swissmedic

Guidance document
Export Certificates

Identification number:	BW690_00_002
Version:	3.2
Valid from:	27.03.2024

List of contents

1 Legislation

Based on the Therapeutic Products Act (TPA)[1], the Medical Devices Ordinance (MedDO)[2] and the Ordinance on In Vitro Diagnostic Medical Devices (IvDO)[3], Swissmedic, the Swiss Agency for Therapeutic Products, issues export certificates (Free Sales Certificates, FSC) for medical devices exported to third countries. Swissmedic can issue those certificates to manufacturers and authorised representatives located in Switzerland, provided they supply the required supporting documentation. Swissmedic does not issue export certificates to companies located outside Switzerland.

Service agreement
The service agreement describes the services provided by Swissmedic in connection with the issuing of export certificates for medical devices. It also describes the rights and obligations of the individuals who make use of the service.

2 Use of export certificates

Export certificates certify the formal conformity of the medical devices in question with the legal requirements in Switzerland and thus their basic eligibility for being marketed at the time the certificate is issued.

Swissmedic can issue export certificates to manufacturers and Swiss authorised representatives based in Switzerland if they submit the necessary documentation. Specific requirements apply for Swiss authorised representatives. These are noted in the information sheet “Obligations Economic Operators CH” on the website Obligations for authorised representatives, importers and distributors (swissmedic.ch).

Swiss manufacturers need to have an authorised representative/importer in the EU in order to place medical devices on the EU market.

Certain countries do not recognise CE conformity marking and require export certificates issued by the competent national authority in the country where the exporting company or the production facility is based for the registration and placing on the market of medical devices. These countries include Peru, Brazil, China, Japan, India, Indonesia, Saudi Arabia, Egypt etc.
A knowledge of the product marketing modalities in the importing country is needed in order to determine whether an export certificate is required or not. To this end, we would recommend that you contact the Ministry of Health in the importing country or its embassy or consulate in Switzerland. The list of foreign representations in Switzerland can be found on the website of the Federal Department of Foreign Affairs (FDFA).

Comment:
Swissmedic does not contact authorities in other states in relation to service provision. The exporting individuals are responsible for complying with the registration procedures.

[1] Art. 50 TPA (Federal Act of 15 December 2000 on Medicinal Products and Medical Devices; RS 812.21)
[2] Medical Devices Ordinance of 1 July 2020 SR 812.213
[3] Ordinance of 4 May 2022 on In Vitro Diagnostic Medical Devices SR 812.219

3 Products concerned

Swissmedic issues export certificates for medical devices. The law deems the following to be medical devices[4]:

> *Products, including instruments, apparatus, devices, in vitro diagnostics, software, implants, reagents, materials and other goods or substances which are intended to have, or are presented as having, a medical use and whose principal effect is not obtained with a medicinal product;*

Products with a non-medical intended use according to Annex I of MedDO are also deemed to be medical devices[5].
Swissmedic issues export certificates for medical devices which, according to the documents submitted, are formally compliant with Swiss law and that may in principle be placed on the Swiss market without restriction.

Swissmedic does not issue export certificates for components of medical devices, only for final products.

Swissmedic is not the authority responsible for issuing export certificates for products that do not satisfy the definition of a medical device as stated in the TPA. Furthermore, certificates are not issued for the following products:

- Certificates for devices for veterinary use. For these devices, please contact the veterinary office of your canton (addresses at https://www.blv.admin.ch/blv/en/home/das-blv.html > About us > Swiss Veterinary Service > Federation of Swiss Cantonal Veterinary Officers).
- Certificates for commodities and foods. For these products, please see the website of the Federal Food Safety and Veterinary Office (FSVO; https://www.blv.admin.ch/blv/en/home/import-und-export/export.html)

4 How to obtain an export certificate

4.1 General comments

- To order an export certificate, the requesting firm needs to duly complete the electronic order form, which is available on the Swissmedic website (www.swissmedic.ch/md-fsc-en) in German, French, Italian and English.
- **Important notice:** the content of the form is read automatically by an electronic system and is transferred unaltered into the dedicated fields of the export certificate or the attestation. The requesting firm is therefore solely responsible for the information listed in the export certificate or in the attestation.

[4] According to Art. 4 para. 1 let. b TPA
[5] Art. 2 para. 3 TPA in conjunction with Art. 1 para. 1 let. b MedDO

- The number of characters that can be entered per field is limited due to the automatic transfer of information.
- Enclose all the required documentation and product list, and submit these via the Swissmedic Portal eGov "eMessage" service: http://www.swissmedic.ch/emessage-de.
- Filenames are limited to 90 characters. The following characters are permitted: ‘A‘ to ‘Z‘; ‘a‘ to ‘z‘, ‘0‘ to ‘9‘, ‘.‘, ‘-‘, and ‘_‘
- Paper-based orders will be rejected.
- In the case of incomplete orders, a deadline will be set. If the application has not been completed within the deadline, the application will not be considered.
- Please complete one order form for each export certificate. However, if you wish to order the same certificate (same medical device group) for several different countries (specified and/or unspecified countries), please complete a single form and enter the various countries in the relevant section (section 5 of the form).
- Since the revision of the Swiss medical devices ordinance (MedDO and IvDO), product lists may only contain medical devices that are certified according to either the current (MedDO and IvDO) or the old legislation (Directive 93/42/EEC, Directive 90/385/EEC, Directive 98/79/EC). For this purpose, two different order forms are available on our website - one for medical devices according to current legislation (MedDO and IvDO) and a second one for medical devices according to old legislation, as well as DEVIT and IVDs.

  Swissmedic confirms with the FSC certificate that the medical device(s) included in the order fall(s) under one of the above mentioned legislations.
  Mixed orders (existing legislation – MedDO and IvDO – and old legislation) are not accepted.
  Please submit a separate order for existing legislation and a separate order for old legislation.
- Duplicates or copies of export certificates are not issued.

4.2 Types of certificate (section 1 of the form)

Only those types of certificate mentioned on the order form can be issued, i.e.:

- **Export certificate (Free Sales Certificate, FSC)**
  Certificate issued for a medical device or medical devices in a single medical device group.
  Please refer to section 4.5 of this guidance document for the definition of the term “medical device group”.

4.3 Requesting company (section 2 of the form)

Only manufacturers[6] and authorised representatives[7] located in Switzerland may order export certificates from Swissmedic[8].
The export certificates are delivered **only** by registered letter to the address of the requesting company in Switzerland.

[6] Art. 4 para.1 let. f MedDO
[7] Art. 4 para. 1 let. g MedDO
[8] Art. 50 para. 2 TPA

4.4 Billing address (section 2 of the form)

Invoices are issued by Swissmedic to an invoice address in Switzerland only.

4.5 Medical device groups, medical devices and list of products (section 3 of the form)

What is a medical device group?
Medical devices form a **medical device group** if

- the devices have the same legal manufacturer
- the devices are covered by at most one certificate of conformity (or linked certificates of conformity), see table in chapter 4.6 of this guidance document, and
- the devices can be defined by a maximum of 20 different codes (GMDN, UMDNS, EDMA, EMDN etc.).

List of products

- State the CHRN (Swiss Single Registration Number) of the manufacturer and/or authorised representative (if available)

In the list of products, the following information needs to be supplied **for each medical device**:

- Basic-UDI-DI (if available)
- Unique identification number of the certificate issued by the aforementioned office and the Certificate of conformity (if available)
- UDI-DI (if available)
- Reference or article number
- Name
- Class
- GMDN-Code, UMDNS-Code, EDMA-Code, EMDN-Code or code of another recognized nomenclature.

Please supply a separate list of products:

- in the **.pdf file format**
- **Formatting: A4, a margin of at least 2 cm shall be left (at the top, at the bottom, on the left-hand side, on the right-hand side)**
- with the **letterhead** of the requesting company (full company name and address)
- with consecutive **page numbering** (e.g. “page 1 of 1”, page 1 of 10”, “page 2 of 10” etc.)
- including, for each device, the information according the section “List of products” above.

The product list is an integral part of the export certificate, hence the product list is stamped by Swissmedic.

Language

The information concerning the medical device group (e.g. “Name of Medical device(s) Group”) and the product list are to be supplied in English.

4.5.1 Example of product list

Please find below an example of a product list.

a margin of at least 2 cm shall be left
(at any side; left, right, top, bottom)

at least 2 cm

Logo

letterhead of the requesting company (full company name and address)

List of products

State the CHRN (Swiss Single Registration Number)
of the manufacturer and/or authorised representative (if one exists)

Basic-UDI-DI (if available)	**Reference or article number**	**Name of medical device**	**Class**	**GMDN-Code, UMDNS-Code, EDMA-Code, EMDN-Code or other code** (max. 20 different codes)	**Legal Manufacturer**	**Unique identification number of the certificate issued by aforementioned office** (if available)
xxx	xxx	Medical device	IIa	xxx	Full Name of legal manufacturer	xxx
xxx	xxx	Medical device	IIa	xxx	Full Name of legal manufacturer	xxx
xxx	xxx	Medical device	IIa	xxx	Full Name of legal manufacturer	xxx
xxx	xxx	Medical device	IIb	xxx	Full Name of legal manufacturer	xxx
xxx	xxx	Medical device	IIb	xxx	Full Name of legal manufacturer	xxx
xxx	xxx	Medical device	IIb	xxx	Full Name of legal manufacturer	xxx
xxx	xxx	Medical device	IIb	xxx	Full Name of legal manufacturer	xxx
…	…	…	…	…	…	…

The name of the requesting company may also appear in the footer.

The consecutive page numbering can also be in the header.

at least 2 cm

at least 2 cm

«Page 1 of 1» or «Page 1 of 5» etc.

4.6 Supporting documents for CE conformity (section 4 of the form)

The supporting documents must be valid and complete, otherwise the order will be rejected. Swissmedic may request additional information or documents.

4.6.1 Devices according to old legislation (Directive 93/42/EEC, Directive 90/385/EEC, Directive 98/79/EC)

Type of medical device (MD)	Legislation	Class	Declaration of conformity	Certificate of CE conformity	Further documents
Classical medical devices	Dir. 93/42/EEC	Class I	X	---	- Explanation of why these devices may continue to be placed on the market (higher classification according to MDR)
	Dir. 93/42/EEC	Class Is, Ims	X	Annex II excl. (4), *or* Annex V	
	Dir. 93/42/EEC	Class Im Class IIa	X X	Annex II excl. (4), *or* Annex IV, *or* Annex V, *or* Annex VI(3)	
	Dir. 93/42/EEC	Class IIb	X	Annex II excl. (4), *or* Annex III + Annex IV, *or* Annex III + Annex V, *or* Annex III + Annex VI (3)	
	Dir. 93/42/EEC	Class III	X	Annex II excl. (4) + Annex II (4), *or* Annex III + Annex IV, *or* Annex III + Annex V	
Active implantable medical devices (AIMD)	Dir. 90/385/EEC		X	Annex 2 excl. (4) + Annex 2 (4), *or* Annex 3 + Annex 4, *or* Annex 3 + Annex 5	

Type of medical device (MD)	Legislation	Class	Declaration of conformity	Certificate of CE conformity	Further documents
In vitro diagnostic medical devices (IVD)	Dir. 98/79/EC	General	X	---	
	Dir. 98/79/EC	Self testing	X	Annex III (6), *or* Annex IV excl. (4), *or* Annex V + Annex VI, *or* Annex V + Annex VII (3)	
	Dir. 98/79/EC	List B	X	Annex IV excl. (4), *or* Annex V + Annex VI, *or* Annex V + Annex VII (3)	
	Dir. 98/79/EC	List A	X	Annex IV excl. (4) + Annex IV (4), or Annex V + Annex VII (3) / VII (5)	
Products with devitalised tissues or cells of human origin, according to Art. 1 para. 3, let. c, no. 2 and let. d MedDO, that were lawfully placed on the market or put into service before 26 May 2021	MedDO	---	---	---	
DEVIT products according to Art. 2a, para. 2 TPA	TPA	---	---	---	

4.6.2 Devices according to applicable legislation (MedDO)

Type of medical device and legislation	Class	Declaration of conformity[9]	Certificate of conformity
Medical device according to MedDO in conjunction with MDR[10]) (Regulation (EU) 2017/745)	Class I	X	---
	Class Im, Ir, Is	X	Annex IX Chapter I (EU quality management certificate), *or* Annex XI Part A (EU quality assurance certificate)
	Class IIa	X	Annex IX Chapter I (EU quality management certificate) *or* Annex XI Section 10 (EU quality assurance certificate) *or* Annex XI Section 18 (EU product verification certificate)
	Class IIb	X	Annex IX Chapter I (EU quality management certificate) and – if implantable in accordance with Art. 52 para. 4 MDR – Annex IX Chapter II (EU technical documentation assessment certificate) *or* Annex X (EU type-examination certificate) and Annex XI Part A (EU quality assurance certificate) *or* Annex X (EU type-examination certificate) and Annex XI Part B (EU product verification certificate)
	Class III	X	Annex IX Chapter I (EU quality management certificate) and Annex IX Chapter II (EU technical documentation assessment certificate) *or* Annex X (EU type-examination certificate) and Annex XI Part A (EU quality assurance certificate) *or* Annex X (EU type-examination certificate) and Annex XI Part B (EU product verification certificate)

[9] According to Art. 29 MedDO in conjunction with the Annex IV EU Declaration of Conformity of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

[10] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

4.6.3 Devices according to applicable legislation (IvDO)

Type of medical device and legislation	Class	Declaration of conformity[11]	Certificate of conformity
In vitro diagnostic medical devices according to IvDO in conjunction with IVDR[12]) (Regulation (EU) 2017/746)	Class A	X	---
	Class As	X	Annex IX (EU quality management certificate) *or* Annex XI (EU production quality assurance certificate)
	Class B	X	Annex IX Chapters I and III (EU quality management certificate) *and* for devices for self-testing and for near-patient testing, also Annex IX Section 5.1 (EU technical documentation assessment certificate)
	Class C	X	Annex IX Chapters I and III (EU quality management certificate) *and* – for devices for self-testing and for near-patient testing, also Annex IX Section 5.1 (EU technical documentation assessment certificate) – for companion diagnostics also Annex IX Section 5.2 (EU technical documentation assessment certificate) *or* Annex X (EU type-examination certificate) and Annex XI [excluding Section 5] (EU production quality assurance certificate)
	Class D	X	Annex IX Chapter I, II [excluding Section 5] and III (EU quality management certificate and EU technical documentation assessment certificate) *or* Annex X (EU type-examination certificate) and Annex XI (EU product quality assurance certificate)

[11] According to Art. 25 IvDO in conjunction with the Annex IV EU Declaration of Conformity with Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices

[12] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices

4.6.4 Transitional provisions (Directive – MDR/IVDR)

Details regarding the transitional provisions are included in the information sheet “Obligations Economic Operators CH” on the website Obligations for authorised representatives, importers and distributors (swissmedic.ch).

N.B.:
If the validity period of the supporting documents is less than 3 months from the date of issue of the export certificates, the granting of those certificates will be subject to conditions. If the requesting company fails to provide valid supporting documents within 3 months of the expiration of the validity of the supporting documents, Swissmedic will revoke the issued export certificates or manufacturing certificates.

In the event of a change of company name or address, the supporting documents must be updated before ordering export certificates.

4.6.5 Notifications for in vitro diagnostics (IVDs)

- In vitro diagnostic medical devices (IVDs) according to IVDR13 that are placed on the market in Switzerland for the first time by manufacturers must, according to Art. 90 para. 1 IvDO[14] in conjunction with Art. 6 oMedDO[15], be notified to Swissmedic.

  The notification obligation applies only to manufacturers based in Switzerland. Swiss authorised representatives are not subject to the notification obligation according to Art. 90 IvDO.
- According to Art. 46 and Art. 47 IvDO, repackaged or relabelled devices must be notified to Swissmedic.
  The notification obligation applies to persons (importers and distributors) domiciled in Switzerland.
- According to Art. 10 IvDO, IVDs that are manufactured and used in healthcare institutions (in-house IVDs) must be notified to Swissmedic.

  The notification obligation applies to healthcare institutions in Switzerland before the IVDs are put into service.

The notification confirmations do not need to be included with the order. Details regarding notifications are included in the information sheet “FAQ on in vitro diagnostic medical device Notifications” on the website Notification of IVD medical devices (swissmedic.ch)

[13] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
[14] Ordinance of 4 May 2022 on In Vitro Diagnostic Medical Devices (SR 812.219)
[15] Medical Devices Ordinance of 17 October 2001 (SR 812.213)

4.7 Country of importation and number of certificates (section 5 of the form)

As a general rule, one export certificate is issued for each country of importation, or one export certificate per distributor if the country of importation is Algeria, Saudi Arabia, Libya or Turkey (see 4.7.1).
If the countries of importation are known, please enter the name of the country.
If the country of importation is not yet known, complete as many lines as necessary with the entry "Unspecified country".

4.7.1 Placer on the market in the country of importation (section 5 of the form)

The details of the placer on the market in the country of importation are essential when ordering an export certificate for Algeria, Saudi Arabia, Libya or Turkey. In this case, an export certificate is issued for each placer on the market in the country of importation.

4.7.2 Period of validity

Export certificates are valid for 3 years, or 5 years if the country of importation is Thailand.

4.8 Special case: Ordering export certificates for systems and procedure packs (sections 2-4 of the order form)

Swissmedic issues export certificates for systems and procedure packs (Art. 11 MedDO).

The systems and procedure packs need to belong to a **single medical device group**, i.e. (i) the systems/procedure packs have the same system/procedure pack assembler and (ii) the systems / procedure packs can be defined by a maximum of 20 different codes (GMDN, EMDNS, UMDNS, EDMA etc.).

Supporting documents to be submitted with the order: The supporting documents according to section 4.6 of this guidance document (e.g. declarations of conformity, EC certificates of conformity) for all medical devices that are part of the systems / procedure packs need to be submitted. To this end, a summary list showing which EC certificate of conformity belongs to which device within the system/procedure pack must also be provided.
Furthermore, for each system and procedure pack, either a **declaration according to Art. 12 of Directive 93/42/EEC or according to Art. 22 and 29 para. 2 MDR** needs to be included with the order.

List of products: In addition to the information according to section 4.5 of this guidance document, the following information needs to be included in the product list for each product:

- Medical devices (names), which are part of the system / the procedure pack
- Manufacturers (company names) of the medical devices in the systems/procedure packs.

Ordering form: Please indicate the address of the **system** / **procedure pack assembler** in the field “legal manufacturer”.

5 Language used on export certificates

The export certificates are issued in English only.

6 Deadlines

6.1 Processing periods

Export certificates are issued by Swissmedic **within 30 days** of receipt of the order and the electronic submission of complete and appropriate documentation.

6.2 Deadlines for incomplete applications

Any ordering party that submits an incomplete application has a deadline of 30 days to submit a complete version. If the application is not submitted in full by the deadline or the additional documents issued are not complete or incorrect, Swissmedic will not deal with the application and will remove it from the business directory. The ordering party will then be invoiced a flat fee of CHF 100. This corresponds to half of the fee for an export certificate FSC [16]. In order to obtain the certificate in this case, a completely new order must be made with all the necessary information and documents.

7 Fees

The ordinance of the Swiss Agency for Therapeutic Products on its fees[17] specifies the following fees:

- Issue of an export certificate (Art. 4, para. 1 and annex 2 GebV-Swissmedic): CHF 200 per certificate.
- Swissmedic can reduce the fees if an application cannot be accepted (Art. 8, para. 1 GebV-Swissmedic).

8 Contact

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

For further information on export certificates, including the order forms «BW690_00_001defi_FO Orders for export certificates for medical devices » and «BW690_00_002defi_FO Orders for export certificates for medical devices subject to old legislation as well as DEVIT products and IVD», go to: www.swissmedic.ch/md-fsc-en.

Swissmedic portal eGov "eMessage" service: www.swissmedic.ch/emessage-en

[16] Annex 2 of the Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic; SR 812.214.5)
[17] Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products of 14 September 2018, FeeO-Swissmedic, SR 812.214.5

Change history

Version	Change	sig
3.2	Clarification of the section 4.6.2	sch
3.1	New layout, no content adjustments to the previous version	tsj
2.5	Clarification of the section 2.3.4	ler
3.0	Chapter 8 Correction of the department name	lej
2.6	Clarification of the section 2.3.4 and history	ler
2.4	Adaptation of the ordering process, deadlines for incomplete applications	ler
2.3	Additions in point 4.1	sch
2.2	Modified following entry into force of IvDO	ler
2.1	Customization product code	sch
2.0	Content of the table must be adapted (class I notification confirmation must be removed)	ler
1.0	Doc newly created owing to revision of MD regulatory provisions; old doc ID: BW540_00_003e_MB	pej