swissmedic

Information sheet
Obligations Economic Operators CH

Identification number:	MU600_00_016
Version:	6.0
Valid from:	01.01.2025

List of contents

1 Introduction

1.1 Revision of medical devices law

Following the entry into force of the revised Medical Devices Ordinance on **26 May 2021**, the Federal Council enacted the new Ordinance on In Vitro Diagnostic Medical Devices 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.
Since the MRA was not updated on 26 May 2021, Switzerland has established measures designed to limit the negative consequences of this development, particularly the inability of the Swiss authorities

[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)

to access the European database for medical devices (Eudamed 3) and the lack of cooperation in market monitoring. These include e.g.:
- the appointing of 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**.
Due to the customs treaty[3] between Switzerland and Liechtenstein, the terms “established in Switzerland” and “on the market in Switzerland” refer to the common market of Switzerland and Liechtenstein (customs union) if the devices are placed on the market based on MedDO/IvDO[4].

The present information does not extend to devices manufactured and used in healthcare institutions according to Art. 9 MedDO / Art. 9 IvDO[5].

Information on devices without an intended medical purpose according to Annex 1 MedDO can be found at www.swissmedic.ch > Medical devices.

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

[3] Treaty between Switzerland and Liechtenstein on the Accession of the Principality of Liechtenstein to the Swiss Customs Area (SR 0.631.112.514)
[4] Due to the EEA agreement and the Liechtenstein-Switzerland customs treaty, two legal systems apply in parallel to medical devices in Liechtenstein. Medical devices can either be placed on the market based on MDR/IVDR or on MedDO/IvDO. The Switzerland/Liechtenstein common market relates only to placing on the market according to MedDO/IvDO. A placement on the market in Switzerland according to MDR/IVDR only is not contemplated.
[5] Information on devices manufactured and used in healthcare institutions are available at the link www.swissmedic.ch > Medical devices > Regulation of medical devices – Frequently Asked Questions

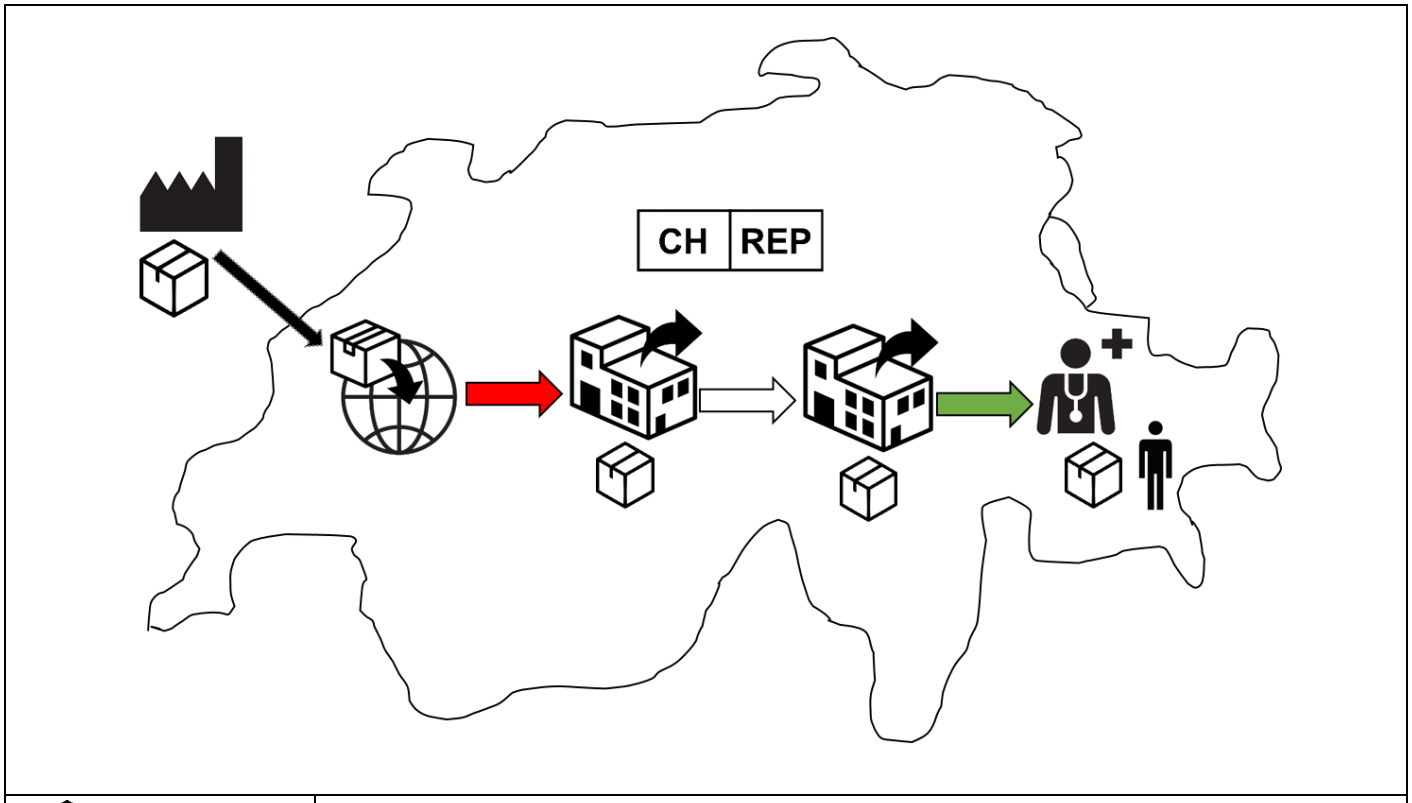
CHRN	Swiss Single Registration Number assigned according to Art. 55 MedDO/Art. 48 IvDO
TD	Technical Documentation
UDI	Unique Device Identification
CH	Switzerland
MDD/AIMDD device	Device that has been CE-marked under the former Directive 93/42/EEC concerning medical devices or Directive 90/385/EEC on 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

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.
CH-REP	Authorised representative in Switzerland
EC-REP	Authorised representative in a Member State of the European Union, Iceland, Liechtenstein and Norway.
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[6]. Note: The term “medical device” includes in vitro diagnostic medical devices and the associated accessories.[7]
	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.
CH REP	**Authorised representative**[8] 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[9]. This also applies to manufacturers established in the EU/EEA.

[6] 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
[7] Art. 3 para. 1 IvDO
[8] The symbol can be downloaded from www.swissmedic.ch > Medical devices
[9] Art. 51 para. 1 MedDO, Art. 44 para. 1 IvDO

	The designation of the authorised representative shall be effective at least for all devices of the same generic device group[10].
	**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 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[11]. 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). The concept of placing on the market refers to **each individual device**, **not** to a type of device[12]. 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)

[10] 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

[11] See chapter 2.2 of the “Commission Notice - The ‘Blue Guide’ on the implementation of EU product rules 2022”, OJ C 247, 29.6.2022

[12] See chapter 2.3 of the “Commission Notice - The ‘Blue Guide’ on the implementation of EU product rules 2022”, OJ C 247, 29.6.2022

4 Transitional provisions

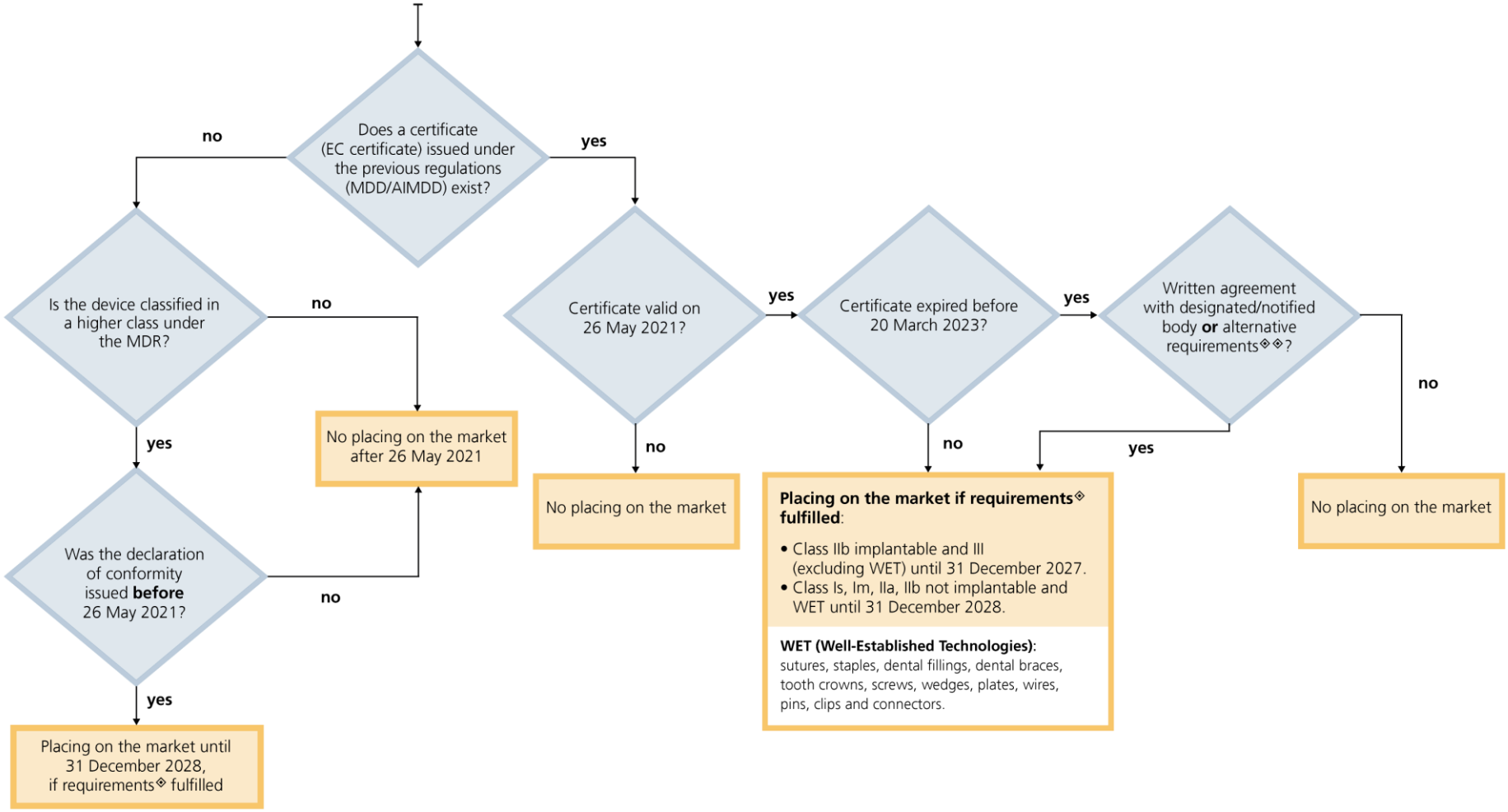
4.1 Making available on the market devices according to Directives 93/42/EEC, 90/385/EEC and 98/79/EEC

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**.
According to the following flowcharts (chapter 4.2 MDD / AIMDD, Chapter 4.3 IVDD), devices subject to the old legislation (MDD/AIMDD/IVDD) may be **placed on the market**[13]. The information presented here is simplified. A complete overview can be obtained from the legal references stated in the footnotes.

Devices that have been lawfully placed on the market prior to 26 May 2021 (MDD/AIMDD) or prior to 26 May 2022 (IVDD) according to the previous legislation, and devices that were placed on the market since 26 May 2021 (MDD/AIMDD) or since 26 May 2022 (IVDD) according to the flowcharts below in sections 4.2 / 4.3, may continue to be **made available on the market or put into service**[14].

[13] Art. 100 para. 2 and 3 MedDO, Art. 101 MedDO / Art. 82 para. 1 let. a IvDO
[14] Art. 101 para. 3 MedDO / Art. 82 para. 3 IvDO

4.2 MDD/AIMDD devices



◈ **Requirements**[15]:

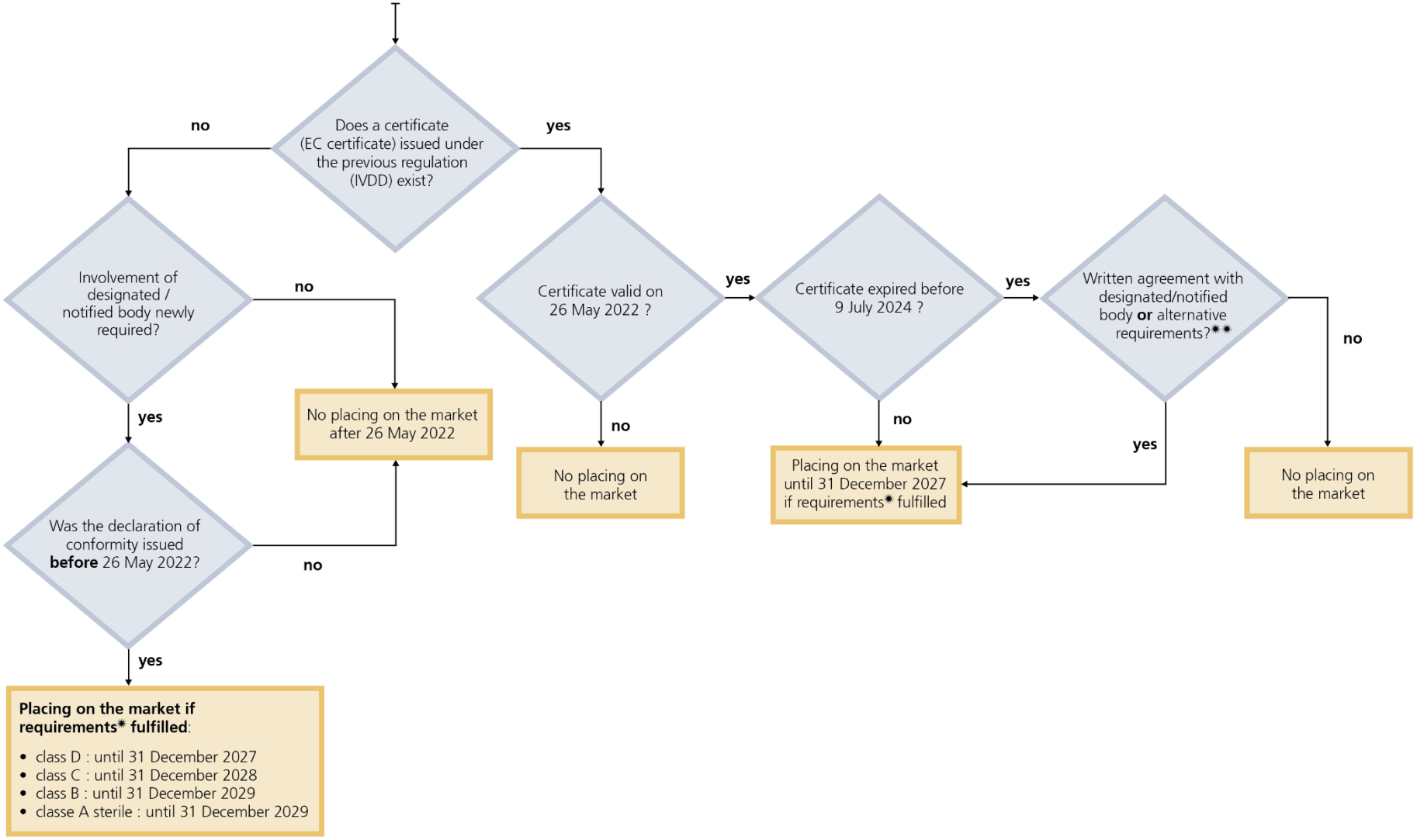
- The devices comply with the old legislation (Directive 93/42/EEC, Directive 90/385/EEC) i.e., were **CE-marked** according to this regulation
- They have not undergone **any significant changes**[16] in their design or intended purpose
- The devices **do not** represent an unacceptable risk to health or safety
- By 26 May 2024, the manufacturer has put in place a **quality management system** according to Art. 10 para. 9 MDR, and
- By 26 May 2024, the manufacturer/authorised representative has lodged an **application for a conformity assessment procedure according to MDR** with a designated/notified body, and the manufacturer has signed a corresponding **written agreement** with this body by 26 September 2024.

◈ ◈ **Alternative requirements**[17]**:**

- Swissmedic or a competent EU/EEA authority has granted a derogation from the conformity assessment procedure[18]; **or**
- as part of its market surveillance activities, the competent authority has required the manufacturer to carry out the applicable conformity assessment procedure within a defined period[19].

[15] Art. 101 para. 1bis MedDO
[16] MDCG 2020-3 Rev. 1
[17] Art. 100 para. 3 let. B and c MedDO
[18] Art. 22 para. 1 MedDO / Art. 120 para. 2 subpara. 2 let. b MDR
[19] Art. 75 para. 2 MedDO / Art. 97 para. 1 MDR

4.3 IVDD devices



✷ **Requirements**[20]:

- The devices comply with the old legislation (Directive 98/79/EC), i.e., were **CE-marked** according to this regulation
- They have not undergone any **significant changes**[21] in their design or intended purpose
- The devices **do not** represent an unacceptable risk to health or safety
- By 26 May 2025, the manufacturer has put in place a **quality management system** according to Art. 10 para. 8 IVDR
- The manufacturer/authorised representative has lodged an **application for a conformity assessment procedure according to IVDR** with a designated/notified body no later than the date indicated below:
  - devices covered by certificates according to the old legislation and class D devices: 26 May 2025
  - class C: 26 May 2026
  - class A sterile und class B: 26 May 2027
- and the manufacturer has signed a corresponding **written agreement** with the designated/notified body no later than the date indicated below:
  - devices covered by certificates according to the old legislation and class D devices: 26 September 2025
  - class C: 26 September 2026
  - class A sterile und class B: 26 September 2027.

✷ ✷ **Alternative requirements**[22]:

- Swissmedic or a competent EU/EEA authority has granted a derogation from the conformity assessment procedure[23]; **or**
- as part of its market surveillance activities, the competent authority has required the manufacturer to carry out the applicable conformity assessment procedure within a defined period[24].

[20] Art. 82 para. 1bis IvDO
[21] MDCG 2022-6
[22] Art. 81 para. 3 let. b and c IvDO
[23] Art. 18 para. 1 IvDO / Art. 110 para. 2 subpara. 2 let. b IVDR
[24] Art. 66 para. 2 IvDO / Art. 92 para. 1 IVDR

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. 48 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

#	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[25]	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 of conformity). 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	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 act had yet been published at the time this information sheet was prepared.		

[25] Art. 55 MedDO/ Art. 48 IvDO, for more information see www.swissmedic.ch > Medical devices > Market access > Single registration number (CHRN)

#	Obligation	CH-REP	CH-importer	CH-distributor
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
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 and 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[26] and withdrawals[27]	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 register Art. 13 para. 6 MDR, Art. 13 para. 6 IVDR	Keep a register 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 register and provide them with any information upon their request Art. 14 para. 5 MDR, Art. 14 para. 5 IVDR

[26] Recall means any measure aimed at achieving the return of a device that has already been made available to the end user (Art. 4 para. 2 MedDO in conjunction with Art. 2 point 62 MDR / Art. 4 para. 2 IvDO in conjunction with Art. 2 point 65 IVDR)
[27] Withdrawal means any measure aimed at preventing a device in the supply chain from continuing to be made available on the market (Art. 4 para. 2 MedDO in conjunction with Art. 2 point 63 MDR / Art. 4 para. 2 IvDO in conjunction with Art. 2 point 66 IVDR)

#	Obligation	CH-REP	CH-importer	CH-distributor
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
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

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.

Devices from a foreign country:
The **importer** can be indicated on the device or on the packaging or in a document accompanying the device[28].
The **CH-REP** must be indicated according to the following table.

Due to the customs treaty between Switzerland and Liechtenstein,[29] a manufacturer in Liechtenstein is not obliged to designate an authorised representative in Switzerland.

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[30]
MDR devices	On the label
MDD/AIMDD devices with EU/EEA[31] manufacturer or EC-REP	- MDD: On the label or in the instructions for use **or** in a document accompanying the device[32]. - AIMDD: On the sales packaging and in the instructions for use **or** in a document accompanying the device
MDD/AIMDD devices without EU/EEA manufacturer or without EC-REP	- MDD: On the label or in the instructions for use - AIMDD: On the sales packaging and in the instructions for use

[28] Art. 53 para. 2 MedDO, Art. 46 para. 2 IvDO
[29] 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)
[30] Basis for affixing the address: MDR devices: Art. 16 para. 1 MedDO in conjunction with Annex I point 23.2 let. d MDR; 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 let. d IVDR, Art. 87 IvDO/IVDD devices: Art. 7 para. 1 let. c oMedDO in conjunction with Annex I point 8.4 let. a IVDD
[31] EEA states are the member states of the EU, Iceland, Norway and Liechtenstein. Due to the customs treaty between Switzerland and Liechtenstein, a manufacturer in Liechtenstein is not obliged to designate an authorised representative in Switzerland.
[32] 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.

IVDR devices NOT intended for self-testing	On the label **or** in a document accompanying the device[33]
IVDR devices for self-testing	On the label
IVDD devices with EU/EEA manufacturer or EC-REP	On the label, on the outer packaging, in the instructions for use **or** in a document accompanying the device[34]
IVDD devices without EU/EEA manufacturer or without EC-REP	On the label, on the outer packaging **or** in the instructions for use

Deadline: The date of placing on the market is relevant (see definitions in section 3).

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).

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 when they are placed on the market and 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, question 8) for supply-related reasons.

7 Translation of product information and repackaging

MedDO and IvDO regulate the translation of the product information[35] and the repackaging of devices by importers and distributors (Art. 53 para. 4 and Art. 54 para. 4 MedDO in conjunction with Art. 16

[33] Art. 15 para. 9 IvDO .
[34] 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.
[35] Art. 16 para. 1 MedDO / Art. 15 para. 1 IvDO

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 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[36]. In particular, the quality management system of the importer or distributor must be audited by a designated/notified body, which then issues a **certificate** in accordance with Art. 16 para. 4 MDR / Art. 16 para. 4 IVDR, provided the quality management system complies with the requirements.

8 Frequently asked questions

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

b) **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[37]. Since these devices did not require a certificate under MDD, the deadlines given in section 4.2 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[38] and therefore now require a certificate[39]. For this reason, the deadlines for class D in-vitro diagnostic medical devices in section 4.3 of this information sheet apply.

c) **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, 1bis and 1ter MedDO or Art. 82 para. 1 and 1bis IvDO; these allow conforming MDD/AIMDD/IVDD devices to be placed on the market after the

[36] www.swissmedic.ch > Medical devices > Market access
[37] Art. 23 MedDO in conjunction with Art. 52 para. 7(c) MDR
[38] MDCG 2020-16 rev.2
[39] Art. 19 IvDO in conjunction with Art. 48 para. 3 and 4 IVDR

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[40].

d) The provision concerning the transitional periods leads to the situation that for medical devices there are certificates of conformity (EC certificates) whose validity date has expired. How must I, as a CH-REP or importer, check that these certificates satisfy the legal requirements and are therefore still recognised as valid?

CH-REPs and importers are obliged to check aspects relating to conformity, in particular whether **valid certificates of conformity (EC certificates)** exist (cf. row 6 of the table in section 5 of this information sheet).
The importer must be able to prove that the conformity assessment has been carried out by the manufacturer and that the device is conforming[41]. Where an importer considers or has reason to believe that a device is not in conformity with the requirements of the Medical Devices Ordinance, it must not place the device on the market until it has been brought into conformity[42].

A CH-REP/importer cannot assume that all certificates with an expired period of validity and all devices covered by these certificates satisfy the legal requirements for extending the certificate's period of validity and can therefore be placed on the market. As part of their verification and due diligence obligation[43], the CH-REPs and importers are responsible for **checking the plausibility of expired certificates and of the conformity of devices**.
These aspects can be verified by the economic operators by checking the plausibility of the following items of evidence:

- A manufacturer's declaration stating that the requirements for extending the period of validity of the certificate issued under the old legislation are satisfied (a template has been published by the EU industry associations[44]);
- A confirmation letter from the designated/notified body stating that the manufacturer has lodged an application for a conformity assessment procedure / has signed a written agreement with a designated/notified body (a template has been published by Team-NB[45]).

Swissmedic also relies on European practice when interpreting the applicable provisions. Further information on the extension of the validity of certificates issued under the old legislation is provided in the guidances published by the European Commission Q&A[46].

---

[40] Art. 101 para. 2 MedDO / Art. 82 para. 2 IvDO
[41] Art. 21 Abs. 2 MedDO / Art. 17 para. 2 IvDO
[42] Art. 53 Abs. 3 MedDO / Art. 46 para. 3 IvDO
[43] Art. 3 HMG
[44] www.medtecheurope.org > resources & data > resource library > Manufacturer's Declaration in relation to Regulation (EU) 2023/607 (non-IVD) / Manufacturer's Declaration in relation to Regulation (EU) 2024/1860 (IVD)
[45] European Association for Medical devices of Notified Bodies: www://health.ew.team-nb.org > Team-NB Documents > Team-NB Positions papers > Team-NB PositionPaper NB-ConfirmationLetterEU2023-607 V2 (non-IVD) / Team-NB-IVDConfirmationLetterTemplate-V2-20240710 (IVD)
[46] https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en > Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 - Extension of the MDR transitional period and removal of the "sell off" periods, and Q&A on practical aspects related to the implementation of the extended transitional period provided for in the IVDR, as amended by Regulation (EU) 2024/1860

e) **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.

f) **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.

g) **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**.

h) **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 medical devices"). Do I have to register twice?**
No, you need to register only once. Any changes (e.g., of the address) need to be submitted via the database swissdamed[47].

i) **As an importer, I import devices from a foreign country and dispense these directly to the end customers in Switzerland, i.e., there are no distributors in the distribution chain. Do I satisfy my declaration requirement specified in Art. 53 para. 2 MedDO / Art. 46 para. 2 IvDO if I am indicated as the importer on e.g., customs documents, invoices from foreign suppliers or other accompanying documents that do not accompany the devices when they are placed on the market (i.e., dispensed to the end customers)?**
No. When a device is placed on the market (transfer/cession in Switzerland), the importer must be stated on the device or on its packaging or on a document accompanying the device so that this economic operator is clearly identifiable along the supply chain.

j) **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.**

[47] For more information see www.swissmedic.ch > Medical devices > Market access > Single registration number (CHRN) and www.swissmedic.ch > Medical devices > swissdamed

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).

k) **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.

l) **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.

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	Change	sig
6.0	Amendment due to new version of the IvDO of the 01.01.2025	mea
5.0	Amendment due to new version of the MedDO / IvDO	mea
4.0	Amendment section 1.2 (Liechtenstein) Correction section 4.1 (translation error in the English version)	mea
3.0	Amendments due to entry into force of IvDO; modification of symbols section 3	mea
2.0	Updating of section 6	kom
1.0	New doc ID, no content changes. Old doc ID: MU603_00_017 (version 1.0 dated 10.08.2021)	mea