SWISS MEDTECH

Placing Medical Devices on the Swiss Market before 26 May 2024

29 April 2024

Daniel Delfosse, Vice Director

Webinar Rules

Participants on mute

Camera off

Questions via chat

Session recorded

Host
Daniel Delfosse,
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Experts
- Sandra Item (Integrated Scientific Services, ISS AG)
- Eva von Mühlenen (Sidley Austin LLP)

Pdf and recording available on homepage: https://www.swiss-medtech.ch/

Overview

1. What is «placing on the market»?
2. Which products are concerned?
3. What can you do before 26 May 2024?

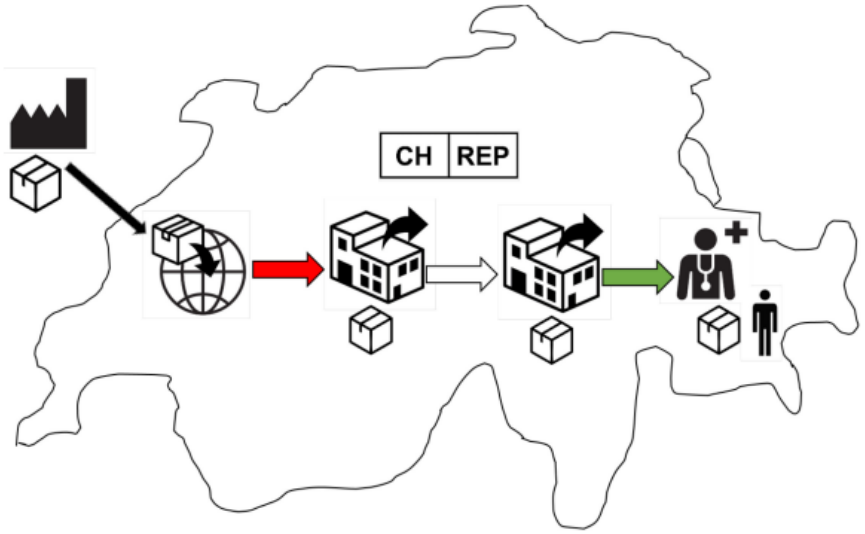
LINK to guidance (MDR portal):

https://www.swiss-medtech.ch/en/news/mdr-portal

Placing on the Market

Definition of «placing on the market» in Switzerland:

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).



The red arrow shows the placing on the market, the white arrow the making available on the market.

From Swissmedic information sheet MU600_00_016e_MB

Placing on the Market

Definition of «placing on the market» in the EU:
(Blue Guide (2022/C 247/01), Section 2.3)

*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 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.*

→ To be evaluated on a **case-by-case basis**!

Products Concerned

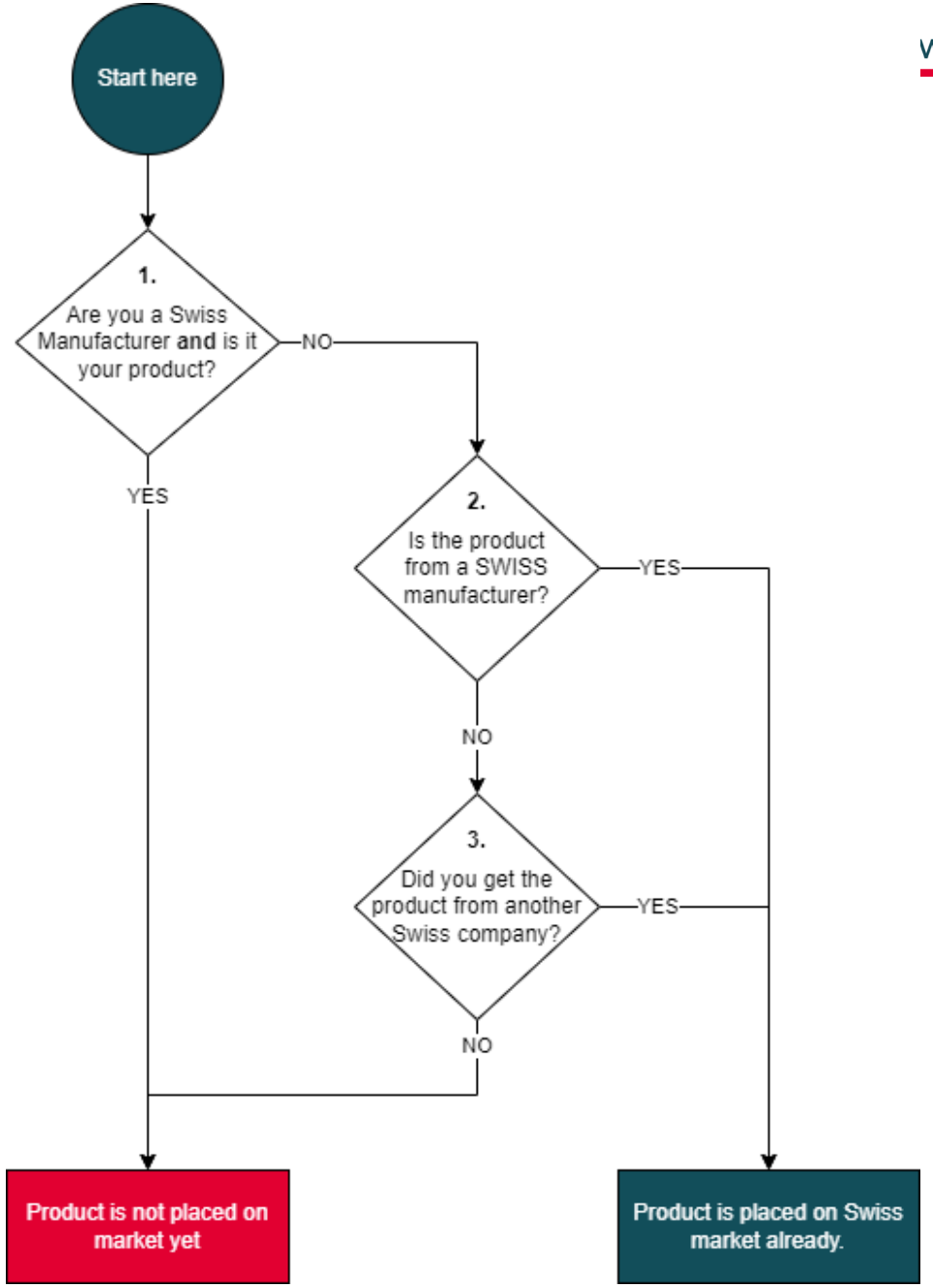
Deadline of 26.05.2024 applies to medical devices that were CE-marked under MDD/AIMD and will **not be transitioned to MDR** (Medical Device Regulation (EU) 2017/745).

These devices do not profit from the transition period under Regulation (EU) 2023/607 (→ end of 2027/28)

Please note:
26.05.2024 is Sunday
→ Deadline 24.05.2024

Products Concerned

Is the product placed on
the Swiss market already?



Products Not Concerned

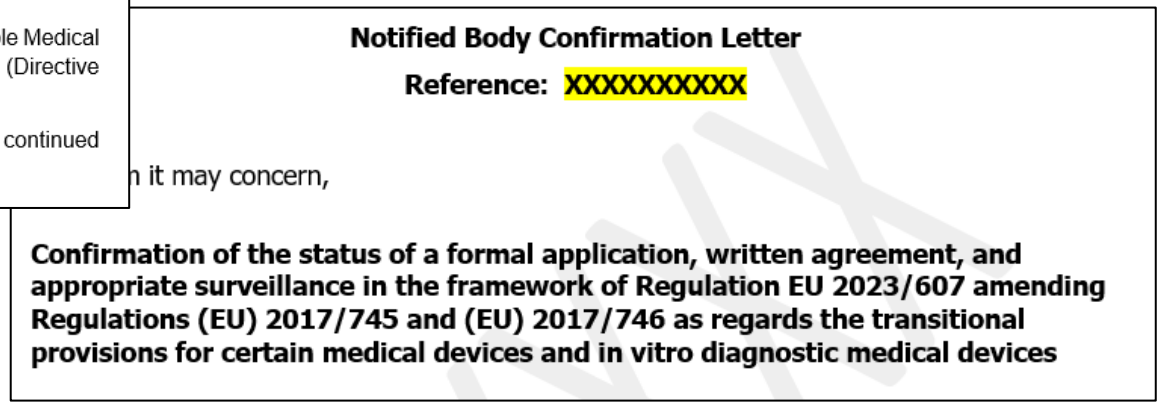
Which products are NOT concerned?

1. All medical devices with MDR certificate
   All medical devices of risk class I (but not Im, Is, Ir)
2. All medical devices with a MDD certificate + Manufacturer's Declaration (> 26.05.2024)
   All medical devices with a MDD certificate + Notified Body Confirmation Letter (> 26.09.2024)

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service



Notified Body Confirmation Letter

Reference: XXXXXXXXXX

h it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Actions

What can you do before 26 May 2024?

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 must be **done before 26.05.2024**, 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.

Actions

1. **Selling Product to End Customers**

2. **Selling Product to another Economic Operator (Distributor)**

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

3. **Sell Product to natural or legal person and buy it back**

This transfer could be for payment or free of charge. It does not require the physical handover of the product.

Risks: Potential tax implications, namely with VAT.

Mitigation: Document procedures, refer to the Swiss Medtech guidance

Actions

4. Consignment Warehouse

According to the Blue Guide, time of placing the product on the market can be defined when the product is transferred to the consignment warehouse, because it is now supplied for distribution, consumption or use

Risks: If the consignor can take goods back and sell it to other customers, it could be argued that this warehouse is just another warehouse of the importer/manufacturer

Mitigation: Document procedures, define the moment of “placing on the market” when the product is delivered to the consignment warehouse, set up agreement with consignee

Actions

5. Swiss Online Web Shop

According to MedDO (“Distant sales”, Art. 7 para. 1bis), 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: Distant sales meant for “users”, not B2B. Only products in conformity with MedDO Art. 53 can be placed on Swiss market (correct labelling, CH-REP – unless direct procurement)

Mitigation: Document procedures, define the moment of “placing on the market” when the product has been checked for conformity and is stored in the warehouse ready to be shipped to Swiss users

Stand-alone software: Define and document the versions of the software which are considered to be placed on the Swiss market

Actions

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

In analogy to the Blue Guide, “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.

Risks: Checks for the requirements in Art. 53 MedDO can only be done after the devices have been “placed on the market”

Mitigation: Document procedures, check and document the compliance with requirements of Art. 53 MedDO as an incoming good inspection, make sure products are labelled for Swiss market

Conclusions

1. Select the appropriate action(s) for your company
2. Define and document the time of “placing on the market” on a **case-by-case basis**
3. Do this **before 26.05.2024**

Goals:

- No need to discard any compliant medical devices from your stock
- Help to avoid bottlenecks in patient care