SWISS MEDTECH

Information for Swiss Distributors and Importers

Guidance

Designation of a Swiss Authorised Representative under the new MedDO

CH REP

03 January 2022

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Content

Management Summary

This document outlines the provisions regarding Swiss ARs under the revised MedDO without an updated MRA.

The European Medical Device Regulation (MDR) has come into force on 26 May 2021– the same day when the corresponding Swiss Medical Device Regulation (MedDO) entered into effect. Switzerland and the European Union (EU) were not able to agree on an update of the Mutual Recognition Agreement (MRA) before 26 May 2021; or on a transitional solution whereby the previous MRA would continue to apply.

As a result, all Swiss distributors of medical devices have to comply with new regulatory requirements of the MedDO because Switzerland is no longer part of the EU common market for medical devices. The revised MedDO uses, equivalent to the MDR, the concept of Swiss Authorised Representatives (Swiss AR or CH-REP) that are mandatory for all manufacturers based outside of Switzerland to place medical devices on the Swiss market. Since the MRA has not been updated, the task of the Swiss AR can no longer be fulfilled by a European company (European Legal Manufacturer or European Authorised Representative) as it has been done previously.

The original version of the revised MedDO has been prepared with a fully functional MRA in mind. Since the MRA has not been updated, certain provisions of this version of the MedDO were not implementable or only implementable to a limited extent. The final revision of the MedDO aims to address these issues. However, there are still uncertainties left regarding the implementation of certain requirements. Swiss Medtech is working in collaboration with Swissmedic and the FOPH to clarify these aspects.

The advice from Swiss Medtech to all Swiss distributors of imported medical devices is to take the following actions:

- Ensure that foreign manufacturers appoint a CH-REP for all medical products they export to Switzerland before the end of the transitional periods (MepV Art. 104a).
- Ensure that in the case of MDD products, the CH-REP and the importer are indicated on the delivery note.
- Ensure that the CH-REP is indicated on the product or packaging (e.g. label) of MDR products in accordance with the provisions of the MedDO.

1. Introduction

The regulatory situation

The previous European medical device legislation, the MDD (93/42/EEC) and AIMDD (90/385/EEC), has been replaced by the Medical Device Regulation (EU 2017/745) on 26 May 2021. In order to maintain mutual access to the markets, Switzerland has revised its Therapeutic Products Act TPA [1] and Medical Device Ordinance MedDO [3] and aligned them with the European Medical Device Regulation MDR [2], establishing legal equality. The revised MedDO has come into force on 26 May 2021, the date when the transition period of the MDR has ended.

The MedDO, forming the legal basis for medical devices in Switzerland, has been revised and aligned with the MDR in view of maintaining the unrestricted trade and supervision of medical devices between Switzerland and the EU. To create legal certainty and guarantee the equivalence of Swiss law with European law, the Mutual Recognition Agreement MRA [4] between Switzerland and the EU is needed. The MRA is a key element for market access, coordinated market supervision, exchange of information and mutual recognition of conformity assessments. Implementation of all these aspects would have required an update of the MRA.

The MedDO requires any manufacturer not based within Switzerland who wants to place its devices on the Swiss market to designate an authorised representative within Switzerland (Swiss AR or CH-REP). This also holds true for manufacturers from EU/EFTA member states. Only an updated MRA would have limited this requirement to manufacturers from third countries, i.e. non-EU/EFTA member states. An update of the MRA would also have assured that EU authorised representatives of manufacturers from third countries are recognised by Switzerland, eliminating the need for additional Swiss ARs.

The European Commission has previously linked the MRA update to the conclusion on the institutional agreement InstA between Switzerland and the EU. The EU Commission has stated that it will no longer negotiate new market access agreements and will not update existing agreements until the InstA has been agreed on. On 26 May 2021 however, the Swiss Federal Council concluded that substantial differences between Switzerland and the EU on key aspects of the InstA remain and terminated the negotiations. Therefore, an update of the MRA in the foreseeable future seems unlikely.

Swiss authorities face the problem that without a renewed MRA which coordinates market surveillance and the exchange of information between the authorities in Switzerland and the EU member states, no legal means are available to control medical devices of foreign manufacturers or to prosecute the manufacturers if necessary. The Swiss AR is therefore an important tool for the authorities to maintain control over the medical device market in Switzerland.

However, the requirements imposed by the MedDO on Swiss ARs and on the foreign manufacturers lead to increased efforts for the latter. These requirements are equivalent to those imposed by the MDR on EU ARs and Non-EU manufacturers, despite the much smaller Swiss market compared to the EU market. It has been argued that many manufacturers might decide

to withdraw from the Swiss market rather than incur this additional effort and expense, possibly jeopardizing the security of supply of the Swiss healthcare system regarding medical devices.

The MedDO has undergone a final revision and measures have been implemented to dampen these negative effects while still guaranteeing adequate market surveillance of medical devices in Switzerland.

If it should become clear that the MRA will not be updated in the foreseeable future, these measures will serve as a temporary solution until Switzerland has established its own medical device regulation independent of European law and infrastructure. This would involve another revision of the relevant legislation, including the MedDO.

2. Provisions regarding Swiss Authorised Representatives under the MedDO

Article 51 of the MedDO states that any manufacturer not based in Switzerland may only place its products on the Swiss market when it has delegated a person based in Switzerland as its authorised representative (Swiss AR).

The MedDO is very closely aligned with the MDR. The provisions regarding a Swiss AR stated in the MedDO are mostly equivalent to those of the MDR for an European AR. These provisions have already been outlined in a former *Swiss Medtech guidance for compliance with third country requirements* [6]. In the following, the differences in the requirements for Swiss and European ARs are specifically addressed.

Designation of a Swiss AR

The MedDO defines an authorised representative as *any natural or legal person established within Switzerland who has received a written mandate from a manufacturer located in another country to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligation under this Ordinance*[1,2].

The definition of authorised representative in the MDR differs in that it requires an AR to have '*received **and accepted** a written mandate from a manufacturer'.* However, the MedDO references article 11 of the MDR where it is stated that the mandate '*shall be valid only when accepted in writing by the authorised representative'*.

The foreign manufacturer will have to designate a single Swiss AR for all products of a generic device group.

According to MedDO article 55, Swiss ARs will have to register with Swissmedic and obtain a *Swiss Single Registration Number CHRN* [8] within three months of placing their first product on the Swiss market. However, article 104a of the MedDO includes transitional periods for the designation of Swiss ARs (see details below).

Tasks and obligations of the Swiss AR

The Swiss AR shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance with the requirements of the MedDO. The responsibility of this person as well as exceptions and further modalities are in accordance with article 15 of the MDR.

[1] MedDO article 4, paragraph 1.g.

[2] Note that there is no official English text of the revised MedDO yet. All passages from the MedDO referenced in this document have been translated by the author or were taken from other official English documents.

The tasks of a Swiss AR are similar to those of an EU AR and include:

- Verification of compliance with registration requirements
- Guarantee access to a copy of the technical documentation
- Support of the authorities during audits and product tests
- Reporting of incidents and complaints (Vigilance Report)

In contrast to EU ARs, the Swiss AR does not have to possess a copy of the technical documentation but can also arrange contractually that the manufacturer sends the documentation directly to Swissmedic upon request (MedDO Article 51(3bis)).

The Swiss AR has to assume the obligations of manufacturers to report serious incidences and field safety corrective actions within Switzerland to Swissmedic, including final reports pursuant to Article 89(5) of the MDR. The assignment of these duties from the manufacturer to the Swiss AR must be laid down in the mandate (MedDO Article 66(2bis)).

Some of the manufacturer's obligations can specifically not be delegated to a Swiss AR:

- Ensuring the conformity of the products
- Maintenance of a risk management system
- Performing clinical evaluations
- Writing and updating of technical documentation
- Preparation of the declaration of conformity
- Maintaining the UDI database
- Maintenance of the manufacturer's quality management system
- Establishment of a post-market monitoring system
- Preparation of labelling and instructions for use
- Definition of necessary corrective measures

Analogous to the European AR, if the manufacturer does not comply with his obligations according to the MedDO, Swiss ARs are jointly and severally liable with the manufacturer for defective products. They are obliged to have sufficient financial cover for damages caused by defective medical devices[3].

There is no specific insurance solution for Swiss authorised representatives. Each one has to arrange this individually for his or her needs. It is therefore important that the authorised representative is registered as a "co-dependant company" in the manufacturer's insurance policy.

[3] Art 47d revHMG, BBl 2019 2589

Overview of MedDO articles addressing Swiss AR and references to the MDR

MedDO	Reference to MDR
– Art. 51 Duties (of the authorised representative)	– Art. 11 Authorised representative – Art. 12 Change of authorised representative
– Art. 52 Person responsible for regulatory compliance, referencing MedDO Article 49, Paragraphs 2 - 4	– Art. 15 Person responsible for regulatory compliance
– Art. 53 Importer – Art. 54 Distributor	– Art. 13 General obligations of importers – Art. 14 General obligations of distributors – Art. 16 Cases in which obligations of manufacturers apply to importers, distributors or other persons
– Art. 55 Registration of manufacturers, authorised representatives and importers	– Art. 30 Electronic system for registration of economic operators, Paragraph 3 – Art. 31 Registration of manufacturers, authorised representatives and importers
– Art. 16 Product information	– Annex I, chapter III

Labeling requirements

The name and address of the Swiss AR must be stated on the packaging of the products as per MDR Annex I section 23.2 (d). Stating the Swiss AR on the product itself, the instructions for use or in documents enclosed with the product is not mandatory.

The following symbol should be used on the packaging, accompanied by the name and address of the Swiss AR [9]:

Alternatively, the terms ‘CH authorised representative’, ‘CH-REP’ or ‘Authorised representative for Switzerland’ can be used instead of the symbol (in the three national languages).

For medical devices subject to previous legislation (MDD/AIMD products), the labelling can also be indicated on a document accompanying the product (e.g. delivery note). See chapter 6 of the Swissmedic informationsheet "Obligations Economic Operators CH". For MDR class I products, a transitional period until 31.07.2023 applies.

Change of a Swiss AR

If a manufacturer wishes to change their Swiss AR, the detailed arrangements must be clearly defined in an agreement between the manufacturer, the outgoing and the incoming authorised

representative in accordance with article 51, paragraph 4 of the MedDO (article 12 of the MDR).

Transitional periods

Article 104a of the MedDO defines the following transitional periods for the designation of Swiss ARs for manufacturers from EU/EFTA countries and manufacturers from third countries who have already designated an EU AR:

- for class III devices, class IIb implantable devices and active implantable medical devices: until 31 December 2021
- for non-implantable class IIb devices and class IIa devices: until 31 March 2022
- for class I devices as well as systems and procedure packs: until 31 July 2022

These transitional periods are also applicable for products with valid certificates issued under the previous MedDO/MDD as well as class I products for which the declaration of conformity has been issued under the previous MedDO/MDD and which would be up-classified under the new MedDO/MDR (see MedDO Article 101 and 100 for details).

3. Recommendation for action

The new MedDO came into force on 26 May 2021 without an updated MRA. This makes the establishment of a Swiss AR mandatory for all manufacturers based outside of Switzerland to continue placing their products on the Swiss market.

The establishment of a Swiss AR may involve the following steps:

1. Decision who will act as Swiss AR (you as distributor/importer yourself or a third party)
2. Information to all your foreign manufacturers
3. Negotiation with all manufacturers to determine who will continue to supply their medical devices to Switzerland and who may decide to withdraw
4. Search for substitute products for all medical devices that will no longer be available
5. Plan for altered logistics, including labelling
6. Assessment of the impact on your own business and on your customers'

The risk class of the devices determines the transitional period for establishing a Swiss AR and the time available for implementing these measures.

The advice from Swiss Medtech to all Swiss distributors of imported medical devices is to take the following actions:

- Ensure that foreign manufacturers appoint a CH-REP for all medical products they export to Switzerland before the end of the transitional periods (MepV Art. 104a).
- Ensure that in the case of MDD products, the CH-REP and the importer are indicated on the delivery note.
- Ensure that the CH-REP is indicated on the product or packaging (e.g. label) of MDR products in accordance with the provisions of the MedDO. Ideally, as many foreign manufacturers as possible should be encouraged to indicate the CH-REP directly on the product labelling as part of the transition from MDD/AIMD to MDR.

References

[1] CC 812.21 Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA)

[2] Regulation (EU) 2017/745 on Medical Devices (MDR)

[3] Swiss Medical Device Ordinance, SR 812.213 (MedDO) of 1. July 2020 (no English text available)

[4] Mutual Recognition Agreement between Switzerland and the EU
EU: Document 02002A0430(05)-20171222, CH: SR 0.946.526.81 (no English text available)

[5] EUDAMED Actor Module FAQs, Nov. 2020, https://ec.europa.eu/health/sites/health/files/md_eudamed/docs/md_actor_module_q-a_en.pdf

[6] Swiss Medtech Guideline for Designation of a European Authorised Representative (in German: https://www.swiss-medtech.ch/sites/default/files/2020-12/Wegleitung_Schweizer%20Hersteller_DE.pdf, in French: https://www.swiss-medtech.ch/sites/default/files/2020-12/Wegleitung_Schweizer%20Hersteller_FR_0.pdf)

[7] FOPH - Explanatory report on revision of medical devices legislation (July 2020, no English text available)

[8] Swissmedic information on Unique identification number - CHRN

[9] Swissmedic - Information on Swiss authorised representative (CH-REP)

[10] Swissmedic – Information on the obligations for authorised representatives, importers and distributors

Document Release and Change History

Version	Date	Author	Review	Release	Comments
00	15.12.2020	Kaspar Gerber (ISS)	Hansjörg Riedwyl (ISS) Bernhard Bichsel (ISS) Jörg Baumann (SMT)	Daniel Delfosse (Swiss Medtech)	Initial document as «Preliminary Guideline»
01	29.01.2021	dito	dito	dito	"Guidance" with inclusion of the role of Swiss importers
02	16.07.2021	dito	Beni Hirt (Decomplix), Helena Lacalle (Decomplix)	dito	Revision after coming into force of the new MedDO
03	03.01.2022	dito	Daniel Delfosse (Swiss Medtech)	dito	Update on labelling obligations and insurance coverage; new recommendation for action

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