swissmedic

Online event

Information on the new medical devices regulation

Thursday, 2 September 2021

Registration and reporting obligations of economic operators

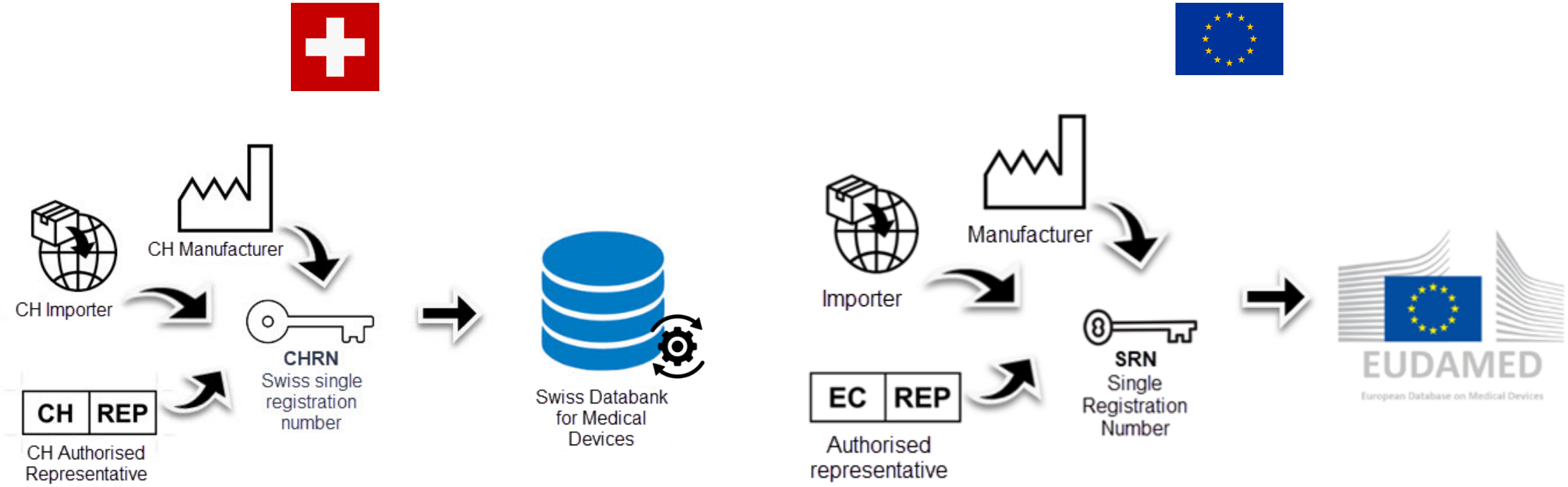
Registration of economic operators and their devices

Janine Conde, Head of Department, Medical Devices Operations and Hospitals

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

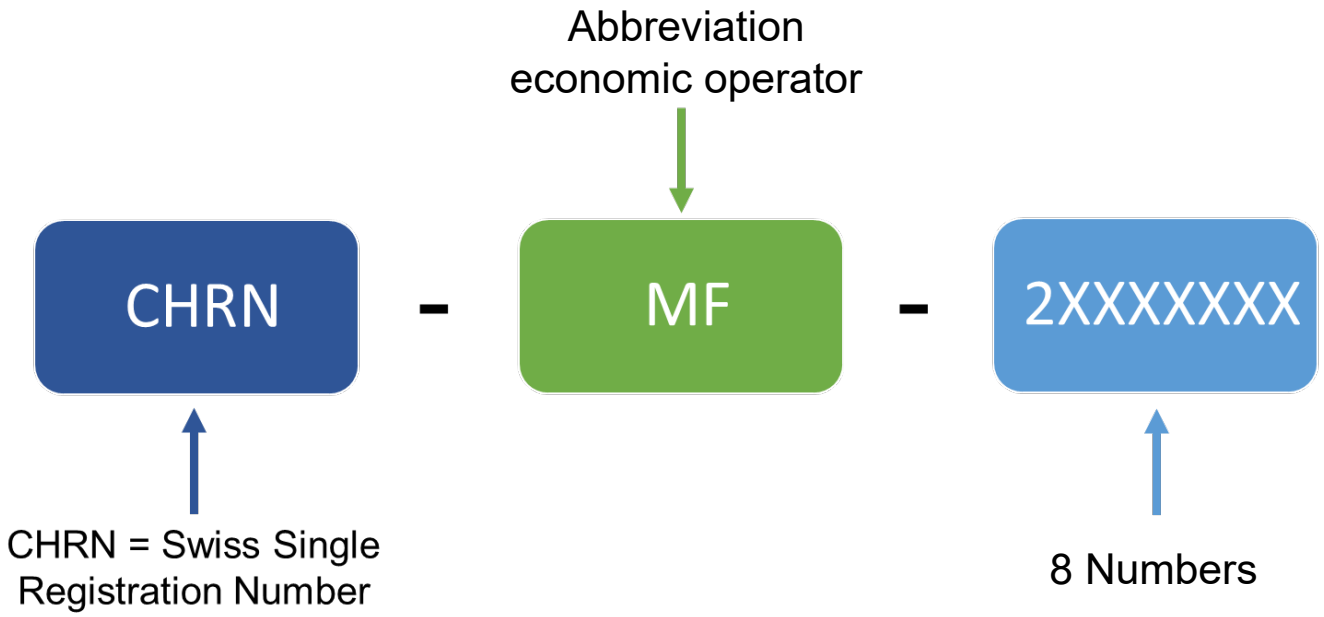
Hallerstrasse 7, 3012 Bern
www.swissmedic.ch

Every economic operator role must be clearly identified



Swiss Single Registration Number - CHRN

Required for clearly identifying the economic operator



MF Manufacturer
AR Authorised Representative
PR System & procedure pack producer
IM Importer

Examples of CHRN

example 1

The economic operator is established in Switzerland and acts as:
- Manufacturer

The economic operator must register his role with Swissmedic. After successful verification, he receives his unique identification number:
CHRN-MF-2XXXXXXX

example 2

The economic operator is established in Switzerland and acts as :
- **Manufacturer**
- **Importer**

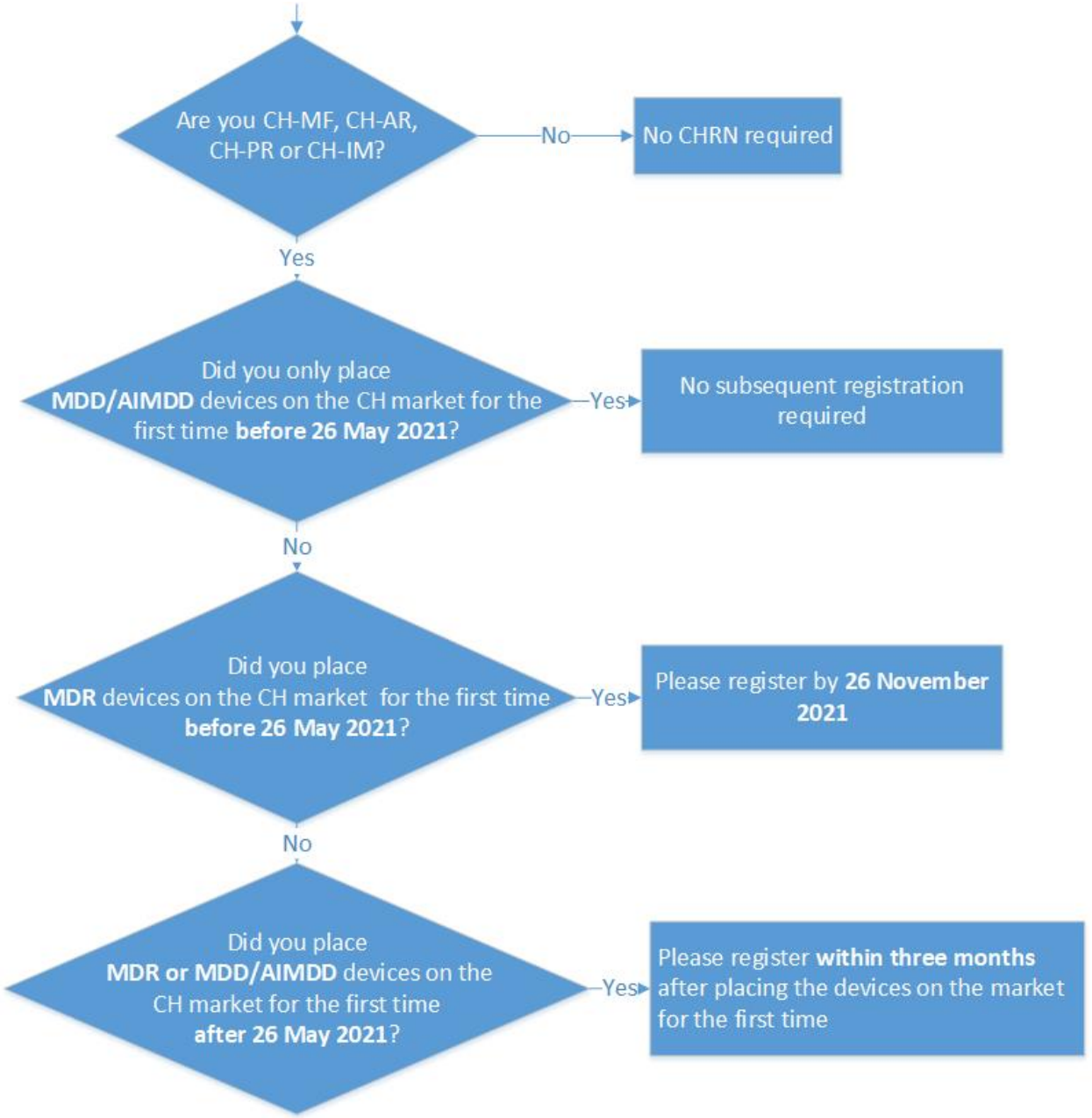
The economic operator must register his roles with Swissmedic. After successful verification, he receives his unique identification numbers:
CHRN-MF-2XXXXXXX
(Manufacturer)
CHRN-IM-2XXXXXXX
(Importer)

Who must register by when?

- **MF** Manufacturer
- **AR** Authorised Representative
- **PR** System & procedure pack producer
- **IM** Importer

The following must register: Swiss manufacturers (CH-MF), Swiss authorised representatives (CH-AR), Swiss manufacturers of systems and procedure packs (CH-PR) and Swiss importers (CH-IM).

- Foreign manufacturers cannot register
- If the authorised representative is also an importer, it must also register as an importer and therefore receives two CHRNs.

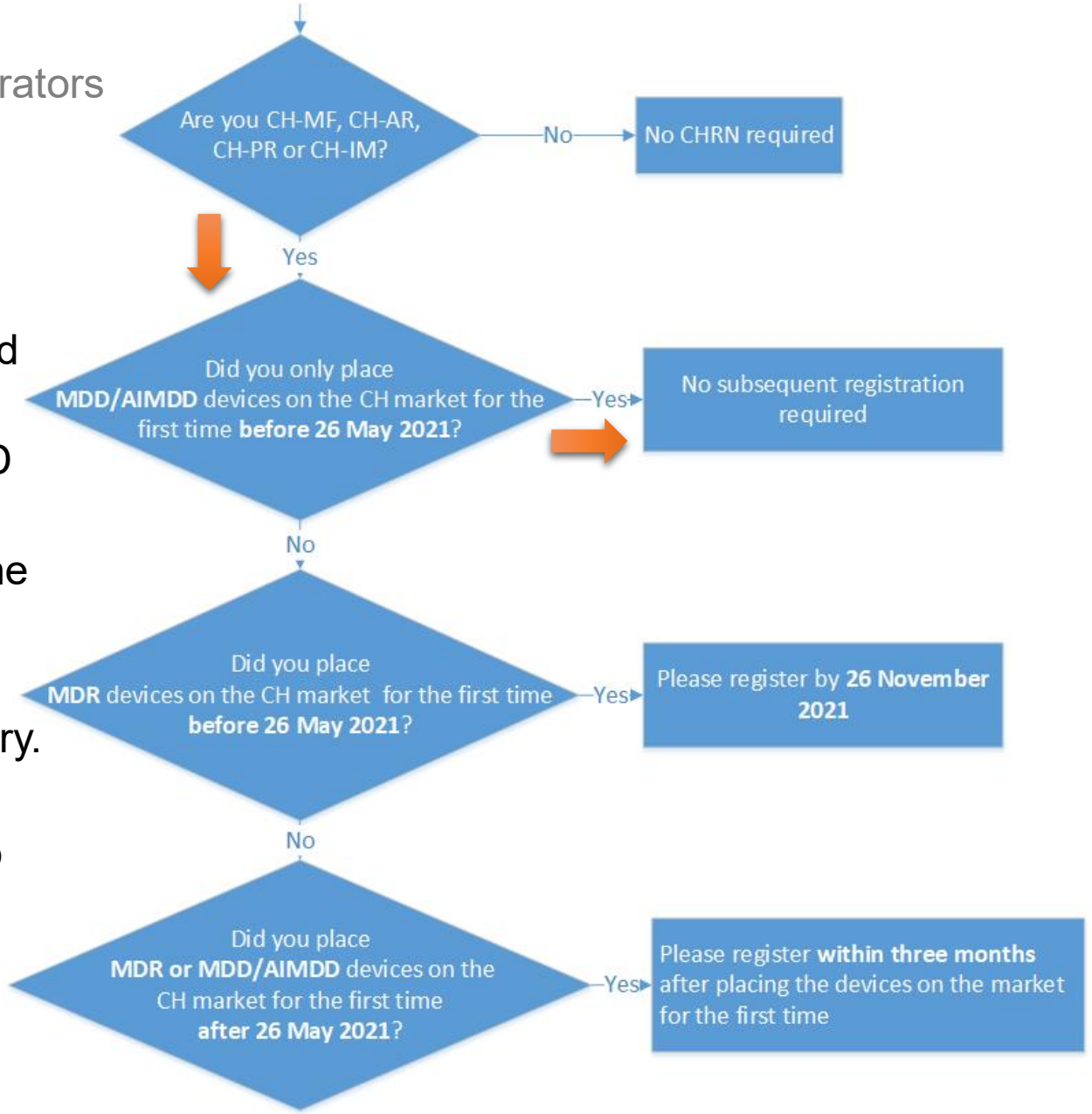


Example:
Manufacturer & MDD devices

- Swiss manufacturer of MDD devices that were placed on the market for the first time on 15 March 2021
- The manufacturer possesses a certificate for its MDD devices that is valid until May 2024
- The manufacturer does not place MDR devices on the market

→ In this case, no retrospective registration is necessary.

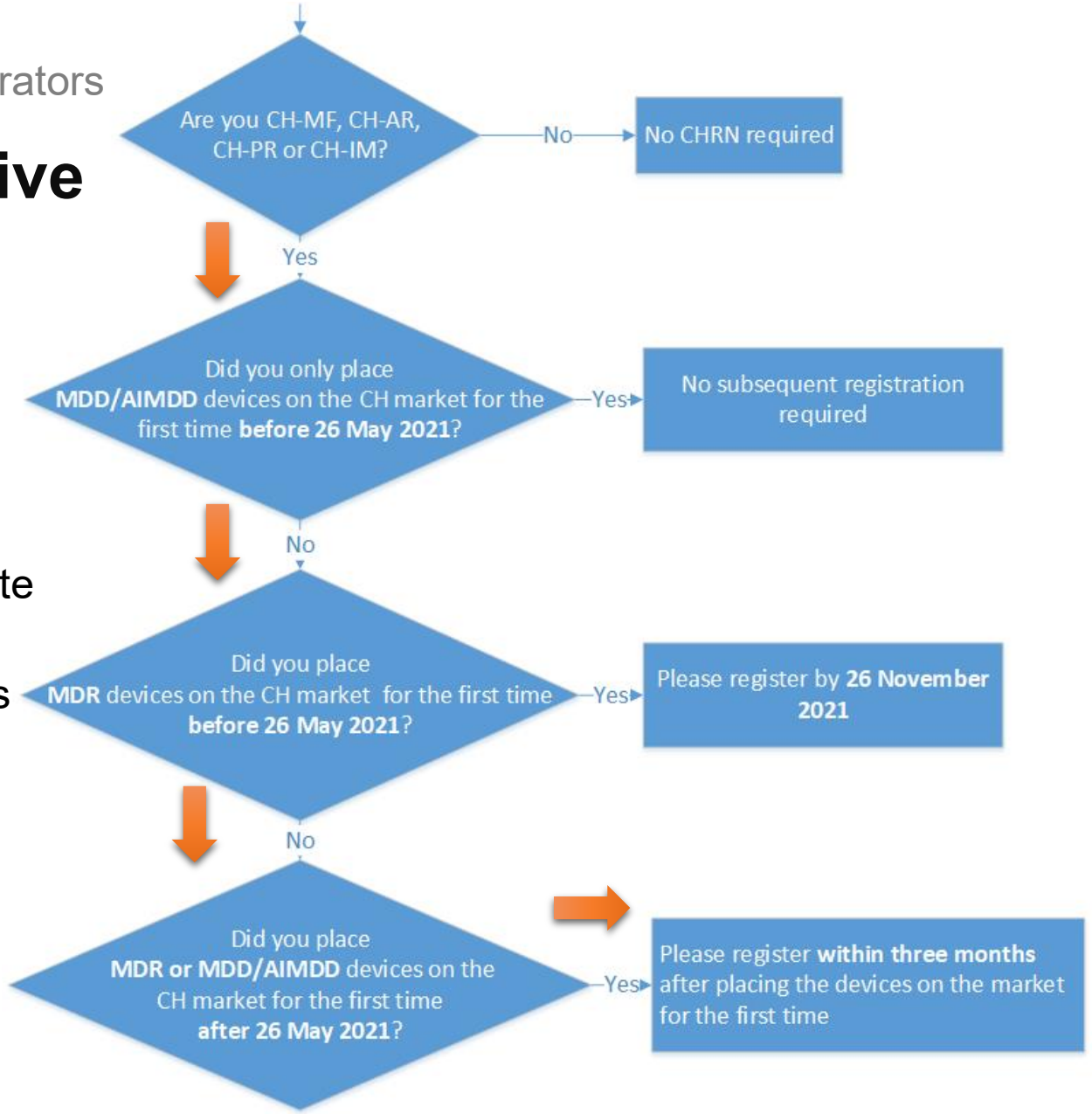
Nevertheless, Swissmedic recommends registration so that the manufacturer is ready for the future medical devices database.



Example: **Authorised representative & MDD devices**

- The devices of a foreign manufacturer were placed on the market for the first time on 17 February 2020
- The manufacturer does not place MDR devices on the market
- The Swiss authorised representative accepts a mandate from this foreign manufacturer **on 5 June 2021**
- The authorised representative places the MDD devices on the market for the first time on **3 July 2021**

→ The authorised representative must register by 3 October 2021 (three months from first placing on the market)



How do I register?

Forms available on the website
www.swissmedic.ch

Home › Medical devices › Market access › Unique identification no. (CHRN)

Order forms

- BW630_11_001defi_FO Registration application single registration no. in accordance with Art. 55 MedDO (PDF, 1 MB, 25.06.2021)
- BW630_12_002defi_FO Change of registration message in accordance with Art. 55 MedDO (PDF, 1 MB, 26.05.2021)
- BW630_11_003e_FO Mandate registration form (PDF, 1 MB, 04.08.2021)

LINK

swissmedic

VO-Formular
Registration application single registration no. in accordance with Art. 55 MedDO

Application for Swiss Single Registration Number (CHRN) in accordance with MedDO Art. 55

Before submitting forms, you are required to ensure that you are using the latest version of the forms, which can be downloaded at any time from our website.

If you wish to receive information automatically on forms that have just become available on the internet, you can subscribe to the Swissmedic newsletter specifically for medical devices.
https://www.swissmedic.ch/swissmedic/en/home/news/newsdienste.html

Important Form content is automatically imported and taken over unchanged.

Role of economic operator

○ Manufacturer ○ Authorised representative for Switzerland ○ Importer ○ Manufacturer of system and treatment units

Details of economic operator

Company

Commercial register

Link to the UID-Register

What is checked by Swissmedic?

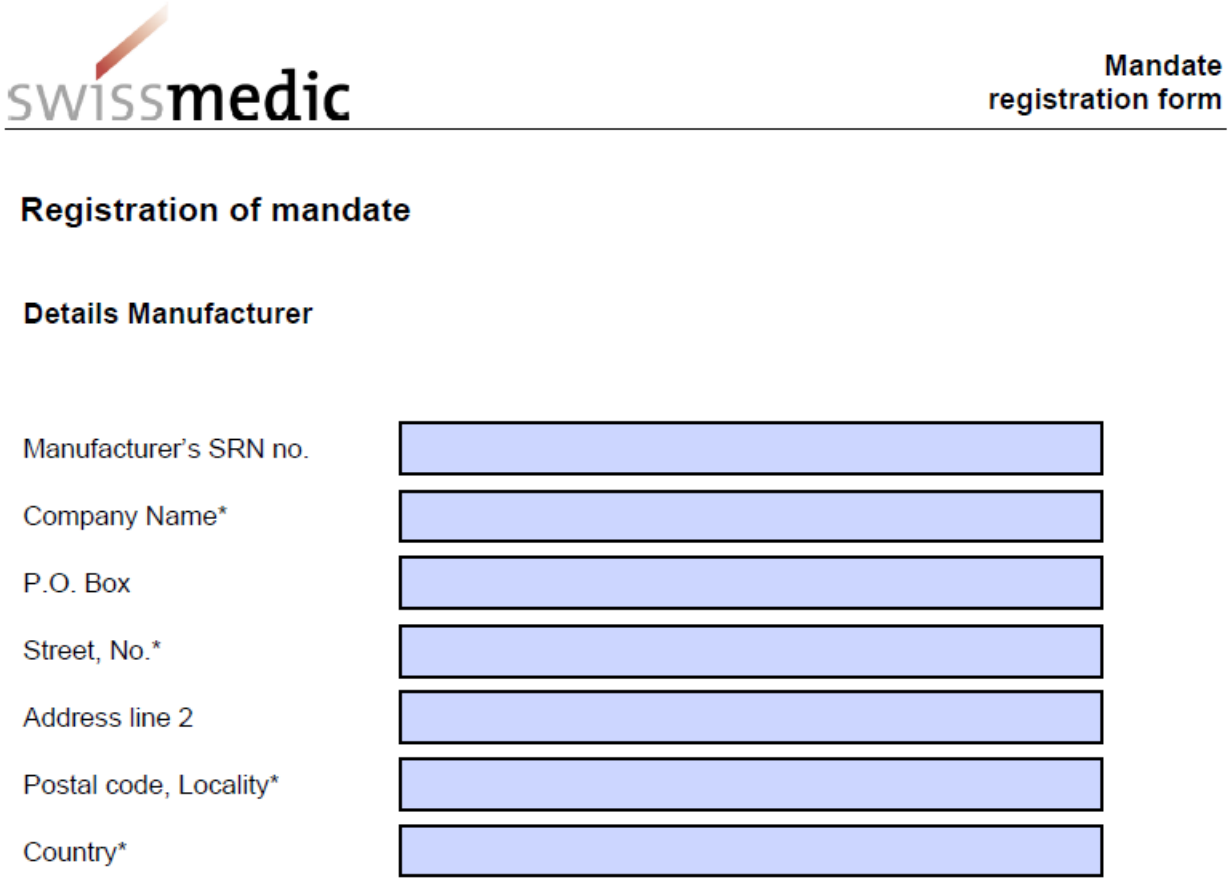
- Commercial Register extract as proof of the company's existence
- For Swiss authorised representatives: Presence of a mandate with foreign manufacturer

Order forms

BW630_11_001defi_FO Registration application single registration no. in accordance with Art. 55 MedDO (PDF, 1 MB, 25.06.2021)

BW630_12_002defi_FO Change of registration message in accordance with Art. 55 MedDO (PDF, 1 MB, 26.05.2021)

BW630_11_003e_FO Mandate registration form (PDF, 1 MB, 04.08.2021) LINK



swissmedic

Mandate registration form

Registration of mandate

Details Manufacturer

Manufacturer's SRN no.	
Company Name*	
P.O. Box	
Street, No.*	
Address line 2	
Postal code, Locality*	
Country*	

What is the procedure if changes are made?

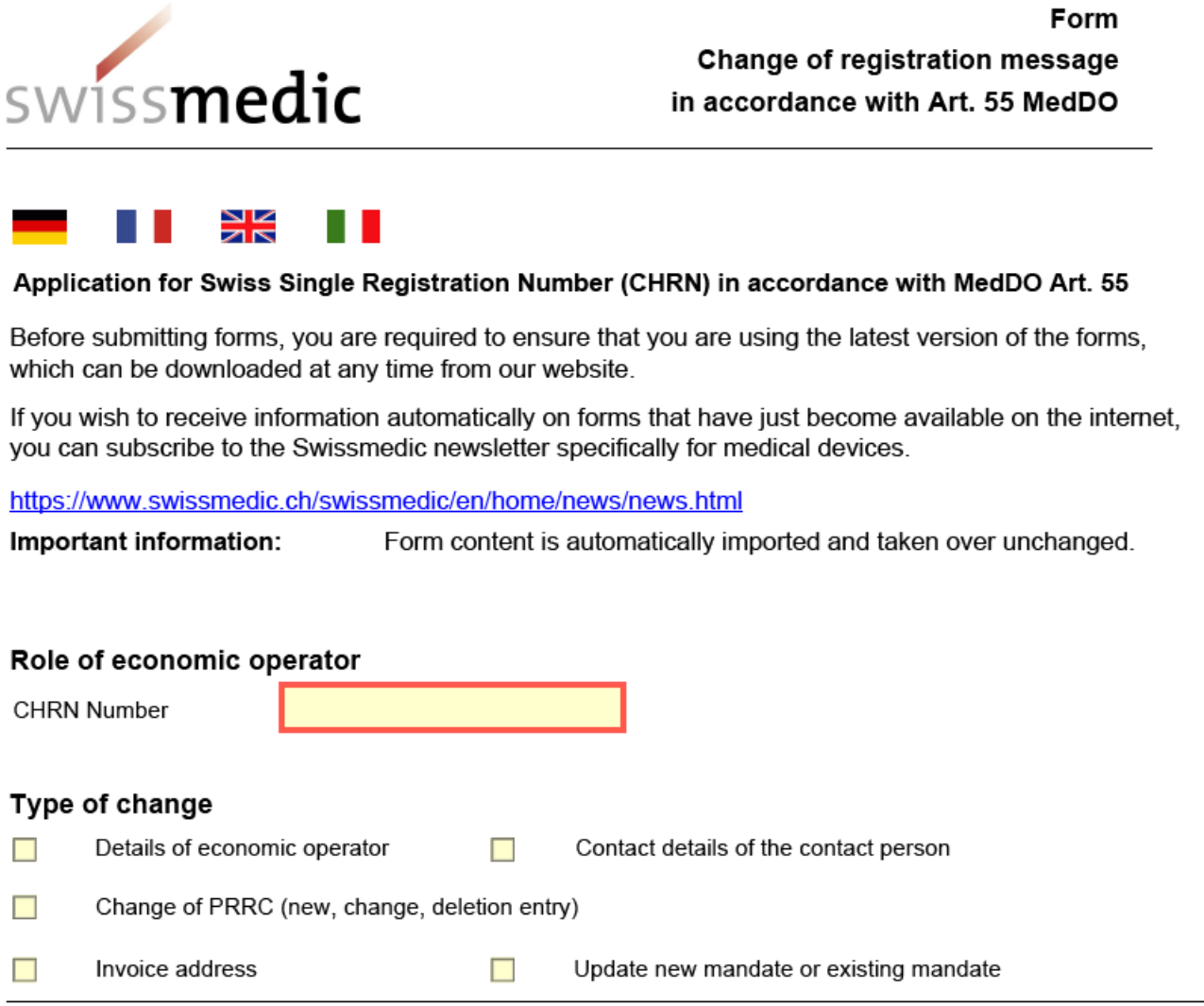
Under Art. 55 para. 2 MedDO, the economic operator in question is responsible for reporting any changes to the information to Swissmedic within one week.

Order forms

BW630_11_001defi_FO Registration application single registration no. in accordance with Art. 55 MedDO (PDF, 1 MB, 25.06.2021)

BW630_12_002defi_FO Change of registration message in accordance with Art. 55 MedDO (PDF, 1 MB, 26.05.2021) LINK

BW630_11_003e_FO Mandate registration form (PDF, 1 MB, 04.08.2021)



swissmedic

Form
Change of registration message
in accordance with Art. 55 MedDO

Application for Swiss Single Registration Number (CHRN) in accordance with MedDO Art. 55

Before submitting forms, you are required to ensure that you are using the latest version of the forms, which can be downloaded at any time from our website.

If you wish to receive information automatically on forms that have just become available on the internet, you can subscribe to the Swissmedic newsletter specifically for medical devices.

https://www.swissmedic.ch/swissmedic/en/home/news/news.html

Important information: Form content is automatically imported and taken over unchanged.

Role of economic operator

CHRN Number

Type of change

☐ Details of economic operator ☐ Contact details of the contact person

☐ Change of PRRC (new, change, deletion entry)

☐ Invoice address ☐ Update new mandate or existing mandate

Publication of the Swiss Single Registration Number (CHRN)

- The registered Swiss economic operators and their CHRNs are published

- As soon as the Swiss database for medical devices is ready, the information in this database will be made available

Registration of devices

From when?

- Art. 17 para. 5 MedDO: [30] To enter into force in due course (Art. 110 para. 2).
  - Art. 110 para. 2 MedDO: Entry into force - Article 17 para. 5 and Art. 108 para. 2 enter into force **in due course**.

How?

- Art. 17 para. 4 MedDO: The obligations and modalities associated with product identification and registration are governed by Articles 27, 29 and Annex VI EU-MDR, […]
- We will stick as closely as possible to the requirements of the MDR. Work has started on the required Swiss medical devices database.
- A retrospective reporting obligation will apply according to the explanations in the document Explanatory report: Revision of the Medical Devices Ordinance (Article 108)