Transition Timelines MedDO

As of August 11, 2022

Author: inmedis GmbH, 6300 Zug
Published: August 11, 2022
Version: 2.0

Content

1. Political situation

The Regulation 2017/745 on Medical Devices (MDR)[1] has become fully applicable on May 26, 2021. At the same time, the negotiations between Switzerland (CH) and the European Union (EU) on the Institutional Framework Agreement (InstA) were broken off and the amended Swiss Medical Devices Ordinance (MedDO)[2] came into force.
Since Switzerland and the European Union have not yet been able to agree on a political solution, the economic operators must be prepared for drastic consequences. This was also made clear by the EU Commission with the "Notice to stakeholders"[3] which, however, contains legally controversial passages[a].

The existing MDR transition timelines[4] for the European market also apply to the Swiss market, but with some adjustments due to the updated Medical Devices Ordinance.

2. Objective and purpose

The amended Medical Devices Ordinance (MedDO)[2] leads to new obligations for economic operators[5] who want to place their products on the Swiss market. This document should help to keep an overview of the most important consequences and deadlines for the Swiss market.

The direct procurement of foreign medical devices by healthcare professionals in Switzerland, which is permitted under certain conditions, is not described in detail in this document[6].

[a] Legally controversial for products approved under MDD. Affected companies have filed a lawsuit with the EU for products that have been approved by SQS according to MDD.
It is still unclear how individual countries will behave. The SQS certificates assigned under MDD are currently accepted in Germany, the situation in other countries is unclear.

3. Appointment of authorized representatives

A written mandate is required for the appointment of an authorized representative[7]. In addition, the authorized representative must be able to rely on at least one "person responsible for regulatory compliance" (PRRC) on a permanent basis.

According to Swissmedic, PRRC(s) of manufacturers or EC-REPS may also take on this role for the CH-REP[8].

			
For Swiss manufacturers placing their products on the EU market, an **EU Representative (EC-REP)** is required since:		For EU manufacturers placing their products on the Swiss market, a **Swiss Representative (CH-REP)** is required since:	
May 26, 2021	all medical devices	July 31, 2022	Class I systems and procedure packs
		March 31, 2022	Class IIa / Class IIb non-implantable devices
		Dec 31, 2021	Class IIb / III implantable devices active implantable devices

For manufacturers from non-EU/EEA countries and without an EC-REP, the obligation to designate a CH-REP applies from May 26, 2021. These provisions apply to both MDD/AIMDD and MDR products[5].

4. Recognition of Certificates

ISO certificates such as for QM systems according to ISO 13485 remain valid. For product certificates the rules according to the following table are applicable:

	
For Swiss manufacturers placing their products on the EU market:	For EU manufacturers placing their products on the Swiss market:
Product certificates from notified bodies based in Switzerland are no longer officially recognized by the EU (exception Germany). [a]	Product certificates are recognized by Switzerland. EU manufacturers need an authorized representative in Switzerland.
Product certificates from notified bodies based in the EU are recognized by the EU, provided the Swiss manufacturer has established an authorized representative in the EU.	

5. Obligation to register and report to Swissmedic

The registration with Swissmedic[9] includes the allocation of a unique identification number (CHRN)[10] for the affected economic operators.

The requirements and deadlines listed in the following table also apply to economic operators who assemble systems or procedure packs. However, the information to be registred differs in detail from that of the manufacturer (MedDO article 55 and 108).

Who	Requirements	Deadline
CH manufact.	Registration of the manufacturer (MedDO article 55).	within 3 months after placing on the market[b]
	Registration of economic operators who have already placed MDR-compliant medical devices on the Swiss market before May 26, 2021 (MedDO article 104b).	Nov 26, 2021
	Reporting of incidents by the manufacturer to Swissmedic (MedDO article 66).	deadlines acc. to MDR
NOT-CH manufact.	Designation of a Swiss importer (MedDO article 55).	within 3 months after placing on the market[b]
	Registration of manufacturer, Swiss authorized representative and Swiss importer with Swissmedic (MedDO article 55).	
	Registration of economic operators who have already placed MDR-compliant medical devices on the Swiss market before May 26, 2021 (MedDO article 104b).	Nov 26, 2021
	Appointment of a Swiss authorized representative (MedDO article 51).	section 3
	Reporting of incidents by the Swiss authorized representative to Swissmedic (MedDO article 66).	deadlines acc. to MDR

6. Labeling requirements

According to the updated Swissmedic information sheet[5] from December 30, 2021, the following requirements currently apply to the labeling of products placed on the Swiss market:

- The manufacturer of the device must always be defined and indicated on the label.
- 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.
- For imported devices, the CH-REP and the importer should be indicated according to the following table.

[b] Refers to the first placing on the market after May 26, 2021.
Economic operators who only placed MDD products on the market before May 26, 2021 are exempt from registration.

Device	CH-REP	CH-Importer
MDR devices Class I	**Deadline:** ➢ from May 26, 2021[c], ➢ resp. deadlines stated in section 3[d] **Where:** ➢ until July 31, 2023: either on the label or in a document accompanying the device ➢ after July 31, 2023: on the label	**Deadline:** ➢ from May 26, 2021 **Where:** ➢ on the device or ➢ on the packaging or ➢ in a document accompanying the device[e]
MDR devices Class IIa, IIb und III	**Deadline:** ➢ from May 26, 2021[c], ➢ resp. deadlines stated in section 3[d] **Where:** ➢ on the label	
MDD/AIMDD devices with EU/EEA manufacturer or EC-REP	**Deadline:** ➢ deadlines stated in section 3 **Where:** ➢ MDD: on the label or in the instructions for use or in a document accompanying the device ➢ AIMDD: on the sales packaging and in the instructions for use or in a document accompanying the device	**Deadline:** ➢ from July 31, 2022 **Where:** ➢ on the device or ➢ on the packaging or ➢ in a document accompanying the device
MDD/AIMDD devices without EU/EEU manufacturer or without EC-REP	**Deadline:** ➢ from May 26, 2021 **Where:** ➢ MDD: on the label or in the instructions for use ➢ AIMDD: On the sales packaging and in the instructions for use	

[c] For manufacturers from a non-EU/EEA country without EC-REP
[d] For manufacturers from an EU/EEA country or with an EC-REP
[e] The "document accompanying the device" can be attached to the device or separate from the device. Examples of documents accompanying the device are: delivery note, guarantee certificate, customs documents, invoice, a sticker on the packaging or the instructions for use.

7. Bibliography / References

No. in the present document	Literature	Hyperlink
1	**Regulation (EU) 2017/745** on medical devices Last modification: April 24, 2020	Link
2	**Swiss Medical Devices Ordinance (MedDO),** SR 812.213 Last modification: May 26, 2022	Link
3	**Notice to stakeholders:** status of the EU-Switzerland Mutual Recognition Agreement (MRA) for medical devices Last modification: May 26, 2021	Link
4	**Transition Timelines MDR** Last modification: August 11, 2022	Link
5	**Information sheet, Obligations Economic Operators CH,** MU600_00_016e Last modification: May 26, 2022	Link
6	**Guidance, Direct procurement of foreign medical devices by healthcare professionals in Switzerland** Last modification: March 17, 2022	Link
7	**Guidance, Designation of a Swiss Authorised Representative under the new MedDO** Last modification: January 03, 2022	Link
8	**Authorised representatives, importers and distributors, Obligations of economic operators in Switzerland** Last modification: September 02, 2021	Link
9	**Information sheet, Service agreement for CHRN,** BW630_10_004e Last modification: May 26, 2022	Link
10	**Information sheet, CH registration number CHRN,** BW630_10_003e Last modification: May 26, 2022	Link

8. Our Experience - Your Benefit

We at inmedis are the experts for quality management and regulatory affairs in medical technology. With our well-founded know-how we support you in case of questions about placing products on the Swiss market. I look forward to hearing from you.

Kind regards

inmedis GmbH

Matthias Bissig
Partner