Incident Assessment Form

Regulatory requirements:

EU Regulation 2017/745 (MDR)	Art. 87 and 89 (Vigilance, incident analysis, field safety corrective actions)
ISO 13485:2016	Para. 8.2.3
German Medical Devices Law (MPDG)	Chapter 5, Art. 71 - 83
German Medical Device EU Adjustment Ordinance (MPEUAnpV)	All
MDCG 2023-3	All
MEDDEV 2.12/1 rev. 8	All

Related Documents:

- SOP Vigilance

Summary

This template is used to assess whether an event with a potentially negative impact on the state of health constitutes a serious and reportable incident.

General Information	
Description of the Event:	*<Describe e.g. the cause that led to the event, the relationship between device and event, urgency of required actions>*
Report Date and Time:	
Affected Medical Device:	*<Enter UDI-DI here>*
Incident Assessment:	The event is a reportable incident:( ) Yes ( ) No
Action Planned:	*<Describe FSCA>*

Incident Assessment Framework

The following criteria are based on the MEDDEV 2.12/1 rev. 8 and MDCG 2023-03 guidance documents. Any event which meets **all three criteria listed below** is considered a serious incident and must be reported to the competent national authorities. Events that are not evaluated as reportable serious incidents

may still be required to be documented and and considered in other quality management system processes (e.g. CAPA or post-market surveillance).

> Keep in mind that this form can be also used to document appropriately why an event was NOT considered a reportable incident.

(1) General Event Description and Occurrence

Criterion: An event has occurred that meets the definition of an incident according to Art. 2(64) MDR.

Note #1: An 'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect."

Note #2: The incident assessment must also consider information resulting from testing, reading the instructions for use or scientific data that indicate implications as outlined in step 3 below.

Applicable?	( ) Yes ( ) No
Explanation:	*<If no, describe why this is not applicable. The form does not have to be filled out any further.>*
Category of event	

> Examples for possible incidents are as follows. For more information, see MDCG 2023-3, para. 2.
>
> - technical failure mode leading to malfunctions of the medical device
> - unclear or inadequate instructions for use
> - use errors caused by ergonomic device features and abnormal use (e.g. off-label use), see MDCG 2023-3, para. 6
> - undesirable side effects (see MDCG 2023-3, para. 8)

(2) Relationship Between the Device and Event

Criterion: A (direct or indirect) causal relationship between the incident and the medical device has been established, is reasonably possible or suspected.

Applicable?	( ) Yes ( ) No
Explanation:	<if no, describe why this is not applicable>

Note: When assessing the relationship between the device and event the Person Responsible for Regulatory Compliance must take the following points into consideration:

- *The opinion of subject matter experts (e.g. physicians)*
- *The PRRC assessment;*
- *Previous / similar events and incidents*

This decision should be made conservatively, i.e. if the situation is complex and/or potentially caused by multiple medical devices, the PRRC should have a tendency to assess this as "applicable" even if the matter still remains unclear.

(3) Event Outcomes

Criterion: The event led, might have led, or might lead to one of the following outcomes as defined in Art. 2(65) MDR:

Applicable? ( ) Yes ( ) No
Explanation: <if no, describe why this is not applicable>
Outcome: ( ) death of a patient, user or other person ( ) serious deterioration in state of health of a patient, user or other person ( ) serious public health threat

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A serious deterioration in state of health results in at least one of the following:

- *life-threatening illness or injury*
- *permanent impairment of a body structure or a body function*
- *hospitalization or prolongation of patient hospitalization or a condition which requires medical or surgical intervention to prevent any of the above*
- *chronic disease*
- *any indirect harm as a consequence of an incorrect diagnostic result when used within manufacturer's instructions for use*

  Please note: Serious incidents may also include events where serious medical consequences have not occurred yet but could occur in the future under similar circumstances. If you are unsure, check the intended use of the device to assess whether the event should be excluded based on its (counter-)indications.

Guidance for Assessment

Guidance Document	Explanation
Intended Purpose *See MEDDEV 2.12/1, section 4.6 'Definitions'; See MDD Article 1.2 paragraph (g)*	The use for which the device is intended according to the data supplied by the manufacturer on the labeling, in the instructions for use and/or in promotional materials.

Guidance Document	Explanation
Incident*See MEDDEV 2.12/1, section 4.6 'Definitions' and annex I for examples*	Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health.

Guidance Document	Explanation
Direct or Indirect Harm*See MEDDEV 2.12/1, section 4.6 'Definitions'*	A physical injury or damage to the health of people, or damage to property or the environment.In the majority of cases, diagnostic devices will, due to their intended use, not directly lead to physical injury or damage to health of people. These devices are more likely to lead to indirect harm. Harm may then occur as a consequence of the medical decision, action taken/not taken on the basis of information or result(s) provided by the device or as a consequence of the treatment of cells or organs outside of the human body that will later be transferred to a patient.Examples of indirect harm include misdiagnosis, delayed diagnosis, delayed treatment, inappropriate treatment, absence of treatment transfusion of inappropriate materials. Indirect harm may be caused by imprecise results, inadequate quality controls, inadequate calibration, false positive or false negative results.

Guidance Document	Explanation
Field Safety Corrective Actions*See MEDDEV 2.12/1, section 4.6 'Definitions'*	FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. Such actions, whether associated with direct or indirect harm, should be reported and should be notified via a field safety notice.FSCA may include: the return of a device to the supplier; device modification; device exchange; device destruction; advice given by manufacturer regarding the use of the device and/or the follow-up of patients, users or others (e.g. where the device is no longer on the market or has been withdrawn but could still possibly be in use).Manufacturers can as part of ongoing quality assurance identify a failure of a device to perform according to the characteristics specified in the information for use provided by the manufacturer. If the failure might lead to or might have led to death or serious deterioration in the state of health associated with the use of a medical device and has an impact on a product that has already been placed on the market the manufacturer must initiate a FSCA.Examples of failure modes may include software anomalies (e.g. incorrect correlation between patient sample and the obtained result, invalid controls or invalid calibrations).A device modification can include:- Permanent or temporary changes to the labeling or instructions for use (for example: advice for revised quality control procedures such as use of third party controls,