Contents

1 Introduction

1.1 Revision of medical devices law

The Federal Council enacted Switzerland's revised medical devices legislation on **26 May 2021**. To ensure that quality, safety and efficacy standards match those in EU member states, this legislation is based on the new EU Regulation on medical devices (**MDR**[1]). The European Regulation on in vitro diagnostics (**IVDR**[2]) is due to be implemented in Switzerland on 26 May 2022.
Under the previous regulations (Directives 90/385/EEC, 93/42/EEC and 98/79/EC), the Swiss-EU agreement on the mutual recognition of conformity assessments (Mutual Recognition Agreement or MRA) gave Switzerland access to the European single market for medical devices on an equal partnership basis. As a result, Switzerland was able to effectively and efficiently perform market surveillance by working in cooperation with the relevant authorities in the EU member states, and thus avoid technical barriers to trade between both parties. Moreover, Swiss patients benefited from access to the full range of medical devices available in Europe.

The MRA was due to be updated concurrently with the entry into force of Switzerland's new medical devices regulation. However, the EU Commission decided not to proceed any further with updating the agreement with effect from 26 May 2021 owing to the broader political context (discontinuation of the negotiations on the institutional framework agreement between Switzerland and the EU).

[1] **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, OJ L 117, p. 1 (Medical Device Regulation, MDR)
[2] **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, OJ L 117, p. 176 (In Vitro Diagnostic Medical Devices Regulation, IVDR)

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Since the MRA has not been updated, Switzerland has established measures designed to limit the negative consequences of this development, particularly the inability of the Swiss authorities to access the European database for medical devices (Eudamed 3) and the lack of cooperation in market monitoring. These include e.g. the staggered timelines for appointing an authorised representative ("CH-REP"), the need for economic operators to register with Swissmedic, the reporting of serious incidents to Swissmedic and the recognition of EU certificates of conformity in Switzerland.

1.2 Scope

This information refers to **medical devices, their accessories and products without an intended medical purpose**[3] according to Art. 1 of the Medical Devices Ordinance (MedDO; SR 812.213). For the purposes of this information sheet, the term "devices" is used generally to refer to these products. For in vitro diagnostic medical devices, the provisions of the old law continue to apply (see Art. 105 MedDO).

This information sheet refers exclusively to **economic operators established in Switzerland** and to devices that are **made available on the market in Switzerland**.

2 Basis and abbreviations

2.1 Legal basis

TPA	Therapeutic Products Act; SR 812.21
MedDO	Medical Devices Ordinance of 1 July 2020; SR 812.213
oMedDO	Old (former) Medical Devices Ordinance of 17 October 2001 (version of 1 August 2020)
MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
IVDR	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices

2.2 Abbreviations

SRN	EU Single Registration Number, assigned according to Art. 31 MDR
CHRN	Swiss Single Registration Number (CH identification number) assigned according to Art. 55 MedDO
TD	Technical Documentation
UDI	Unique Device Identification
CH	Switzerland
EO	Economic operators
MDD/AIMDD device	Device that has been CE-marked under the former regulations (Directive 93/42/EEC concerning medical devices or Directive 90/385/EEC on active implantable medical devices). Often also referred to as "legacy device".
MDR device	Device that has been CE-marked according to the MDR

[3] Information on medical devices without an intended medical purpose (Annex I MedDO and Annex XVI MDR) can be found at www.swissmedic.ch > Medical devices

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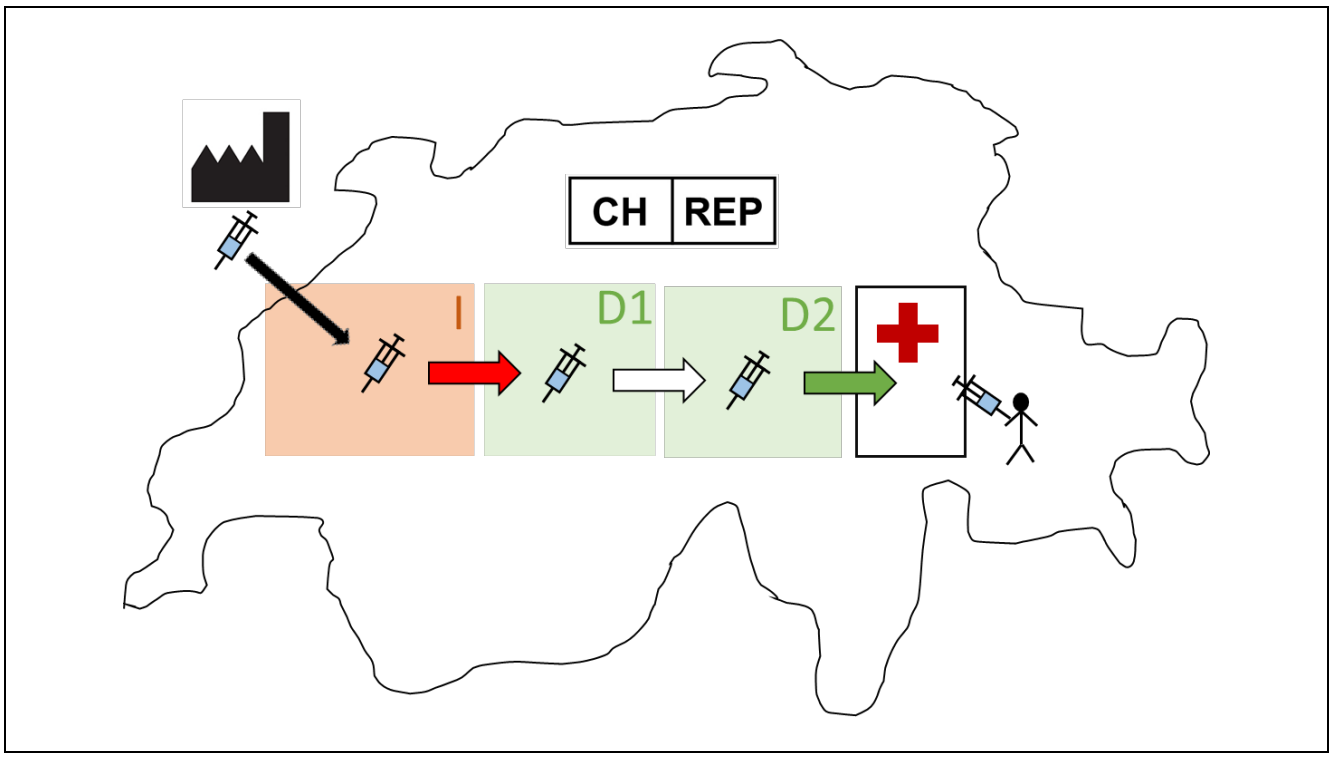
2.3 Operators and concepts

Manufacturer	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 manufacturer's obligations also apply to persons who carry out the activities specified in Art. 16 para. 1 MDR; Art. 4 para. 1 let. f MedDO.
CH-REP	Authorised representative; natural or legal person **in Switzerland** who has been mandated in writing by a **manufacturer established in a foreign country** to act on the manufacturer's behalf in relation to specified tasks in accordance with MedDO; Art. 4 para. 1 let. g MedDO
CH-importer	Natural or legal person **in Switzerland** that places a **device from a foreign country on the Swiss market**; Art. 4 para. 1 let. h MedDO.
CH-distributor	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; Art. 4 para. 1 let. i MedDO.
Contracting state	States with which Switzerland has concluded an MRA; Art. 4 para. 1 let. m MedDO.
EU/EEA state	Member states of the European Union, Iceland, Liechtenstein and Norway. United Kingdom and Turkey are **not** EU/EEA states.
CH-EO EU-EO	Economic operator established in Switzerland / established in the European Union. Collective term for manufacturer, authorised representative, importer, distributor (Art. 4 para. 1 let. j MedDO).

3 Placing devices on the market and economic operators

The following graphic and corresponding captions explain the roles of the economic operators using the example of a foreign manufacturer with a Swiss supply chain. Other configurations (e.g. transfer / supply of products for the public from distributors to patients, supply chains without distributors in Switzerland) are also possible.



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CH REP	**Authorised representative**[4] in CH (Art. 4 para. 1 let. g MedDO) Is **appointed** in writing by the **manufacturer** (**mandate**) to act on the manufacturer's behalf in relation to specified tasks. If the manufacturer of a device is not established in Switzerland, its devices may only be placed on the market once an authorised representative established in Switzerland has been designated[5]. This also applies to manufacturers established in the EU/EEA. The designation shall be effective at least for all devices of the same generic device group[6].
I	CH-**importer** (Art. 4 para. 1 let. h MedDO) An importer **is not "designated"**, but its role arises from the activity that is carried out when a natural or legal person places a device from a foreign country on the Swiss market.
D1 D2	CH-**distributor** (Art. 4 para. 1 let. i MedDO) Economic operator in the supply chain, other than the manufacturer or importer, who makes a device available on the market, up to the stage of putting it into service.
	**Making available on the market** (Art. 4 para. 1 let. a MedDO) Collective term referring to the transfer or supply of a device. The use of a product by a professional user (e.g. a device or dressing material) does not mean making available on the market. The making available of a product supposes an offer or an agreement (written or verbal) between two or more legal or natural persons for the transfer of ownership, possession or any other right concerning the product in question after the stage of manufacture has taken place[7]. The transfer does not necessarily require the physical handover of the product. This transfer can be for payment or free of charge.
	**Placing on the market** (Art. 4 para. 1 let. b MedDO) **First** making available of a device on the Swiss market (e.g. via a transfer or supply between economic operators or from a Swiss economic operator to a healthcare facility / the consumer). The concept of placing on the market refers to **each individual device**, **not** to a type of device[8]. Consequently, each individual device is placed on the market even if devices of the same model or type have already been placed on the market.
	**Putting into service** (Art. 4 para. 1 let. c MedDO) The stage at which the device is made available to the final user / healthcare facility for the first time.
	Healthcare facility (Art. 4 para. 1 let. k and l MedDO)
	Product
	Manufacturer (Art. 4 para. 1 let. f MedDO)

[4] The symbol can be downloaded from www.swissmedic.ch > Medical devices
[5] Art. 51 para. 1 MedDO
[6] Art. 51 para. 3 MedDO in conjunction with art. 11 para. 2 MDR
Definition for «generic device group»: art. 4 para. 2 MedDO in conjunction with art. 2 para. 7 MDR and MDCG 2019-13 no. 3.2
[7] See chapter 2.2 of the "The 'Blue Guide' on the implementation of EU products rules 2016", OJ C 272, 26.7.2016
[8] See chapter 2.3 of the "Commission Notice - The 'Blue Guide' on the implementation of EU products rules 2016", OJ C 272, 26.7.2016

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4 Transitional provisions

4.1 Placing devices on the market according to Directive 93/42/EEC or Directive 90/385/EEC ("legacy devices")

The new Medical Devices Ordinance entered into force on 26 May 2021 and basically applies to all devices. Certain devices that comply with the old legislation and were CE-marked according to oMedDO or Directive 93/42/EEC or Directive 90/385/EEC may continue to be placed on the market, or made available on the market, even after the entry into force of MedDO, provided certain conditions are met[9] (so-called "legacy devices").

This exemption concerns the following devices:
- Class I devices with a declaration of conformity issued before 26 May 2021, for which a certificate (i.e. involvement of a notified body) is required according to the new regulations (e.g. reusable surgical instruments[10], devices classified in a higher class according to MDR); or
- Devices with a valid certificate[11] ("CE certificate") under the old regulations.

Provided these devices comply with the relevant directive and have not undergone any significant changes in their design or intended purpose[12], they may be placed on the market after 26 May 2021 until the certificates expire, but in any case not later than 26 May 2024. They may continue to be made available in the distribution chain until 26 May 2025.
After 26 May 2025 no devices covered by the old regulations may be made available on the market.

4.2 CH-REP

The following timelines apply to manufacturers established in an EU/EEA state or which have an authorised representative in an EU/EEA state for designating a Swiss authorised representative[13].

- High-risk devices (Class III, IIb implantable and AIMD): 31 December 2021
- Moderate-risk devices (non-implantable Class IIb, Class IIa): 31 March 2022
- Low-risk devices (Class I): 31 July 2022
- Systems and procedure packs: 31 July 2022

EEA states are the member states of the EU, Iceland, Norway and Liechtenstein. However, the timelines only apply to EU states, Norway and Iceland. Due to the customs treaty[14] between Liechtenstein and Switzerland, a manufacturer in Liechtenstein is not obliged to designate an authorised representative in Switzerland.

All other foreign manufacturers are required to appoint a Swiss authorised representative with effect from 26 May 2021. These provisions apply both to MDD/AIMDD and MDR devices.
See section 6 for information on indicating the CH-REP "on the device" or in a document accompanying the device (including deadlines).

[9] Art. 101 MedDO
[10] Art. 23 MedDO and Art. 52 para. 7 letter c MDR
[11] Art. 10 para. 1 in conjunction with Annex 3 MedDO
[12] Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMD, MDCG 2020-3 (https://ec.europa.eu/health/md_sector/new_regulations/guidance_en)
[13] Art. 104a MedDO
[14] Art. 1 of the Vertrag zwischen der Schweiz und Liechtenstein über den Anschluss des Fürstentums Liechtenstein an das schweizerische Zollgebiet (SR 0.631.112.514)

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5 Obligations

The table provides an overview of the obligations of Swiss authorised representatives, importers and distributors.
The cited **provisions from MDR are applicable according to Art. 6 para. 2, 51 para. 3, 53 para. 4 and 54 para. 4 MedDO**.

#	Obligation	CH-REP	CH-importer	CH-distributor
1	Basic information	Responsible for the formal and safety-related issues connected with the placing on the market of the device. Art. 51 para. 2 MedDO Keep available the technical documentation or contractually agree that the manufacturer shall, on request, submit the documentation directly to Swissmedic within 7 days. Art. 51 para. 3bis MedDO	May only place devices on the market that comply with MedDO. Art. 53 para. 1 MedDO	In the context of its activities, act with due care in relation to the applicable requirements. Art. 54 para. 1 MedDO
2	Legal references for the obligations	Art. 51 and 52 MedDO Art. 11 MDR	Art. 53 MedDO Art. 13 MDR Art. 55 para. 3 MedDO / Art. 30 para. 3 MDR (verification of registration)	Art. 54 MedDO Art. 14 MDR
3	Written mandate with manufacturer	Required Art. 51 para. 1 MedDO Art. 11 paras. 3 and 4 MDR	No obligation	No obligation
4	Person Responsible for Regulatory Compliance in the organisation (PRRC)	Required Art. 52 para. 1 MedDO PRRC requirements, Art. 49, paras. 2-4 MedDO	No obligation	No obligation

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#	Obligation	CH-REP	CH-importer	CH-distributor
5	Registration of the economic operators/ CHRN Swiss identification number (for timelines see the section at the end of the table)	Required Art. 55 MedDO	Required Art. 55 MedDO	No / not possible
6	Verification of the device	Required Check that declarations of conformity and TD have been drawn up and that conformity assessment procedures have been carried out (certificates) Check the manufacturer's registration obligations regarding devices Art. 11 para. 3 let. a and c MDR	Before placing on the market: formal verification according to Art. 53 para. 1 MedDO In the event of non-conformities, inform manufacturer and authorised representative Art. 13 para. 2 MDR	Before making available on the market: Formal verification according to Art. 54 para. 1 MedDO In the event of non-conformities, inform manufacturer and, where applicable, importer and authorised representative Art. 14 para. 2 MDR
7	Traceability of devices (see explanation at the end of the table)	Required	Required	Required
8	Storage and transport	n.a. (not part of the supply chain)	According to manufacturer's instructions Art. 13 para. 5 MDR	According to manufacturer's instructions Art. 14 para. 3 MDR
9	Report serious incidents and safety corrective actions in Switzerland to Swissmedic, trend reports	Responsible for ensuring that the reports are sent to Swissmedic Art. 66 para. 2bis MedDO	Not required	Not required
10	Immediate forwarding of complaints and reports about suspected incidents	To manufacturer Art. 11 para. 3 let. g MDR	To manufacturer, if applicable to authorised representative Art. 13 para. 8 MDR	To manufacturer, if applicable to importer and authorised representative Art 14 para. 5 MDR
11	Register of complaints, non-conforming devices, recalls and withdrawals ("Complaints List")	Access to technical documentation, including data on post-market surveillance, see row # 1 of the table. Art. 11 para. 3 let. b MDR	Keep a "Complaints List" Art. 13 para. 6 MDR	Keep a "Complaints List" Art 14 para. 5 MDR

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#	Obligation	CH-REP	CH-importer	CH-distributor
12	Cooperation within the supply chain on the investigation of complaints	Not part of the supply chain, obligations are based on the written mandate with the manufacturer.	Provide the manufacturer, authorised representative and distributors with any information requested by them so that they can investigate complaints Art. 13 para. 6 MDR	Keep the manufacturer and, where available, the authorised representative and the importer updated about the "Complaints List" and provide them with any information upon their request Art 14 para. 5 MDR
13	Corrective actions / Preventive actions	Cooperation with Swissmedic in all preventive or corrective actions Art. 11 para. 3 let. f MDR	Assist with the implementation of corrective actions (including recalls) Art. 13 para. 7 MDR	Assist with the implementation of corrective actions (including recalls) Art 14 para. 4 MDR
14	Document retention requirements	Keep available a copy of the TD, or contractually agree that the manufacturer shall, on request, submit the documentation directly to Swissmedic within 7 days. Declarations of conformity and certificates. 10 years (15 years for implantable devices) after the last device was placed on the market Art. 51 3bis MedDO Art. 11 para. 3 let. b and 10 para. 8 MDR	Declarations of conformity and certificates 10 years (15 years for implantable devices) after the last device was placed on the market Art. 13 para. 9 MDR Art. 10 para. 8 MDR	No requirements according to therapeutic products legislation

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To section # 5 Registration of the economic operators / CHRN Swiss identification number[15]:

Devices placed on the market	CH-manufacturer or CH-REP CH-importer	CH-distributor
MDR devices	EO places product on the market **for the first time** after 26 May 2021: Registration within 3 months. Subsequent registration for EOs that have placed devices on the market **for the first time** before 26.05.2021: by 26.11.2021[16]	do not need to register
Only MDD/AIMDD devices	EO places product on the market **for the first time** after 26 May 2021: Registration within 3 months. Subsequent reregistration for EOs that have placed devices on the market for the first time before 26.05.2021: no obligation	do not need to register

To section # 7: Traceability of devices includes the following:

- EOs shall cooperate so as to achieve an appropriate level of traceability of devices (Art. 64 para. 1 MedDO).
- At the request of Swissmedic, EOs shall disclose the following: all EOs from whom they have acquired a device, and all EOs, healthcare facilities and healthcare professionals to whom they have supplied a device. This duty of disclosure continues for at least 10 years, or for at least 15 years for implants, after the last product covered by the declaration of conformity was placed on the market (Art. 47c TPA and Art. 64 para. 2 MedDO).
- EOs (and healthcare facilities) shall store and keep, preferably by electronic means, the UDI of the class III implantable devices which they have supplied, or with which they have been supplied (Art. 65 MedDO)

6 Indication of the manufacturer, CH-REP and importer

The manufacturer of the device must always, without exception, be defined and indicated on the label.

For imported devices, the CH-REP and the importer should be indicated according to the following table.

Distributors are **not** obliged to indicate the address on the device or in a document accompanying the device.

The details of the economic operators include **the name and address of the registered place of business**.

[15] Art. 55 MedDO, see www.swissmedic.ch > Medical devices > Market access > Unique identification number (CHRN) for more information
[16] Art. 104b MedDO

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Device	CH-REP	CH importer
MDR devices Class I	**Deadline:** From 26.05.2021, if applicable after the deadlines stated in section 4.2 of this information sheet **Where:** **Until 31.07.2023** either on the label **or** in a document accompanying the device[17]. **After 31.07.2023** On the label	**Deadline**: From 26.05.2021 **Where**: On the device or on the packaging or in a document accompanying the device
MDR devices Class IIa, IIb or III	**Deadline**: From 26.05.2021, if applicable after the deadlines stated in section 4.2 of this information sheet **Where**: On the label	
MDD/AIMDD devices with EU/EEA manufacturer or EC-REP	**Deadline**: After the deadlines stated in section 4.2 of this information sheet. **Where**: - MDD: On the label or in the instructions for use **or** in a document accompanying the device[18]. - AIMDD: On the sales packaging and in the instructions for use **or** in a document accompanying the device[18].	**Deadline**: from 31 July 2022[19] **Where**: On the device or on the packaging or in a document accompanying the device
MDD/AIMDD devices without EU/EEA manufacturer or without EC-REP	**Deadline:** From 26.05.2021 **Where**: - MDD: On the label or in the instructions for use - AIMDD: On the sales packaging and in the instructions for use	

Legal framework for affixing the address
CH-REP and MDR devices: Art. 16 para. 1 MedDO in conjunction with Annex I point 23.2 (d) MDR
CH-REP and MDD/AIMDD devices: Art. 7 para. 1 let. a and b oMedDO in conjunction with Annex I point 13.3 MDD and Annex I points 14.2 indent 1 and 15 indent 2 AIMDD
Importer: Art. 53 para. 2 MedDO

Deadline: The date of placing on the market is relevant (see definitions in section 3). Art. 101 para. 3 MedDO applies without prejudice.

Label: Written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices (Art. 2 point 13 MDR).

[17] The legal basis for the temporary, relaxed requirement to indicate the CH-Rep for Class I MDR devices shown in the table, is to be created during the revision of the MedDO in connection with the entry into force of the IvDO. Until then, such relaxations are applied within the scope of tolerance in enforcement of the law. Swissmedic reserves the right to modify the information sheet as required in accordance with the subsequently approved ordinance text.
[18] Given the non-uniform implementation among the EU member states with respect to legacy devices from Switzerland, and to prevent potential supply shortfalls due to a mandatory affixation on the label of legacy devices, it is accepted – in analogy to the importer information – to indicate this information in a document accompanying the device.
[19] In version 1 of this information sheet, Swissmedic stated that it will provisionally (i.e. until the EU practice becomes known or, if not specified by the EU, until 31 July 2022) not require the CH-importer to be stated on legacy devices. Since version 2 of this present information sheet, an interpretation of the term "accompanying document" that is different from the EU (see MDCG 2021-27 of December 2021, question 8) has been adopted; hence, the subsequent procedure of the EU is no longer relevant in this respect, although the tolerance period up to 31 July 2022 is retained.

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What does "in a document accompanying the device" mean?
The "document accompanying the device" can be affixed to the device or be separate from the device. Examples of documents accompanying the device include: delivery note, guarantee certificate, customs documents, invoice, a sticker on the packaging or the instructions for use. Such documents must accompany the devices through the supply chain so that distributors are able to fulfil their verification obligation stated in Art. 54 para. 1 let. d MedDO (indicating the importer). Therefore, the "document accompanying the device" does not necessarily need to reach the end user. The aim and purpose of the information is to allow rapid and unambiguous identification of the economic operators responsible for the relevant devices (importer and, if applicable, CH-REP), e.g. for implementing product recalls, reporting incidents, reporting dangerous devices or non-conformities, and in the context of enforcement.

Note: This is the Swiss interpretation of the term "document accompanying the device", which differs from the European interpretation (MDCG 2021-27 of December 2021, question 8) for supply-related reasons.

7 Translation of product information and repackaging

The MedDO regulates the translation of the product information[20] and the repackaging of devices by importers and distributors (Art. 53 para. 4 and Art. 54 para. 4 MedDO in conjunction with Art. 16 paras. 3 and 4 MDR). Accordingly, this is permitted under the specified conditions, e.g. if parallel imported devices are adapted to the linguistic requirements applicable in Switzerland. Swissmedic bases its interpretation of the applicable provisions on the European practice. Guidance published by the European Commission can be found on this website https://ec.europa.eu/health/md_sector/new_regulations/guidance.

Repackaged or relabelled devices must be notified to Swissmedic before they are placed on the market by the importer or distributor established in Switzerland[21].

8 Frequently asked questions

Do authorised representatives, importers and distributors of devices need an authorization from Swissmedic?
No, but authorised representatives and importers must register themselves ("CHRN").

What are the obligations of importers and distributors with respect to MDD/AIMDD devices (legacy devices)?
Whereas Art. 53 and 54 MedDO apply without restrictions for MDR devices, for MDD/AIMDD devices the obligations specified in Art. 53 and 54 MedDO should be considered in conjunction with the transitional provisions as per Art. 101 para. 2 MedDO; these allow conforming MDD devices to be placed on the market after 26 May 2021 even if the requirements of MDR are not completely met. The following provisions of the MDR are applicable: post-market surveillance and market surveillance, vigilance and registration of economic operators and of the devices[22].

What are the obligations of pharmacies, supermarkets, online shops and other dispensing outlets?
They are considered to be importers with respect to devices received directly from another country and which they place on the Swiss market.
As regards devices procured in Switzerland, the dispensing outlets assume the role of distributor.
In both cases, compliance with the corresponding obligations must be ensured.

[20] Art. 16 para. 1 MedDO
[21] www.swissmedic.ch > Medical devices > Market access
[22] Art. 101 para. 2 MedDO

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Two companies import identical devices from another country (e.g. in connection with a parallel import) and place these on the market in Switzerland. Which of the two companies is the importer?
Both companies assume the role of importer (see definitions of importer and placing on the market, sections 2.3 and 3), i.e. both companies must comply with the corresponding obligations.

A company imports a device from a manufacturer in another country and places this on the market in Switzerland. The same company is mandated as a CH-REP by the manufacturer. What are the company's obligations?
The company is subject to the obligations of both the CH-REP and importer. The companymust register both as an importer and CH-REP and receives two CHRN.

The disclosure requirements stated in Art. 47c TPA require economic operators to disclose the following to Swissmedic on request: a. all economic operators from whom they have acquired a medical device; b. all economic operators to whom they have supplied a medical device; and c. all healthcare facilities or healthcare professionals to whom they have supplied a medical device. In concrete terms, what does this mean for data recording? What data am I, as an economic operator, obliged to record and keep?
In order to satisfy the disclosure requirements, an economic operator must record the devices that it has acquired and forwarded (source of supply and recipient of the devices, quantities, lot and serial numbers, dates of deliveries). The data must be stored such that the economic operator can provide the information stated in Art. 47c TPA without great effort (i.e. at very short notice if necessary) (e.g. in connection with the administrative surveillance of field safety corrective actions or market surveillance procedures).
The duty of disclosure does not require each individual device to be traced (exception: class III implantable devices, see Art. 65 MedDO).

I would like to sell devices as a private person, e.g. via an online platform. What must I bear in mind?
As a private person you are subject to the same obligations as any other importer or distributor.

As a healthcare facility, we dispense patients devices used for their treatment (e.g. dressing material for changing at home, support stockings, stoma bags). So are we importers / distributors?
The answer depends on the individual case. If the situation involves putting into service associated with use/treatment (Art. 4 para. 1 let. c MedDO), the obligations for users/final users apply. On the other hand, if a trading activity exists (Art. 4 para. 1 let. i MedDO) and this has no direct relationship with the treatment/use, the obligations of the distributor (or the importer in the case of an import) must be observed. In the case of a direct import from another country associated with direct use in Switzerland, Art. 70 MedDO should also be observed, and the user assumes responsibility for the conformity of the device.

9 Further information

Information on registration, CHRN, UDI, and FAQ on various MDR issues can be found at www.swissmedic.ch > Medical devices.

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Change history

Version	Valid and binding from	Description, comments (by author)	Author's initials
2.0	30.12.2021	Updating of section 6	mea
1.0	23.11.2021	New doc ID, no content changes. Old doc ID: MU603_00_017 (version 1.0 dated 10.08.2021)	mea

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