[Organization logo]

[Organization name]

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PROCEDURE FOR CORRECTIVE AND PREVENTIVE ACTION

Code:	
Version:	0.1
Created by:	
Approved by:	
Date of version:	
Signature:	

Commented [AES2]: The document coding system should be in line with the organization's existing system for document coding; in case such a system is not in place, this line may be deleted.

Distribution list

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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

The purpose of this Procedure is to describe all activities related to the initiation, implementation and keeping of records of corrections, as well as corrective and preventive actions.

This procedure is applied to all potential and incurred nonconformities related to product, process and the Quality Management System (QMS).

Users of this document are all persons responsible for processes in [organization name].

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

2. Reference documents

- ISO 13485:2016 standard, clauses 8.5.2 and 8.5.3
- MDR 2017/745, article 10(9) and Annex IX – Chapter I
- Procedure for Production and Service Provision
- Internal Audit Procedure

Commented [AES5]: Delete this if your organization does not need to be compliant with MDR.

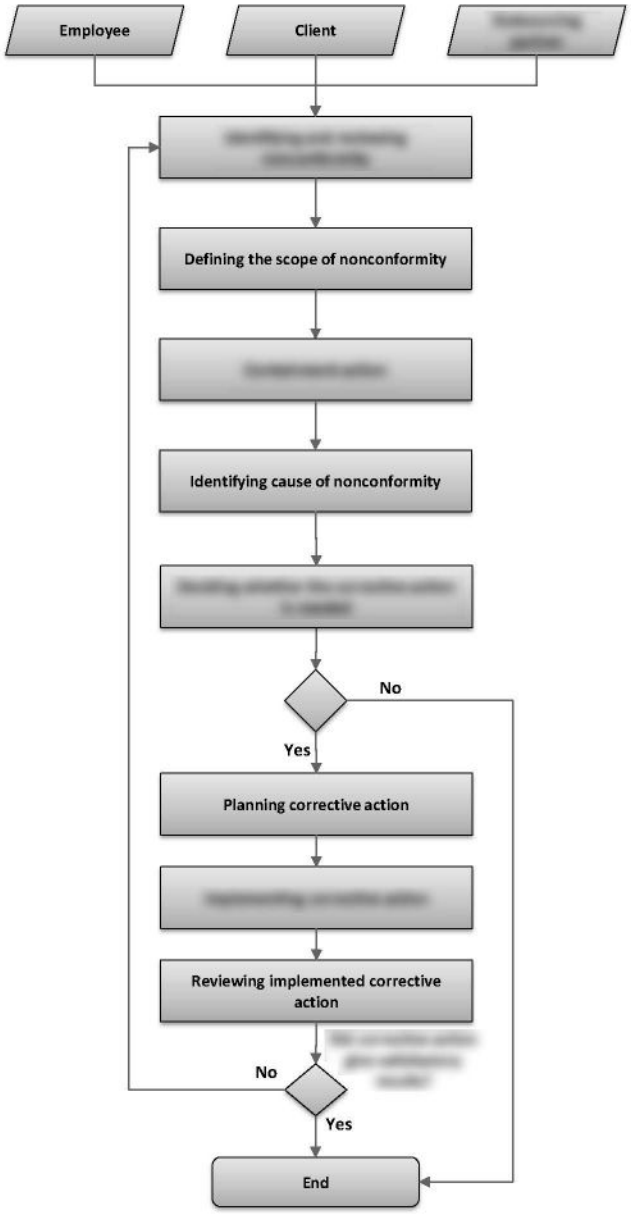
You can find the full text of the MDR on the following link: https://advisera.com/13485academy/mdr/

Commented [AES6]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "12_Production_and_Service_Provision".

Commented [AES7]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "24_Internal_Audit".

3. Corrections and corrective actions

3.1. Process flow



3.2. Nonconformities and corrections

Nonconformity is any failure to meet the requirements of the standards, internal documentation, regulations, contractual and other planned arrangements of the QMS. Nonconformities can be identified during an internal or external audit, based on results of the management review, after incidents, during normal business operations or in any other occasion.

[illegible]

The prerequisite for a successful correction is a clear problem definition and relevant evidence (What, When, Who, Where, and How much (as applicable)). [Job title] must ensure that any corrections as short-term actions are performed in minimal time in order to allow the organization's further functioning.

Commented [AES8]: Adapt to the organization's practice.

[illegible]

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Examples of corrections are:

- containment and corrections on products in production processes
- stoppage of shipment / supply (Finished Product – inspection and test records, quality audits, etc.)
- issuance of advisory notice (Regulatory Requirements – result of a regulatory inspection, audits, etc.)
- [illegible]
- [illegible]

3.3. Corrective actions

A corrective action may be initiated by any employee or (where appropriate) client, supplier or outsourcing partner of the organization. [illegible]

Corrective actions must be appropriate to the consequences of occurred nonconformities that can have a negative influence on:

- business performance of the organization
- products, processes and QMS
- [illegible]

By reviewing corrective actions, [job title] ensures that consequences of the corrective action don't have a negative influence on other parts of the system.

3.4. Implementation of corrective actions

A corrective action is implemented in the following way:

Step	Person responsible for implementation
1. Identifying and reviewing nonconformity	Anyone with a role in the QMS
2. Defining the scope of nonconformity by identifying all processes and products affected by nonconformity	Process owner together with Manager Representative
3. Containment actions that immediately correct nonconformity or prevent recurrence	Person responsible for process in which nonconformity was discovered
4. Identifying cause of nonconformity	Person responsible for resolving nonconformity
5. Deciding if it is needed to initiate corrective action depending on complexity of nonconformity	Person responsible for resolving nonconformity
6. Planning corrective action	Person responsible for the area/process where the nonconformity has been identified
7. Implementing corrective action	Person responsible for the area/process where the nonconformity has been identified
8. Reviewing whether the action taken resulted in the elimination of causes of nonconformity	Person responsible for the area where the nonconformity has been identified
9. Reviewing whether the action does not have an adverse effect	Process owner together with Manager Representative

Each of the above steps must be recorded in the form for corrective or preventive actions.

After the approval of the corrective action from [job title], a successful verification action must be implemented according to a defined time schedule.

[Job title] must ensure that any necessary corrective actions are taken without undue delay.

[Job title] must ensure that the actions' effectiveness is checked, approved, and verified by [job title].

4. Preventive actions

The purpose of preventive action is to prevent undesired effects by determining activities aimed at eliminating the cause of a potential nonconformity in order to prevent its occurrence.

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Preventive actions are implemented in the same way as described for corrective actions.

5. Managing records kept on the basis of this document

Record name	Code	Storage		
		[illegible]	[illegible]	[illegible]
Corrective/Preventive Action Request	PR25.1	[illegible]	[illegible]	[illegible]
Registry and Status of Corrective and Preventive Actions	PR25.2	[illegible]	[illegible]	[illegible]

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6. Appendices

- Appendix 1 – Corrective/Preventive Action Request
- [illegible]

[job title]
[name]

_____
[signature]

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