

[Organization logo]

[Organization name]

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PROCEDURE FOR CUSTOMER COMMUNICATION, FEEDBACK AND COMPLAINTS

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Change history

Date	Version	Created by	Description of change
	0.1	Advisera	Basic document outline

Table of contents

1. PURPOSE, SCOPE AND USERS	3
2. REFERENCE DOCUMENTS	3
3. COMMUNICATION, FEEDBACK AND COMPLAINT-HANDLING PROCESS	4
3.1. PROCESS FLOW	4
3.2. COMMUNICATION WITH CUSTOMERS	4
3.3. GATHERING CUSTOMER FEEDBACK	4
3.4. HANDLING CUSTOMER COMPLAINTS	5
3.5. RESOLVING CUSTOMER COMPLAINTS	6
4. MANAGING RECORDS KEPT ON THE BASIS OF THIS DOCUMENT	6
5. APPENDICES	6

1. Purpose, scope and users

The purpose of this Procedure is to provide a systematic approach to the receipt, investigation and resolution of customer complaints which relate to the product from [organization name].

This Procedure describes the customer complaint handling process.

This Procedure refers to all aspects of necessary activities to handle complaints of medical devices from external sources (customers) in order to recover and improve customer satisfaction and minimize negative effects of customer dissatisfaction towards the company and to identify and use the feedback contained in the complaints. This Procedure also addresses determining the need to report information to the appropriate regulatory authorities.

2. Reference documents

- ISO 13485:2016 standard, clauses 7.2.3, 8.2.1, 8.2.2, 8.2.3, and 8.3.3
- MDR 2017/745, article 10(9)
- Sales Procedure
- Procedure for Risk Management
- Procedure for Production and Service Provision
- Procedure for Vigilance and Adverse Event Investigation and Reporting
- Procedure for Corrective and Preventive Action
- Quality Manual

Commented [AES4]: Include the name of your organization.

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You can find the full text of the MDR on the following link:
<https://advisera.com/13485academy/mdr/>

Commented [AES6]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "08_Sales".

Commented [AES7]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "07_Risk_Management".

Commented [AES8]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "12_Production_and_Service_Provision".

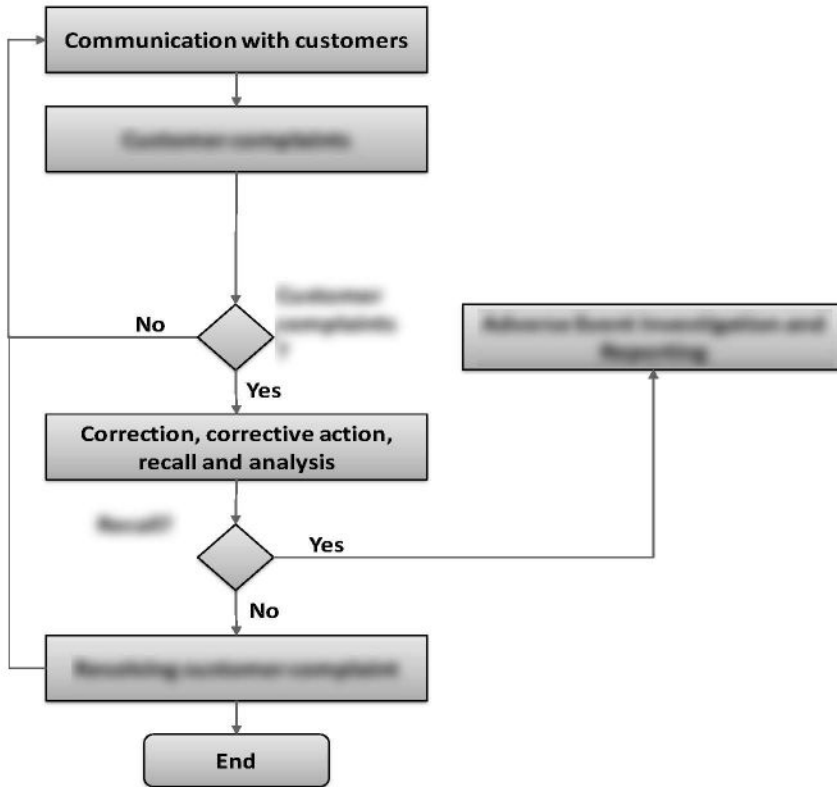
Commented [AES9]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "19_Adverse_Event_Investigation".

Commented [AES10]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "25_Corrective_and_Preventive_Action".

Commented [AES11]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "03_Quality_Manual".

3. Communication, feedback and complaint-handling process

3.1. Process flow



3.2. Communication with customers

[Job title] communicates with customers via phone, email, verbal communication, etc.

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Communication with customers includes, but it is not limited to:

- product information;
- inquiries, contracts, or order handling, including amendments;
- customer feedback, including complaints;
- other issues.

All information and suggestions from the customer must be reviewed.

3.3. Gathering customer feedback

[organization name]

After the service or product is delivered, [job title] must gather customer feedback. Oral or written feedback must be recorded by [job title] in Customer Feedback Report.

Commented [AES13]: E.g., Sales Manager, QA Manager.

Commented [AES14]: E.g., Sales Manager, QA Manager,

[Organization name] may be notified of complaints via:

Commented [AES15]: Include the name of your organization.

- customers
- organization's personnel

3.4. Handling customer complaints

[Job title] is responsible to handle each complaint. Distributors and sub-contractors must assign one person of contact,

Commented [AES16]: E.g., Complaint Manager, Complaint Investigator.

Commented [AES17]: Include the name of your organization.

[Job title] is responsible for the complete investigation resulting from any quality issues discovered by QA relating to the complaint.

Commented [AES18]: E.g., Complaint Manager, Complaint Investigator.

[Job title] is responsible for review of complaints to determine if they need an investigation and

Commented [AES19]: E.g., Complaint Manager, Complaint Investigator.

[Job title] must ensure that any complaint involving the possible failure of a product, and its specifications are reviewed,

Commented [AES20]: E.g., Complaint Manager, Complaint Investigator.

[Job title] must ensure that all complaints are to be investigated to determine if corrective action is needed in accordance with the Procedure for Corrective and Preventive Action.

Commented [AES21]: E.g., Complaint Manager, Complaint Investigator.

[Job title] must ensure that all returned product is evaluated, if possible, and review the appropriate

Commented [AES22]: E.g., Complaint Manager, Complaint Investigator.

[Job title] is responsible for reviewing each complaint and determining whether or not a recall is required, and if it's necessary to inform the appropriate regulatory body, and enters information about this report into the Registry of Reports to the Authorities.

Commented [AES23]: E.g. Complaint Manager, Complaint Investigator.

Commented [AES24]: E.g., Complaint Manager, Complaint Investigator.

[Job title] must ensure periodic analysis of complaints to effectively monitor product defects, complaints, and to determine if there are any increasing trends concerning specific products that

Commented [AES25]: E.g., Complaint Manager, Complaint Investigator.

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[organization name]

3.5. Resolving customer complaints

[Job title] suggests ways of resolving the complaint to [job title]. [Job title] is responsible for approval and checking results of the correction or corrective actions.

Commented [AES27]: E.g., Complaint Manager, Complaint Investigator.

Commented [AES28]: E.g., Quality Manager or QA Manager

4. Managing records kept on the basis of this document

Record name	Code	Storage			Responsibility
		Retention period	Location	Access	
Customer Feedback Report	PR09.1	3 years	Quality Management System	Quality Manager	
Registry of Customer Complaints	PR09.2	3 years	Quality Management System	Quality Manager	
Registry of Reports to the Authorities	PR09.3	3 years	Quality Management System	Quality Manager	

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5. Appendices

- Appendix 1 – Customer Feedback Report
- Appendix 2 – Registry of Customer Complaints

• Appendix 3 – Registry of Reports to the Authorities

[job title]

[name]

[organization name]

[signature]

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