swissmedic

Information sheet
Swiss Single Registration Number - CHRN

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1 Legislation

Based on the Medical Devices Ordinance[1] and the Ordinance on In Vitro Diagnostic Medical Devices[2] Swissmedic, the Swiss Agency for Therapeutic Products, assigns the Swiss Single Registration Number (CHRN). The CHRN is a number to unambiguously identify a manufacturer, authorised representative or importer domiciled in Switzerland or Liechtenstein. Swissmedic does *not* issue CHRNs to companies established outside Switzerland or Liechtenstein.

1 Art. 55 MedDO (Medical Devices Ordonance of 1 July 2020, SR 812.213)
2 Art. 48 IvDO (Ordinance of 4 May 2022 on In Vitro Diagnostic Medical Devices, SR 812.219)

As a result of the update of the applicable law for medical devices and in-vitro diagnostic medical devices (Annex I to the Customs Treaty) of 18th October 2022, economic operators established in Liechtenstein must also register with Swissmedic.

Service agreement
The service agreement describes the services provided by Swissmedic in connection with the assigning of the Swiss Single Registration Number (CHRN). It also describes the rights and obligations of the individuals who make use of the service.

1.1 Abbreviation

SRN	EU Single Registration Number, assigned according to Art. 31 EU-MDR[3]/ Art. 28 EU-IVDR[4]
CHRN	Swiss single registration number (CHRN) assigned according to Art. 55 MedDO/Art. 48 IvDO
MDD/AIMDD device	Device that has been CE-marked under the former Directive 93/42/EEC concerning medical devices or Directive 90/385/EEC on active implantable medical devices. Often also referred to as "legacy devices".
IVDD device	Device that has been CE-marked in accordance with the previous Directive 98/79/EC on in vitro diagnostic medical devices.
MDR device	Device that has been CE-marked according to MDR
IVDR device	Device that has been CE-marked according to IVDR

2 Swiss Single Registration Number (CHRN)

The Swiss Single Registration Number (CHRN) is a number that Swissmedic assigns to Swiss or Liechtenstein manufacturers, authorised representatives and importers upon request. The CHRN is used to unambiguously identify a manufacturer, authorised representative or importer.

Until the MRA (Mutual Recognition Agreement) is updated, Swissmedic is unable to assign a European Single Registration Number (SRN) via EUDAMED for economic operators who are domiciled in Switzerland. To mitigate the consequences of this loss of information and to continue to ensure market surveillance in Switzerland, it is necessary for manufacturers, authorised representatives and importers domiciled in Switzerland or Liechtenstein to register once with Swissmedic.

2.1 Delimitation

The CHRN is used for registering the economic operators. It is *not* used for registering the products. The MedDO and IvDO articles on product registration (Art. 17 para. 5 MedDO / Art. 16 para. 5 IvDO) will come into force at a later date (Art. 110 MeDO / Art. 91 IvDO). You can find further information on

3 Regulation (EU) 2017/745 on medical devices (MDR) of 05.04.2017
4 Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) of 05.04.2017

notifying (in vitro diagnostic) medical devices here: Notification of medical devices and Notification of IVDs.

3 Economic operators concerned

Under Art. 55 para. 1 MedDO and Art. 48 para. 1 IvDO, manufacturers, their authorised representatives if applicable and importers are required to submit to Swissmedic the necessary information under Annex VI Part A section 1 MDR and IVDR within three months of placing a product on the market for the first time. Distributors do *not* need a CHRN.

Anyone placing systems and treatment units in accordance with Art. 11 MedDO on the market for the first time must register their name and the address at which they can be contacted with Swissmedic within three months of placing the system or treatment unit on the market. If an authorised representative is required in accordance with Article 51 para. 5 MedDO, their name and address must also be registered with Swissmedic.

As regards manufacturers, authorised representatives and importers domiciled in Switzerland or Liechtenstein[5], under Art. 55 para. 4 MedDO and Art. 48 para. 4 IvDO Swissmedic is responsible for reviewing the data and for assigning CHRNs to manufacturers, authorised representatives and importers in Switzerland.

The MedDO and IvDO out requirements and responsibilities for operators in the medical devices supply chain. The following Information sheet outlines the roles and obligations of the Swiss and Liechtenstein authorised representative, the importer and the distributor: Obligations Economic Operators CH

3.1 Manufacturer

Art. 4 para. 1 let. f MedDO and Art. 4 para. 1 let. e IvDO defines the term "manufacturer" as "any natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark; (…)". According to the current law (SR 0.631.112.514), economic operators domiciled in Liechtenstein can act as manufacturer in Switzerland.

3.2 Swiss authorised representative (CH-REP) / Liechtenstein authorised representative

Art. 4 para. 1 let. g MedDO and Art. 4 para. 1 let. f IvDO defines the term "authorised representative" as "any natural or legal person established within Switzerland who has received and accepted a written mandate from a manufacturer located in another country to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligation under this Ordinance". According to the current law (SR 0.631.112.514), economic operators domiciled in Liechtenstein can act as authorised representatives in Switzerland.

5 “Domiciled in Switzerland or Liechtenstein” should be understood to mean that headquarters in Switzerland are required.

The transitional periods defined in Art. 104a MedDO and Art. 86 IvDO apply to the authorised representative.

Further information on the Swiss authorised representative (CH-REP) and Liechtenstein authorised representative can be found in the following information sheet: Obligations Economic Operators CH

3.3 Importer

Art. 4 para. 1 let. h MedDO and Art. 4 para. 1 let. g IvDO defines the term "importer" as "any natural or legal person established within Switzerland that places a device from a foreign country on the Swiss market". According to the current law (SR 0.631.112.514), economic operators domiciled in Liechtenstein can act as importers in Switzerland.

3.4 PRRC - Person responsible for regulatory compliance

The term “Person responsible for regulatory compliance” (PRRC) is defined as follows in Art. 49 MedDO and Art. 42 IvDO: “Manufacturers must have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of (in vitro diagnostic) medical devices. (…)”.

In Art. 52 MedDO and Art. 45 IvDO it is likewise stated that: “Authorised representatives must ensure that they have permanently and continuously at their disposal at least one person who possesses the requisite expertise as regards the requirements for (in vitro diagnostic) medical devices in under this Ordinance and who is responsible for regulatory compliance. In other respects, Art. 49 para. 2-4 MedDO and Art. 42 para. 2-4 IvDO apply.”

Can the manufacturer's PRRC also act for the authorised representative?
- The MedDO and IvDO does not specify any corresponding requirements, i.e. the possibilitythat the PRRC may also be the PRRC of an EC-REP or manufacturer is not ruled out.

Must the PRRC of the authorised representative be domiciled in Switzerland or Liechtenstein?
- The MedDO and IvDO does not place any restrictions on the residence of the PRRC; the relevant factor here is that the tasks should be carried out regardless of any geographical distance

4 Issue of CHRN

4.1 General comments

- To register, the company applying must complete the electronic application form in full: Application CHRN
  Please note: The language of the form can be changed by clicking on the relevant language (abbreviation) in the top left corner.
- Applications should be submitted via e-mail only to chrn@swissmedic.ch
- Hard-copy applications and scanned forms will be rejected. All details from an application form are transferred into the Swissmedic business case processing system via XML import. Scanned forms lead to technical issues as the information is not recognised by the system and cannot be read.
- If a company holds several roles (manufacturer, authorised representative, importer), please complete one application form per role. It is not possible to issue a single CHRN number for several roles.

- Any incomplete application will be rejected.
- Receipt of the application will be confirmed automatically by e-mail. If your e-mail concerns an application for a CHRN, a notification of change or notification of a new mandate, please note that these generally take 30 days for Swissmedic to process.

4.2 Information and documents required for registration

- Completed Application CHRN form
- Commercial Register extract as proof of the company's existence in Switzerland or Liechtenstein. If no Commercial Register extract exists, other proof of the company's existence in Switzerland or Liechtenstein.
- For Swiss-domiciled or Liechtenstein-domiciled authorised representatives: completed Notification mandate form

4.3 Notification regarding changes to the information

Under Art. 55, para. 2 MedDO and Art. 48 para. 2 IvDO, the economic operator in question is responsible for reporting changes to the information to Swissmedic within a period of one week. Changes must be reported using the form Notification changes to the information and sending it to chrn@swissmedic.ch. This notification is not subject to a fee. Please note: The language of the form can be changed by clicking on the relevant language (abbreviation) in the top left corner.

4.4 Swiss authorised representatives (CH-REP) domiciled in Switzerland or Liechtenstein authorised representative domiciled in Liechtenstein

The existence of a mandate from a manufacturer domiciled outside Switzerland or Liechtenstein is necessary. This information must be provided with the completed Notification mandate form. Required information are:

- Details Manufacturer
- Details Swiss authorised representative or Liechtenstein authorised representative

4.4.1 Taking on further mandates at a later date

If you have registered with Swissmedic once as a Swiss authorised representative (CH-REP) or Liechtenstein authorised representative, you can take on additional mandates at a later time. A notification to Swissmedic is not required in this case but is possible. If you would like to notify Swissmedic of additional mandates, please send the completed form Notification mandate to chrn@swissmedic.ch. This notification is not subject to a fee.

4.4.2 Confirmation of notification of mandates

No confirmation of notification of a mandate as a Swiss authorised representative (CH-REP) is provided. Should you require confirmation, this can be requested from chrn@swissmedic.ch.

4.5 Registration deadlines for Swiss or Liechtenstein manufacturers, importers, authorised representatives

Economic operators must register within three months of placing their first product on the Swiss market. This timeframe is intended to avoid delays in bringing compliant products onto the market and to prevent supply bottlenecks in Switzerland.

The following timelines apply to manufacturers established in an EU/EEA state or which have an authorised representative in an EU/EEA state for designating a Swiss authorised representative[6].

MDD/AIMDD and MDR devices:

- Classes III, IIb implantable and AIMD: 31 December 2021
- Non-implantable Class IIb, Class IIa: 31 March 2022
- Class I: 31 July 2022
- Systems and procedure packs: 31 July 2022

IVDD and IVDR devices:

- Class D: 31 December 2022
- Classes C and B: 31 March 2023
- Class A: 31 July 2023

EEA states are the member states of the EU, Iceland, Norway and Liechtenstein. However, the timelines only apply to EU states, Norway and Iceland. Due to the customs treaty[7] between Switzerland and Liechtenstein, a manufacturer in Liechtenstein is not obliged to designate an authorised representative in Switzerland.

All other foreign manufacturers are required to appoint a Swiss authorised representative with effect from 26 May 2021 (for MDD/AIMDD and MDR devices) or from 26 May 2022 (for IVDD and IVDR devices).

[6] Art. 104a MedDO, Art. 86 IvDO
[7] Art. 1 of the Vertrag zwischen der Schweiz und Liechtenstein über den Anschluss des Fürstentums Liechtenstein an das schweizerische Zollgebiet (SR 0.631.112.514)

Devices placed on the market	CH-manufacturer or CH-REP CH-importer	CH-distributor
MDR devices	EO places device on the market **for the first time** after 26 May 2021: Registration within 3 months. Subsequent registration for EOs that have placed devices on the market **for the first time** before 26 May 2021: by 26 November 2021[8]	do not need to register
Only MDD/AIMDD devices	EO places device on the market **for the first time** after 26 May 2021: Registration within 3 months. Subsequent registration for EOs that have placed devices on the market for the **first time** before 26 May 2021: no obligation	do not need to register
IVDR devices	EO places device on the market **for the first time** after 26 May 2022: Registration within 3 months. Subsequent registration for EOs that have placed devices on the market for the **first time** before 26 May 2022: by 26 November 2022[9]	do not need to register
IVDD devices only	EO places device on the market **for the first time** after 26 May 2022: Registration within 3 months. Subsequent registration for EOs that have placed devices on the market for the **first time** before 26 May 2022: no obligation	do not need to register

4.6 Billing

Invoices are issued by Swissmedic to an invoice address in Switzerland or Liechtenstein only. As a recipient of invoices from Swissmedic, you have the option of registering to receive PDF invoices by e-mail: PDF invoice by e-mail

4.7 Invalid / missing documents

If documents are missing from an application or if submitted documents are invalid, Swissmedic will notify the company. If Swissmedic has not received a reply or the requested documents after 30 days, it will not process the application. The costs will be billed on the basis of the work involved.

5 Overview registered Swiss or Liechtenstein economic operators

The overview shows all manufacturers, importers and authorised representatives domiciled in Switzerland or Liechtenstein registered at Swissmedic. The list is updated daily. List of CHRN Actors

6 Processing periods

The CHRN is assigned by Swissmedic **within 30 days** of receipt of the application and the electronic submission of complete and appropriate documentation.

7 Fees

The ordinance of the Swiss Agency for Therapeutic Products on its fees[10] specifies the following fees:

[8] Art. 104b MedDO
[9] Art. 88 IvDO
[10] Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products of 14 September 2018, FeeO-Swissmedic, SR 812.214.5

- Fees for issuing the CHRN and validating the documents required as evidence will be billed on the basis of the work involved in accordance with Art. 4 FeeO-Swissmedic. According to Art. 4 para. 2 FeeO-Swissmedic, the rate for work charged on an hourly basis is CHF 200 per hour. Experience has shown that issuing the CHRN requires one hour of work, which therefore generally corresponds to a fee of CHF 200.
- An administrative fee (Art. 4, para. 2 GebV-Swissmedic) of CHF 200 per hour will be charged for additional administrative work, e.g. due to incomplete or inappropriate documentation, withdrawal of an application after work has already been carried out or requests for information.

8 Contact

Swissmedic, Swiss Agency for Therapeutic Products
Medical Devices surveillance, Medical Devices Operations & Development
E-mail: chrn@swissmedic.ch

For further information on CHRN, including all necessary application forms, go to: Swiss Single Registration Number (CHRN)

Application forms

- BW630_11_001defi_FO Application CHRN
- BW630_12_002defi_FO Notification changes to the information
- BW630_11_003e_FO Notification mandate

Advice

Please note: As the supervisory authority in the area of medical devices, Swissmedic does not provide any advice regarding the development, qualification, classification, registration, certification, conformity or marketing of medical devices. If necessary, please contact an appropriate consultancy or industry association.

Change history

Version	Change	sig
3.3	Modification of contact data New layout, no content adjustments to the previous version.	stj hem
3.2	Adjustments concerning the update of the Liechtenstein Customs Treaty	stj
3.1	Change of e-mail address	stj
3.0	Modified following entry into force of IvDO	pej
2.0	Extensive revision of the document: change to structure, inclusion of additional relevant information, change of document name	pej
1.1	Doc modified owing to revision of MedDO regulatory provisions	stj/coj
1.0	Doc newly created owing to revision of MedDO regulatory provisions; old doc ID: BW530_00_005e_MB	stj/ler