Contents

Change history

Version	Valid and binding as of	Description, comments (by author)	Author's initials
3.1	03.05.2023	Link to Liechtenstein website corrected	wic
3.0	13.01.2023	Amendment due to revision of Customs Treaty with Liechtenstein	wic
2.0	26.05.2022	Amendments due to entry into force of IvDO.	wic
1.0	26.05.2021	Doc newly created owing to revision of MD regulatory provisions; old doc ID: MU510_00_001e_MB	wic

1 Terms, definitions, abbreviations

1.1 Abbreviations

CIRS	Critical Incident Reporting System
FSCA	Field Safety Corrective Action
IvDO	Ordinance of 4 May 2022 on In Vitro Diagnostic Medical Devices (SR 812.219)
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
MedDO	Medical Devices Ordinance of 1 July 2020 (SR 812.213)
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
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

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according to Art. 1 para. 1 IvDO. Where provisions apply only to specific devices or device groups 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:
  - undesirable side-effect

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

Serious incident[2]: any 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]: a 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; this definition is subject to the clarifying explanations and exceptions in Art. 16 paras. 1 and 2 MDR and Art. 16 paras. 1 and 2 IVDR.

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.

1.3 Introduction

According to Art. 67 MedDO and Art. 60 IvDO, hospitals both in Switzerland and in Liechtenstein* are required to set up an internal reporting system as part of an established quality management system. They must appoint a suitable qualified person as a vigilance contact person, who assumes responsibility for reporting serious incidents with devices to Swissmedic.

[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
* 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]) (Customs Treaty between Switzerland and Liechtenstein, concluded on 29.03.1923, SR 0.631.112.514, most recent clarifications in the announcement of 18 October 2022 regarding the revised Annexes to the Customs Treaty. 2022.280 | Lilex - law database of the Principality of Liechtenstein). For devices made available in Liechtenstein in accordance with the Customs Treaty, vigilance is subject to MedDO (Arts. 66–67) and IvDO (Arts. 59–60). Among other things, this means that professional users in Liechtenstein must report any serious events in Liechtenstein relating to devices made available in Liechtenstein in accordance with the Customs Treaty to the supplier and Swissmedic, and that hospitals in Liechtenstein must have a reporting system within the framework of an established quality management system.

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2 Objective

This document is intended to give hospitals, and particularly the vigilance contact persons for medical devices, an overview of the development steps that a device undergoes until it is placed on the market and its post-market surveillance, focusing on the contribution made by the hospitals to this monitoring process. It explains the requirements applicable to the reporting system in a hospital and the role played by the vigilance contact person[5].
Further information on serious incidents and the reporting time limits can be found in the guidance document *MU680_20_008e_WL_MDV_Incident report user*.

3 Introduction devices

The TPA defines medical devices as follows: Products, including instruments, apparatus, appliances, In Vitro Diagnostics, software, implants, reagents, materials and other goods or substances which are intended to have, or are presented as having, a medical use and which do not achieve their principal intended action by pharmacological, immunological or metabolic means[6].
There is a wide variety of devices, ranging from wheelchairs, patient beds, contact lenses, dental prostheses, sphygmomanometers, blood glucose meters, pregnancy tests, laboratory systems, infusion pumps, hip implants, cardiac pacemakers and artificial heart valves to surgical robots, x-ray machines, surgical equipment and patient monitoring systems.
Some product groups without an intended medical purpose are subject to the same legislation as that for medical devices, including coloured non-prescription contact lenses, hyaluronic acid for treating wrinkles, cryolipolysis devices for reducing body fat, and hair-removal lasers. For a more precise list of the products that fall into this category, please see Annex I MedDO.

A device group with the designation "system" or "procedure pack" also exists. SPPPs combine CE-marked devices with other medical devices or other devices and place them on the market in the form of a system or procedure pack. The activity of combining is subject to appropriate methods of internal monitoring, verification and validation[7].

The lifecycle of a device is roughly divided into 3 phases.

1st phase

During the **development phase** a manufacturer produces various prototypes. These prototypes first undergo technical testing, e.g. in the laboratory. However, these laboratory tests are usually not sufficient for proving that the device can also be used safely and is effective or that the performance (e.g. analytical performance, clinical performance) is achieved for In Vitro Diagnostic Medical Devices. Therefore, clinical trials or performance studies are often conducted during the development phase with "precursors" or "prototypes" of devices that may only be used within the clinical trial or performance studies. During clinical trials or performance studies device manufacturers are required to collect and evaluate any adverse events with consequences for the patients or product defects that

[5] Art. 67 para. 2 MedDO and Art. 60 para. 2 IvDO
[6] Art. 4 para. 1 let. b TPA
[7] Art. 11 MedDO in conjunction with Art. 22 MDR

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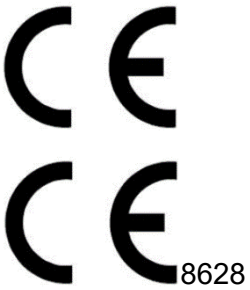
are noted. To this end, patients/subjects are closely monitored during the clinical trial or performance study in order to detect and prevent any risks as soon as possible.

2nd phase

The **market launch** phase is entered once the manufacturer is able to prove through recording of scientific data collected during the product development phase that the device is reasonably safe and effective to use, or in case of In Vitro Diagnostic Medical Devices, that the performance (e.g. analytical performance, clinical performance) is achieved.
Unlike medicinal products, a medical device is not approved by Swissmedic. The manufacturer is responsible for conforming with the legal requirements and for ensuring that an appropriate conformity assessment procedure has been carried out. Once this assessment procedure has been successfully completed, the device receives a declaration of conformity. In addition, an independent conformity assessment body must be consulted for devices associated with a higher risk (e.g. infusion sets, implants, x-ray machines, HIV test). Following a successful assessment, this body issues a certificate of conformity for the device concerned. The visible result of a completed conformity assessment procedure is the CE mark (with or without numbers) on the device. With this mark, devices can be placed on the market within the EU (European Union) or EEA (European Economic Area) as well as in Switzerland.



3rd phase

From the time a device is made available on the market, it must be used according to its intended purpose. Since its use is no longer monitored as part of a clinical trial or performance study, the manufacturer is required in this phase – known as the **market surveillance phase** – to continue monitoring the device such that it is able to react immediately when an increased or new risk is discovered. This includes the systematic collection and evaluation of serious incidents and other feedback from the market and, if necessary, taking corresponding measures for minimising unacceptable risks. This system for monitoring risks connected with the use of devices is termed the **materiovigilance system**.

4 The vigilance system

Vigilance refers to a system for monitoring risks connected with the use of therapeutic products. Therapeutic products can be medicinal products, medical devices or blood and blood components. Accordingly, a distinction is made between:

Pharmacovigilance: Monitoring the risks of adverse reactions connected with the use of medicinal products.

Haemovigilance: Monitoring the risks connected with the provision of blood and blood components, from the donor to the recipient

Materiovigilance: Monitoring the risks connected with the use of medical devices.

In principle, this involves collecting and analysing incidents that have resulted – or that could have resulted – in a temporary or permanent serious risk to the health of individuals or in death, so that risks are identified and any risk mitigation is initiated as soon as possible. Serious incidents with devices can include:

- Early revision surgery for a knee prosthesis, e.g. due to loosening of the implant
- A patient dies and there is reason to believe that the defibrillator implanted in the patient was not functioning properly
- An infusion pump delivers much more than the programmed quantity. No alarm is triggered and overdosing occurs.

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- An erroneous result of an In Vitro Diagnostic Medical Device leads to an unnecessary treatment or a critical condition.
- An increase in incorrect results from an In Vitro Diagnostic Medical Device that are not clearly documented in the product information or the technical documentation.

4.1 Materiovigilance – the roles

The cooperation of all those involved is needed for the materiovigilance system to function correctly:

- Manufacturers / SPPPs 
- Swissmedic swissmedic
- Users of devices (hospitals) 

The manufacturer of devices and **the SPPP** are responsible to ensure that their devices as well as systems or procedure packs can be used safely and effectively. For example, they must systematically collect and analyse all feedback and incidents that are brought to their attention and take any required measures. The manufacturer and SPPP are required by law to report all serious incidents in Switzerland or Liechtenstein to Swissmedic. If the manufacturer or SPPP take measures to minimise risks – e.g. due to serious incidents – they must also report these measures to Swissmedic. Risk-reducing, corrective measures (known as Field Safety Corrective Actions or FSCAs), for example a product recall, must be reported to Swissmedic even if these actions were not based on a serious incident.

Swissmedic collects and reviews reports on serious incidents, analyses the risks associated with the incidents, evaluates the investigation planned by the manufacturer and the results and, if necessary, orders additional actions. The FSCAs are published and updated by Swissmedic on its website. Once a week, an e-mail listing the newly published actions is sent to all vigilance contact persons for medical devices in hospitals (Swissmedic – New recalls).

Hospitals as users of devices use the devices and are therefore usually the first to notice possible problems or risks through incidents. Users report the incidents to the manufacturer or supplier for analysis. If the users are professionals (e.g. healthcare providers in hospitals), they are legally required to report serious incidents both to the supplier and to Swissmedic.

If all parties involved fulfil their obligations, then Swissmedic receives the report of any given serious incident twice, once from the manufacturer and once from the hospital. The law incorporates this duplication in the system deliberately in order to ensure that incidents are reported and that any required measures can be taken as soon as possible.

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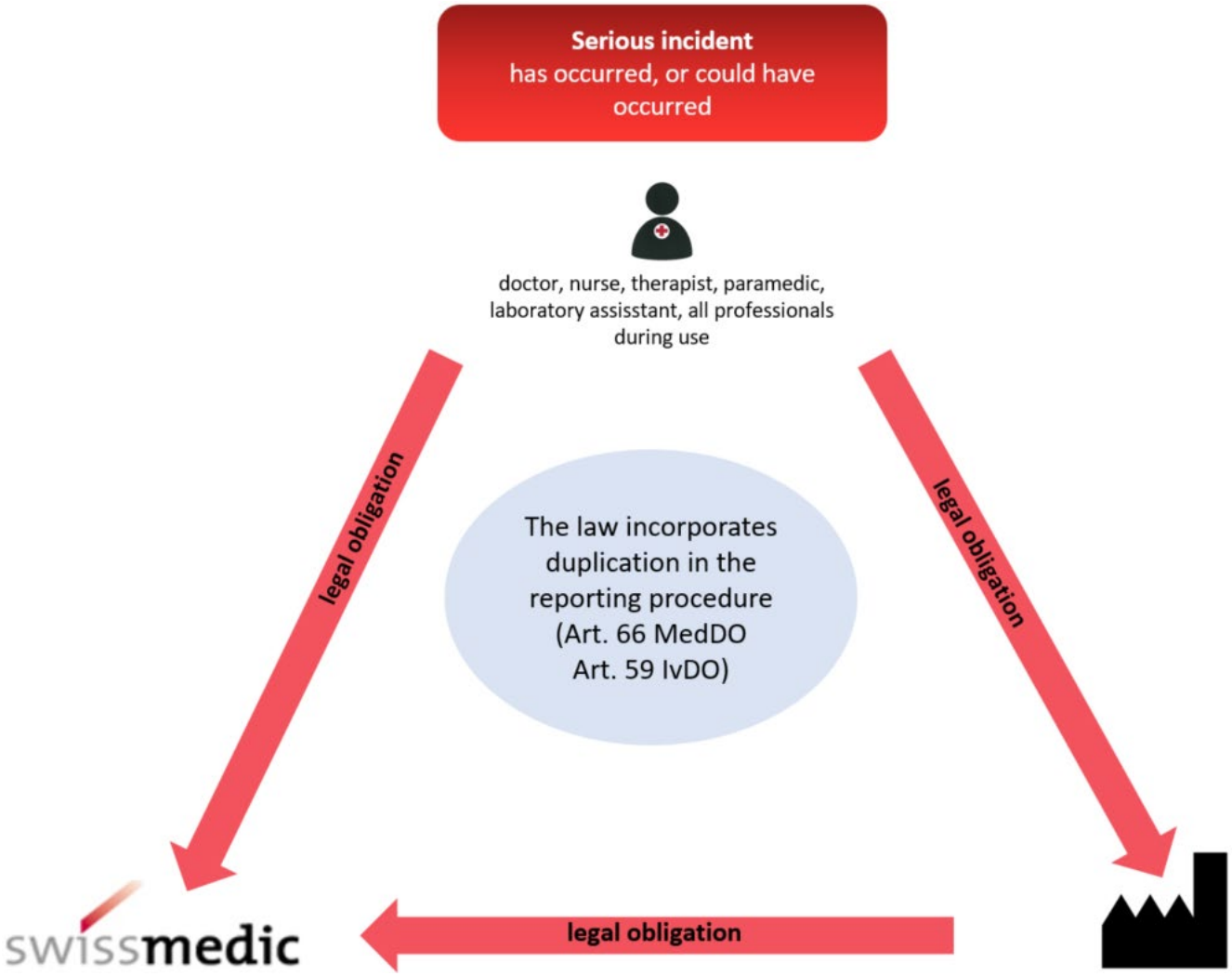

4.2 Reporting system in the hospital

A hospital is defined as a healthcare facility in which inpatient treatments for illnesses, medical rehabilitation or medical measures for cosmetic purposes are provided by medical or nursing interventions.[8]
Hospitals are required to set up a reporting system as part of an established quality management system[9]. What does this mean?

Serious incidents with devices can basically occur wherever devices are used. If such incidents occur in a hospital, they usually come to the attention of professionals, e.g. doctors, therapists, laboratory technicians, paramedics or nurses. All professionals are legally required to report serious incidents.[10] Anyone who fails to comply with this reporting obligation is liable to a fine.[11] The hospital must define and document the details of the reporting process according to the principles of its quality assurance system. For example, many hospitals have a Vigilance Manager in every department who collects – and possibly pre-sorts – the reports and then forwards them to a defined vigilance contact person for

[8] Art. 4 para. 1 let. l MedDO and Art. 4 para. 1 let. k IvDO
[9] Art. 67 MedDO and Art. 60 IvDO
[10] Art. 66 para. 4 MedDO and Art. 59 para. 4 IvDO
[11] Art. 87 para. 1 let. c TPA

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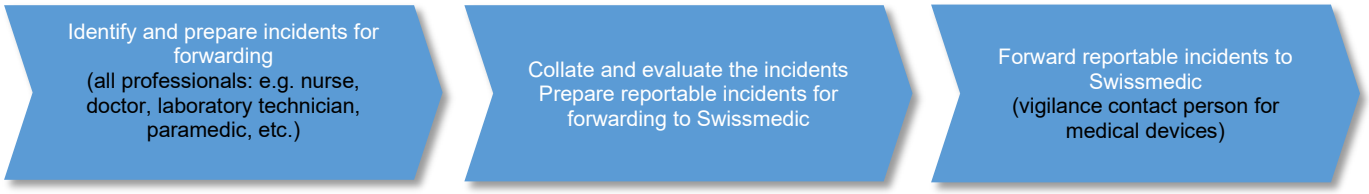
medical devices in the hospital.[12] The vigilance contact person for medical devices must report a serious incident to Swissmedic using the official report form. In other hospitals, the report is entered in an electronic system (e.g. CIRS) directly by any professional who notices an incident. Via this electronic system the reports then reach the vigilance contact person for medical devices, who carries out the final sorting and decides which incidents actually need to be forwarded to Swissmedic. This process works only if the individuals who use the devices notice incidents, realise that these must be reported and process them correctly.



The following is stipulated by law:

- who is responsible for identifying and initial forwarding (all professionals)
- who is responsible for the final forwarding of the reportable incidents to Swissmedic (contact persons)
- that this Vigilance Contact Person for medical devices should be officially notified to Swissmedic (hospital)
- that all reports should be forwarded to Swissmedic in accordance with the requirements published on the Swissmedic website
- that a reporting system based on an established quality management system must be defined and used (hospital)
- that all documents produced in connection with the quality management system must be archived for at least 15 years (hospital)

Among other things, the following should be defined in the reporting process:

- Areas of competence and responsibilities for devices specified in MedDO and/or IvDO (incl. deputising arrangements)
- Definitions, e.g. of a serious incident
- Procedure, e.g. how the information about an incident passes from the location where the incident occurred to the vigilance contact person for medical devices
- Criteria for deciding whether a reportable incident is involved
- Where and how the decisions are documented
- Reporting time limits
- How it can be ensured that all individuals concerned know, at a given time, who is responsible for which part of the process

The guidance document *MU680_20_008e_WL_MDV_Incident report user* provides information on how a serious incident is defined, how it must be reported to Swissmedic and what time limits must be observed.

[12] Art. 67 para. 2 MedDO and Art. 60 para. 2 IvDO

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4.3 The vigilance contact person for medical devices

Hospitals are legally required to designate a suitable qualified person with medical or technical training to assume responsibility for the requirement to report to Swissmedic.[13]
Since the vigilance contact person for medical devices acts in an official capacity in relation to Swissmedic, the vigilance contact person must also be officially notified in writing to Swissmedic[14].
Swissmedic must also be informed of any changes in the contact details or personnel change. The corresponding form for notifying the vigilance contact person for medical devices can be found on the Swissmedic website www.swissmedic.ch/md-materiovigilance-user.

A vigilance contact person for medical devices has the following tasks:

- Act as the contact, both within the hospital and for Swissmedic, to answer questions concerning vigilance for devices
- Collate all incident reports within a hospital
- Sort the incidents according to the criteria defined in the process and decide which need to be reported and forwarded to Swissmedic.
- For these reportable incidents, the vigilance contact person completes the form provided by Swissmedic and forwards it to Swissmedic.
- If necessary, disseminate new, relevant information from Swissmedic, e.g. the weekly e-mail with the list of field safety corrective actions, within the hospital.

Requirements applicable to the vigilance contact person for medical devices:

An incident involving a device usually raises both medical and technical issues (What complications have occurred or might occur? What defect has occurred? What are the implications of an incorrect diagnostic test result for the patient's treatment?). The vigilance contact person should therefore possess sufficient expertise in both medical and technical areas. The vigilance contact person for medical devices can either be responsible for devices according to MedDO or for devices according to IvDO, or for devices specified of both ordinances. However, the vigilance contact person must possess the required medical and technical expertise relating to the respective devices for which they are responsible. Swissmedic deliberately refrains from stating specific requirements for the professional qualification of contact persons with the intention to give the hospital the as much flexibility as possible in designating the corresponding function. When designating a contact person the hospital should ensure that he/she

- is accepted by the professional users of devices
- possesses sufficient medical expertise for devices specified in MedDO and/or IvDO for describing complications
- possesses sufficient technical expertise for devices specified in MedDO and/or IvDO for describing technical problems
- be interested in quality assurance aspects.

All the necessary skills can be acquired through both training and experience. The hospital is responsible for preparing and/or training the contact persons so that they are able to carry out their tasks.
Given the short reporting deadlines in regards to certain incidents, a deputy must be organised for the vigilance contact person.

The role of the vigilance contact person for devices means that other healthcare professionals are able to report serious incidents to Swissmedic **anonymously**. The vigilance contact person can therefore preserve the anonymity of the user in relation to Swissmedic while, at the same time, ensuring that further inquiries are possible.

[13] Art. 67 para. 2 MedDO and Art. 60 para. 2 IvDO
[14] Art. 67 para. 2 MedDO and Art. 60 para. 2 IvDO

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