



HANDLING COMPLAINTS

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HANDLING COMPLAINTS

1 Aim of the procedure

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

2 Interested parties

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

3 Requirements

The procedure of handling complaints 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 for 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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- In case of any incoming remark it is decided by the General Manager (or his assigned deputy) whether it is considered an appeal of a complaint.
- In case of an appeal the procedure must be performed according to **CMR-E-07 Procedure of appeal**, while in case of complaint according to this procedure.
- Any verbal complaint has to be committed to writing by the person who was informed about it. The written complaint has to be send to the plaintive so that the plaintive can acknowledge it. Henceforth the handling of complaints corresponds with the handling of written complaints.
- After receiving, all complaints have to be registered. Plaintive has to be informed in writing without undue delay about the fact of registration and the date and number of registration.
- The Quality Manager is responsible for inspection of incoming complaints. Is case his/her involvement, the General Manager is obliged to appoint another person responsible for the inspection. The latter person has to be independent from the matter of complaint.
- Should the complaint have any legal consequence or compromise the reputation of CE Certiso Kft., a legal expert has to be involved in the inspection.
- Should the inspection of the complaint generate disproportionally high expenditures, plaintive has to be informed about that in case of causeless of his complaint the costs of the inspection has to be reimbursed completely or partially by him.
- Complaints related to an invoice are handled by the Operation manager and the Office Manager.
- All steps of a complaint inspection has to be documented and during the procedure, the confidentiality has to be safeguarded.
- In the beginning of the inspection, if it is necessary, the incoming data have to be controlled, refined or completed.
- Both plaintive and the one affected by the complaint has to be given the opportunity to make out one's case in details in verbal or written form.
- A client certified by CE Certiso Kft. has to be informed about any concerning complaint in proper time depending on the nature of the complaint.
- The inspection has to be finished in 30 days following the receipt of the complaint, and within deadline, the plaintive has to be informed in writing about the result of the procedure. The General Manager is entitled to ask for continuous information on the inspection.
- Due to his/her objection the plaintive cannot suffer any bias. The plaintive has to be informed about that should the plaintive be discontented with the result of the

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inspection, the plaintive 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 inspection of a complaint

- The one responsible for the inspection is obliged to report the result of it.
- Both the complainant and the interested parties shall be informed in writing about the result of the procedure.
- Should the complaint demand any corrective or preventive action, the pertinent procedure has to be followed.
- In case of an inspected justifiable complaint against a client certified by CE Certiso Kft. which makes necessary the suspension or the withdrawal of the certificate or the permission on using the certification mark, the suspension or the withdrawal has to be executed according to **RTK-E-02 Certification process / CMK-E-02 Conformity assessment process / CMR-E-02 Conformity assessment process.**
- The documentation of the inspection of a complaint has to be filed following **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. Chapter 5: Recording of task for the Operation Manager. | 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. completed with the procedure RTK-E-07 5. Chapter 5. indication of appeal organisations 6. Chapter 6. completed with the procedure RTK-E-02 7. Chapter 6. the identification of procedure CMK-E-02 and CMR-E-02 completed with the name of the procedures | 1. Combination of the quality management system certification procedure and conformity assessment procedure. 2-3. Deletion of unnecessary information. 4. Combination of the quality management system certification procedure and conformity assessment procedure.. 5. Minor adjustments of the rules of procedure. 6. Combination of the quality management system certification procedure and conformity assessment procedure.. 7. Combination of the quality management system certification procedure and conformity assessment procedure.. |