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Information sheet
Products without an intended medical purpose

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List of contents

1 Introduction

Certain products without an intended medical purpose that are used to change a person's appearance have been governed by the Medical Devices Ordinance[1] since 26 May 2021. These include, for example, coloured contact lenses, products for lipolysis and dermal filling and laser devices for skin resurfacing. The common specifications provided for these products without a medical purpose (products according to Annex 1 MepV) had not yet been designated by 31 October 2023, so that the provisions of the relevant sectoral decree continued to apply to these products.
On 1 December 2022, the European Commission issued Implementing Regulations (EU) 2022/2346 and (EU) 2022/2347, which define the common specifications and classification rules for product groups without an intended medical purpose. These new provisions and requirements were adopted in the Swiss Medical Devices Ordinance in an equivalent form in autumn 2023.
As a result, the legal requirements applicable in Switzerland to products without an intended medical purpose will be changing from 1 November 2023. As of this date, products without an intended medical purpose must fulfil the common specifications and the general safety and performance

[1] MedDO, SR 812.213, https://www.fedlex.admin.ch/eli/cc/2020/552/en

requirements set out in MedDO. Making devices available on the Swiss market is also subject to MedDO. However, transitional periods are provided to allow economic operators to adapt to the new requirements and market these products in a compliant manner.
This Information sheet is intended to help manufacturers, importers, authorised representatives and users of products without an intended medical purpose to understand the new regulatory requirements and comply with the transitional provision. The information and legal provisions presented are reproduced in a simplified form for better understanding. Ultimately, the provisions of the laws and regulations apply.

2 Definitions and other valid documents

2.1 Definitions

Authorised representative	If the manufacturer of a device is not domiciled in Switzerland, its devices may only be placed on the market once an authorised representative domiciled in Switzerland has been designated. The manufacturer has mandated (in writing) an authorised representative to act on the manufacturer's behalf in relation to specified tasks.
Certificate of conformity	Also known as an “EU certificate” or “EC certificate”. The certificate of conformity is issued by the designated / notified body which controls the manufacturer’s conformity assessment and confirms its compliance with the legal requirements in this certificate. Whether or not a designated body is involved in the conformity assessment procedure depends on the classification of the device; it is a requirement for medical devices associated with moderate and high risks. If a check by a designated body is required, the CE mark may only be affixed to a device if a corresponding certificate has been issued by the designated body. The CE mark (or also the MD mark in Switzerland) must then be accompanied by the designated body’s four-digit number (CE nnnn).
Common specifications	A set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system[2].
Conformity assessment	Process demonstrating whether the requirements of the Medical Devices Ordinance relating to a device have been fulfilled.
Declaration of conformity	Also referred to by the abbreviation DoC. This declaration is issued by the manufacturer in which they confirm that the device complies with the legal requirements. An EU declaration of conformity (which confirms the conformity of the device with EU MDR / EU IVDR or the regulations under the old legislation) is recognised in Switzerland. A declaration of conformity is a legally required evidence of conformity for all medical devices, irrespective of whether or not a designated / notified body was involved in the procedure.
Designated body	Designated bodies are organisations designated and monitored by the government. They act on behalf of the manufacturers, supporting and checking their conformity assessments of, for example, various types of medical devices (conformity assessment bodies). They are referred to in the EU MDR as **notified bodies.**
Device	The term “device” comprises medical devices and accessories, products without an intended medical purpose from the product groups in Annex 1 MedDO and in vitro diagnostic devices.

[2] Art 2 no. 71 EU MDR in conjunction with Art. 4 para. 2 MedDO

Distributor	Any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the Swiss market, up until the point of putting into service
Economic operator	Any manufacturer, authorised representative, importer or distributor and any person that assembles systems and procedure packs.
Healthcare professional	Equivalent in meaning to the term used in the EU. According to the Healthcare Occupations Act[3], the term also includes registered nurses, osteopaths, physiotherapists, occupational therapists, midwives and nutritionists (university of applied sciences or Bachelor-level qualification)
Importer	Any natural or legal person established in Switzerland who places a device from a foreign country on the Swiss market.
Incident	Any malfunction or deterioration in the characteristics or performance of a device that has already been made available on the market, including use errors due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side effect.
Instructions for use	Information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken.
Intended purpose	The use for which a device is intended in accordance with the information provided by the manufacturer on the label, in the instructions for use or in promotional or sales material or information and the information stated in the clinical evaluation.
Labelling	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.
Layperson	A person who has no formal education in the relevant field of healthcare or medical discipline.
Making available	The supply or transfer of a device in return for payment or free of charge. The use of a device by a professional user does not constitute making available on the market.
Manufacturer	Any 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 own name or trademark.
Medical professional	Defined in the Medical Professions Act[4] as doctors, dentists, pharmacists, veterinary surgeons and chiropractors. They have a university (Master's level) qualification.
Placing on the market	First time a device is made available on the Swiss market.
Product information	Product information comprises the labelling and instructions for use.
Professional	A person with formal training in the relevant field.
Putting into service	The stage at which the device is made available to the end user for the first time.
User	Any healthcare professional, professional or layperson who uses a device.

2.2 Other valid documents

Abbreviation	Document ID
EU MDR[5]	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
Implementing Regulation 2022/2346[6]	Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 laying down common specifications for the groups of products without an

[3] HOA; SR 811.21

[4] MedPA; SR 811.11

[5] EUR-Lex - 32017R0745 - EN - EUR-Lex (europa.eu)

[6] https://eur-lex.europa.eu/eli/reg_impl/2022/2346/oj

	intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices
Implementing Regulation 2022/2347[7]	Commission Implementing Regulation (EU) 2022/2347 of 1 December 2022 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards reclassification of groups of certain active products without an intended medical purpose
MDD	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
MedDO	Medical Devices Ordinance; SR 812.213
MU600_00_016	Swissmedic information sheet on the obligations of economic operators
MU600_00_006	Swissmedic information sheet on the procurement of medical devices in health institutions
MU100_00_001	Swissmedic information sheet on injectable products for wrinkle treatment
O-NIRSA	Ordinance to the Federal Act on Protection against the Risks associated with Non-Ionising Radiation and with Sound; SR 814.711
TPA	Therapeutic Products Act; SR 812.21

3 General

3.1 What are products without an intended medical purpose?

According to Annex 1 MedDO, products without an intended medical purpose are products that do not fulfil a medical purpose but which, from a patient safety perspective present a risk to humans comparable to the risk presented by medical devices. Accordingly, these products must fulfil essentially the same general safety and performance requirements as medical devices.

Annex 1 MedDO defines six distinct groups of products without an intended medical purpose:

Table 1: Product groups without an intended medical purpose in accordance with Annex 1 MedDO

Group	Description
1	**Contact lenses** or other items intended to be introduced into or onto the eye.
2	Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of **modifying the anatomy** or fixation of body parts with the exception of tattooing products and piercings.
3	Substances, combinations of substances, or items intended to be used for facial or other **dermal or mucous membrane filling** by subcutaneous, sub-mucous or intradermal injection or other introduction, excluding those for tattooing.
4	Equipment intended to be used to **reduce, remove or destroy adipose tissue**, such as equipment for liposuction, lipolysis or lipoplasty.
5	**High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment** intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum light such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other **skin treatment**.
6	Equipment intended **for brain stimulation** that applies electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

[7] https://eur-lex.europa.eu/eli/reg_impl/2022/2347/oj

3.2 Why do we have this new regulation?

The devices that fall under Annex 1 MedDO can pose significant potential health risks to the persons concerned (customers or self-users) as well as professional users.
Stricter regulation of manufacturing, marketing and use is required to better guarantee the safety of the people using or applying these products. This is particularly important given that some of these products may be used by non-professional users at home.
The new regulations are intended to ensure that manufacturing, quality and surveillance of these products meet the same requirements as for devices with an intended medical purpose.

4 Making available on the market and transitional provisions

With the entry into force of the revised MedDO on 1 November 2023, two options will be open for marketing products that fall under Annex 1 MedDO:

A) Products that fall under Annex 1 MedDO fulfil the common specifications adopted by Swissmedic in accordance with Art. 45 para. 4 TPA (Art. 8 para. 1 MedDO) and are thus placed on the market under the new legislation. These devices must fulfil all requirements of MedDO before they are placed on the market. In this case, Swissmedic is responsible for market surveillance.
B) Products that fall under Annex 1 MedDO can continue to be placed on the market or put into service under the existing legislation up to the dates specified in Art. 106 MedDO provided the conditions set out in Art. 106 MedDO are fulfilled.

4.1 Transitional provisions

Under the transitional provisions in Art. 106 para. 2 to 6 MedDO, it will be possible to market devices in the product groups listed in Annex 1 MedDO without any restriction until 1 May 2024 under the existing sector-specific legislation.
To benefit from the transitional provisions, however, devices that fall under Annex 1 MedDO:

a. must have been legally marketed in Switzerland prior to **1 May 2024** and continue to comply with applicable legislation,
b. must not have been substantially changed.

Compliance with the general safety and performance requirements under Art. 6 MedDO is demonstrated by means of a clinical evaluation[8]. The clinical evaluation of products without an intended medical purpose is based on relevant clinical data on performance and safety[9] and must satisfy the requirements of the common specifications. These clinical data must include information from post-market surveillance, post-market clinical follow-up and, if applicable, data from specific clinical investigations.

[8] Art. 61 EU MDR in conjunction with Art. 21 MedDO
[9] Art. 6 para. 2 MedDO

- If a manufacturer is planning a clinical investigation to obtain clinical data for the clinical evaluation, prodcuts may be placed on the market or put into service under the existing legislation until **31 December 2029** provided the following additional requirements are met:
    a. From 1 November 2024, the study sponsor must have received confirmation from the responsible authority that the application for a clinical study is complete and falls under MedDO.
    b. From 2 May 2025, the study sponsor must have initiated the clinical investigation.
    c. From 1 January 2028, a written agreement on the performance of the conformity assessment must exist between the manufacturer and a designated body.

- If a manufacturer is not planning a clinical investigation, products may be placed on the market or put into service under the existing legislation until **31 December 2028** provided the following additional requirements are met:
    a. From 1 January 2027, a written agreement on the performance of the conformity assessment must exist between the manufacturer and a designated body.

If these conditions are fulfilled, the products may still be placed on the market in Switzerland under the existing legislation up to the dates given. The competent national or cantonal authority remains responsible for the market surveillance of products that were marketed on the basis of the transitional provisions.

Once the transitional deadlines have passed or if a manufacturer fails to comply with the transitional provisions, any device that falls under Annex 1 MedDO may only be placed on the market, made available on the market or put into service if it has successfully completed the conformity assessment procedure under MedDO and if it carries a corresponding CE mark (see Annex 1 of this information sheet).

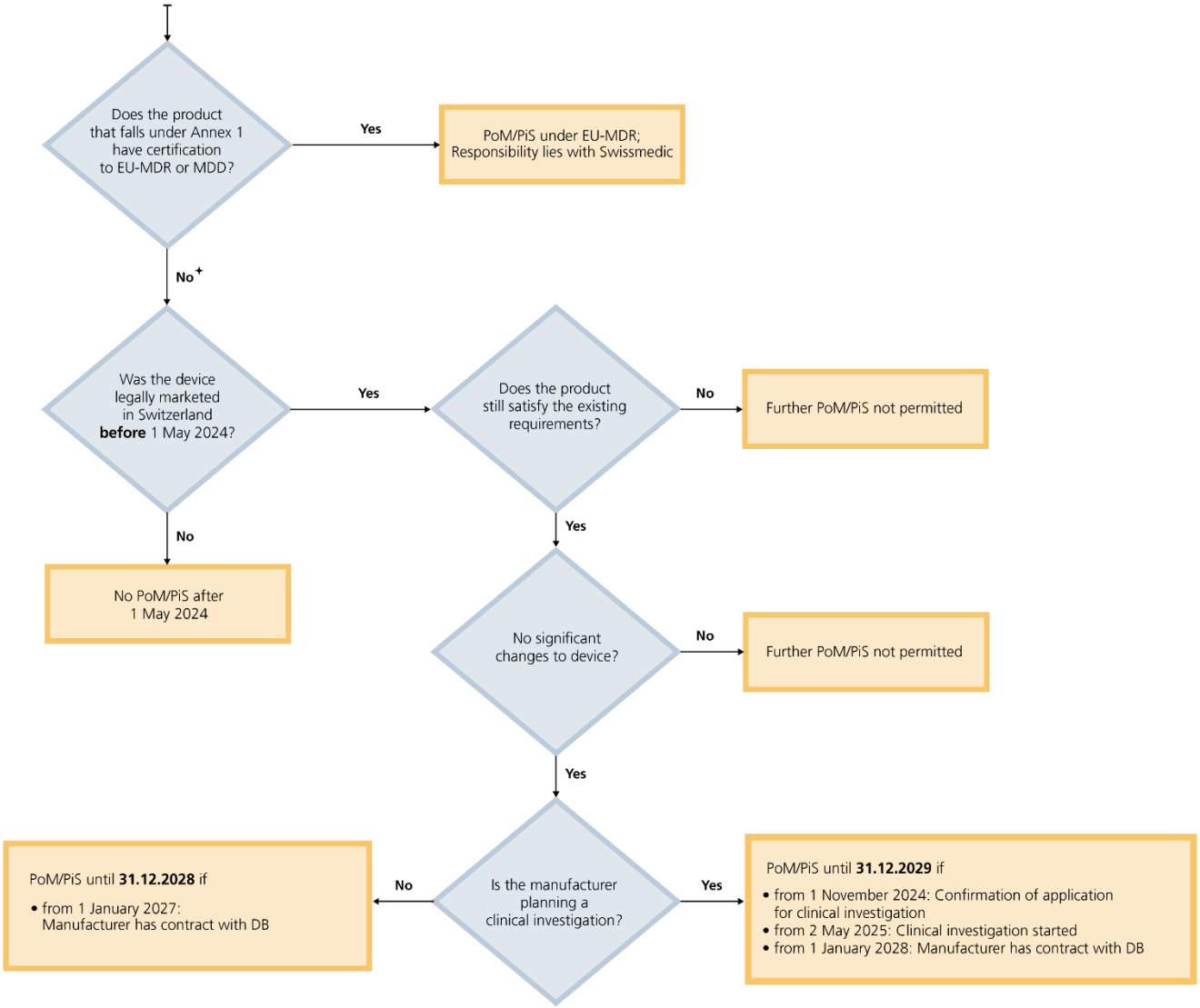

Figure 1: Schematic representation of the transitional deadlines and conditions

5 Information relevant to manufacturers

5.1 Device requirements under Annex 1 MedDO

In MedDO, the term “devices” applies to medical devices and the associated accessories[10] and product groups without an intended medical purpose in accordance with Annex 1 MedDO[11]. Accordingly, they must also carry a conformity mark[12] and have a declaration of conformity[13] (see section 4 Transitional provisions of this information sheet).
Manufacturers of products that fall under Annex 1 MedDO must conduct a conformity assessment procedure involving a designated body. Once the procedure has been successfully completed, a declaration of conformity can be issued and the CE mark attached.
The differences in requirements compared with medical devices are described in the common specifications (i.e., in Annexes I-VII of Implementing Regulation 2022/2346) that were adopted with effect from **1 November 2023**.

5.2 Making available of devices under own name

Anyone who currently markets products that fall under Annex 1 MedDO under their own name, trading name or trade mark will assume the obligations applicable to manufacturers[14] from 1 November 2023 and must demonstrate the conformity of their products.
The only exception is where the distributor or importer has concluded an agreement with the manufacturer under which the manufacturer is indicated as such on the labelling and is responsible for compliance with the requirements applicable to manufacturers.

6 Information relevant to economic operators

6.1 Reviewing the conformity of products without an intended medical purpose

Importers and distributors may only place or make available on the market products that comply with the MedDO[15].
Where products without an intended medical purpose have undergone a conformity assessment procedure under EU MDR, (see section 4, variant **A)**), this can be demonstrated using the declaration and certificate of conformity (see Annex 1 of this information sheet).
Products without an intended medical purpose that are placed on the market under existing sector-specific law under the transitional provisions (section 4, variant **0**) will not have a declaration of conformity issued under EU MDR. In this case, economic operators and users must establish whether the manufacturer complies with the requirements of the transitional provisions.
This must be established by consulting the manufacturer (or importer or distributor if appropriate). The manufacturer must know whether it is planning a clinical investigation, whether it has confirmation of

[10] Within the meaning of Art. 3 MedDO
[11] Art. 1 para. 2 MedDO
[12] Art. 13 MedDO
[13] Art. 21 MedDO
[14] Art. 16 para 1 EU MDR in conjunction with Art. 53 and 54 MedDO
[15] Art. 6 MedDO

its application for a clinical investigation or whether a contract has been concluded with a designated body.

6.2 Obligations for importers, authorised representatives and distributors

With regards to making available and placing on the market and the associated obligations of the economic operators, products that fall under Annex 1 MedDO and are placed on the market under the new legislation (see section 4 variant **A)**) are subject to the same requirements as medical devices. Information on the obligations of economic operators for medical devices can be found in the information sheet “Obligations Economic Operators” Obligations for authorised representatives, importers and distributors (swissmedic.ch)[16].

Devices that fall under Annex 1 MedDO and are placed on the market in compliance with the transitional periods (see section 4, variant **0**) will continue to be placed on the market under the existing sector-specific legislation.

7 Information relevant to users

The regulations governing the use of products that fall under Annex 1 MedDO vary between product groups. Different provisions apply, depending on the product group. Products are generally supplied in accordance with their intended purpose and the information provided by the manufacturer.[17] Additional information can be found on the Swissmedic website at Medical devices (swissmedic.ch)[18].

8 Reporting obligation

Professionals who use devices, have a **legal obligation** to report **serious incidents** to Swissmedic (materiovigilance)[19]. For example, **quality defects** (e.g., device malfunctions) that actually or potentially jeopardise the safety of consumers and/or users are classified as serious incidents and must be reported to Swissmedic. This extends to incidents where “things turned out well in the end”, in other words, where there was potential for damage to health, but no actual damage occurred.

[16] https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-access/pflichten-bevollmaechtigte.html
[17] Art. 68 MedDO
[18] www.swissmedic.ch/swissmedic/en/home/medical-devices.html
[19] Art. 66 para. 4 MedDO

Customers and self-users can also report non-conformities or serious incidents to the competent authority.
Further information on reporting serious incidents can be found on the Swissmedic website at Reporting incidents & FSCAs (vigilance) (swissmedic.ch)[20].

9 Frequently asked questions

1st Can I continue to use devices that are currently used in my institution after 1 November 2023?

Devices that were placed on the market, put into service and used **before** 1 November 2023 are not affected by the new version of the Ordinance and can be used until the end of their life cycle provided the manufacturer does not call their conformity and safety into question.
Note: Placing on the market (timing) is determined for each device individually and must not be confused with earlier marketing of the same device type.

2nd Whom should I contact if I am uncertain whether the device fulfils all requirements (conformity, etc.)?

Please contact your device supplier, who will either have the information themselves or will be able to obtain it from the supply chain.
We also recommend that healthcare institutions read the information sheet Procurement (swissmedic.ch)[21] and Annex 1 of this information sheet.

3rd The certificate of conformity for a product (e.g. epilation unit) that we use in our centre/institute expires shortly and the manufacturer does not intend to renew it. Does that mean we will have to stop using the device?

The expiry date of certificates of conformity should not be equated with product service life and does not affect the product use.
It is the facility's responsibility to ensure that the product is correctly maintained[22] in order to guarantee the safety of users and the people receiving treatment.

[20] https://www.swissmedic.ch/swissmedic/en/home/medizinprodukte/vorkommnisse---fsca-melden--materiovigilance-.html
[21] https://www.swissmedic.ch/swissmedic/en/home/medical-devices/reprocessing---maintenance/beschaffung.html
[22] Art. 71 MedDO

4th What does it mean if a product without a medical intended purpose was legally marketed before 1 May 2024?

To ensure that products that fall under Annex 1 MedDO continue to be available on the market during the transitional period, it should be permissible to continue to sell and make them available under the old legislation. However, this applies only to devices that were already being marketed in Switzerland before 1 May 2024 and which satisfy or satisfied the sector-specific requirements. It is assumed in this case that they were marketed in legally compliant fashion. While MedDO provides a definition of “placing on the market”, it does not provide one of “marketing”.
This makes it possible to take more general account of products without an intended medical purpose that are covered by other sector-specific provisions. Legally compliant marketing in Switzerland in accordance with the old provisions is therefore a precondition for devices benefiting from the transitional provisions under Art. 106 MedDO.

5th My device already has CE marking. What does that mean?

CE marks can be issued and attached on the basis of varying legal requirements. In the context of medical devices, only CE marks issued under EU MDR are relevant.
CE marking issued under other European Directives or Regulations, such as the Low Voltage Directive (2014/35/EU) or Electromagnetic Compatibility Directive (2014/30/EU), are not sufficient for the conformity of medical devices or products that fall under Annex 1 of MedDO. Verifying whether the device carries a CE mark is not sufficient on its own. The associated European Directive or Regulation must also be examined. The European directive or regulation to which the CE mark refers can be found in the product's declaration of conformity.

6th We are an importer. The product was certified under MDD. Can we continue to distribute the product in Switzerland?

Products that fall under Annex 1 MedDO and which have MDD certification benefit from the transitional periods for legacy devices (see Economic operators information sheet[23]).

Provided compliance with the transitional provisions is assured, the products can still be placed on the market in accordance with MedDO.

7th As an importer/dealer, can I attach my trading name to a manufacturer’s product and market it?

Anyone who makes a device available on the market under their own name, trading name or brand name also assumes the obligations incumbent on the manufacturer. They must therefore be able to demonstrate the device’s conformity by means of its conformity assessment procedure.

[23] https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-access/pflichten-bevollmaechtigte.html

The only exception is where the distributor or importer has concluded an agreement with the manufacturer under which the manufacturer is indicated as such on the labelling and is responsible for compliance with the requirements applicable to manufacturers[24].

8th In which language must the information on the product be provided?

Product information comprises the labelling and instructions for use.[25] If the products are intended for the public, product information must be provided in all three official languages of Switzerland[26] (German, French and Italian).
However, the product information may be provided in fewer than the three official languages of Switzerland or in English if:

a) the device is supplied exclusively to healthcare professionals [...]
b) it is certain that the users possess the necessary professional and linguistic skills and have agreed to the language restriction;
c) the protection of the person receiving treatment, users and third parties is nevertheless guaranteed; and
d) the effective and efficient application is not compromised.

If requested, additional information must be provided to users in one of the official languages of Switzerland.[27]

9th From when do products that fall under Annex 1 MedDO require a Swiss authorised representative?

Products that fall under Annex 1 MedDO which are placed on the market or put into service under the Medical Devices Ordinance and the conformity of which has been demonstrated by a declaration of conformity under EU MDR must satisfy all the requirements of MedDO. This means that any manufacturer domiciled in a different country has to appoint a Swiss authorised representative in writing if it wants to sell these devices in Switzerland.
Products that fall under Annex 1 MedDO which are marketed under the transitional provisions must comply with existing legislation and do not require a Swiss authorised representative.

[24] Art. 16 EU MDR
[25] According to .Art. 16 para. 1 MedDO
[26] According to .Art. 16 para. 2 MedDO
[27] According to Art. 16 para. 3 and 4 MedDO

10 Contact

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Website: www.swissmedic.ch/md

E-mail: questions.devices@swissmedic.ch

Annex 1: Formal requirements for conforming devices

Prodcuts that fall under Annex 1 MedDO and are placed on the market under MedDO can be verified on the basis of the requirements below:

Symbol / Term	Requirements / Obligations
CE MD	Every medical device or product that falls under Annex 1 MedDO and which is placed on the market in Switzerland must carry a conformity mark (CE or MD mark)[28].
CE nnnn MD nnnnn	In the case of **most devices**, the conformity mark is followed by the four-digit number of the notified body that was involved in the assessment of the medical device. Since all products that fall under Annex 1 MedDO are in risk classes IIa, IIb or III, a designated body must be involved. This means that once the transitional periods have expired, all products that fall under Annex 1 MedDO will have to carry a CE mark specifying a notified body (CE nnnn). **Note**: The EU's publicly accessible NANDO Information System[29] lists all European notified bodies and the identification numbers assigned to them[30]. Designated body for Switzerland: SQS, identification number 1250.
Manufacturer 	**Every device** must be identified with unique manufacturer information, including the address of the manufacturer.
Swiss authorised representative CH-REP 	Devices from manufacturers domiciled outside Switzerland must be supplied with details (name and address) of the Swiss authorised representative "CH-REP".[31]
Importer 	Devices from manufacturers domiciled **outside** Switzerland must be supplied with details (name and address) of the importer domiciled in Switzerland.[31] This should not be confused with the EU importer (importer domiciled within the EU).
Declaration of conformity Declaration of conformity (DoC)	The declaration of conformity is an accompanying document and can be requested from the supplier. A declaration of conformity must have been issued for **every device** placed on the market in Switzerland. The declaration of conformity: ▪ is written by the **manufacturer** ▪ certifies that the medical device complies with the medical device provisions. Medical device without IVD: Directive 93/42/EEC, 90/385/EEC or EU MDR IVD: Directive 98/79/EC or EU IVDR

[28] Art. 8 para. 1 MedDO in conjunction with Annexes 1 and 5 MedDO.

[29] https://webgate.ec.europa.eu/single-market-compliance-space/#/home

[30] https://ec.europa.eu/growth/tools-databases/nando/

[31] Details of the information to be supplied for the CH-REP and importer can be found in the information sheet "Obligations Economic Operators CH" on our website: Obligations for authorised representatives, importers and distributors (swissmedic.ch).

Certificate of conformity EU certificate	The certificate of conformity (also called “EU certificate” or “EC certificate”) is an accompanying document and can be requested from the supplier. The manufacturer must be able to produce a valid certificate of conformity for all devices that fall under Annex 1 MedDO. The certificate of conformity is issued by an independent Swiss or European **designated body**. It shows: ▪ the address of the **manufacturer** (identical to the manufacturer stated on the device) ▪ the **medical devices** subject to certification ▪ **the selected conformity assessment procedure** in accordance with the selected annexes of MDD or MDR (e.g. Annex II excluding section 4 of Directive 93/42/EEC, Annex IX excluding Chapter 2 of EU MDR or similar).

Change history

Version	Change	sig
1.2	New layout, no content adjustments to the previous version	tsj
1.1	Minor changes	zys
1.0	Initial version	zys