct of the UDEM Adriatic d.o.o's certification process or its outcome.

UDEM Adriatic d.o.o encourage applicants who experience a problem with the service to initially raise the matter informally to UDEM Adriatic d.o.o. Should customer wish to formally appeal the decision made on his/her's application, or wish to make a formal complaint about any aspect of the certification process (having first contacted the UDEM Adriatic d.o.o Team on an informal basis), a formal complaints and appeals procedure is available as detailed in this document.

Submission, investigation and decision on complaints and appeals may under no circumstances result in discriminatory actions against the appellant.

4.1 Assessment of complaints:

Complaints received by UDEM Adriatic d.o.o may be about;

1. UDEM's Adriatic d.o.o system certification, or product certification activities in accordance with 2017/745/EU MDR.
1. UDEM's Adriatic d.o.o certificated customers,
2. Or any other subject.

UDEM Adriatic d.o.o personnel who receives the complaints fill in the **FRM.38-Complaints-Appeals Assessment Form** and submits the same to the Management Representative. When the Management Representative reviews the complaint, he should first confirm that the complaint is related to UDEM's Adriatic d.o.o activities or its customers, and handle it if so.

Management Representative create a team from **Complaint and Appeal Evaluation Committee List (LST.10)** to handle depending on the subject of complaint. The team that will investigate the complaint shall be made up from persons who are competent enough to evaluate the subject. These persons should also be independent with the subject of the complaint and apart from the persons who gave certification decision and auditors. The assessment team informs Management Representative about suitable corrective or preventive actions. Submission, investigation and decision of appeals are handled to not result any discriminatory actions against complaint.

Upon receipt of a complaint, UDEM Adriatic d.o.o checks whether the complaint related to certification activities we are responsible for. If it is something about the activities then we step up to run the procedure.
If the complaint relates to a certified client by Udem Adriatic d.o.o, while examining the complaint we check the effectiveness of the certified management system. This check may be done by evaluating the documents in the certification file, or Udem Adriatic d.o.o. may request more info or proof documents from the certified company. If Udem Adriatic d.o.o. finds a suspicious situation or foresight non-compliance to standards or rules, may plan short-notice audit regarding the 9.6.4.2 of ISO EN/IEC 17021-1.

Also this complaint is directed to the certified company in 3 working days after receiving.

Note: If the complaint is related with the one of the person in the auditors list that person cannot be involved in the certification committee. Second person in the related area is selected from the auditors list.

The action to be taken about the complaint and the persons in charge will be notified in writing by the Management Representative to the complainant with the same form, latest within 1 week. The result of actions taken will be notified in writing to the complainant by the Management Representative latest within 1 month as from the date the complaint is received.

Follow-up of the process covering stages including the assessment of complaint, taking of necessary CPA, closing the complaint, application results etc. will be conducted by the Management Representative.
If the complainant disagrees with the set solution methods, then the complaint becomes an appeal and is handled according to the appeal assessment procedure.

When the complaint and appeal confirmation procedure is making, the results of complaints and appeals shall be taken into consideration.

UDEM Adriatic d.o.o shall specify whether the complaint issue and its solution are announced to the public, or not and if this will be given, and also UDEM Adriatic d.o.o shall specify which scope this will be given, with client and complainant.

Information about customer received from other sources (e.g. complainant, regulators) is treated as confidential.

Except as required in the International Standard and MDR 2017/745/EU, the information about a particular client or individual are not disclosed to a third party without the written consent of the client or individual concerned.

UDEM Adriatic d.o.o takes all the responsibility for all decisions at all levels of the complaint-handling process.

4.1 Assessment of appeals:

UDEM Adriatic d.o.o personnel who receives the appeals fill in the **FRM.38-Complaints-Appeals Assessment Form** and submits the same to the Management Representative. When the Management Representative reviews the appeal, he should first confirm that the appeal is related to UDEM's Adriatic d.o.o activities or its customers, and handle it if so.
The Management Representative starts the necessary corrective or preventive measures in consideration of the subject and significance of the appeal. Three (3) external members who have comprehensive knowledge of the subject are found by Management Representative. **FRM.24 Committee Member Service Agreement** is signed with these members and required notification is made to have membership criteria. The team that will investigate the appeal shall be made up from persons who are competent enough to assess the subject. These persons should also be independent with the subject of the appeal and apart from the persons who gave certification decision and auditors. The assessment team informs the Management Representative about suitable corrective or preventive measure.

After the inquiry is received, the committee is immediately summoned for a meeting and meets latest within 1 week. The committee should notify UDEM Adriatic d.o.o about its decision latest within 1 month. If the complainant is not satisfied with the committee decision, legal process is initiated by UDEM's Adriatic d.o.o General Manager. The jurisdiction of Courts of Zagreb will be binding in the legal process.
The Procedure for Complaints and Appeals has three stages. The process will be different depending on which stage your complaint is being considered under.

UDEM Adriatic d.o.o takes all the responsibility for all decisions at all levels of the appeals-handling process. UDEM Adriatic d.o.o. guarantees that the persons engaged in the appeals-handling process are different from those who carried out the audits and made the certification decisions.

4.2.1 Stage One – Informal Resolution

UDEM Adriatic d.o.o aim to resolve complaints quickly and locally by encouraging early resolution within the department that provides the service. This could mean an apology, an explanation if something has gone wrong, or immediate action to resolve a problem. Sometimes a matter will have to be referred to more than one member of staff to find the right answer, or receive approval for an outcome, but UDEM Adriatic d.o.o will aim to keep customer informed as we go along.

If customer is not satisfied with the response UDEM Adriatic d.o.o give at this stage, UDEM Adriatic d.o.o will tell customer what he/she can do next. The matter may need be escalated within the same department. If customer choose to, he/she can take complaint to Stage Two of the procedure.

4.2.2. Stage Two – Formal Investigation

Stage Two deals with complaints that have not been resolved at Stage One and those that are complex and require detailed investigation. Submissions should be made via email or via letter or other appropriate way which can be traced, to **info@udemadriatic.com,** or UDEM Adriatic d.o.o post office address along with any supporting evidence. All submissions made to this UDEM Adriatic d.o.o inbox are treated confidentially.

UDEM Adriatic d.o.o will:

- Acknowledge receipt within three working days and tell you who is dealing with customer's complaint,
- Provide customer with an outcome as soon as possible and normally within twenty working days.

If UDEM Adriatic d.o.o investigation will take longer than twenty working days, UDEM Adriatic d.o.o will inform customer.

4.2.3 Stage Three – Complaints and Appeals Evaluation Committee

Stage Three is the review stage and looks at complaints that have not been resolved at Stage Two. Criteria for making a submission at Stage Three include that there is additional

evidence which could not have reasonably been made available at Stage Two and/or because our policies and procedures were not followed in the handling of customer's original complaint.

Complaints under Stage Three should be submitted via email to **info@udemadriatic.com**, or via post to UDEM Adriatic d.o.o postal address. UDEM Adriatic d.o.o:

- Acknowledge receipt of your complaint within three working days,
- Refer to the General Manager to determine whether the committee should be convened in accordance with the criteria,
- If appropriate, convene a meeting of the Complaints Evaluation committee, consisting of a Chairman, a Secretary, a staff member from the UDEM Adriatic d.o.o unrelated to the complaint (but with experience and knowledge of the complaint area), lawyer and external auditor,
- Meet within twenty working days (excluding holiday periods) of acceptance of the complaint at Stage Three,
- Give customer a full response/explanation of the decision within ten working days of the meeting of the Complaints Evaluation committee.

If the committee will take longer than the agreed timescales, UDEM Adriatic d.o.o will inform customer.

If customer's complaint has completed in Stage Three you will be provided with a Completion of Procedures letter.

If customer is dissatisfied with the outcome or the way UDEM Adriatic d.o.o dealt with customer's complaint, customer can submit a complaint to the "Office of the Independent Adjudicator" in accordance with their rules. Complaint can be made to the competent accreditation body, (HAA Croatian Accreditation Agency), for Product and Service Accreditation and/or to the relevant ministry.

4.2.4. In the following cases;

- The decision of the committee is not accepted by complainant or the complainant is not satisfy with the decision,
- The Committee's complaint resolution time is exceeded,

The complainant can apply to Product and Service Accreditation Agency and/or related Ministry.

5. Storage and Processing of Complaints and Appeals Information

5.1 All complaint and appeals will be dealt with confidentially and with due regard for privacy. Information may be disclosed to members of the UDEM Adriatic d.o.o who have a need to see it in order to investigate the appeal or complaint.

5.2 The information will be stored and processed in accordance and under the Data Protection Act. The record of the complaint/appeal and any supporting papers will be archived in accordance to the **PD.03 Control of records procedure**, following resolution of the case.

Information about customer received from other sources (e.g. complainant, regulators) is treated as confidential.

Except as required in the International Standard, and MDR 2017/745/EU, the information about a particular client or individual are not disclosed to a third party without the written consent of the client or individual concerned.

PREPARED BY	APPROVED BY
Management Representative	General Manager
Danijela Babić	Zekeriya Aytaç

Part No.	Rev. Date	Rev. No.	Description of Revision
Last page and 4.1 Article 1	04.01.2019	01	Revision table is added into the last page. The sentence" inspection and laboratory activities" is deleted.
Whole document	26.08.2019	02	Articles 3 and 4 were rewritten. Changes are made in text. Add article 5.
Whole document	03.05.2021	03	Articles 4.1. i 4.2., add part regarding complaints and appeals.
The whole document Article 3. Article 4.1	16.06.2023.	04	In the whole document, errors in the translation relating to the terms complaints and appeals, as well as all other errors in the translation, have been corrected. In Article 3, the definitions of complaints and appeals have been corrected. In article 4.1. the reference to the Machinery Directive has been deleted.