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Change history

Version	Valid and binding as of	Description, comments (by author)	Author's initials
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3.1	08.03.2023	Correction of translation errors so that it corresponds to the original German version V3.0 in terms of content.	wic
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1 Terms, definitions, abbreviations

1.1 Abbreviations

ClinO-MD	Ordinance on Clinical Trials with Medical Devices (SR 810.306)
FSCA	Field Safety Corrective Action
IvDO	Ordinance of 4 May 2022 on In Vitro Diagnostic Medical Devices (SR 812.219)

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IVDR	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
MedDO	Medical Devices Ordinance of 1 July 2020 (SR 812.213)
PSR	Periodic Summary Report
SPPP	System and Procedure Pack Producer
TPA	Therapeutic Products Act of 15 December 2000 (SR 812.21)

1.2 Terms, definitions

Device: In this guidance document, the term "device" refers to medical devices and other devices according to Art. 1 MedDO and in vitro diagnostic medical devices and the associated accessories according to Art. 1 para. 1 IvDO. Where provisions apply only to specific devices or groups of devices in an ordinance (MedDO or IvDO), this is explicitly stated.

Incident[1]: 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.

- For devices specifically according to MedDO, the term incident also covers:
  - any undesirable side-effect

- For devices specifically according to IvDO, the term incident also covers:
  - any harm as a consequence of a medical decision or an action taken or not taken on the basis of information or results provided by the device

Serious incident[2]: an incident that directly or indirectly led, might have led or might lead to any of the following:

a) the death of a patient, user or other person,
b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
c) a serious public health threat

Manufacturer[3]: any natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark; the clarifications and exceptions listed in Art. 16 para. 1 and 2 of the MDR and Art. 16 para. 1 and 2 of the IVDR are reserved.

System and procedure pack producer[4]: System and procedure pack producer (SPPP) refers to the natural or legal person that assembles a system or procedure pack.

[1] Art. 4 para. 2 MedDO in conjunction with Art. 2 no. 64 MDR and Art. 4 para. 2 IvDO in conjunction with Art. 2 no. 67 IVDR
[2] Art. 4 para. 2 MedDO in conjunction with Art. 2 no. 65 MDR and Art. 4 para. 2 IvDO in conjunction with Art. 2 no. 68 IVDR
[3] Art. 4 para. 1 let. f MedDO and Art. 4 para. 1 let. e IvDO
[4] Art. 11 MedDO in conjunction with Art. 22 MDR

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Authorised representative[5] *: any natural or legal person established within Switzerland who has received and accepted a written mandate from a manufacturer located in another country to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Ordinance.

Importer[6] **: any natural or legal person established within Switzerland that places a device from another country on the Swiss market.

Distributor[7] ***: any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the Swiss market, up until the point of putting into service.

Economic operator[8]: manufacturer, authorised representative, importer or distributor and the person referred to in Art. 22 para. 1 and 3 MDR (SPPP).

2 Introduction

An incident is an event that occurs in connection with a device. Incidents that are considered to be serious and have occurred in Switzerland – or, depending on the national law under which the device was supplied in Liechtenstein, in Liechtenstein**** – must be reported to Swissmedic. Swissmedic systematically collects and evaluates these reports. This reporting system is designed to protect the health of patients and users. In particular, it aims to avoid recurrences of incidents based on problems with the design, manufacture or use of devices.

3 Objective

This document describes the requirements that have to be met in respect of incident reports by the manufacturer, SPPP or its Swiss authorised representative. The applicable provisions should be summarised and presented in easily understandable language and in a form that can be used directly in practice. The legal provisions apply in all cases.

[5] Art. 4 para. 1 let. g MedDO and Art. 4 para. 1 let. f IvDO
* Based on the Customs Treaty between Liechtenstein and Switzerland, the following applies: Manufacturers domiciled in Switzerland do not have to appoint an authorised representative to place their medical devices on the market in Switzerland. By the same token, manufacturers domiciled in Switzerland also do not have to appoint an authorised representative to place their devices on the market in Liechtenstein. Switzerland and Liechtenstein are therefore considered to be a single region. A manufacturer outside of this region must therefore appoint an authorised representative in either Switzerland or Liechtenstein before placing their device on the market in Switzerland and/or Liechtenstein.
[6] Art. 4 para. 1 let. h MedDO and Art. 4 para. 1 let. g IvDO
** Based on the Customs Treaty between Liechtenstein and Switzerland, Switzerland and Liechtenstein are considered to be a single region. An economic operator in Switzerland who wishes to place a device from another country on the market in Switzerland or Liechtenstein is considered to be an importer. An economic operator who places a device from Switzerland on the market in Liechtenstein is not considered to be an importer.
[7] Art. 4 para. 1 let. l MedDO and Art. 4 para. 1 let h IvDO
*** Based on the Customs Treaty between Liechtenstein and Switzerland, Switzerland and Liechtenstein are considered to be a single region. An economic operator in Liechtenstein who purchases a device from an economic operator in Switzerland is considered to be a distributor.
[8] Art. 4 para. 1 let. j MedDO and Art. 4 para. 1 let i IvDO
**** Owing to the EEA Agreement and the Swiss-Liechtenstein Customs Treaty, two jurisdictions apply in parallel to medical devices in Liechtenstein (parallel marketability). Medical devices can be placed on the market in Liechtenstein either on the basis of EU-MDR or the MedDO (see LI website under Marktzugang [in German]). Swissmedic is responsible for processing vigilance reports for devices supplied under Customs Treaty law in Liechtenstein (Customs Treaty between Switzerland and Liechtenstein, concluded on 29 March 1923, SR 0.631.112.514, most recently revised by the announcement of 18 October 2022 on changes to the Annexes to the Customs Treaty.
2022.280 | Lilex - law database of the Principality of Liechtenstein)

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4 Legal basis

The legal requirements governing incident reports are set out in the following pieces of legislation:

- Art. 59 TPA) describes the reporting obligations for therapeutic products.
- Reports of serious incidents with devices according to MedDO are regulated in Art. 57 and Art. 66 of MedDO.
- Art. 87 MDR sets out the requirements for reporting serious incidents and field safety corrective actions (FSCAs)[9].
- Reports of serious incidents in connection with devices according to IvDO are regulated in Art. 50 and Art. 59 IvDO.
- Art. 82 IVDR sets out the requirements for reporting serious incidents and field safety corrective actions (FSCAs)[10]

5 Reporting serious incidents

Manufacturers and SPPPs must report serious incidents to the relevant competent authorities[11], i.e. **all serious incidents that have occurred in Switzerland or in Liechtenstein** involving devices that were supplied in Liechtenstein under Customs Treaty law must be reported to Swissmedic regardless of whether the manufacturer or SPPP is based in Switzerland or Liechtenstein or not. The reporting process for serious incidents, as described in this guidance document, applies to all devices of all classes. Serious incidents that are exempt from the reporting obligation can be found in section 6.1.

If the manufacturer or SPPP is not domiciled in Switzerland or Liechtenstein, the authorised representative is responsible for reporting[12]. In this case, the reports can be submitted to Swissmedic by the manufacturer, the SPPP or also by the authorised representative if they have access to the information contained in the form (e.g. from the technical documentation).
The authorised representative is also responsible for immediately informing the manufacturer or SPPP about complaints and reports related to a device for which they have been designated as the representative.[13]

Importers are required to immediately forward any complaints and reports about suspected incidents related to a device which they have placed on the market to the manufacturer or SPPP and its authorised representative[14].

Distributors that have received complaints and reports related to a device they have made available must immediately forward these to the manufacturer and, where applicable, the manufacturer's or SPPP's authorised representative and the importer[15].

Professionals are obliged to report serious incidents to the supplier and to Swissmedic[16]. Such reports should be forwarded within the supplier's organisation as quickly as possible.

[9] Further information on the reporting of FSCAs can be found in the guidance document MU680_21_010e_WL_MDV_FSCA_Econiomic_Operators.
[10] Further information on the reporting of FSCAs can be found in the guidance document MU680_21_010e_WL_MDV_FSCA_Economic_Operators.
[11] Art. 57 para. 2 and Art. 66 para. 1 MedDO as well as Art. 50 para.2 and Art. 59 para. 1 IvDO
[12] Art. 51 para. 3 MedDO, in conjunction with Art. 11 MDR and Art. 66 para. 2bis MedDO and Art. 44 para. 3 IvDO in conjunction with Art. 11 IVDR and Art. 59 para. 3 IvDO
[13] Art. 51 para. 3 MedDO in conjunction with Art. 11 para. 3 let. g MDR and Art. 44 para. 3 IvDO in conjunction with Art. 11 para. 3 let. g IVDR
[14] Art. 53 para. 4 MedDO in conjunction with Art 13 para 8 MDR and Art. 46 para. 4 IvDO in conjunction with Art. 13 para. 8 IVDR
[15] Art. 54 para. 4 MedDO in conjunction with Art. 14 para. 5 MDR and Art. 47 para. 4 IvDO in conjunction with Art. 14 para. 5 IVDR
[16] Art. 66 para. 4 MedDO and Art. 59 para. 4 IvDO

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6 Which serious incidents must be reported to Swissmedic?

All serious incidents that occur in Switzerland and all serious incidents that occur in Liechtenstein with devices that were supplied under Customs Treaty law must be reported to Swissmedic[17]. These reports are mandatory for all devices, regardless of when they were placed on the market.

If a serious incident occurs outside Switzerland and Liechtenstein, the case must be reported to the corresponding national authority. Swissmedic is not responsible for processing serious incidents that have occurred outside Switzerland and Liechtenstein.

6.1 Exemptions from the reporting obligation

The following are exempt from the reporting obligation[18]: expected side-effects of devices according to MedDO and IvDO, and expected erroneous results for devices according to IvDO which are clearly documented and quantified in the product information and the technical documentation, and are subject to trend reporting (see section 9.1).

7 How should serious incidents be reported to Swissmedic?

The MIR (Manufacturer's Incident Report) form published by Swissmedic must be used for reporting serious incidents. This form can be downloaded from the Swissmedic website (www.swissmedic.ch/md-materiovigilance-manufacturers (Incidents section)). All reports of serious incidents must be submitted to Swissmedic electronically and in machine-readable format using this form[19]. Reports may be submitted in one of the official Swiss languages or in English. All mandatory fields must be completed. The completed report form should be sent to the following e-mail address: materiovigilance@swissmedic.ch. Further information on completing the MIR form is provided in the guidance document *MU680_20_013e_WL_helptext_new_mir* which can be found on the above-mentioned website. The help text includes important information on additional details that must be provided, but which could not be marked as mandatory fields in the form in order to cover all the circumstances for devices on the market. This information includes, for example, trend data covering four periods, except for devices that have recently been placed on the market.

Note: If you report a serious incident as a manufacturer or SPPP based outside Switzerland and Liechtenstein or as an authorised representative, you must select the "Other, please specify" option in section 1.3.1 of the MIR form "Submitter of the report" and enter "CH Rep" in the adjacent text field. The contact details of the authorised representative should be entered in section 1.3.4 "Submitter's details". An economic operator domiciled in Liechtenstein can also take on the role of CH Rep.

8 When should serious incidents be reported?

If the serious incident evidently constitutes, or has the potential to constitute, a serious and imminent threat to the **life or health of a large number of persons** (serious public health threat), the report must be submitted immediately, and not later than **2 calendar days** after its awareness.[20]
The report must be submitted without delay, and at the latest **within 10 calendar days** if the serious incident has resulted in death or unanticipated serious deterioration in a person's state of health.[21]
All other serious incidents must be reported without delay and no later than **15 calendar days** following the date of awareness of the incident.[22]

[17] Art. 66 para. 1 let. a MedDO and Art. 59 para. 1 let. a IvDO
[18] Art. 66 para. 2 MedDO in conjunction with Art. 87 para. 1 let. a MDR and Art. 59 para. 2 IvDO in conjunction with Art. 82 para. 1 let. a IVDR
[19] Art. 66 para. 5 MedDO and Art. 59 para. 5 IvDO
[20] Art. 66 para. 2 MedDO in conjunction with Art. 87 para. 4 MDR and Art. 59 para. 2 IvDO in conjunction with Art. 82 para. 4 IVDR
[21] Art. 66 para. 2 MedDO in conjunction with Art. 87 para. 5 MDR and Art. 59 para. 2 IvDO in conjunction with Art. 82 para. 5 IVDR
[22] Art. 66 para. 2 MedDO in conjunction with Art. 87 para. 3 MDR and Art. 59 para. 2 IvDO in conjunction with Art. 82 para. 3 IVDR

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If the manufacturer, SPPP or authorised representative has not received sufficient information within the statutory time limit to decide whether an incident is reportable or not reportable, an Initial Report must be sent to Swissmedic.[23]

Note: The manufacturer or SPPP is considered to have been informed once the report of the incident enters its jurisdiction, e.g. when a responsible employee has been made aware of the incident.

9 Reporting procedure

The Initial Report (initial MIR) must be sent to Swissmedic by the reporting deadline. This Initial Report must contain all the information that is available at this point concerning:

- the incident,
- the device concerned,
- the consequences for the patient.

The Initial Report must also:

- state whether immediate actions are planned,
- provide a rough description of the scheduled investigation (e.g. whether and, if so, how the device is to be analysed),
- provide a rough timetable for the scheduled investigation,
- state the approximate date of the Follow-up or Final Report.

An Interim Report (follow-up MIR) must be sent to Swissmedic if the original actions arising from the investigation are changed, or if the deadline for the Final Report is postponed. This follow-up report must contain all of the available results from the investigations conducted hitherto.

The Final Report (final MIR) must contain all the information that was not yet available at the time of the Initial Report. In particular, this must include:

- the results of the investigation,
- the conclusions,
- any scheduled corrective actions and the rough timetable for their implementation.

A combined Initial-Final Report (combined initial-final MIR) can be sent to Swissmedic when all the information required for a Final Report is already available by the reporting deadline for a serious incident.

Notes:

- Please note that all the fields highlighted in red in the MIR form must be completed.
- Please observe the help text on the MIR form for other mandatory fields under specific conditions
- When sending the information, please ensure that you are not forwarding to Swissmedic any sensitive data that enables the patient to be identified (e.g. full name and address).

Evaluation by Swissmedic

Swissmedic systematically collates the received reports, evaluates them and then decides whether further actions are needed. For Initial Reports, Swissmedic particularly evaluates the risk and decides whether immediate actions are necessary. For Final Reports, the evaluation focuses particularly on the results of the investigation, the trend data and the conclusions of the manufacturer or SPPP.

9.1 Trend Reports

If a manufacturer or SPPP notices a statistically significant increase in the frequency or severity of

- non-serious incidents
- expected undesirable side-effects
- expected erroneous results established in comparison to the stated performance of the device

[23] Art. 66 para. 2 MedDO in conjunction with Art. 87 para. 7 MDR and Art. 59 para. 2 IvDO in conjunction with Art. 82 para. 7 IVDR

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they must report this, and any implemented actions, in a Trend Report.[24]
They must use the Trend form published by Swissmedic for this purpose. This form can be downloaded from the Swissmedic website (www.swissmedic.ch/md-materiovigilance-manufacturers (Trend Report & Periodic Summary Report & Periodic Update Report section)).

9.2 Periodic Summary Report (PSR)

Similar serious incidents that satisfy the following criteria can be grouped together and reported as Periodic Summary Reports (PSRs):

- The root cause is known or
- a FSCA has been implemented or
- the incidents occur frequently and are well documented.

The form, content and frequency must be agreed with Swissmedic beforehand.[25]
The PSR form published by Swissmedic must be used for this purpose. This form can be downloaded from the Swissmedic website (www.swissmedic.ch/md-materiovigilance-manufacturers (Trend Report & Periodic Summary Report & Periodic Safety Update Report section)).

9.3 Serious adverse events relating to products in the context of clinical trials

If CE-marked devices are used according to their intended purpose in category A[26] clinical trials (devices covered by MedDO) or category A performance studies (devices covered by IvDO; Post-Market Clinical Follow-Up [PMCF] studies or Post-Market Clinical Performance Studies [PMPF]), serious incidents are reported as described above.[27]

By contrast, two separate information sheets

- *BW600_00_015e_MB_Information_clinical_investigations_MD_KlinVMEP* and
- *BW600_00_016e_MB_Information_performance_studies_IVD_KlinVMEP*

provide information on reporting requirements in ongoing clinical investigations or performance studies with devices that are not CE-marked, or for uses that are outside the scope of the intended purpose of the CE-marking or for devices whose placing on the market, putting into service or use is prohibited in Switzerland. These can be found on the Swissmedic website (in English only): www.swissmedic.ch/md-clinicaltrials-en

10 Obligations of the manufacturer and SPPP in respect of user reports

Professionals are subject to a reporting requirement and must submit user reports to Swissmedic using the corresponding user report forms provided by Swissmedic. Patients can also report serious incidents to Swissmedic. Swissmedic forwards such reports to the manufacturer, SPPP or distributor, unless they have already been informed by the relevant person. The economic operator that receives a report from Swissmedic must treat this like any other report of an incident. The receipt of a report by Swissmedic does not release the economic operators from their own reporting obligation t Swissmedic. On receipt of a user report, the following procedure should therefore be followed:

- Distributors, importers and authorised representatives that receive a report must forward this within the supply chain back to the manufacturer or SPPP in accordance with section 6 of this guidance document.
- The manufacturer or SPPP must evaluate the report and decide whether it is a serious, and thus a reportable incident, or not.
    - If it is a serious incident, the Initial Report must be sent to Swissmedic within the statutory time limits (see sections 8-10 of this guidance document). On completion of the

[24] Art. 66 para. 2 MedDO in conjunction with Art. 88 MDR and Art. 59 para. 2 IvDO in conjunction with Art. 83 IVDR
[25] Art. 66 para. 2 MedDO in conjunction with Art. 87 para. 9 MDR and Art. 59 para. 2 IvDO in conjunction with Art. 82 para. 9 IVDR
[26] Art. 6 para 1 Clin-MD
[27] Art. 33 Clin-MD

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investigation, the Final Report must also be sent to Swissmedic (see section 10 of this guidance document).
  - If the event is deemed as non-serious incident, a corresponding justification based on the definition of a serious incident must be submitted to Swissmedic by e-mail[28].

  Note: If the manufacturer, SPPP or its authorised representative does not have sufficient information to decide within the statutory time limit whether the incident is reportable or not, an initial report must be sent to Swissmedic.
- Quality management systems demand effective rules for informing customers in the event of complaints. Accordingly, the affected user and Swissmedic must be informed in writing of the results of the investigation of the relevant incident.
- Swissmedic likewise forwards incidents received from users that are clearly not reportable to the manufacturer or SPPP for information purposes, provided no economic operator has been informed about the incident in advance by the actual user.

11 Data protection

If there is an overriding legitimate interest in preserving the secrecy of the data collected in accordance with the Therapeutic Products Act, Swissmedic is obliged to treat such data as confidential[29]. The processing and disclosure of data (including in other countries) are based on the requirements of Section 4 of the Therapeutic Products Act (Obligation of Secrecy and Data Processing)[30].

[28] Art. 66 para. 2 MedDO in conjunction with Art. 87 para. 11 MDR and Art. 4 para. 2 MedDO in conjunction with Art. 2 nos. 64 and 65 MDR and Art. 59 para. 2 IvDO in conjunction with Art. 82 para. 11 IVDR and Art. 4 para. 2 IvDO in conjunction with Art. 2 nos. 67 and 68 IVDR
[29] Art. 62 TPA
[30] Art. 61 ff. TPA

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