

Assessment Of Complaints And Appeals Procedure

1. Revision History

Rev. No	Date of Rev.	Definition of Rev.	Reason of Rev.
2	8.03.2022	Necessary changes are made.	Continuous improvement and harmonisation with MDCG guidelines.
1	25.02.2021	Structural changes have been made.	Continuous Improvement
0	21.09.2020	INITIAL RELEASE	

2. Related Standards, Guide Documents and Laws

Code	Title
EN ISO 17021-1 MCA	Conformity assessment - Requirements for bodies providing audit and certification of management systems

3. Related Directives / Regulations

Code	Title
MCA (EU) 2017/2185	COMMISSION IMPLEMENTING REGULATION (EU) 2017/2185 of 23 November 2017 on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council
MCA Corrigendum-1	Corrigendum to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
MCA Corrigendum-2	Corrigendum to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
MCA (EU) 2017 745	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
MCA (EU) 2020/561	REGULATION (EU) 2020/561 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions

4. Related Internal Documents

Code	Title
MCA FR.02	Complaint Appeal And Suggestion Form
MCA PR.02	Quality Records Procedure
MCA TL.03	Appeal Committee Selection And Working Instructions

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 EN ISO/IEC 17021-1 and (EU) 2017/745 Regulation.

Malta Conformity Assessment Ltd. will be referred as 'MCA' in this document.

Definitions

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

Appeal: Request to change/re-evaluate the decisions taken during conformity assessment tasks by MCA.

Appeal Committee: The committee which is authorized to impartially assess and resolve on the appeals that have not resolved by Quality Manager and Department Manager by received from the appeal holder related to MCA activities.

Appeal holder: The personnel or organisation who makes appeals to the decisions of MCA conformity assessment activities. The appeal holder can be related parties such as authorities, customers, MCA employees, etc.

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

Responsibilities

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

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, the appeal and complaint committee provide its recommendation as a result of the evaluation. The final decision is taken by the full-time employee of MCA. MCA 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 MCA, this person 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.

The Appeal Committee establishment and working principals are defined in TL.03 Appeal Committee Assignment and Working Instructions.

8.1. Sources of Appeals;

- Appeals made against decisions of MCA pursuant to application review and resource allocation (scope, duration, pricing, method of conformity assessment, sampling, assessment team, etc.),
- Appeals made against the findings and decision of assessment team during and after conformity assessment.
- Appeals made against the decisions on certifications.

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 MCA are kept under record with FR.02 Customer Complaint Appeal and Suggestion form which is available on the MCA website, in electronic media or are recorded with the FR.02 Complaint, Appeal and Suggestion Form by the Management Representative or the relevant MCA Personnel or Quality Manager FR.02 complaint appeal and suggestion form created for accessing in the website. 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 received.

8.3.2. After receipt of the complaint, Quality Manager and relevant department managers shall inquire the complainant to verify that it is related to the activities performed by MCA or not.

8.3.3. If the complaint is not related to MCA activities, written information is provided to complaint-holder by Quality Manager within maximum 7 days.

8.3.4. If the complaint is related to the MCA activities or the personnel working within MCA, 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 MCA 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. Both case decisions and transactions shall be recorded with FR.02 Complaint Objection and Suggestion Form. Written information shall be communicated to the complainant about the outcome of the assessment within 7 days unless otherwise requested. If the complaint is forwarded to the 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 Printed copies without original signature are uncontrolled copies.

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 his item, for a complaint about the Quality Manager.)

8.3.6 The Quality Manager shall record the assessments made on the complaint in the FR.02 Complaint Appeal and Suggestion Form. As a result of the evaluation in the form, it may be decided to initiate Corrective / Preventive Activity, if such decision is taken, the activity shall be followed up with Corrective / Preventive Activity in accordance with PR.09 Corrective and Preventive Actions Procedure.

8.3.7. Upon completion of the work initiated for the complaint, the Quality Manager shall be given written information to the complainant within maximum 7 days.

8.3.8. If the complainant is dissatisfied of the activity carried out, the issue shall be notified by the Quality Manager with FR.02 Complaint and Appeal Form to appeal committee and customer is informed.

8.3.9 Complaints which are related to the complainant of MCA 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 adopted by MCA shall be kept under record with FR.02 Complaint Appeal and Suggestion Form by the Management Representative or Quality Manager or relevant MCA personnel in electronic media with FR.02 Complaint Appeal and Suggestion Form created for accessing in the website. Appeals shall be accepted in 30 days after the notification date of MCA decision.

8.4.2. After receipt of the appeal, the Quality Manager and relevant Department Manager shall inquire the appeals to verify that it is related to the decisions adopted by MCA or not.

8.4.3. If the appeal is not related to the decisions adopted by MCA, 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 adopted by MCA, 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 appellant 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 Customer 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 consist of a final reviewer and decision maker shall be implemented and 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 appellant and requests his feedback. The evaluation and assessment which is specified above shall be finalized in 30 days after the appeal received.

8.4.10. If appeal holder is dissatisfied with the decision of appeal committee or actions are taken, then appeal holder may seek the legal remedies. The appeal holder has the right to appeal to MCA for a second time if the appeal holder is not satisfied with the decision and action taken by the committee. MCA 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, MCA shall notify the appeal holder of the current legal rights and the periods regarding the exercise of these rights.