PROCEDURE FOR CONTROL OF NON-CONFORMING PRODUCTS

Code:

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1. Purpose, scope and users

The purpose of this procedure is to describe all activities related to identifying and managing non-conforming product in order to prevent its unwanted use or shipment and to define responsibilities and authorities related to treatment of non-conforming product.

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

Users of this document are members of top management of [organization name], as well as the owner of processes in which the non-conformity occurred.

2. Reference documents

- ISO 13485:2016 standard, clause 8.3 and 8.3.4
- ISO 9001:2015 standard, clause 8.7
- Quality Manual
- Procedure for Corrective and Preventive Actions
- MDR 2017/745
- IVDR 2017/746
- MEDDEV 2.12/1 rev. 8 Vigilance System
- [national regulations for vigilance system]

[Commented [13A4]: Please include the name of your company.]

[Commented [13A5]: Delete if the company hasn’t implemented ISO 9001:2015.]

[Commented [13A6]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder “01_Quality_Manual”.]

[Commented [13A7]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder “21_Corrective_and_Preventive_Action”.]

[Commented [13A8]: Delete if it is not applicable to your organization.]

[Commented [13A9]: Delete if your medical device is not an in vitro diagnostic medical device.]

[Commented [13A10]: Please include reference to your national regulation that covers the matter of how adverse events should be handled.]
3. Managing non-conformity

3.1. Process flow

3.2. Reporting and consideration of non-conformities

A non-conformity can be generated by various processes:

- Non-conforming raw materials
- Non-conforming production
- Non-conforming equipment
- Non-conforming measurement equipment

Every employee who notices a non-conformity must report to [job title]. The non-conformity is then evaluated to determine its root cause. Corrective actions are taken to eliminate the cause of the non-conformity and prevent its recurrence.

3.3. Separation, marking and storage of non-conforming products

[job title] separates non-conforming product from conforming products. Responsible for separation, marking and storage of non-conforming products in order to prevent misuse and unauthorized use.
Non-conforming raw materials and the final products are labeled with a sign reading NON-
conforming. The non-conforming raw materials and final products are clearly marked and
about the non-conformity in the Registry of Non-Conformities.

3.4. Handling non-conforming product

[Job title] selects members of the Team for non-conforming products depending on the process in

Methods for dealing with non-conforming product are:

- The product fulfills demands for the product or process in which it will be used. RL: Who is
responsible?

- Doubt about the compliance of any operation with a policy, procedure or work instruction,

- or non-conformance to its intended acceptance level. [Job title] is responsible for

corrections.

conforming product*) and store in a designated rework area.

- After all corrective actions are completed, the [job title] informs the [job title] that the

- included with the report of an authorized body

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3.5. Recall and withdrawal of non-conforming product

If all corrective actions are verified by the [job title], the product is approved and ready for

[Job title] decides which method for resolving non-conforming product will be used and it is

3.5.1. Forming a Product Recall Team

Information about problems with product may come from different sources:

- Customer complaints
- Returns due to non-conformity
- Warning from regulatory authorities
- Field experience

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

<table>
<thead>
<tr>
<th>Team function</th>
<th>Job title</th>
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<tbody>
<tr>
<td>Team leader</td>
<td>[Sales Manager]</td>
</tr>
<tr>
<td>Member</td>
<td>[Warehouse Manager]</td>
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<tr>
<td>Member</td>
<td>[PR Manager]</td>
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<tr>
<td>Member</td>
<td></td>
</tr>
</tbody>
</table>

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:

- [Explanation or justification]

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 the market when necessary. The product is replaced with another product, removed from the warehouse and labeled RECALLED or WITHDRAWN PRODUCT.

3.5.4. Effectiveness analysis of product recall process

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

<table>
<thead>
<tr>
<th>% of recalled product</th>
<th>Recall effectiveness</th>
</tr>
</thead>
</table>

4. Managing records kept on the basis of this document

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<td>[office of Management Representative]</td>
<td>[job title]</td>
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5. Appendices

- Appendix 1 – Non-Conforming Product Record
- Appendix 2 – Registry of Non-Conformities
- Appendix 3 – Registry of Recalled / Withdrawn Products