COMPLAINTS AND APPEALS ASSESSMENT PROCEDURE

A) DOCUMENT APPROVALS

No	Definition	Action	Created By	Date
1	Document approved	Approval	Nurgül Çınar	21.07.2023
2	Translation approved	Approval	Çağla Tufanç	20.07.2023

B) REVISION HISTORY

No	Definition	Reason	Approval Date	Release Date
29	Appeal duration is added for Medical Department.	To eliminate the lack of rules by ensuring integrity between documents.	21.07.2023	21.07.2023
28	Article 8.3.13 is documented and a notification rule is added for the Medical Department.	The revision is carried out within the scope of MDD - 2/2 ~ 2023-41 CAPA (Internal audit).	11.05.2023	11.05.2023
27	The process for appeals received within the scope of IECEx activities has been defined.	IECEx Authorization Assessment Report NCR4 / CAPA No 2023-77	05.05.2023	05.05.2023
26	Since complaints, appeals, suggestions and information requests have been tracked through the IQMemo software Feedback Module as of 01.03.2023, the procedure has been harmonized with the IQMemo software.	Use of IQMemo software Feedback Module as of 01.03.2023	23.03.2023	23.03.2023
25	Transferred to IQMemo program.	Switching to new program	04.02.2023	04.02.2023

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5. Aim and Scope

The purpose of this procedure is to determine the evaluation principles of the suggestions, complaints and objections of the relevant parties related to the conformity assessment activities carried out by SZUTEST, within the framework of the legal regulations, other relevant legislation and auxiliary documents *, according to the ISO / IEC 17021-1, ISO / IEC 17020, ISO / IEC 17065, ISO / IEC 17024, ISO / IEC 17025, OIC / SMIIC standards and Vocational Qualifications Authority, Examination, Measurement, Evaluation and Certification Regulation.

*Medical Devices Regulation for medical devices (93/42 EC, 2007/47 / EC), regulation 920/2013 and other legal regulations and auxiliary documents (standards, NBOG, MEDDEV, GHTF, IMDRF, etc.), other relevant documents are stated under the title of “External Document” in the definitions tab of this procedure of the relevant QMS software.

6. Definitions

Complaint: It is an expression of dissatisfaction sent to SZUTEST concerning the services provided by SZUTEST, different from an appeal to the decision taken in a conformity assessment activity.

Appeal: Request of the institution for the re-examination of the resolution adopted by SZUTEST in relation to the subject.

Appeal Committee: The committee which is authorized to impartially assess and resolve the appeals received from customers or parties related to SZUTEST activities.

Conformity Assessment: It is the demonstration that specified requirements relating to a product, process, system, person or body are fulfilled, and they are the conformity assessment (audit, inspection, testing, exam, surveillance, certification, etc.) methods SZUTEST carries out.

Technical Personnel: The personnel who carry out conformity assessment activities, are technical manager, technical regulation responsible, directive manager, inspection personnel, inspection staff, lead auditor, auditor, technical expert/auditor, exam maker, test responsible, sampling responsible, certification committee members, Islamic Issues Specialist and decision-makers.

QMS software: Quality Management System Software

IQMemo Feedback Module: A software module where complaints, appeals, suggestions and information requests received from related parties are recorded and followed up.

Planning Responsible: It is the person who follows the determination of the decisions and the actions taken within the department during the Feedback (Complaint, Appeal, Suggestion, Information Request) stages and records the results to IQMemo. It generally consists of Department Manager / Unit Manager and/or Quality Coordinator D and/or SZUTEST Personnel appointed by the Quality Manager when necessary.

7. Responsibilities

General Manager, Appeal Committee, Quality Manager, related Department Managers and all SZUTEST personnel related to appeals and complaints are responsible for the implementation of this procedure.

8. Method

In the handling of complaints or appeals, personnel who carries out an assessment or passes resolution is elected amongst the persons who are fully independent of the complaint or appeal subject; however, he/she must be full-time employees of SZUTEST. SZUTEST does not subcontract the decisions taken. When necessary, the relevant committee can provide technical information support from outside. SZUTEST does not appoint his own personnel who provided consultancy to its customer or employed by its customer (including those in manager position) in review or approval of solution of any complaints or appeals of such customer for two years following termination of such consultancy or employment. Appeal Committee establishment and working principles are defined in TL.03 Appeal Committee Assignment and Working Instructions.

8.1 Sources of Appeals ;

- Appeals made against the findings and decision of technical personnel during/after conformity assessment.
- Appeals made against the decisions of appeal relevant to SZUTEST services

8.2. Sources of Complaint ;

- Complaints arisen from the activities carried out by SZUTEST during the application process (Complaints related to the receipt of the application, complaints related to the offer submitted, complaints about the contact personnel, etc.).
- Complaints due to the activities carried out by technical personnel during the conformity assessment (performing the conformity assessment, behaviors of technical personnel, scope, duration, and method of conformity assessment, exam questions and answers, certification decisions, etc.)
- Complaints arising after conformity assessment activities of SZUTEST (accounting activities, certificate delivery, etc.)
- Complaints received from relevant third parties related to SZUTEST's applications and/or organizations/personnel that are certified.

8.3. Handling of Complaints

8.3.1. Suggestions and complaints from the customer person, organization and/or related parties regarding SZUTEST services are being recorded with the FR.02 Feedback (Complaint Appeal Suggestion Information Request) Form, which is available on the SZUTEST website, in electronic media or the information received by the Quality Manager or the relevant SZUTEST Personnel is recorded in IQMemo Feedback Module.

8.3.2. After receipt of the complaint, the Quality Manager and the relevant Department Manager inquires the complaint to verify whether it is related to the activities performed by SZUTEST or not.

8.3.3. If the complaint is not related to SZUTEST activities, written information is provided to the complaint-holder by the Quality Manager.

8.3.4. If the complaint is related to the activities of SZUTEST or the personnel working in SZUTEST, the Quality Manager decides with the relevant Department Manager which way will be followed for the risk and evaluation of the complaint. If the complaint involves the determination of a situation that causes a systematic error within the activities and if a serious risk is detected that does not comply with the SZUTEST Impartiality, Independence and Confidentiality policies, A Complaint and Appeals Committee, with at least 3 persons independent of the complaint, is invited and asked to evaluate the complaint and make a decision. It is ensured that at least one member of the committee is an Islamic Issues Expert in case of complaints and objections regarding Halal Certification decisions. If the complaint does not include the situations listed in the previous sentence, the Quality Manager and Department Manager investigate the actions to be taken to resolve the complaint and determine the necessary actions. In both cases, decisions and actions are recorded in the IQMemo Feedback Module by the Planning Responsible. Unless otherwise requested, written information is sent to the complainant about the evaluation result of the complaint within 7 days. If the complaint is submitted through the institution/organization on a certain deadline, the relevant period is taken into account for written information.

8.3.5. In case of a complaint over the authority level of the Quality Manager (for example: General Manager, Deputy General Manager, etc.), at least 3 people from the senior management, independent of the people who are the subject of the complaint, are invited to evaluate the complaint. The process continues as described in article 8.3.4 of this procedure.

8.3.6. The Quality Manager may decide to initiate a Corrective / Preventive Action as a result of the evaluation of activities regarding the complaint recorded by the Planning Responsible in the IQMemo Feedback Module. If such a decision is taken, the action is followed up with a Corrective / Preventive Action in accordance with the PR.09 Corrective and Preventive Actions Procedure.

8.3.7. After completion of the works initiated for complaint, written information is given by the Quality Manager to the complainant.

8.3.8. Approval of customer on the activity carried out is recorded in the IQMemo Feedback Module.

8.3.9. If the customer is dissatisfied with the activity carried out, the issue is recorded and notified by the Quality Manager in the IQMemo Feedback Module to the appeal committee and written information is provided to the customer.

8.3.10. Complaints made to SZUTEST about customer persons/organizations are received as stated above. They are evaluated by the Quality Manager.

8.3.11 If deemed necessary for certified organizations, a short notice audit is performed in accordance with the procedures of the relevant department for conformity assessment activities. For organizations certified by the Medical Department, unannounced audits are carried out within the scope of the legislation related to Medical Devices.

8.3.12 If a complaint is received about the certified personnel, the certified person is informed about the complaint. If necessary, the complainant is expected to provide evidence related to the subject of the complaint. Within 10 (ten) days from the date of the complaint, written defense of the complaint (with evidence, if any) is requested from the certified personnel. The defense is evaluated by SZUTEST. As a result of the evaluation, if it is determined that the certified person is wrong, the certificate is canceled and the complainant is informed about the issue. If the result of the evaluation indicates that the certified person is right, the use of the certificate continues and the complainant is informed about the issue in writing.

8.3.13 In case of any complaint regarding product safety and performance within the scope of the activities of the Medical Department; even if no non-compliance is detected and no further action is taken by SZUTEST and the manufacturer as a result of the complaint's assessment, the Competent Authority shall be informed about the subject by SZUTEST.

8.4. Handling of Appeals Appeals

8.4.1. Appeals from the customer and/or related parties regarding SZUTEST decision are recorded with the FR.02 Feedback (Complaint Appeal Suggestion Information Request) Form, which is available on the website, in electronic media or the information received by the Quality Manager or the relevant SZUTEST Personnel is recorded in IQMemo Feedback Module. Appeals are accepted 30 days after the notification date of Szutest decision.

8.4.1.1. The acceptance period for appeals from the relevant customer and/or related parties in Personnel Certification activities is 7 days from the date of the decision subject to appeal.

8.4.1.2. In the activities of the Medical Department, the customer may appeal to a decision taken by SZUTEST in writing within 10 working days.

8.4.2. After receipt of the appeal, the Quality Manager and relevant Department Manager inquire the appeals to verify whether they are related to the decisions adopted by SZUTEST or not.

8.4.3. If the appeal is not related to the decisions adopted by SZUTEST, then written information is provided by the Quality Manager to the appeal holder.

8.4.4. If the appeal is related to the decisions adopted by SZUTEST, then the Quality Manager notifies the issue to the appeal committee with the FR.02 Feedback (Complaint Appeal Suggestion Information Request) Form and provides written information to the appealer.
The evaluation study of the relevant appeal in the Appeals Committee is carried out in accordance with the TL.03 Appeal Committee Determination and Working Instruction Rules.

8.4.5. The Appeal committee convenes in order to evaluate the appeals not later than 15 days and discusses the issue.

8.4.6. If necessary, the appeal committee may receive information and help from experts in the field and/or parties in dispute. The Appeal committee takes the decision not later than one week and records the decision taken in the FR.02 Feedback (Complaint Appeal Suggestion

Information Request) Form and notifies the Quality Manager.

8.4.7. The customer or parties are informed in writing within 7 days at the latest regarding the decision taken and the activity to be carried out.

8.4.8. Corrective action is initiated by the Quality Manager regarding the activity to be carried out, and its follow-up is carried out in accordance with the PR.09 Corrective and Preventive Actions Procedure.

8.4.9. After the Corrective Action is carried out, written information is given to the appealer by the Quality Manager and feedback is requested. The above-mentioned review and evaluation are concluded within 30 days from the notification of the appeal.

8.4.10. If the appealer is not satisfied with the decision taken by the appeal committee and the activity carried out, he has the right to appeal to SZUTEST for a second time. SZUTEST allows the appealer to appeal against the decision and ensures that this objection is examined by a person or persons who have no previous relationship with the decision in question, but who have sufficient knowledge and experience on the subject and can act independently. When the result of the activity is notified to the appealer, if the appealer is still not satisfied, SZUTEST notifies the appealer of the existing legal rights and the periods for using these rights.

8.4.11. The appealer can take legal action when necessary. No third party organizations or persons can be informed about the studies and correspondence in this procedure other than the Accreditation Bodies (TÜRKAK, HAK, etc.) * for which SZUTEST has accreditation, relevant ministries *, institutions/organizations authorized (Vocational Qualifications Authority, etc.) * and Turkish Courts.

* The information is given to be the Institution/Organization to which the appeal is related.

8.4.12 SZUTEST can carry out the demo complaint / appeal process related to conformity assessment activities that have not received any complaints/ appeals within at least one year, provided that it is applicable.

8.4.13 Within the scope of IECEx activities for which SZUTEST is authorized, a manufacturer and/or applicant may request an appeal to SZUTEST for their "rejection" or the rejection, suspension and/or cancellation of their existing certificate. If the appealer is not satisfied with the decision taken and/or the action taken as a result of the evaluation of the appeal, they may appeal to the IEC Board of Appeal regarding the object of the appeal.

8.5. Complaint Flow Cart

It is defined in PR.04 (Process) Assessment of Complaints and Appeals.