Contents

1 General 1
2 Services, entitlements and obligations of the Agency 2
2.1 Service description 2
2.2 Distinction 2
2.3 Services provided by the Agency 2
2.3.1 Service triggers 2
2.3.2 Scope of service provided 2
2.3.3 Deliverables 3
2.3.4 Time limits 3
3 Applicants' obligations and responsibility 3
3.1 Authorised applicants 3
3.2 Mandatory notification 3
3.3 Agreement of the applicant 3
3.4 Responsibility 3
3.5 Formal requirements 3
4 Fees/costs 3
5 Invoicing and terms of payment 4
5.1 Advance payments 4
6 Data protection 4
7 Exclusion of liability 4
8 Applicable law and place of jurisdiction 4
9 Final provisions 4

Change history

Version	Valid and binding from	Description, comments (by author)	Author's initials
2.0	26.05.2022	Modified following entry into force of IvDO	pej
1.0	26.05.2022	First version	stj/coj

1 General

This service agreement describes the services that the Swiss Therapeutic Products Agency (hereafter the Agency) provides in terms of issuing the Swiss Single Registration Number (CHRN) in the area of medical devices. It also describes the entitlements and obligations of the persons who make use of this service.

Swissmedic • Hallerstrasse 7 • 3012 Berne • www.swissmedic.ch • Tel. +41 58 462 02 11 • Fax +41 58 462 02 12

2 Services, entitlements and obligations of the Agency

2.1 Service description

Swissmedic, the Swiss Therapeutic Products Agency, issues the Swiss Single Registration Number (CHRN) based on the Medical Devices Ordinance[1] and the Ordinance on In Vitro Diagnostic Medical Devices[2]. The CHRN is a number which makes it possible to unequivocally identify a manufacturer, authorised representative or importer domiciled in Switzerland. Swissmedic does not issue CHRNs for companies headquartered in another country.

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 EU-MDR[3] or EU-IVDR[4] within three months of placing a product on the market for the first time. There is no registration requirement for distributors; they do *not* require 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 Art. 51 para. 5 MedDO, their name and address must also be registered with Swissmedic.

Under Art. 55 para. 4 MedDO and Art. 48 para. 4 IvDO, Swissmedic is responsible for reviewing the data and for issuing CHRNs to manufacturers, authorised representatives and importers domiciled in Switzerland[5].

2.2 Distinction

A distinction must be made between CHRNs (Swiss Single Registration Numbers) and the SRNs assigned by EUDAMED. As the MRA[6] has not been updated, the Agency issues its own swiss single registration numbers for manufacturers, authorised representatives and importers.

2.3 Services provided by the Agency

2.3.1 Service triggers

Fully completed application form submitted to Swissmedic electronically via its CHRN mailbox (srn@swissmedic.ch) accompanied by a commercial register extract and, if necessary, proof of a mandate in accordance with Art. 51 MedDO and Art. 44 IvDO.

Hardcopy applications will not be accepted.

2.3.2 Scope of service provided

On receipt, applications are electronically recorded and their content is reviewed. The documents required to verify the situation undergo a formal check for accuracy. If all criteria are fulfilled, a CHRN is issued.

If the documentary evidence is insufficient to verify formal accuracy, Swissmedic will issue an objection. If the necessary documents are not submitted in response to the objection, the application will not be processed.

[1] Art. 55 MedDO (Medical Devices Ordinance 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)
[3] Medical Devices Regulation; Regulation (EU) 2017/745 on medical devices (MDR) of 5 April 2017
[4] In-vitro Diagnostic Regulation: Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) of 5 April 2017
[5] "Domiciled in Switzerland" should be understood to mean that headquarters in Switzerland are required
[6] Agreement between the Swiss Confederation and the European Union on the mutual recognition of conformity assessments (Mutual Recognition Agreement, MRA)

Swissmedic • Hallerstrasse 7 • 3012 Berne • www.swissmedic.ch • Tel. +41 58 462 02 11 • Fax +41 58 462 02 12

2.3.3 Deliverables

A letter of confirmation containing the CHRN will be sent to the applicant by post.

2.3.4 Time limits

The Agency will process the application within a period of 30 days as of the date on which all the information and documents needed to provide the service are in its possession.

3 Applicants' obligations and responsibility

3.1 Authorised applicants

Manufacturers, authorised representatives and importers domiciled in Switzerland. The applicant must also provide an invoicing and delivery address in Switzerland.

3.2 Mandatory notification

Manufacturers, their authorised representatives if applicable and importers are required to submit the information required under Annex VI Part A section 1 EU-MDR and EU-IVDR[7] to the Agency within three months of placing a product on the market for the first time.

The economic operator in question is responsible for reporting changes in this information to Swissmedic within a period of one week[8].

3.3 Agreement of the applicant

By accepting this agreement, the applicant consents to the Agency providing foreign authorities with information about CHRNs that it has issued without consulting the applicant and at the foreign authorities' request, e.g. in order to verify certificates' authenticity or validity if there is a suspicion that they may be counterfeit.

Non-conformities of medical devices or in vitro diagnostic medical devices that are discovered during the provision of the service may be reported to the Market Surveillance of Medical Devices function of the Agency for investigation; this may lead to administrative proceedings.

3.4 Responsibility

The applicant is responsible for ensuring that all information provided on the application form is correct, true and complete.

3.5 Formal requirements

To obtain the service, the completed electronic form, including commercial register extract and, if necessary, evidence of mandate in accordance with Art. 51 MedDO and Art. 44 IvDO, must be submitted to the Agency via e-mail (srn@swissmedic.ch).

4 Fees/costs

The Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products[9] specifies the following fees:

- 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.

[7] Art. 55 para. 1 MedDO and Art. 48 para. 1 IvDO
[8] Art. 55 para. 2 MedDO and Art. 48 para.2 IvDO
[9] Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products of 14 September 2018, FeeO-Swissmedic, SR 812.214.5

Swissmedic • Hallerstrasse 7 • 3012 Berne • www.swissmedic.ch • Tel. +41 58 462 02 11 • Fax +41 58 462 02 12

- An administrative fee (Art. 4, para. 2 FeeO-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 written information.

5 Invoicing and terms of payment

Invoices will be issued solely to an invoicing address in Switzerland and will be sent immediately after the service has been provided, i.e. after the confirmation letter containing the CHRN has been sent.

5.1 Advance payments

The Agency may require an appropriate advance payment of part or all of the expected fee from persons subject to payment of fees in justifiable cases, in case of payment arrears or if debt collection proceedings are ongoing[10].

6 Data protection

The Agency processes data in accordance with Swiss data protection legislation and the relevant legal standards, and protects data generated in the course of application processing against unauthorised access.

7 Exclusion of liability

Issuing a CHRN does not constitute a conformity certificate, an officially reviewed registration of the products placed on the market by the company or an assessment of the quality of those products.

The Agency reserves the right to modify its services and the service agreement at any time. Modifications will be announced by the Agency in a suitable manner.

8 Applicable law and place of jurisdiction

The contractual relationship is subject solely to Swiss law. The sole place of jurisdiction is Bern.

9 Final provisions

Should individual provisions of the service agreement prove to be invalid or illegal, this shall not affect the validity of the service agreement as a whole.

[10] Art. 10 GFeeO (SR 172.041.1)

Swissmedic • Hallerstrasse 7 • 3012 Berne • www.swissmedic.ch • Tel. +41 58 462 02 11 • Fax +41 58 462 02 12