[Organization logo]

[Organization name]

Commented [AES1]: All fields in this document marked by square brackets [ ] must be filled in.

PROCEDURE FOR CONTROL OF NONCONFORMING PRODUCTS

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

Commented [AES3]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

Copy no.	Distributed to	Date	Signature	Returned	
				Date	Signature

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 identifying and managing nonconforming product in order to prevent its unwanted use or shipment and to define responsibilities and authorities related to treatment of nonconforming product.

This Procedure is applied to all processes and/or areas (parts of organization) within the Quality Management System (QMS).

Users of this document are members of top management of [organization name], as well as the owners of processes in which the nonconformity occurred.

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

2. Reference documents

- ISO 13485:2016 standard, clause 8.3
- Quality Manual
- Procedure for Corrective and Preventive Action
- MDR 2017/745, article 10(9) and Annex IX – Chapter I
- IVDR 2017/746
- MEDDEV 2.12/1 rev. 8 Vigilance System
- [national regulations for vigilance system]

Commented [AES5]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "03_Quality_Manual".

Commented [AES6]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "25_Corrective_and_Preventive_Action".

Commented [AES7]: Delete this if your organization does not need to be compliant with MDR.

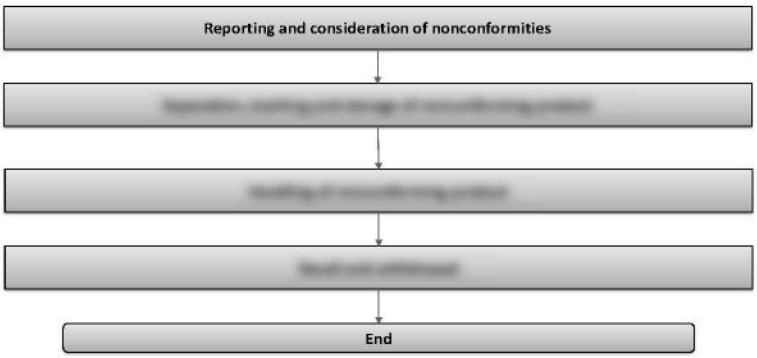
You can find the full text of the MDR on the following link: https://advisera.com/13485academy/mdr/

Commented [AES8]: Delete if your medical device is not an in vitro diagnostic medical device.

Commented [AES9]: Include reference to your national regulation that covers the matter of how adverse events should be handled.

3. Managing nonconformity

3.1. Process flow



3.2. Reporting and consideration of nonconformities

A nonconformity can be generated by various processes:

- Nonconforming materials identified during incoming inspection
- Finished product nonconforming to the specifications of the product
- [illegible]
- [illegible]

Every employee who notices a nonconformity must report it to [job title]. The nonconformity is recorded in the Nonconforming Product Record by [job title]. [illegible]

Commented [AES10]: E.g., Management Representative

3.3. Separation, marking and storage of nonconforming products

[Job title] separates nonconforming product from conforming products. Responsible for separation, marking and storage of nonconforming products in order to prevent misuse and unauthorized use and shipment is [job title] or chief of shift in which the nonconformity is discovered. An employee in the work place where the nonconformity is discovered marks the nonconforming product.

Commented [AES11]: Person responsible for warehousing and storage.

[illegible]

After solving the nonconformity and performing all activities mentioned above, [job title] enters data about the nonconformity in the Registry of Nonconformities.

3.4. Handling nonconforming product

[Job title] selects members of the Team for nonconforming products depending on the process in which the nonconformity has occurred or was discovered.

Commented [AES12]: E.g., Management Representative, QA Manager

[illegible]

Methods for dealing with nonconforming product are:

Commented [AES13]: Choose one or more methods and adapt

- Write-offs (Scrap) – [job title] is responsible to organize the write-off by handing over the product to an organization licensed for deposition, recycling or destruction of the product.
- Reusing or classification for other purposes – used in cases when the nonconforming product fulfills demands for the product or process in which it will be used.
- Approval of use (Use "As Is") – is performed by [job title] by approving the shipment based on consent of the user or the decision of a relevant authority and customer if necessary.
- [illegible]
- [illegible]

Commented [AES14]: This is usually a person responsible for

Commented [AES15]: This can be laboratory for

Commented [AES16]: Adapt to the organization's practice.

When a correction is needed, [job title] prepares and issues the working order, which defines the additional demands that need to be fulfilled.

Commented [AES17]: E.g., production worker

Commented [AES18]: If your product could not be reworked,

Commented [AES19]: Adapt to the organization's practice.

[illegible]

Commented [AES20]: Adapt to the organization's practice.

All the controls must be repeated to the full extent after the corrections. Impact of rework to the product must be investigated and such possible influence must be controlled.

- After all corrective actions are completed, the [job title] informs the [job title] that the product is ready for repeated controls.
- After all rework is complete, the product must pass all phases, identical with the regular process.
- [illegible]
- [illegible]

[Job title] decides which method for resolving nonconforming product will be used and it is recorded in the Nonconforming Product Record by the team leader.

Commented [AES21]: E.g., Production Manager

3.5. Recall and withdrawal of nonconforming product

Product recall is the process of retrieving nonconforming product from consumers as a result of safety concerns or manufacturing defect in a product.

Product withdrawal is part of the recall process and occurs when the organization removes the product from the marketplaces and distribution centers due to safety issues or product defect. [Job title] is responsible for recall.

Commented [AES22]: E.g., Sales Manager

[illegible] will inform about product withdrawal the distributors of the device in question and, where applicable, the authorized representative and importers. The local Competent Authority must also be notified of the withdrawal. [illegible]

Commented [AES23]: E.g., Sales Manager

Commented [AES24]: Delete this if it is not applicable to your device, e.g.:
- if your device is classified as class I

[illegible]

On the following link you can find the Notified Bodies in EU per country: [illegible]

3.5.1. *Forming a Product Recall Team*

Information about problems with product may come from different sources:

- test results from external laboratory
- customer complaints
- [illegible]
- [illegible]

Based on this information, [job title] forms a Product Recall Team that consists of:

Team function	Job title
Team leader	[Sales Manager]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	

Commented [AES25]: Adapt to the organization's needs.

3.5.2. *Assessment of hazard of product*

The team conducts hazard analysis of using a product considering customer safety and, if necessary, makes the decision to conduct:

Commented [AES26]: Adapt to the organization's practice.

[illegible]

- Public recall, in cases when the wider public should be alerted
- [illegible]

The team is responsible to issue notices to interested parties considering regulatory requirements.

3.5.3. *Recall, withdrawal and storage of product*

The Product Recall Team defines a way of withdrawing product from consumers, and removing them from marketplaces and distribution centers, if necessary. [illegible]

3.5.4. Effectiveness analysis of product recall process

After completion of the product recall process, the team holds a meeting to assess the effectiveness of the product recall process and defines corrective actions according to the Procedure for Corrective and Preventive Actions.

Effectiveness of the product recall process is assessed as a ratio of recalled and distributed products.

% of product recalled	Recall effectiveness
100	Excellent
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]

Commented [AES27]: This scale is a suggestion; adapt to the [illegible]

4. Managing records kept on the basis of this document

Record name	Code	Storage		[illegible]
		[illegible]	[illegible]	
Nonconforming Product Record	PR18.1	[illegible]	[illegible]	[illegible]
Registry of Nonconformities	PR18.2	[illegible]	[illegible]	[illegible]
Registry of Recalled / Withdrawn Products	PR18.3	[illegible]	[illegible]	[illegible]

Commented [AES28]: If the record is in electronic form, write [illegible]

Commented [AES29]: If the record is in electronic form, write [illegible]

Commented [AES30]: If the record is in electronic form, write [illegible]

5. Appendices

- Appendix 1 – Nonconforming Product Record
- Appendix 2 – Registry of Nonconformities
- [illegible]

[organization name]

[job title]
[name]

_____

[signature]

Commented [AES31]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.