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1. Legislation

Based on the Therapeutic Products Act (TPA)¹ and the Medical Devices Ordinance (MedDO)², Swissmedic, the Swiss Agency for Therapeutic Products, issues export certificates (Free Sales Certificates, FSC) and manufacturing certificates (attestations) for medical devices exported to third countries. Swissmedic can issue those certificates to companies (natural and legal persons) located in Switzerland, provided they supply the required supporting documentation. Swissmedic does not issue export certificates or manufacturing 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 and manufacturing 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 and manufacturing certificates

Switzerland has entered into a Mutual Recognition Agreement (MRA) in relation to conformity assessment with the European Union (EU)³ and the countries in the European Free Trade Association (EFTA: Iceland, Liechtenstein, Norway and Switzerland)⁴. Thanks to these agreements, CE-marked medical devices can be exported directly from Switzerland to any of these countries without an export certificate.

Turkey⁵ has concluded a Protocol E with EFTA on the mutual recognition of the conformity assessment of products (specifically medical devices and CE marking), which entered into force on July 5th 2011. However, Turkey can request an export certificate if the export of a medical device is subject to reimbursement via an insurance policy in Turkey. In this case, the export certificate serves as proof of conformity of the medical device for reimbursement.

Certain countries do not recognise CE conformity marking and require export certificates or manufacturing 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 registration procedures in the importing country is needed in order to determine whether an export certificate or a manufacturing certificate is required. 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 third 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 812.213)

² Art. 22 MedDO (Ordinance of 17 October 2001 on Medical Devices; RS 812.213)

³ [Agreement between the Swiss Confederation and the European Community in relation to conformity assessment](#) (RS 0.946.526.81)

⁴ [Convention establishing the European Free Trade Association](#) (RS 0.632.31)

⁵ [Protocol E Mutual recognition of conformity assessments of products](#), entry into force on 5 July 2011

3. Products concerned

Swissmedic issues export certificates and manufacturing certificates for classical medical devices, in vitro diagnostic medical devices (IVD), active implantable medical devices (AIMD) and medical devices containing devitalised human tissue (DEVIT). Swissmedic does not issue export certificates for the components of medical devices, only for final products.

In accordance with the MedDO, Swissmedic issues export certificates and manufacturing certificates for medical devices that comply with Swiss law⁶ and that can be placed on the Swiss market without restriction and exported to the EU and EFTA countries and Turkey.

Swissmedic is not the authority responsible for issuing export certificates and manufacturing certificates for products that do not satisfy the definition of a medical device as stated in the MedDO. Nor does Swissmedic issue

- 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 / a manufacturing certificate

4.1. General comments

- To order an export certificate or a manufacturing 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.
- The number of characters that can be entered per field is limited due to the automatic transfer of information.
- 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.
- Any incomplete order will be rejected.
- Please complete one order form for each export certificate or manufacturing certificate. However, if you wish to order the same certificate (identical type of certificate and 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).
- Duplicates or copies of export certificates and manufacturing certificates are not issued.

⁶ For further information on the requirements applicable to medical devices, go to www.swissmedic.ch/md_regulation

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 information sheet for the definition of the term “medical device group”.

- **Manufacturing certificate (attestation)**
Certificate issued for a company (subcontractor, original equipment manufacturer, supplier, etc.) that produces, for example, for a manufacturer as defined in the applicable European Medical Devices Directives (93/42/EEC, 90/385/EEC, 98/79/EC, Art. 1, para. 2 f).

4.3. Requesting company (section 2 of the form)

Only those companies (natural and legal persons) located in Switzerland may order export certificates and manufacturing certificates from Swissmedic. The requesting company can be the legal manufacturer, the European representative, a subcontractor, a production facility, a distributor, an importer, etc.

The export certificates and manufacturing certificates are delivered only to the address of the requesting company.

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 lists 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 EC certificate (or linked EC certificates), see table in chapter 4.6.1 of this information sheet, and
- the devices can be defined by a maximum of 20 different codes (GMDN, UMDNS, EDMA etc.).

List of products

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

- Reference or article number
- Name
- Class
- GMDN-Code, UMDNS-Code, EDMA-Code or code of another recognized nomenclature.

With **5 or less devices**: Please compose the list of products directly in the order form.

With **more than 5 devices**: Please supply a separate list of products:

- in the **.pdf file format**
- with the **letterhead** of the requesting company
- with consecutive **page numbering**
- including, for each device, the information according the section “List of products” above.

The list of products is an integral part of the export certificate / the manufacturing 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.

4.6. Supporting documents (section 4 of the form)

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

4.6.1 Supporting documents for CE conformity which must accompany an order for an export certificate:

Type of medical device (MD)	Legislation	Class	Declaration of conformity	Certificate of CE conformity (EC Certificate)
Classical medical devices	Dir. 93/42/EEC	Class I	x	---
	2017/745/EU	Class I	x	---
	Dir. 93/42/EEC	Class Is, Ims	x	Annex II excl. (4), or Annex V
	Dir. 93/42/EEC	Class Im	x	Annex II excl. (4), or Annex IV, or Annex V, or Annex VI(3)
		Class IIa	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 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
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)
DEVIT	MedDO		---	---

4.6.2 Supporting documents which must accompany an order for a manufacturing certificate

Type of MD	Directive	Class	Self-declaration by subcontracting manufacturer	Certificate ISO 13485
Classical medical devices	Dir. 93/42/EEC	all	x	x
Active implantable medical devices (AIMD)	Dir. 90/385/EEC	all	x	x
In vitro diagnostic medical devices (IVD)	Dir. 98/79/EC	all	x	x
DEVIT	Dir. 93/42/EEC	all	x	x

N.B.:

If the validity period of the supporting documents is less than 3 months from the date of issue of the export certificates or the manufacturing certificates, the granting of those certificates will be subject to conditions (Art. 22, para. 3 MedDO). 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 or manufacturing certificates.

4.6.3 Notifications according to Art. 6 MedDO

When completing the order, the requesting company is required to confirm that it disposes of notification confirmations from the competent authority for all classical devices in class I (I, Is, Im, Ism), devices containing devitalised human tissue and in vitro diagnostic devices if such devices are included in the list of products. However, the notification confirmations do not need to be included with the order.

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

As a general rule, one export certificate / manufacturing certificate is ordered 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 and manufacturing 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 (Definition see art. 3 para. 1 let. b^{ter} 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, UMDNS, EDMA etc.).

Supporting documents to be submitted with the order: The supporting documents according to section 4.6.1 of this information sheet (e.g. declarations of conformity, EC certificates) for all medical devices that are part of the systems / procedure packs need to be submitted. Furthermore, for each system and procedure pack, the **declaration according to art. 12 of the directive 93/42/EEC** needs to be included with the order.

List of products: In addition to the information according to section 4.5 of this information sheet, 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 / manufacturing certificates

The export certificates and manufacturing certificates are issued in English only.

6. Processing periods

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

7. Fees

The ordinance of the Swiss Agency for Therapeutic Products on its fees⁷ specifies the following fees:

- Issue of an export certificate (Art. 4, para. 1 and annex 2 GebV-Swissmedic): CHF 200 per certificate.
- The estimated time for issuing a manufacturing certificate is one hour, for which the requesting company is charged CHF 200 (Art. 4 GebV-Swissmedic).
- An administrative fee (Art. 4 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 order after work has already been carried out, requests for information or the correction of a

⁷ Verordnung des Schweizerischen Heilmittelinstituts über seine Gebühren („Ordinance of the Swiss Agency for Therapeutic Products on its fees“ from 14 September 2018, GebV-Swissmedic, SR 812.214.5

certificate as a result of a mistake made by the requesting company. No fees are charged for the correction of a mistake made by Swissmedic.

8. Contact

Swissmedic, Swiss Agency for Therapeutic Products

Medical Devices division

E-mail: fsc@swissmedic.ch

For further information on export certificates and manufacturing certificates, including the order form BW540_00_002e_FO_Order_form_export_certificates_MD, go to: www.swissmedic.ch/md-fsc-en.

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

Change history

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