freyr®

# SWISSMEDIC GUIDE

company/freyrsolutions

www.ec-repservices.com | sales@freyrsolutions.com

# Switzerland Authorized Representative

The EU-Swiss Institutional Framework Agreement (IFA) was intended as the foundation to enhance and develop the EU-Swiss bilateral relations with a core purpose to operate as a Single Market. However, the Swiss exited from the IFA, and as a result, the Mutual Recognition Agreement (MRA) between the Swiss and the EU was updated and lapsed on May 26, 2021. As a result, the barrier-free access for the medical device industry is terminated between the EU and Switzerland.

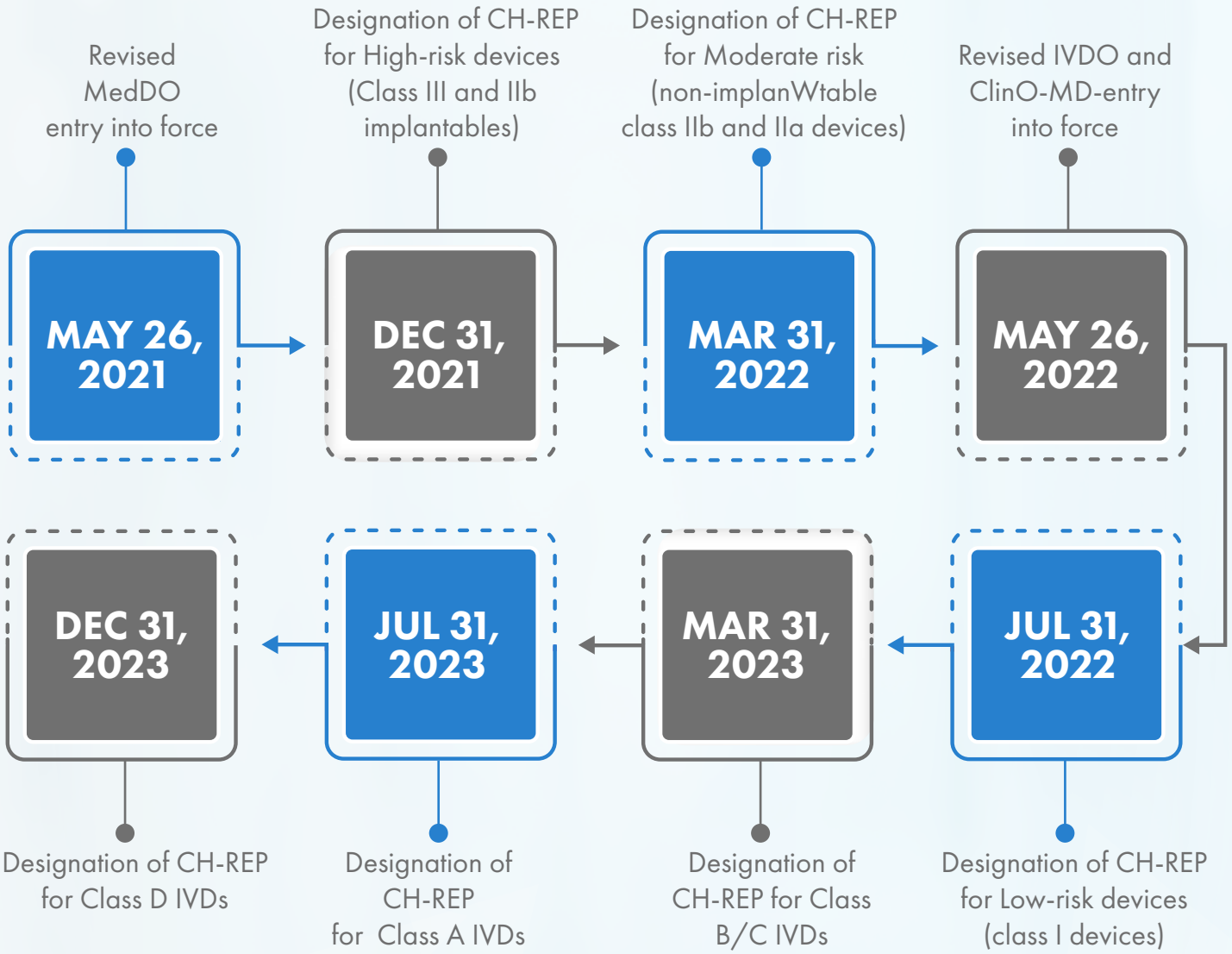
On May 26, 2021, the Swissmedic's Medical Device Ordinance (MedDO), which is in line with the EU Medical Device Regulation (EU) 2017/745 (EU MDR), entered into force. The new MedDO requires all non-Swiss manufacturers to appoint a Swiss AR (CH-REP) domiciled in Switzerland as a pre-requisite to market their medical devices in Switzerland.

Swiss AR (CH-REP) will register the manufacturers and device products with Swissmedic before being placed on the Swiss market. Swiss AR (CH-REP) is responsible for reviewing compliance of the device products and informs about the defects in the product, as well as co-operate with Swissmedic for any preventive or corrective actions.

# Timelines for CH-REP Appointment

The revised MedDO was adopted on Oct 25, 2017 and came into force on May 26, 2021. According to the revised MedDO, foreign manufacturers must appoint a CH-REP for high-risk devices by Dec 31, 2021, moderate-risk devices by Mar 31, 2022, and low-risk devices by Jul 31, 2022.

Revised In-vitro Diagnostic Ordinance (IvDO) and Clinical trials of medical device ordinance (ClinO-MD) will be in effect from May 26, 2022, where the foreign IVD manufacturers will have to appoint a CH-REP from Mar 31, 2023, for Class B and C IVDs, Jul 31, 2023, for Class A IVDs and Dec 31, 2023, for Class D IVDs.



# Swiss AR Pre-requisites

Swiss Rep (CH-REP) is a person or entity or an organization with a registered office in Switzerland. Following are the pre-requisites of a Swiss AR

## Registration with Swissmedic

Swiss ARs will have to register with Swissmedic and obtain a CHRN within three months of placing their first product on the Swiss market

## Written Mandate

According to MedDO, AR should have received and accepted a written mandate from a manufacture

## Insurance Liability

Swiss AR and the manufacturer are obliged to take the liability insurance with sufficient coverage

## Proper due deligence

Swiss AR should do due deligence before signing the agreement with the manufacturer

## Liable for product defects

Swiss AR is jointly and legally liable for any product defects.

## Appoint PRRC

Swiss AR must have a PRRC

# Swiss AR and A PRRC

It is mandatory for all the authorized representatives to appoint a Person Responsible for Regulatory Compliance (PRRC) to ensure companies have a qualified Regulatory expert at their disposal. The role of PRRC include

Assumes a central role in PMS surveillance and in the control of medical devices

He/She is personally responsible for the compliance with the duties incumbent on the AR

He/She can be held criminally liable for violation

# The Swiss AR Responsibilities

Swiss AR/CH-REP must represent the foreign manufacturer and act as a point of contact between the manufacturer and the Swissmedic. Following are the responsibilities of a CH-REP

**01**

Must Act on behalf of the foreign manufacturer and register the devices with MeDO

**02**

Verify the declaration of conformity and the technical documentation

**03**

Verify if appropriate conformity assessment procedures have been carried out by the manufacturer

**04**

Verify that the manufacturer has complied with the registration obligations

**05**

Keep a copy of the technical documentation,the declaration of conformity, and relevant certificates along with any amendments and supplements

**06**

In response to a request from Swissmedic, provide information and documentation necessary to demonstrate the conformity of a device

**07**

Forward Swissmedic request for samples or access to a device and ensure Swissmedic receives the samples or is given access to the device

**08**

Coorperate with Swissmedic on any preventive or corrective action or Field safety Corrective action (FSCA)

**09**

Immediately inform the manufacturer about any complaints and reports received from the market

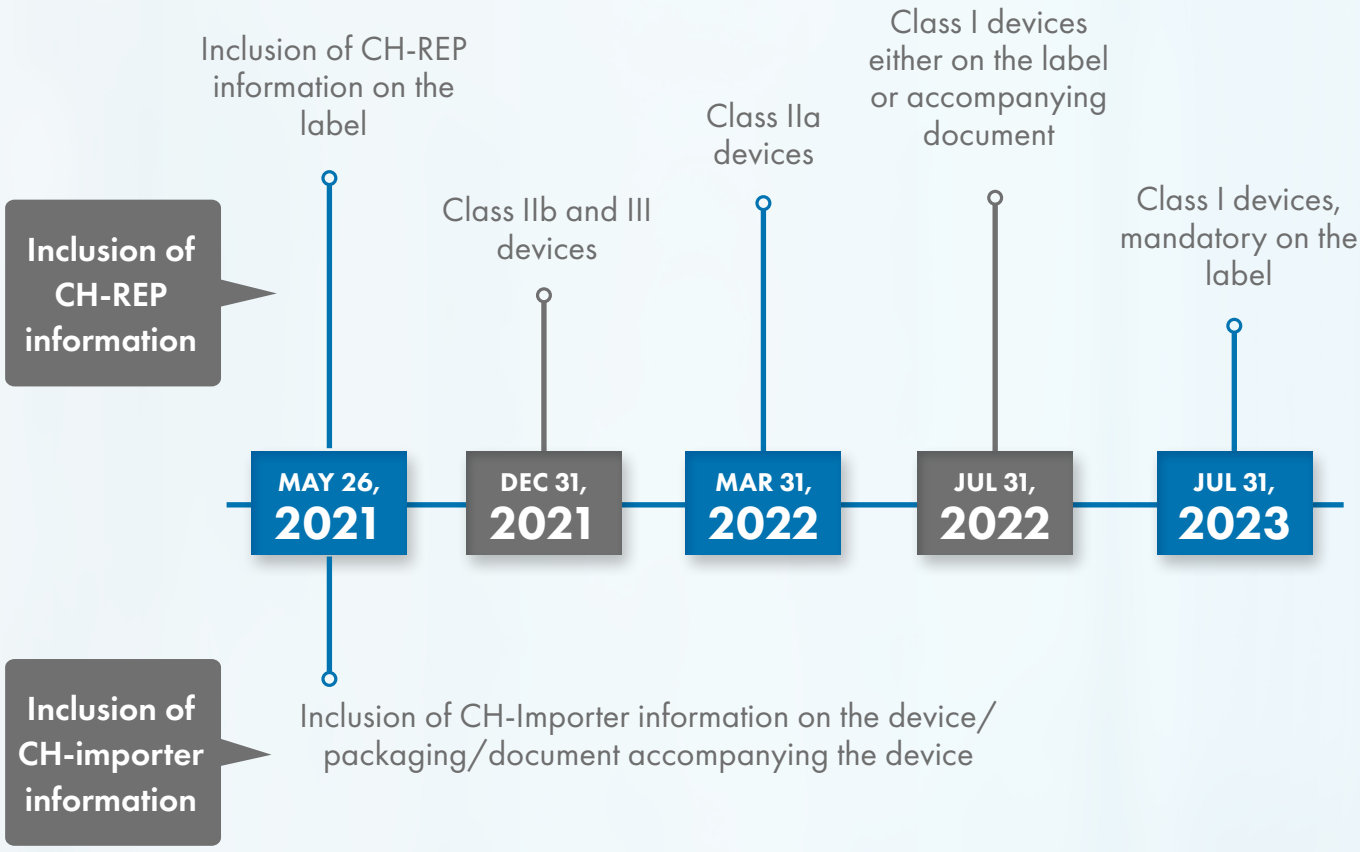
# Key Elements

## 1. Labeling

According to MedDO, all the devices placed on the market must have the CH-REP symbol with the name and address of the Swiss AR on the packaging material of the medical device product placed on the Switzerland market.

CH REP

## MDR devices Labeling Requirements

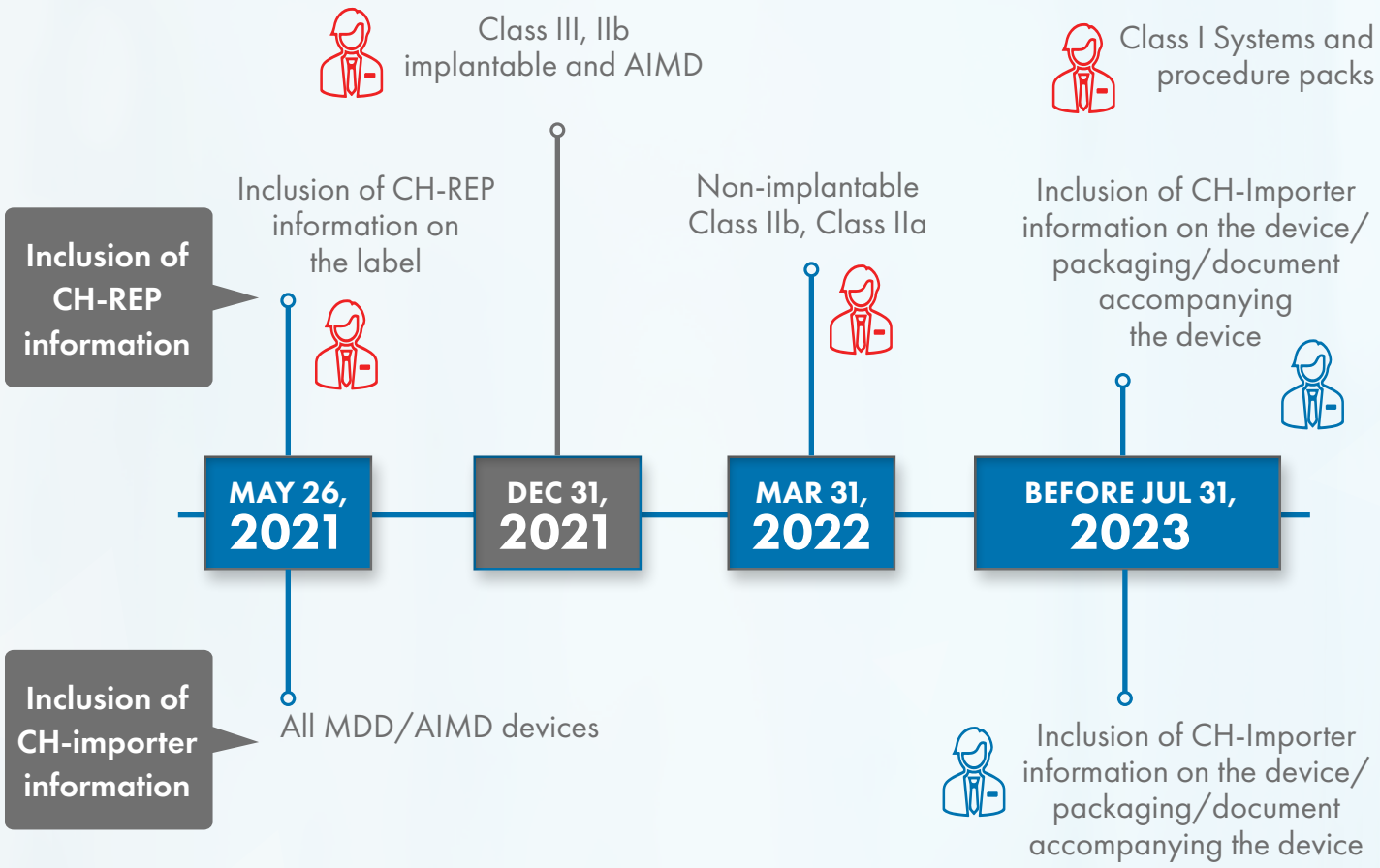



Importers of MDR Class I, IIa, Iib, and III devices must include their details on the device, package or in a document accompanying the device from May 26, 2021. Importers of MDD/AIMDD devices with or without EU/EEA manufacturer or EC-REP must include their details on the device, package, or in a document accompanying the device from July 31, 2022.

# MDD and AIMDD devices Labeling Requirements

## Inclusion of CH-REP and Importer information on the label

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




MDD devices: On the label or in the instructions for use
AIMDD devices: On the sales packaging and in the instructions for use

Inclusion of CH-REP information

Inclusion of CH-Importer information

| Details to be incorporated on | CH-REP Details | | | | |
|---|---|---|---|---|---|
| | I | IIa | IIb | IIb Non-implantable | III |
| Device Label | ✓ Mandatory from Jul 31, 2023 | ✓ | ✓ | ✓ | ✓ |
| Document accompanying the device | ✓ Jul 31, 2022 | | | | |
| **Details to be incorporated on** | **CH-IMPORTER details** | | | | |
| Device Label/ Document accompanying the device/ Packaging and cartons | ✓ | ✓ | ✓ | ✓ | ✓ |

## 2. List of Swissmedic's Reference Regulations and Guidelines

| S.No | Swiss Medical Devices and IVD Guidance Documents | Link to the document |
|---|---|---|
| 1 | Revised or new Medical Device Ordinance (in effect from May 26, 2021) | New medical device ordinance |
| 2 | Older Medical Devices Ordinance | Old medical device ordinance |
| 3 | Swiss Authorized Representative | Swiss authorised representative (CH-REP) (swissmedic.ch) |
| 4 | Swiss AR, Importers, Distributors Obligations | Obligations for authorised representatives, importers and distributors (swissmedic.ch) |
| 5 | Notification of Medical Devices with Swissmedic | Notification of medical devices (swissmedic.ch) |
| 6 | Notification of IVDs with Swissmedic | Notification of IVD medical devices (swissmedic.ch) |
| 7 | Swiss Single Registration Number (CHRN) | Unique identification no. in accordance with Art. 55 MedDO (CHRN – Swiss Single Registration Number) (swissmedic.ch) |
| 8 | Ordinance on Clinical Trials with Medical Devices | Clinical trial ordinance |
| 9 | Portal for clinical trials in Switzerland (SNCTP) | Kofam \| The portal for human research in Switzerland |
| 10 | Vigilance relating to medical devices | Vigilance relating to medical devices (swissmedic.ch) |

# About Freyr

Freyr is a leading, niche, end-to-end global Regulatory solutions and services company supporting large, mid, and small global organizations across different life sciences verticals - Pharmaceuticals | Medical Devices | Biotechnology | Biosimilars | Consumer Healthcare | Cosmetics | Food and Food Supplements | Generics | Chemicals. Freyr supports life sciences organizations in their entire Regulatory value chain -Intelligence Driven Submissions/Product Registrations | Labeling | Artwork | Post- Approval Change Management | Regulatory Software and other related services.

USA | UK | Germany | UAE | India | Canada | Mexico | Malaysia | South Africa

Singapore | Slovenia | Sri Lanka | Australia | Poland | France | Switzerland | China

http://www.ec-repservices.com


+1 908 483 7958 sales@freyrsolutions.com www.freyrsolutions.com

/company/freyrsolutions /Freyrsolutions /Freyrsolutions /user/FreyrInc /freyrsolutions