

PROCEDURE OF APPEAL**Contents**

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PROCEDURE OF APPEAL

1 The aim of the procedure

The aim of this procedure is to regulate the process of handling appeals, **which are related to both the quality management system certification and conformity assessment activities.**

2 Interested parties

General Manager
Certification Manager
Operation Manager
Office Manager
Clinical Leader
Quality Manager

3 Requirements

The procedure of appeal shall be regulated according to regulations of MSZ EN ISO/IEC 17021-1:2016.

4 Terms and definitions

4.1. Complaint

a) Complaint against professional activity (certification, auditing, surveillance) of CE Certiso Kft.:

- consequence of any behaviour or treatment in the relationship of the client and CE Certiso Kft. which is dissatisfactory or believed to be dissatisfactory for the client or
- any direct or indirect remark or objection related to any of CE Certiso Kft's procedures or documents, independently of the type of conveyance (in writing or verbal).

b) Complaint against any organisation certified by CE Certiso Kft.:

any direct or indirect remark or objection made by the certified organisation's customer, client or any affected authority as a consequence of any behaviour or treatment in the relationship of the certified organisation and its client or customer which is dissatisfactory or believed to be dissatisfactory by the client or customer, independently of the type of conveyance (in writing or verbal).

4.2. Appeal

A written petition of the client of CE Certiso Kft. during the certification procedure with the intent of altering any certification decision.

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5 Responding to appeals

- Appealing is only possible in writing within 30 days following the receipt of certification decision.
- During the handling of an appeal all participants has to differ from those persons who performed the audit, the review and made the decision on certification.
- After receiving, all appeals have to be registered. Appealer has to be informed in writing without undue delay about the fact of registration and the date and number of registration.
- The appeals have to be assessed by a temporary Board of Appeal. The formation, function and tasks of the Board are regulated in the ***CMR-SZ-04 Rules of Procedure of the Board of Appeal.***
- Should the assessment of the appeal generate disproportionately high expenditures, applier has to be informed about that in case of causeless of his appeal the costs of the investigation has to be reimbursed totally or partially by him.
- All steps of an appeal assessment have to be documented and during the procedure, the confidentiality has to be safeguarded.
- In the beginning of the investigation, if it is necessary, the incoming data have to be controlled, refined or completed.
- Both applier and staff of CE Certiso Kft. involved in audits, reviews and certification decision has to be given the opportunity to make out one's case in details in verbal or written form.
- The assessment of an appeal has to be finished in 60 days following the receipt of the appeal, and within deadline, the applier has to be informed in writing about the result of the assessment and about the decision. Both the applier and the General Manager is entitled to ask for continuous information on the inspection. If it is reasonable, the General Manager is entitled to extend the assessment deadline with an additional 30 days. In the latter case the applier has to be informed about the extension before the first deadline.
- Due to his/her objection the applier cannot suffer any bias. The applier has to be informed about that should the applier be discontented with the result of the assessment, the applier can bring an action before the court responsible. **He/ she can contact the competent authority and/or NBO in the field of conformity assessment.**

6 Closing the assessment of an appeal

- The Board of Appeal is obliged to report in writing the results of the assessment and prepares a proposal for decision.
- The final decision is made by the CEO, in case of his involvement the Supervisory and Impartiality Board is responsible for decision.

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- Both appealor and involved staff have to receive the decision and its justification.
- Should the appeal demand any corrective or preventive action, the pertinent procedure has to be followed. In repetitive cases, a comprehensive investigation or an internal audit is necessary for revealing the causes and making the required arrangements.
- The documentation of the assessment of an appeal has to be filed following the ***CMR-SZ-02 Regulation of Document and Records Management***.

Modifications

Version, date	Modification	Explanation
v01, 2020.03.20	Initial edition.	CE Certiso Kft. has been designated as the notified body for conducting conformity assessment under MDR (Regulation (EU) 2017/745 on medical devices).
v02, 2021.03.16	Chapter 2: Recording of Operation Manager position. Cancellation of the Head of Secretary position.	Organizational changes.
v03, 2024.02.22.	1. Chapter 1. completed with the scope of the procedure. 2. Chapter 2. modification of the chapter's title. 3. Chapter 2. deletion of the abbreviations. 4. Chapter 5. indication of appeal organisations	1. Combination of the quality management system certification procedure and conformity assessment procedure. 2-3. Deletion of unnecessary information. 4. Minor adjustments of the rules of procedure.