PROCEDURE FOR ADVERSE EVENT INVESTIGATION AND REPORTING

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1. **Purpose, scope and users**

The purpose of this procedure is to define the process of incident investigation, and the minimum requirements for the reporting, investigating, and communicating of adverse events and notification of complaints that meet specified reporting criteria of adverse events used in the QMS (Quality Management System).

This procedure applies to all processes within the QMS scope.

Users of this document are all employees of [organization name] inside the scope of the QMS.

2. **Reference documents**

- ISO 13485:2016 standard, clause 8.2.3
- ISO 9001:2015 standard, clause 8.5.5
- MDR 2017/745
- IVDR 2017/746
- MEDDEV 2.12/1 rev. 8 Vigilance System
- [national regulations for vigilance system]

3. **Adverse Event Investigation**

An adverse event is any unwanted medical device-related incident that may occur during utilization

An adverse event is any event that meets the criteria mentioned below, and must be communicated

Criteria for reporting on adverse events are:

- A death or serious irreversible injury or disease
- A serious injury that results in incapacity
- A serious injury that results in prolonged incapacity
- A serious injury that results in reduced or permanent impairment of the structure or function of the body
- A significant malfunction

[Job title] is responsible for conducting the investigation in a timely manner, and documenting the actual and potential severity. Regulatory forms that need to be completed can be found on the following link [insert link].

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3.1. Reporting (adverse event notification)

The incident or adverse event must be reported to [job title], who will fill out an Incident Investigation Report. Incidents include the following:

- [description of incidents]
- [description of incidents]
- [description of incidents]
- [description of incidents]
- Any other available information.

The report must be issued no later than 12 hours following the incident, or 24 hours for low-level incidents. Adapting to organization’s practice.

In determining the nature of the investigation, the resources needed, and the priority to be given to investigation of an incident, [job title] must take into account:

- [description of considerations]
- [description of considerations]

The report must then be sent out [describe the means to be used] by the incident owner to the [organization name].

3.2. Incident investigation objectives

- prevention of reoccurrence by prescribing the corrective actions
- determination of basic QMS failures
- [description of objectives]

Procedure for Adverse Event Investigation ver. [version] from [date]

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3.3. Determining the cause of the incident

[Job title] initiates the process of incident investigation by identifying possible causes, aiming to understand the root cause of the issue.

3.4. Analysis of the causes of the incident

The incident investigation conducted by [job title] must cover:

3.4.1. Possible causes

A list of possible causes is compiled, and the occurrence of each cause is evaluated against the incident. Possible causes are compared to each other in order to determine which one is the most probable.

3.4.2. Root/source of possible cause (underlying cause)

A root cause is an initiating cause of either a condition or a sequence of events that leads to an adverse event or process failure. This step involves looking for the primary underlying cause.

3.4.3. Real causes

[Job title] conducts the investigation of the real cause by applying the following steps:

- [List of steps]
- consulting with experts who know the processes well and have insight into them

After the investigation, [job title] completes the Incident Investigation Report and delivers it to the
...
Immediately after an incident, the incident owner and required management should ensure that they
[organization name]

3.5. Incident investigation follow-up

Review results are submitted to the CEO and represent an input element in the management review.

4. Managing records kept on the basis of this document

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<td>[office of [job title]] / Records are stored in file cabinet [describe name/location]</td>
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5. Appendices

- Appendix 1 – Investigation Report

[signature]