SWISS MEDTECH

Information for Swiss manufacturers, importers and distributors

Placing on the Swiss Market

or how to ensure you can sell-off all your legacy medical devices after 26.05.2024

Guidance

25. April 2024

This document was written by Swissmedtech with support from Axxos AG and ISS AG.

Freiburgstrasse 3 | CH-3010 Bern
+41 31 330 97 79 | office@swiss-medtech.ch
swiss-medtech.ch

Content

Management summary

This document describes the regulatory requirements for economic operators, who wish to continue to make "legacy devices" (CE-marked under the Medical Device Directive *MDD, 93/42/EEC*) or under the Active Implantable Medical Devices Directive *AIMDD, 90/385/EEC*) that are not transitioned under the Medical Device Regulation *MDR (EU) 2017/745* available on the Swiss market. These devices do not directly benefit from the extended transitional period according to Regulation *(EU) 2023/607*. Accordingly, these products must have been placed on the Swiss market before 26 May 2024 in order to continue to be made available.

The document shows how to determine whether your device has been placed on the market in accordance with Swissmedic's interpretation of the legal bases and also outlines various options, their risks and risk mitigation measures for placing a product on the market, including the following cases:

- Selling product to end customers,
- Selling product to another Economic Operator (distributor),
- Consignment warehouse,
- Swiss online web shop,
- Standalone software through online web shop,
- Storing in specific warehouse dedicated for sale, after release for free circulation and incoming good inspections
- Sell product to natural or legal person and buy it back.

Regardless of which strategy you choose for the further provision of your legacy devices, the following measures are recommended:

- Define and document the “placing on the market” for your devices.
- Keep records of your decisions and actions (e.g., records of incoming goods inspection, agreements, invoices, delivery notes, etc.).
- Be able to always demonstrate that you, as economic operator, fulfill your obligations according to the Medical Devices Ordinance (CC 812.213, MedDO).

1 Introduction

This guidance intends to provide clarification on the regulatory requirements for placing medical devices on the market in Switzerland. It contains general observations on the terms and requirements for “placing on the market” in Switzerland.

During the transition from MDD to MDR, MDD-devices can only be placed on the Swiss market up to a certain date. This date depends on the medical device class, the current certification status and further actions by the manufacturer.

This guidance provides options to place medical devices on the Swiss market to ensure that you do not have to discard any fully compliant medical device in your stock and therefore to avoid shortages of medical devices without lowering current quality or safety requirements.

Regarding the obligations of an importer/distributor and the compliance requirements, please consult Swissmedic’s guideline MU600_00_016e_MB “Obligations Economic Operators CH”.

2 Scope and definition

The guidance applies

a) to medical devices from Swiss manufacturers placed in their warehouse in Switzerland,
b) to medical devices from foreign manufacturers, imported into Switzerland and placed in the importer’s warehouse.

The guidance specifically addresses those medical devices that were CE-marked under MDD/AIMD and will not be transitioned to MDR (Medical Device Regulation (EU) 2017/745). These devices are not eligible to profit from the extended transition period under Regulation (EU) 2023/607.

If these devices are not placed on the Swiss market before 26 May 2024, you can no longer sell them and must discard them on 27 May 2024.

However, the guidance also applies to medical devices already certified according MDR.

Please note: Medical devices of risk class I are not affected by the transition period on 26 May 2024, as they have been considered MDR products since 26 May 2021.

3 Definition of “Placing on the Market”

3.1 Switzerland

“Placing on the market” is defined in the MedDO as the *first making available of a device, other than an investigational 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)* (Art. 4 para. 1 let. b MedDO). As for the definition of “making available on the market” (Art. 4 para. 1 let. a MedDO), the concepts of “transfer or cession” (MedDO) and "supply" (EU-MDR) are – although different wording – nonetheless equivalent.

In Chapter 3 of the Swissmedic information sheet MU600_00_016e_MB “Obligations Economic Operators CH” relevant extracts of the Blue Guide are mentioned, and the concept of “placing on the market” is illustrated in a simplified graphic shown in figure 1. As stated in the introduction and in the table of chapter 3, while the graphic is **one example** (see the formulation with “e.g.“) for a possible supply chain (which is in line with the definition of the Blue Guide), other configurations may occur.

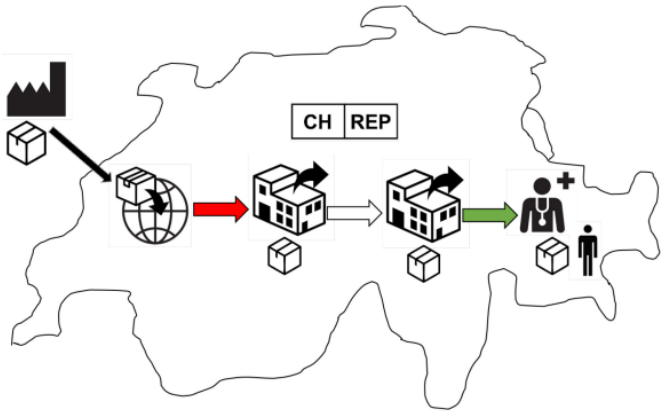


Figure 1: Simplified graphic (from Swissmedic information sheet MU600_00_016e_MB) to explain the roles of the economic operators using the example of a foreign manufacturer with a Swiss supply chain. The red arrow shows the placing on the market, the white arrow the making available on the market.

Furthermore, devices are considered to be made available on the market if devices are offered to users in Switzerland online or via some other form of distance sales (Art. 7 para. 1bis MedDO). This implies that a prior placing on the market has taken place.

There is no discrepancy between the interpretation of placing on the market of Swissmedic and the EU. Therefore, the explanations of the European Blue Guide (see chapter 3.2 below) are also relevant when interpreting the definition.

3.2 The Blue Guide (EU)

The Blue Guide (2022/C 247/01) under Section 2.3. defines “placing on the market” as follows:

For the purposes of Union harmonisation legislation, a product is placed on the market when it is made available for the first time on the Union market. This operation should be done by the manufacturer or by an importer. When a ***manufacturer or an importer supplies a product to a distributor or an end-user*** *for the first time, the operation is* ***always*** *labelled in legal terms as ‘placing on the market’.*

Placing a product on the market requires 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 property right concerning the product in question; it requires that the manufacturing stage has been completed. This transfer could be for payment or free of charge. It does ***not require the physical handover*** *of the product.*

When products imported from countries outside the EU *are presented to customs and declared for the release for free circulation procedure, it can generally be considered that the goods are being placed on the EU market… The placing on the market is the moment in which the product is supplied for distribution, consumption or use for the purposes of compliance with Union harmonisation legislation. Placing on the market* ***can take place before the release for free circulation****, for example, in the case of online or distance sales by economic operators located outside the EU, even if the physical check of the compliance of the products can take place at the earliest when they arrive at the customs in the EU.*

The Blue Guide further details what is not considered as “placing on the market”, i,e., where a product is:

- *manufactured in a Member State with a view to exporting it to a third country,*
- *introduced from a third country in the EU customs territory in transit, placed in free zones, warehouses, temporary storage or other special customs procedures (temporary admission or inward processing), or*
- *in the stocks of the manufacturer (or the authorised representative established in the Union) or the importer, where the product is not yet made available, that is, when it is not being supplied for distribution, consumption or use, unless otherwise provided for in the applicable Union harmonisation legislation*.

It is evident that the definition set out in the Blue Guide leaves room for interpretation. Therefore, the question if a product is to be considered as placed on the market shall be evaluated on a **case-by-case basis** to determine if the elements of the definition are fulfilled.

4 Flowcharts for Swiss manufacturers, importers and distributors

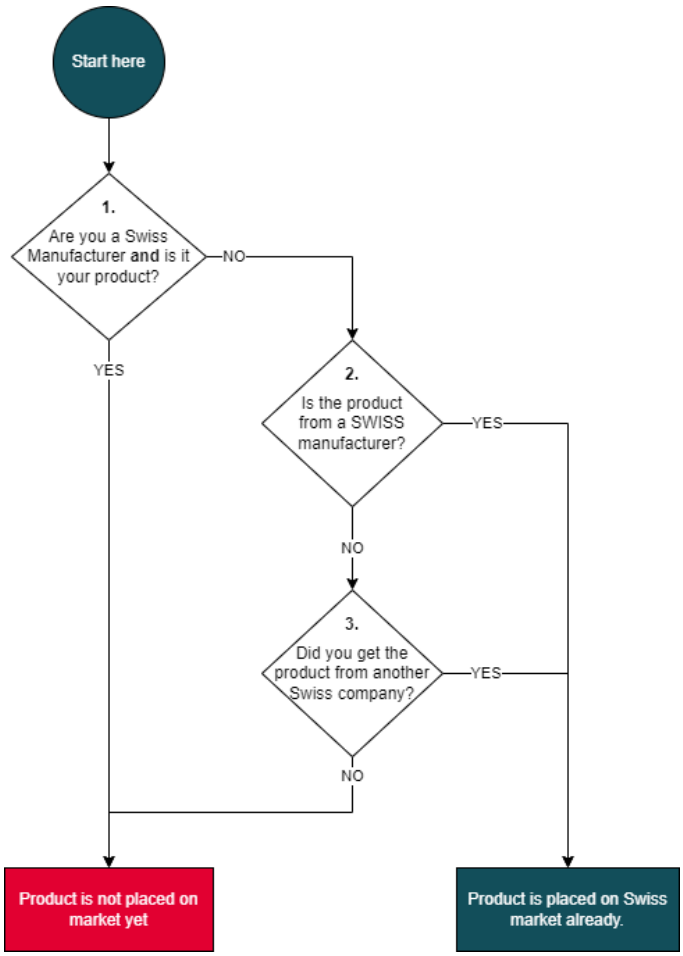
Swiss manufacturers are producing their medical devices in Switzerland or abroad. Once finished, the devices are placed in the stock of the warehouse (assumption: in Switzerland), ready to be sold to customers.

Swiss importers and distributors are buying their medical devices abroad or in Switzerland. The devices are placed in the stock of the warehouse (assumption: in Switzerland), ready to be sold to customers.

The basic workflow is divided in three parts; please start with workflow 1:

1. Identification if the product is already placed on the market (chapter 4.1)
2. Identification of the date on which the product can be placed on the market for the last time (chapter 4.2).
3. Placing product on the market (chapter 4.3)

4.1 Is the product placed on market already?



Product is not placed on Swiss market yet:

A case-by-case evaluation has to take place. Please continue reading in chapter 5.

Product is placed on Swiss market already:

Due to the deletion of the sell-off date for MDD certified products in the last MedDO revision (01. November 2023), the product can be further made available on the Swiss market. The only date to consider is the expiry date of the medical device itself.

For MDR certified products the latest day for making the product available on the market is the expiry date of the CE-certificate of the product, provided that the device complies with MedDO (e.g. labelled with CH-REP & Importer, responsibilities of the economic operators recognized).

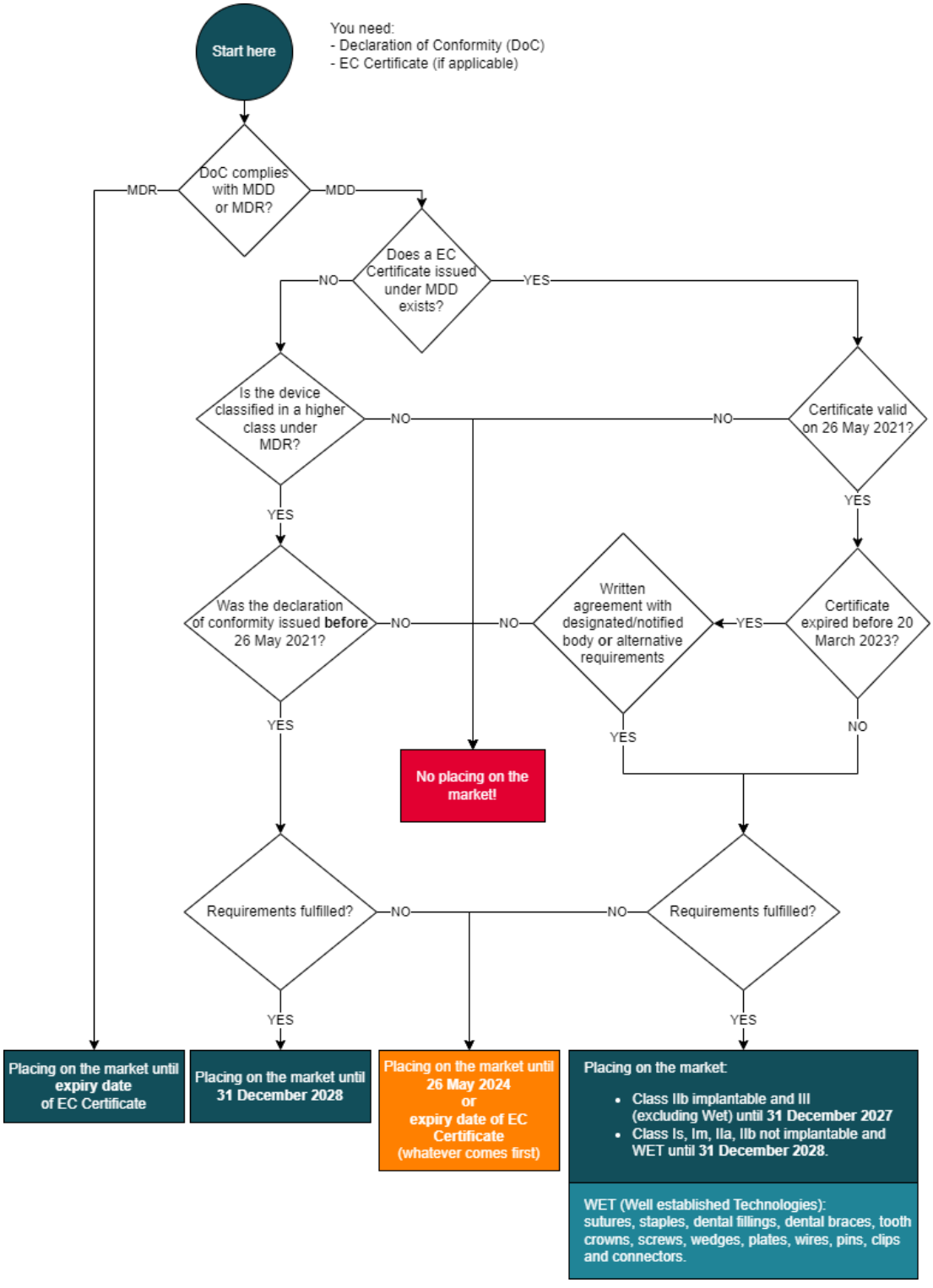
Justification for the workflow:

1. If you are the Swiss manufacturer of your own products, then your role according to the MedDO is "**Manufacturer**". The product in question is still in your stock and not sold to another company, therefore the product is not placed on Swiss market yet.
   If you are not a Swiss manufacturer with your own product, you are either a distributor or an importer.
2. If the product in question is made by a Swiss manufacturer (the manufacturer is identified by the black factory symbol), the step "placing on market" has been done by selling the product from the manufacturer to the next economic actor (maybe you).
   Your role according to the MedDO is "**Distributor**".
3. If the product is made by a foreign manufacturer, the question is if you got the product from another Swiss company. If this the case, the step "placing on market" has been initially done by selling the product from the importer to another distributor (maybe you). This step can be identified by checking the importer's details on the product label or on a document accompanying the product1.
   Your role according to the MedDO is "**Distributor**".
   If this is not the case, you imported the product by yourself from the manufacturer or a distributor from a foreign country.
   Your role according to the MedDO is "**Importer**" and the question whether the product is to be considered as placed on the market will have to be evaluated on a case-by-case basis as described below under chapter 4.3.

[1] Refer to MU600_00_016e_MB "Obligations Economic Operators CH" of 01 November 2023

4.2 Identification of the latest date on which the product can be placed on the market

The following flowchart is a modified representation of the diagram in Swissmedic's information sheet MU600_00_016e_MB "Obligations Economic Operators CH" of 01.11.2023.



Requirements to fulfil:

The amendment to the MDR by Regulation (EU) 2023/607 is intended to ensure that shortages of medical devices are avoided, without lowering current quality or safety requirements. For that purpose, manufacturers and notified bodies (NB) are given more time (until the end of 2027 or 2028) to transition their devices to the MDR. Moreover, the deletion of the 'sell off' date aims to prevent unnecessary disposal of safe devices.

However, the extension of the transitional period beyond 26 May 2024 only applies if the requirements laid down in Article 101 MedDO are fulfilled. The main requirements are:

1. The devices comply with the old legislation (Directive 93/42/EEC) i.e. were CE-marked according to this regulation.
2. They have not undergone any significant changes in their design or intended purpose.
3. The devices do not represent an unacceptable risk to health or safety.
4. The manufacturer must put in place a quality management system (QMS) in accordance with MDR Article 10(9) no later than 26 May 2024.
5. The manufacturer has lodged a formal application for the medical device with a Notified Body domiciled in an EU or EEA member state[2] no later than 26 May 2024.
6. The manufacturer has signed a corresponding written agreement with his Notified Body no later than 26 September 2024.

Compliance with those 6 requirements can be shown by a self-declaration of the manufacturer according to the template of MedTech Europe, which can be found here: https://www.medtecheurope.org/resource-library/manufacturers-declaration-in-relation-to-regulation-eu-2023-607/

Other options are also possible (e.g. Confirmation Letter of the corresponding Notified Body).

Alternative requirements:

- Swissmedic or a competent EU/EEA authority has granted a derogation from the conformity assessment procedure; **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.

Please refer to Swissmedic information sheet MU600_00_016e_MB "Obligations Economic Operators CH".

[2] Refer to NANDO Database. Turkish NBs are excluded because Turkiye is not an EU- or EEA member state.

4.3 Risks when placing products on the Swiss market

Placing a medical device on the market is an important step in its regulatory lifecycle. It is therefore essential to know exactly when this point is. Because from this point on, the product must comply with the MedDO.

As the existing laws and directives leave some room for interpretation, the time of “placing on the market” must be assessed on a case-by-case basis. This date must be before the dates in chapter 4.2, otherwise the product can no longer be placed on the market in compliance with the MedDO and must be discarded or sent back to the supplier.

Various options for placing the product on the market are shown below. Each of these options involves regulatory risks, because the importer/manufacturer may believe that he is placing the products on the market in compliance with the regulations, but Swissmedic, as the competent authority may not share this view. In such a case, Swissmedic may evaluate the situation and will, if it is not conforming to the legals basis, impose measures.

Each option is given a risk classification that takes this into account. This classification illustrates the level of risk for non-conformity and corresponding business risk. **Each importer/manufacturer is responsible for assessing his own risks involved in placing the product on the market.**

Selling Product to End Customers

This is the standard route for placing product on the market. No special risks involved.

Selling Product to another Economic Operator (Distributor)

This is the standard route for placing product on the market. No special risks involved.

Sell Product to natural or legal Person and buy it back

To place the product on the market, the product could be transferred to a natural or legal person and then bought back. This transfer could be for payment or free of charge. It does not require the physical handover of the product (see chapter 2.3 of the Blue Guide).

Risks:

- Potential tax implications, namely with VAT.

- Potential accusation of circumvention of the law, especially if the transfer is made free of charge, for a short time and without a physical handover.

Risk mitigation measures:

- Retention of records and documents
- Reference to this guidance to justify your actions

Consignment Warehouse

A consignment warehouse is a business arrangement whereby a consignor (e.g. importer, manufacturer) places its goods in the possession of another party (the consignee), typically a hospital, without transferring ownership until the goods are removed from the warehouse. This means that the consignor retains ownership of the inventory and only transfers ownership to the consignee once the consignee sells the goods to an end customer. This raises the question of when exactly the product is placed on the market. According to the Blue Guide, it can be argued that the time of placing the product on the market is when the product is transferred to the consignment warehouse, because it is now supplied for distribution, consumption or use.

Risks:

- If the consignor has the option to take the goods back and sell it to other customer, it could be argued that this warehouse is just another warehouse of the importer/manufacturer.

Risk mitigation measures:

- Document procedures defining the time of “placing on the market” when the product is delivered to the consignment warehouse.
- Set up agreement with consignee regarding accessibility/responsibilities of the warehouse.

Swiss Online Web Shop

According to “Distant sales” (Art. 7 para. 1bis MedDO), medical devices being offered to users in Switzerland online via a Swiss Online Web Shop are considered to be made available on the market.

Risks:

- From a practical point of view, however, the situation is not very clear. If the importer buys new devices, it is in question from when on the product is actually placed on market and has to comply with Art. 53 MedDO.
- Art. 7 MedDO mentions “users”. Therefore, if the web shop is mainly designed for B2B, it may pose a risk of not being accepted as applicable.

Risk mitigation measures:

- Document procedures defining the moment of “placing on the market”.
  Check and document the requirements of Art. 53 MedDO as an incoming good inspection and define that the product is placed on the market, when it is stored in a specific warehouse, ready to ship to a potential web shop buyer.
- According to the Blue Guide, the following factors of an online offer contribute to the fact that a product is considered to be made available on the market:
  - the Swiss market is noted as the area to which the product can be delivered
  - the offer is written in one of the national languages
  - the payment options are aligned to the Swiss market.

Standalone Software through Swiss Online Web Shop

The same import and distribution requirements apply to standalone software. The requirements for “placing on the market” and “making available on the market” therefore also apply to the economic operators of standalone software according to the chapter “Distant sales” (Art. 7 para. 1bis MedDO).

Risks:

- From a practical point of view, it is not clearly defined when software is considered to have been placed on the market. Accordingly, it is difficult to recognize whether the importer has fulfilled his obligations.
- As software is not tracked by serial numbers or batch numbers, a software cannot be specifically assigned to a market. Accordingly, software versions are used to identify which product is released for the market. It seems unlikely that the authorities will allow a specific version to benefit indefinitely in accordance with the transitional periods under Art. 101 MedDO.
- Art. 7 MedDO mentions “users”. Therefore, if the web shop is mainly designed for B2B, it may pose a risk of not being accepted as applicable.

Risk mitigation measures:

- Document processes that define when the software is considered as “placed on the market”. The importer shall document the verification according to Art. 53 MedDO. Define the activities and responsibilities of the involved economic operators in an agreement.
- According to the Blue Guide, the following factors of the online offer contribute to the fact that a product is considered to be made available on the market:

  - the Swiss market is noted as the area to which the product can be delivered.
  - the offer is written in one of the national languages.
  - the payment options are aligned to the Swiss market.
- Define and document the versions of the software which are considered to be placed on the Swiss market.

Storing in specific Warehouse dedicated for Sale, after Release for free Circulation and Incoming Good Inspections

This way of placing a product on the market is mainly applicable to importers. By analogy with the Blue Guide, i.e. if we replace all references to the “EU” in the Blue Guide with “Switzerland/Swiss”, the point in time at which medical devices are considered to have been placed on the Swiss market is the time at which the devices are presented to customs and declared for the release for free circulation.
In that regard, “placing on the market” takes place as soon as the importer has declared the products to Swiss customs and all customs formalities have been completed and the devices are brought into Switzerland with the intention of being sold on the Swiss Market. However, at this point in time, the importer did not have the possibility to actually check the devices with regard to Art. 53 MedDO.
Therefore we suggest to define “placing on the market” as the moment when the products are stored in a specific warehouse dedicated for sale, right after the incoming goods inspection.

Risks:

- From a practical point of view, the checks for the requirements in Art. 53 MedDO can only be done after the devices have been “placed on the market”.

Risk mitigation measures:

- Document procedures defining the point of time of “placing on the market”. A recommended approach is to check and document the compliance with requirements of Art. 53 MedDO as an incoming good inspection and to define that the product is placed on the market, when it is stored in a specific warehouse ready for sale.
- It may be advantageous to identify the medical devices itself as ready for sale, either electronically via an ERP-Systems and/or on site.
- If a third party is taking over the activities of checking the product according to the requirements of the importer (e.g., foreign warehouse, foreign legal manufacturer, etc.), the activities (including point of time of (“placing on the market”) and responsibilities shall be defined in an agreement between the parties. In this case, only the activities but not the responsibilities can be transferred, i.e. the importer must continue to prove that he fulfils the obligations under Art. 53 MedDO.

5 Conclusions

Independent on the strategy you use for placing products on the market, it is important that you keep records of your actions, e.g. records of incoming goods inspections, agreements, invoices, delivery notes etc. It is also important to always be able to demonstrate, that the requirements of Art. 53 and 54 MedDO, especially for importers and distributors have been met for the product being sold, even if there is no explicit requirement for documented procedures in the MDR. The MDCG document 2021-27 Rev.1 however states that *importers and distributors should be able to demonstrate to the competent authority (e.g., during an inspection) that the above verifications have been performed, through their internal records or procedures*.

Having documented procedures in place is a good way to demonstrate regulatory compliance – and as a side effect you get greater standardization and consistency as well as the opportunity to increase efficiency, productivity and accountability.

Due to the complexity and the potential legal uncertainty, it is beneficial to seek regulatory advice early on.

6 Legal basis

- MDR: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
- Amendment to the MDR: Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023
- Blue Guide: Commission Notice (2022/C 247/01) of 29 June 2022
- MDCG document 2021-27 Rev.1: Questions and Answers on Articles 13 & 14 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 of December 2023
- MedDO: Swiss Medical Devices Ordinance, CC 812.213, status of 01 November 2023
- Swissmedic Information Sheet: MU600_00_016e_MB “Obligations Economic Operators CH” of 01 November 2023

Document release and change history:

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