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1 Introduction

1.1 1.1 Revision of medical devices law

Following the entry into force of the revised Medical Devices Ordinance (MedDO) on **26 May 2021**, the Federal Council enacted the new Ordinance on In Vitro Diagnostic Medical Devices (IvDO) on **26 May 2022**. To ensure that quality, safety and efficacy standards match those in EU member states, this legislation is based on the new EU Regulations on medical devices (**MDR**[1]) and in vitro medical devices (**IVDR**[2]).
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

[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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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).

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

The information below describes the obligations and transitional provisions applicable to **economic operators established in Switzerland** and to devices that are **made available on the market in Switzerland**.
It does not extend to devices manufactured and used in healthcare institutions according to Art. 9 IvDO.

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)
IvDO	Ordinance of 4 May 2022 on In Vitro Diagnostic Medical Devices; SR 812.219
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/Art. 28 IVDR
CHRN	Swiss Single Registration Number assigned according to Art. 55 MedDO/Art. 48 IvDO
TD	Technical Documentation
UDI	Unique Device Identification
CH	Switzerland
EO	Economic operators
EC-REP	Authorised representative in a Member State of the European Union, Iceland, Liechtenstein and Norway.
MDD/AIMDD device	Device that has been CE-marked under the former Directive 93/42/EEC concerning medical devices or Directive 90/385/EEC on active implantable medical devices. Often also referred to as "legacy devices".
IVDD device	Device that has been CE-marked in accordance with the previous Directive 98/79/EC on in vitro diagnostic medical devices.
MDR device	Device that has been CE-marked according to MDR
IVDR device	Device that has been CE-marked according to IVDR

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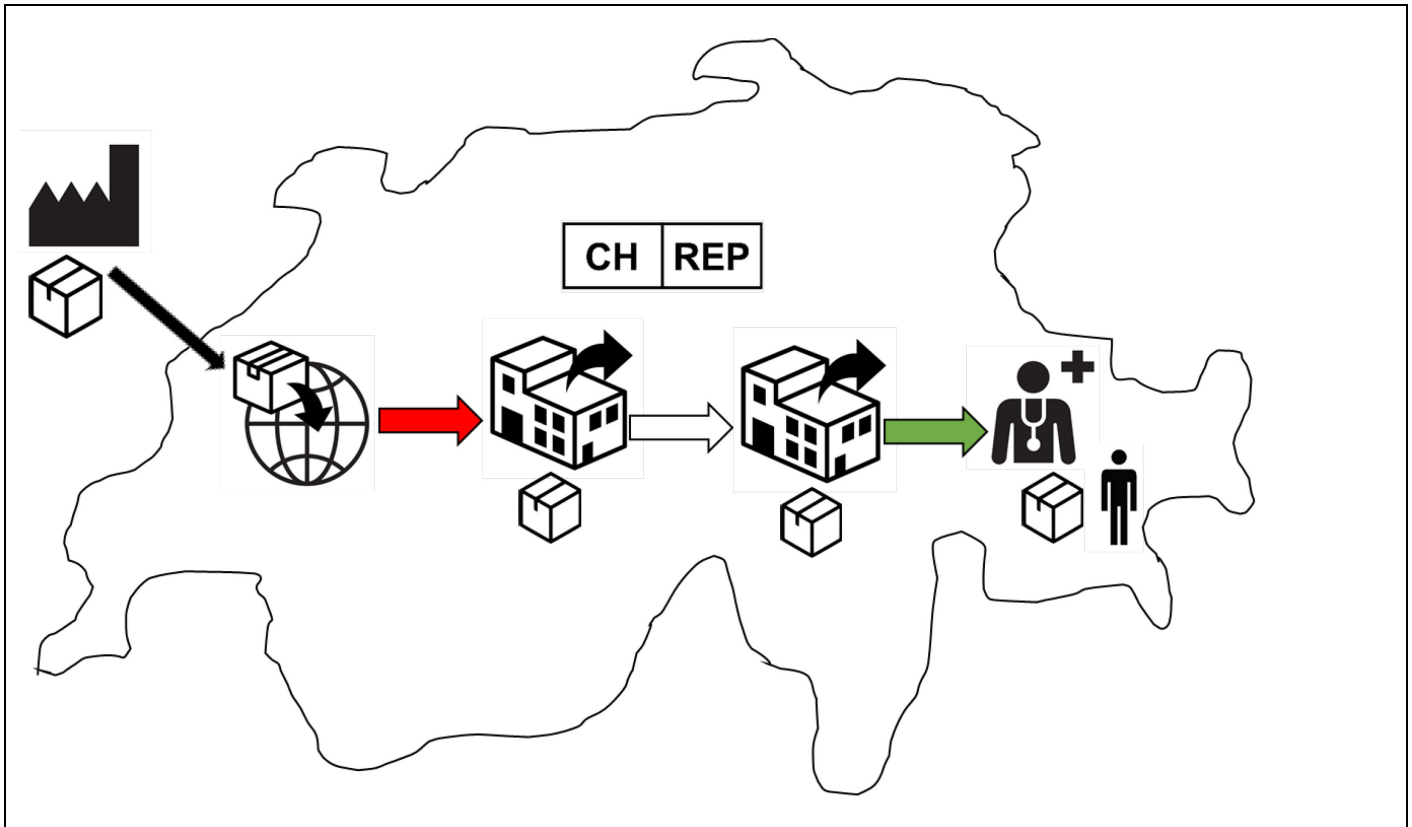
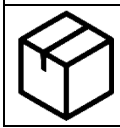
2.3 Operators and concepts

Economic operator (EO)	Manufacturer, authorised representative, importer, distributor and the person who assembles systems and procedure packs in accordance with Art. 22 para. 1 and 3 MDR (Art. 4 para. 1 let. j MedDO / Art. 4 para. 1 let. i IvDO). See section 3 of this information sheet for more information on the individual economic operators.
Contracting state	States with which Switzerland has concluded an MRA (Art. 4 para. 1 let. m MedDO / Art. 4 para. 1 let. l IvDO).
EU/EEA state	Member states of the European Union; Iceland, Liechtenstein and Norway. The 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 / Art. 4 para. 1 let i IvDO).

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.



	**Device(s)** (Art. 1 para. 1 MedDO) Comprises medical devices, the associated accessories and devices without an intended medical purpose[3].

[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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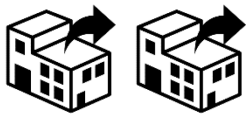
	Note: The term “medical device” includes in vitro diagnostic medical devices and the associated accessories.[4]
	**Manufacturer** (Art. 4 para. 1 let. f MedDO, Art. 4 para. 1 let. e IvDO) Natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or 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 or Art. 16 para. 1 IVDR; Art. 4 para. 1 let. f MedDO / Art. 4 para. 1 let. e IvDO.
	**Authorised representative**[5] in CH (Art. 4 para. 1 let. g MedDO, Art. 4 para. 1 let. f IvDO) Natural or legal person in Switzerland who receives and accepts a written **mandate** from a **manufacturer** located in another country, to act on the manufacturer's behalf in relation to specified tasks in accordance with MedDO / IvDO. 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[6]. 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[7].
	**Importer** (Art. 4 para. 1 let. h MedDO, Art. 4 para. 1 let. g IvDO) An importer **is not "designated"**, its role arising instead from the activity that is carried out when a natural or legal person in Switzerland places a device from another country on the Swiss market.
	**Distributor** (Art. 4 para. 1 let. i MedDO, Art. 4 para. 1 let. h IvDO) Economic operator 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.
	**Making available on the market** (Art. 4 para. 1 let. a MedDO, Art. 4 para. 1 let. a IvDO) Collective term referring to the transfer or supply of a device. The use of a product by a professional user (e.g. an implant or dressing material) does not constitute 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[8]. 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, Art. 4 para. 1 let. b IvDO) **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).

[4] Art. 3 para. 1 IvDO
[5] The symbol can be downloaded from www.swissmedic.ch > Medical devices
[6] Art. 51 para. 1 MedDO, Art. 44 para. 1 IvDO
[7] Art. 51 para. 3 MedDO in conjunction with Art. 11 para. 2 MDR, Art. 44 para. 3 IvDO in conjunction with Art. 11 para. 2 IVDR.
Definition of “generic device group”: Art. 4 para. 2 MedDO in conjunction with Art. 2 para. 7 MDR and MDCG 2019-13 no. 3.2
[8] See chapter 2.2 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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	The concept of placing on the market refers to **each individual device**, **not** to a type of device[9]. 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, Art. 4 para. 1 let. c IvDO) 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, Art. 4 para. 1 let. j IvDO)

4 Transitional provisions

4.1 Placing devices on the market according to Directives 93/42/EEC, 90/385/EEC and 98/79/EEC

The new Medical Devices Ordinance and Ordinance on In Vitro Diagnostic Medical Devices came into force on 26 May 2021 and 26 May 2022 and apply in principle **to all devices**.
Certain MDD/AIMDD/IVDD devices may continue to be placed on the market or made available on the market following the entry into force of MedDO and IvDO, provided they comply with the relevant regulation (Directive 93/42/EEC, Directive 90/385/EEC or Directive 98/79/EC) – i.e. have been **CE-marked** in accordance with these Directives – and provided they have not undergone **any significant change** in their design[10] or intended purpose[11]. This exemption concerns the following devices:

a. **Devices with valid certificates**[12] ("EC certificates") issued under the previous regulations can be placed on the market (PoM) or made available on the market **until their certificates expire**, but not longer than the dates listed in the table below:

Device	Place on the market (PoM) by:	Continue to make available on the market until:
MDD/AIMDD device	Certificate expires or 26 May 2024, whichever occurs sooner	26 May 2025
IVDD device	Certificate expires or 26 May 2025, whichever occurs sooner	26 May 2025 if PoM before 26 May 2022 26 May 2026 if PoM on or after 26 May 2022

These devices may no longer be placed on the market after their certificates have expired or after 26 May 2025 (MDD/AIMDD devices) or 26 May 2025/2026 (IVDD devices), whichever occurs sooner.

b. Devices that **did not require the involvement of a designated body under the previous regulations, but now require the involvement of one under the new regulations** and which possess a declaration of conformity issued before 26 May 2021 (MDD/AIMDD devices) or 26 May 2022 (IVDD devices) can be placed on the market (PoM) or continue to be made available on the market until the dates given in the table below:

Device	PoM by:	Continue to make available on the market until:
Class I MDD device with no certificate, now requiring a certificate under the new legislation	26 May 2024	26 May 2025
IVDD device with no certificate, class D under the new legislation	26 May 2025	26 May 2025 if PoM before 26 May 2022 26 May 2026 , if PoM on or after 26 May 2022
IVDD device with no certificate, class C	26 May 2026	26 May 2025 if PoM before 26 May 2022

[9] 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
[10] MDCG 2020-3 / MDCG 2022-6 (https://ec.europa.eu/health/md_sector/new_regulations/guidance_en)
[11] Art. 101 MedDO and Art. 82 IvDO
[12] Art. 10 para. 1 in conjunction with Annex 3 oMedDO

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under the new legislation		26 May 2027 , if PoM on or after 26 May 2022
IVDD device with no certificate, class B under the new legislation	26 May 2027	26 May 2025 if PoM before 26 May 2022 26 May 2028 , if PoM on or after 26 May 2022
IVDD device with no certificate, class A sterile under the new legislation	26 May 2027	26 May 2025 if PoM before 26 May 2022 26 May 2028 , if PoM on or after 26 May 2022

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].

MDD/AIMDD and MDR devices:

- Classes III, IIb implantable and AIMD: 31 December 2021
- Non-implantable Class IIb, Class IIa: 31 March 2022
- Class I: 31 July 2022
- Systems and procedure packs: 31 July 2022

IVDD and IVDR devices:

- Class D: 31 December 2022
- Classes C and B: 31 March 2023
- Class A: 31 July 2023

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 Switzerland and Liechtenstein, 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 (for MDD/AIMDD and MDR devices) or from 26 May 2022 (for IVDD and IVDR devices).
See section 6 for information on indicating the CH-REP "on the device" or in a document accompanying the device (including deadlines).

[13] Art. 104a MedDO, Art. 86 IvDO
[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 the MDR and from the IVDR are applicable according to Art. 6 para. 2, 51 para. 3, 53 para. 4 and 54 para. 4 MedDO or from Art. 6 para. 2, Art. 44 para. 3, Art. 46 para. 4 and Art. 47 para. 4 IvDO, respectively**.

#	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, Art. 44 para. 2 IvDO 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, Art. 44 para. 4 IvDO	May only place devices on the market that comply with MedDO or IvDO. Art. 53 para. 1 MedDO, Art. 46 para. 1 IvDO	In the context of its activities, act with due care in relation to the applicable requirements. Art. 54 para. 1 MedDO, Art. 47 para. 1 IvDO
2	Legal references for the obligations	Art. 51 and 52 MedDO, Art. 44 and 45 IvDO Art. 11 MDR, Art. 11 IVDR	Art. 53 MedDO, Art. 46 IvDO Art. 13 MDR, Art. 13 IVDR Art. 55 para. 3 MedDO / Art. 30 para. 3 MDR or Art. 46 para. 3 IvDO / Art. 27 para. 3 IVDR (verification of registration)	Art. 54 MedDO, Art. 47 IvDO Art. 14 MDR, Art. 14 IVDR
3	Written mandate with manufacturer	Required Art. 51 para. 1 MedDO, Art. 44 para. 1 IvDO Art. 11 paras. 3 and 4 MDR, Art. 11 paras. 3 and 4 IVDR	No obligation	No obligation

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#	Obligation	CH-REP	CH-importer	CH-distributor
4	Person Responsible for Regulatory Compliance in the organisation (PRRC)	Required Art. 52 para. 1 MedDO, Art. 45 para. 1 IvDO PRRC requirements, Art. 49, paras. 2-4 MedDO, Art. 42 paras. 2-4 IvDO	No obligation	No obligation
5	Registration of the economic operators/ CHRN Swiss registration number (for timelines see the section at the end of the table)	Required Art. 55 MedDO, Art. 48 IvDO	Required Art. 55 MedDO, Art. 48 IvDO	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 Art. 11 para. 3 let. a and c IVDR	Before placing on the market: formal verification according to Art. 53 para. 1 MedDO, Art. 46 para. 1 IvDO In the event of non-conformities, inform manufacturer and authorised representative Art. 13 para. 2 MDR, Art. 13 para. 2 IVDR	Before making available on the market: Formal verification according to Art. 54 para. 1 MedDO, Art. 47 para. 1 IvDO In the event of non-conformities, inform manufacturer and, where applicable, importer and authorised representative Art. 14 para. 2 MDR, Art. 14 para. 2 IVDR
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, Art. 13 para. 5 IVDR	According to manufacturer's instructions Art. 14 para. 3 MDR, Art. 14 para. 3 IVDR
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, Art. 59 para. 3 IvDO	Not required	Not required

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#	Obligation	CH-REP	CH-importer	CH-distributor
10	Immediate forwarding of complaints and reports about suspected incidents	To manufacturer Art. 11 para. 3 let. g MDR, Art. 11 para. 3 let. g IVDR	To manufacturer, if applicable to authorised representative Art. 13 para. 8 MDR, Art. 13 para. 8 IVDR	To manufacturer, if applicable to importer and authorised representative Art. 14 para. 5 MDR, Art. 14 para. 5 IVDR
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, Art. 11 para. 3 let. b IVDR	Keep a "Complaints List" Art. 13 para. 6 MDR, Art. 13 para. 6 IVDR	Keep a "Complaints List" Art. 14 para. 5 MDR, Art. 14 para. 5 IVDR
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, Art. 13 para. 6 IVDR	Keep the manufacturer and, where appropriate, 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, Art. 14 para. 5 IVDR
13	Corrective actions / Preventive actions	Cooperation with Swissmedic in all preventive or corrective actions Art. 11 para. 3 let. f MDR, Art. 11 para. 3 let. f IVDR	Assist with the implementation of corrective actions (including recalls) Art. 13 para. 7 MDR, Art. 13 para. 7 IVDR	Assist with the implementation of corrective actions (including recalls) Art. 14 para. 4 MDR, Art. 14 para. 4 IVDR

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#	Obligation	CH-REP	CH-importer	CH-distributor
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 para. 3bis MedDO, Art. 44 para. 4 IvDO Art. 11 para. 3 let. b and Art. 10 para. 8 MDR, Art. 11 para. 3 let. b and Art. 10 para. 7 IVDR	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. 13 para. 9 IVDR Art. 10 para. 8 MDR, Art. 10 para. 7 IVDR	No requirements according to therapeutic products legislation

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

Devices placed on the market	CH-manufacturer or CH-REP CH-importer	CH-distributor
MDR devices	EO places device 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 May 2021: by 26 November 2021[16]	do not need to register
Only MDD/AIMDD devices	EO places device 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 May 2021: no obligation	do not need to register
IVDR devices	EO places device on the market **for the first time** after 26 May 2022: Registration within 3 months. Subsequent registration for EOs that have placed devices on the market for the **first time** before 26 May 2022: by 26 November 2022[17]	do not need to register
IVDD devices only	EO places device on the market **for the first time** after 26 May 2022: Registration within 3 months. Subsequent registration for EOs that have placed devices on the market for the **first time** before 26 May 2022: no obligation	do not need to register

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

- EOs shall cooperate so as to achieve an appropriate level of device traceability (Art. 64 para. 1 MedDO, Art. 57 para. 1 IvDO).
- 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, from the time the device was procured or supplied (Art. 47c TPA and Art. 64 para. 2 MedDO or Art. 57 para. 2 IvDO).
- EOs and healthcare facilities shall record and store, 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).

  The list of in vitro diagnostic medical devices that EOs and healthcare facilities are required to keep is determined by means of implementing acts of the European Commission (Art. 58 IvDO). No implementing acts had been published at the time this information sheet was prepared.

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 tables.

[15] Art. 55 MedDO/ Art. 48 IvDO, see www.swissmedic.ch > Medical devices > Market access > Unique registration number (CHRN) for more information
[16] Art. 104b MedDO
[17] Art. 88 IvDO

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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**.

Device	CH-REP	CH-importer
MDR devices Class I	**Deadline:** From 26 May 2021, if applicable after the deadlines stated in section 4.2 of this information sheet **Where:** **Until 31 July 2023** either on the labelling **or** in a document accompanying the device. **After 31 July 2023** On the label	**Deadline**: From 26 May 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 May 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	

[18] Given the non-uniform implementation among the EU member states with respect to MDD/AIMDD/IVDD devices from Switzerland, and to prevent potential supply shortfalls due to a mandatory affixation on the label of these 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 MDD/AIMDD 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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Device	CH-REP	CH-importer
IVDR devices NOT intended for self-testing	**Deadline:** From 26 May 2022, if applicable after the deadlines stated in section 4.2 of this information sheet **Where:** **Until 31 March 2025** either on the labelling **or** in a document accompanying the device. **After 31 March 2025** On the label[20]	**Deadline**: From 26 May 2022 **Where**: On the device or on the packaging or in a document accompanying the device
IVDR devices for self-testing	**Deadline**: From 26 May 2022, if applicable after the deadlines stated in section 4.2 of this information sheet **Where**: On the label	
IVDD devices with EU/EEA manufacturer or EC-REP	**Deadline**: After the deadlines stated in section 4.2 of this information sheet. **Where**: On the labelling, on the external packaging, in the instructions for use **or** in a document accompanying the device18.	**Deadline**: From 26 May 2022 **Where**: On the device or on the packaging or in a document accompanying the device
IVDD devices without EU/EEA manufacturer or without EC-REP	**Deadline:** From 26 May 2022 **Where**: On the labelling, on the outer packaging, or in the instructions for use.	

Legal framework for affixing the address

CH-REP

- MDR devices: Art. 16 para. 1 MedDO in conjunction with Annex I point 23.2 (d) MDR, Art. 104a bis MedDO
- 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
- IVDR devices: Art. 15 para. 1 IvDO in conjunction with Annex I point 20.2 (d) IVDR, Art. 87 IvDO
- IVDD devices: Art. 7 para. 1 let. c oMedDO in conjunction with Annex I point 8.4 (a) IVDD

Importer:

- Art. 53 para. 2 MedDO, Art. 46 para. 2 IvDO

Deadline: The date of placing on the market is relevant (see definitions in section 3). Art. 101 para. 3 MedDO or Art. 82 para. 3 and 4 IvDO apply 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, Art. 2 point 13 IVDR).

[20] The facilitation of Art. 87 IvDO is limited until 31 March 2025. This provision will be reassessed at the end of 2023 as part of an evaluation of the situation and, if necessary, adapted to future developments. A decision by the Federal Council is expected by the end of May 2024. This is to ensure that the branch concerned has sufficient time (10 months) to prepare for possible measures (cf. Explanatory report on the new ordinance on in vitro diagnostics and amendments to the Ordinance on Clinical Trials for Medical Devices, May 2022, available in French, German and Italian only).

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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 or Art. 47 para. 1 let. d IvDO (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

MedDO and IvDO regulate the translation of the product information[21] 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, Art. 46 para. 4 and Art. 47 para. 4 IvDO in conjunction with Art. 16 paras. 3 and 4 IVDR). Accordingly, this is permitted under the specified conditions, e.g. if parallel imported devices are adapted to the linguistic requirements applicable in Switzerland. Swissmedic also 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[22].

8 Frequently asked questions

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

I want to place MDD class I devices and “other IVD”-class IVDD devices on the market. I do not know if the devices are subject to a transition period and, if so, how long it is.
To determine whether the deadlines are applicable, you must first classify the devices using the provisions in the new regulations (MDR, IVDR). You will then be able to use the classification to determine whether a deadline applies.
Examples:
– Under MDR, reusable surgical instruments require a certificate[23]. Since these devices did not require a certificate under MDD, the deadlines given in section 4b of this information sheet apply.
– Under IVDD, in-vitro diagnostic (IVD) tests for verifying exposure to SARS-CoV-2 that are not intended for self-testing were regarded as “other IVD” devices and thus did not need a certificate. Under IVDR, however, the tests are classified as class D devices and therefore now require a certificate[24]. For this reason, the deadlines in section 4b of this information sheet apply.

[21] Art. 16 para. 1 MedDO
[22] www.swissmedic.ch > Medical devices > Market access
[23] Art. 23 MedDO in conjunction with Art. 52 para. 7(c) MDR
[24] Art. 19 IvDO in conjunction with Art. 48 para. 3 and 4 IVDR

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What are the obligations of importers and distributors with respect to MDD/AIMDD/IVDD devices?
Whereas Art. 53 and 54 MedDO and Art. 46 and 47 IvDO apply without restrictions for MDR and IVDR devices respectively, for MDD/AIMDD/IVDD devices the obligations specified in Art. 53 and 54 MedDO or Art. 46 and 47 IvDO should be considered in conjunction with the transitional provisions as per Art. 101 para. 1 MedDO or Art. 82 para. 1 IvDO; these allow conforming MDD/AIMDD/IVDD devices to be placed on the market after the new regulations come into force even if the requirements of MDR/IVDR are not completely met. The following provisions of MDR/IVDR are applicable: post-market surveillance and market surveillance, vigilance and registration of economic operators and of the devices[25].

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.

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 company must register both as an importer and CH-REP and **receives two CHRN**.

I am a manufacturer (or CH-REP or importer) both of in vitro diagnostic devices and of medical devices that are not IVD devices ("classic MDs"). Do I have to register twice?
No, you need only register once. You can inform Swissmedic of any changes (e.g. in your address) by means of a change notification.

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).

[25] Art. 101 para. 2 MedDO

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

As a healthcare facility, we dispense to 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 (or Art. 63 IvDO) should also be observed, and the user assumes responsibility for the conformity of the device.

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9 Further information

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

Change history

Version	Valid and binding from	Description, comments (by author)	Author's initials
3.0	26.05.2022	Amendments due to entry into force of IvDO; modification of symbols section 3	mea
2.0	30.12.2021	Updating of section 6	kom
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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