Assessment of Complaints and Appeals Procedure

A) DOCUMENT APPROVALS

No	Definition	Action	Approved By	Date
1	Document approved	Approval	Füsun Tudan	03.11.2025

B) REVISION HISTORY

No	Definition	Reason	Approval Date	Release Date
12	The permanent ban application for experienced single medical devices is defined in Section 8.	Clarification on conflict of interest criteria	03.11.2025	03.11.2025
11	New definitions are added. IQMemo software related to applications are detailed.	Improvement	04.01.2024	04.01.2024
10	The appeal submission duration is added for Medical Department.	Harmonisation.	20.07.2023	20.07.2023
9	Requirements for final decision of the committee are added in Article 8.	Improvement	11.07.2023	11.07.2023
8	The content is transferred to IQMemo	Transition to new software	14.02.2023	14.02.2023

5. Aim and Scope

The purpose of this procedure within the framework of national and international legal regulations defined in the related legislation section is to determine the principles of assessment of suggestions, complaints and appeals received from parties related with the subject in accordance with Standards ISO/IEC 17021-1 and (EU) 2017/745 Regulation.

SZUTEST Konformitätsbewertungsstelle GmbH will be referred as 'SZUTEST' in this document.

6. Definitions

Appeal: Requests to object on the decisions on/for certification.

Complaint: Expression of dissatisfaction, other than appeal, by any person or organization to SZUTEST, relating to the activities of SZUTEST, its personnel, or products certified by SZUTEST.

Complainant: The personnel or organization who makes complaint related SZUTEST activities. The complainant can be related parties such as authorities, customer, SZUTEST employee, etc.

Appeal holder: The person or organisation who makes appeals to the decisions on/for certification. The appeal holder can be related parties such as authorities, customers etc.

Appeal Committee: The committee which is authorized to independencely and impartially assess and resolve on the appeals that have not resolved by Quality Manager and Department Manager.

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 lead auditor, site auditor, product reviewer, certification committee members, final reviewers 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 and/or SZUTEST Personnel appointed by the Quality Manager when necessary.

Refer PR.MED.15 Procedure for Definitions in Medical Devices Procedures for medical devices.

7. Responsibilities

General Manager, Deputy General Manager, Appeal Committee, Quality Manager, related Department Managers and all relevant SZUTEST personnel are responsible for implementation of this procedure.

8. Method

In the handling of complaints or appeals, personnel who carries out an assessment or passes a resolution is elected amongst the persons who are fully independent of the complaint or appeal subject; however, the appeal and complaint committee provides its recommendation as a result of the evaluation. The final decision is taken by the full-time employee of SZUTEST. SZUTEST does not subcontract the decisions taken. When necessary, the relevant committee can provide technical information support from outside.

If a person is previously employed with a client and then later employed by SZUTEST, this personnel cannot be a part of the team reviewing the appeal or complaint coming from this specific client within 3 years after the termination of the employment with that specific client. For medical devices; permanent ban shall be applied for experienced single devices if this person; previously employed by manufacturer, designer, supplier, installer, purchaser, maintainer, and authorized representative of medical devices or was the designer, manufacturer, supplier, installer, purchaser, maintainer, or authorized representative of devices (Including representing parties engaging with this activities) or involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the devices (including representing parties engaging with this activities).

The Appeal Committee' s establishment and working principles are defined in TL.03 Appeal Committee Assignment and Working Instructions.

8.1. Sources of Appeals

- Appeals made against the decisions on/for certification.

8.2. Sources of Complaint

- Complaints due to service quality,
- Complaints due to personnel performance, conduct and behavior,
- Complaints regarding possible violations of independence, impartiality and confidentiality by personnel, top management or administrative personnel.

8.3. Handling of Complaints

8.3.1. Suggestions and complaints received from complainant in relation with applications of SZUTEST shall be kept under record with FR.02 Complaint Appeal and Suggestion Form which is available on the SZUTEST website in electronic media or are recorded with the FR.02 Complaint Appeal and Suggestion Form by the relevant SZUTEST Personnel or

the information received by the Quality Manager or the relevant SZUTEST Personnel is recorded in IQMemo Feedback Module. Within 3 days from the day the complaint is received, the complainant shall be informed by e-mail / written or verbal that the complaint has been received.

8.3.2. After receipt of the complaint, Quality Manager and relevant department managers shall inquire the compliant 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 shall be provided to complaint-holder by Quality Manager within maximum 7 days.

8.3.4. If the complaint is related to the SZUTEST activities or the personnel working within SZUTEST, the Quality Manager shall decide how to proceed with the risk and assessment of the complaint with together related Department Manager within 7 days together with informing the complaint holder that the complaint shall be processed according to procedures.

If the complaint includes the identification of a situation that causes a systematic error in the activities and a serious risk is detected that does not comply with the SZUTEST Impartiality, Independence and Confidentiality policies 3 individuals from appeal committee who are not related and free from the complaint shall be selected. The members shall be invited and asked to make a decision by evaluating the complaint in maximum 7 days.

If the complaint does not include the situations mentioned in the previous sentence, the Quality Manager and the Department Manager shall investigate the activities to be done to determine the complaint and determine the necessary activities. 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 forwarded from an institution/organization by requesting a return on a certain deadline, the relevant period shall be taken into consideration for written information.

8.3.5. If the complaint is received about a person or entity above the level of authority of the Quality Manager (Example: about the General Manager) or complaint related with Quality Manager, the appeal committee members who are not related and free from complaint shall be invited by Quality Manager or Deputy General Manager and asked to make a decision by evaluating the complaint in maximum 7 days. (Section 8.3.6, 8.3.7 and 8.3.8 are carried out by the Deputy General Manager specifically for this item, for a complaint about the Quality Manager.)

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

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

8.3.9 Complaints that are related to the complainant of SZUTEST shall be accepted/treated by the same methods defined as above and evaluated by the Quality Manager. Additionally, unannounced audits might be performed due to the nature of the complaint.

8.4. Handling of Appeals

8.4.1. Appeals received from appeal holder in relation with decisions on/for certification shall be kept under record with FR.02 Complaint Appeal and Suggestion Form ,which is available on the website, by the Quality Manager or relevant SZUTEST personnel in electronic media or the information received by the Quality Manager or the relevant SZUTEST Personnel is recorded in IQMemo Feedback Module. Appeals shall be accepted in 30 days after the notification date of SZUTEST decision.

For the Medical Department activities, the customer may appeal to a decision taken by SZUTEST within 10 working days.

SZUTEST shall publish the status and scope of the certificate through an available national database, through it's certificate search module on its website and through EUDAMED this includes the status of these certificates during the acceptance of the appeal and it's resolution period.

8.4.2. After receipt of the appeal, the Quality Manager and relevant Department Manager shall inquire the appeals to verify whether it is related to the decisions on/for certification or not.

8.4.3. If the appeal is not related to the decisions on/for certification, then written information shall be provided by the Quality Manager to the appeal holder within maximum 7 days.

8.4.4. If the appeal is related with the decisions on/for certification, then the Quality Manager shall notify the issue to appeal committee with FR.02 Complaint, Appeal and Suggestion form and provides written information to the appeal holder within maximum 7 days.

8.4.5. Appeal Committee shall convene in order to evaluate the appeals not later than 7 days and shall discuss 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. Appeal committee takes the decision not later than 7 days and records the decision taken in FR.02 Complaint Appeal and Suggestion Form and notifies it to the Quality Manager and relevant Department Manager. The result of the assessment performed by the appeal committee shall be forwarded to relevant decision makers. A certification committee consists of a final reviewer and decision maker shall be implemented and the final actions to be implemented shall be decided by the certification committee.

8.4.7. Written information shall be provided about the appeal holder related to the decision taken and actions to be taken not later than 7 days.

8.4.8. Quality Manager shall initiate corrective action in relation to the activity to be carried and its follow-up shall be done in accordance with PR.09 Corrective and Preventive Action Procedure.

8.4.9. After completion of corrective action, Quality Manager shall provide written information to the appealer and requests his feedback. The evaluation and assessment which is specified above shall be finalized in 30 days after the appeal is received.

8.4.10. If the appeal holder is dissatisfied with the decision of certification committee or actions are taken, then the appeal holder may seek legal remedies. The appeal holder has the right to appeal to SZUTEST for a second time if the appeal holder is not satisfied with the decision and action were taken by the committee. SZUTEST shall allow the appeal holder to object to the decision and shall ensure that the appeal is evaluated by a person or persons who have no prior relationship with this decision, but who have sufficient knowledge and experience on the subject and who can act independently. When the result of the activity is notified to the appeal holder, if the appeal holder is not satisfied again, SZUTEST shall notify the appeal holder of the current legal rights and the periods regarding the exercise of these rights.