swissmedic

Guidance Document
Export Certificates

Identification number:	BW690_00_002
Version:	4.1
Valid from:	03.08.2026

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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 using 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 authorised representatives based in Switzerland if they submit the necessary documentation. Specific requirements apply for Swiss authorised representatives, as 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 for the registration and placing on the market of medical devices they require export certificates issued by the national competent authority in the country where the exporting company or the production facility is based. These countries include Peru, Brazil, China, Japan, India, Indonesia, Saudi Arabia and Egypt.
The requesting company should clarify the product marketing modalities in the importing country in order to determine whether an export certificate is required. To this end, Swissmedic would recommend contacting 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).

[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

Comment:
For the provision of this service, Swissmedic does not contact authorities in other states. The exporting entities are responsible for complying with the registration procedures.

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 finished goods.

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

- devices for veterinary use. For these devices, please contact the veterinary office of your canton (addresses can be found at https://www.blv.admin.ch/blv/en/home/das-blv.html > About us > Swiss Veterinary Service > Federation of Swiss Cantonal Veterinary Officers).
- commodities and foods. For these products, please consult the website of the Federal Food Safety and Veterinary Office (FSVO; https://www.blv.admin.ch/blv/en/home/import-und-export/export.html)
- DEVIT products in accordance with Art. 2a, para. 2 TPA

Note:
Since 1 July 2026, both devices and systems/procedure packs in Switzerland have to be registered in swissdamed (mandatory device registration). During the initial phase, economic operators have until 31 December 2026 to register their devices. After this date, devices must be registered before they are placed on the market.
Please note that, for FSC orders processed on or after 1 January 2027, all medical devices included in the product list must be registered in the swissdamed database. If, for orders processed on or after 1 January 2027, the devices on this list are not registered, the application will not be considered.

[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

Since fees may be charged in such cases, please take into account the 30-day processing period when submitting an FSC order.

4 Ordering an Export Certificate

4.1 General Comments

- To order an export certificate, the requesting company must 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 transferred automatically and without changes to the corresponding fields of the export certificate by an electronic system. The requesting company is therefore solely responsible for the information listed in the export certificate.
- The number of characters per field is limited due to the automatic transfer of information.
- All required documentation as well as the list of products must be enclosed and submitted 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.
- For incomplete orders, a deadline will be set. If the application has not been completed within the deadline, the application will be denied.
- At least one order form for each export certificate must be completed. If the same certificate (same medical device group) is ordered for several countries (specified and/or unspecified countries), a single form can be completed and the countries can be listed in the relevant section (section 5 of the form).
- Since the revision of the Swiss medical devices ordinance (MedDO and IvDO), lists of products 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 Swissmedic’s website - one for medical devices according to current legislation (MedDO and IvDO) and a second one for medical devices according to old legislation and IVDs.

  With the FSC certificate, Swissmedic confirms that the medical device(s) included in the order are covered by one of the aforementioned legislations.

  Mixed orders (current legislation – MedDO and IvDO – and old legislation) are not accepted. A separate order for current legislation and a separate order for old legislation must be submitted.
- No duplicates or copies of export certificates are issued.

4.2 Types of Certificates (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 belonging to 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 order form and the product list for an FSC can only contain one legal manufacturer. Exception: for systems and procedure packs, multiple legal manufacturers can be indicated on the product list.
Export certificates are delivered exclusively by registered letter to the address of the requesting company in Switzerland.

4.4 Billing Address (Section 2 of the Form)

Invoices are issued by Swissmedic to a billing addresses 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 of one nomenclature (GMDN, UMDNS, EDMA, EMDN etc.).

List of products

- CHRN (Swiss Single Registration Number) of the manufacturer, persons who assembles systems and procedure packs, and/or authorised representative (must match the CHRN of the manufacturer, persons who assembles systems and procedure packs or authorised representative stored in swissdamed)

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

- Basic-UDI-DI for products under the current legislation[9]
- UDI-DI for products under the current legislation[10]

[6] Art. 4 para.1 let. f MedDO
[7] Art. 4 para. 1 let. g MedDO
[8] Art. 50 para. 2 TPA
[9] Art. 17 MedDO and Art. 16 IvDO
[10] Art. 17 MedDO and Art. 16 IvDO

- Unique identification number of the certificate issued by the Notified Body (if available)
- Number/identification of the declaration of conformity (if available)
- Reference or article number
- Name
- Class
- GMDN-Code, UMDNS-Code, EDMA-Code, EMDN-Code or code of another recognized nomenclature

The list of products must satisfy the following requirements:

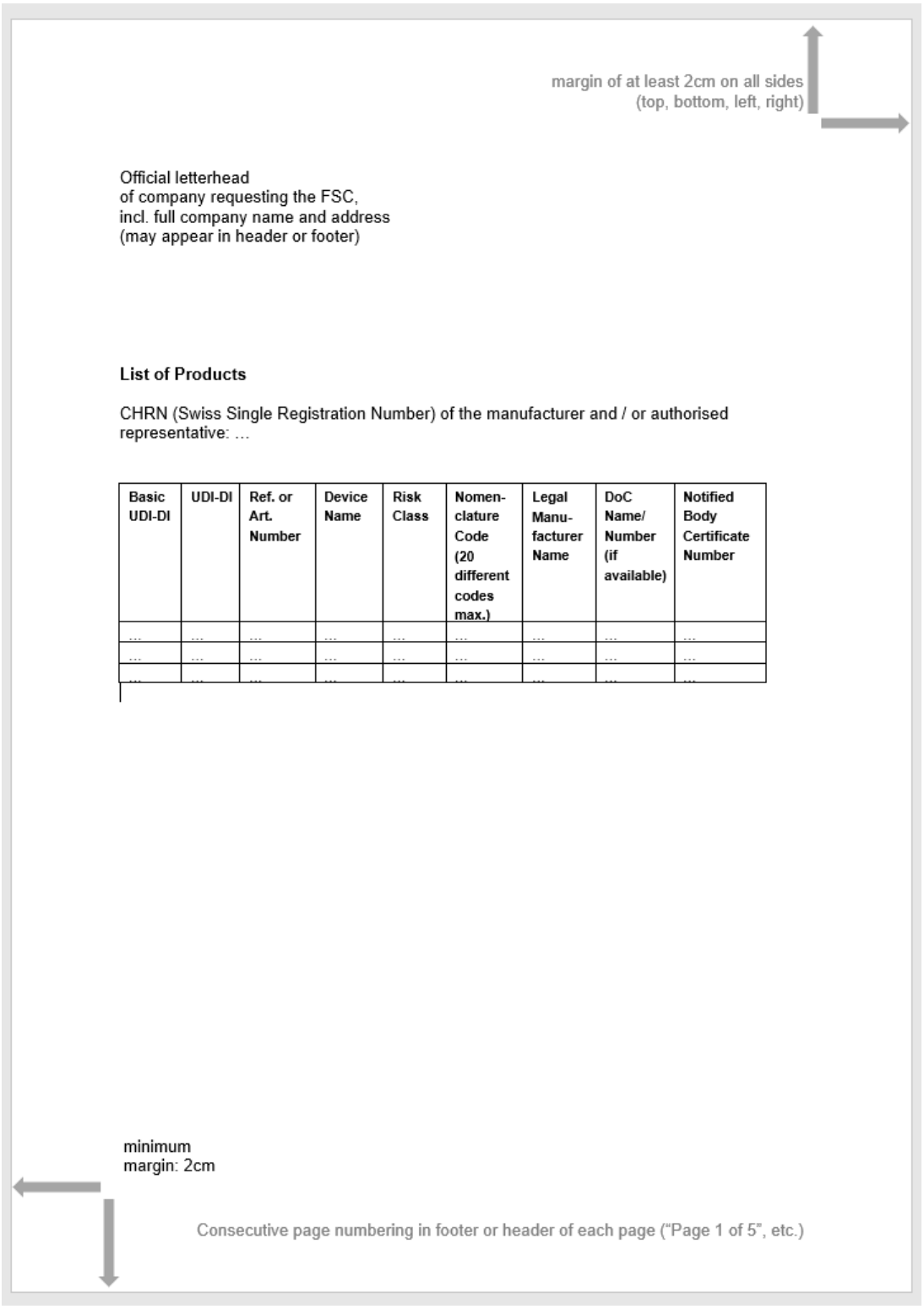
- **pdf format**
- **Formatting: A4, a margin of at least 2 cm (at the top, at the bottom, on the left-hand side, on the right-hand side)**
- **Letterhead** of the requesting company (full company name and address)
- consecutive **page numbering** (e.g. "page 1 of 1", “page 1 of 10", "page 2 of 10" etc.)
- For each device, the information according to the "List of products" section above.

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

Language
The information concerning the medical device group and the product list are to be supplied in **English**.

4.5.1 Example of product list

An example of a product list is shown below.



An example of a product list for systems and procedure packs is shown below.

minimum margin: 2cm on all sides
(top, bottom, left right)

Official letterhead of company requesting the FSC
incl. full company name and address

List of Products (example for systems and procedure packs)

CHRN (Swiss Single Registration Number, as registered in https://www.swissdamed.ch/) of **the person who assembles the systems or procedure packs** (SPP) and/or their authorised representative: ....

SPP						Devices contained in the SPP							
Basic UDI-DI of the SPP	**UDI-DI of the SPP**	**Ref or art. number of the SPP**	**Name of the SPP**	**Risk class of the SPP**	**Nomen-clature code of the SPP (e.g. GMDN, EMDN or other)**	**Names of all devices in the SPP**	**Risk class of each device in the SPP**	**Legal manufacturer of each device in the SPP**	**Certificate number (if applicable) of each device in the SPP**	**DoC number of each device in the SPP**	**Basic UDI-DI of each device in the SPP**	**UDI-DI of each device in the SPP**	**Nomen-clature code of each device in the SPP**
...	...	...	SPP 1 name	...	...	Device 1 name	Risk class device 1	Legal manufacturer device 1	EC certificate device 1	DoC device 1	Basic UDI-DI device 1	UDI-DI device 1	Code device 1
						Device 2 name	Risk class device 2	Legal manufacturer device 2	EC certificate device 2	DoC device 2	Basic UDI-DI device 2	UDI-DI device 2	Code device 2
						Device 3 Name	Risk class device 3	Legal manufacturer device 3	EC certificate device 3	DoC device 3	Basic UDI-DI device 3	UDI-DI device 3	Code device 3
...	...	...	SPP 2 name	...	...	Device 1 name	Risk class device 1	Legal manufacturer device 1	EC certificate device 1	DoC device 1	Basic UDI-DI device 1	UDI-DI device 1	Code device 1
						Device 2 name	Risk class device 2	Legal manufacturer device 2	EC certificate device 2	DoC device 2	Basic UDI-DI device 2	UDI-DI device 2	Code device 2
						Device 3 Name	Risk class device 3	Legal manufacturer device 3	EC certificate device 3	DoC device 3	Basic UDI-DI device 3	UDI-DI device 3	Code device 3

example

minimum margin: 2cm

consecutive numbering on each page:
Page 1 of X

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 Medical Devices under the Old Legislation (Directives 93/42/EEC and 90/385/EEC)

For medical devices under the old legislation, the certificates expired on 26 May 2024 at the latest. In order for these devices to remain marketable, the requirements of the transitional provisions stated in Art. 101 para. 1bis MedDO must be met.
The **plausibility of the conformity of legacy products and the correct application of the transitional periods** can be verified using the following evidence:

- A confirmation letter from the designated / notified body that the manufacturer has submitted an application for a conformity assessment / has signed a written agreement with a designated / notified body (by 26 September 2024 at the latest, see template Team-NB (MDR))

Type of medical device (MD)	Legislation	Class	Declaration of conformity (valid on 25 May 2021)[11]	Certificate of CE conformity
Classical medical devices	Dir. 93/42/EEC	Class I	X	Orders for export certificates for Class I devices under the old legislation without the aforementioned confirmation letter from the Notified Body due to a higher classification according to MDR can no longer be processed.
	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

With regard to the validity of certificates according to the old legislation, please also pay particular attention to our publication "Information sheet obligations economic operators CH".

[11] Declaration of conformity must have been signed **prior to** 26 May 2021 (according to Art. 101 MedDO)

4.6.2 Medical Devices According to Current Legislation (MedDO)

Type of medical device and legislation	Class	Declaration of conformity[12]	Certificate of conformity
Medical device according to MedDO in conjunction with MDR[13]) (Regulation (EU) 2017/745)	Class I	X	---
	Class Im, Ir, Is	X	Annex IX Chapter I and III (EU quality management certificate), *or* Annex XI Part A (EU quality assurance certificate)
	Class IIa	X	Annex IX Chapter I and III (EU quality management certificate) *or* Annex XI Part A (Section 10) (EU quality assurance certificate) *or* Annex XI Part B (Section 18) (EU product verification certificate)
	Class IIb	X	Annex IX Chapter I and III (EU quality management certificate) and – if implantable in accordance with Art. 52 para. 4 MDR – Annex IX Chapter II (EU technical documentation assessment certificate)[14] *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 and III (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)

[12] 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

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

[14] Exception: implantable class IIb devices using well-established technologies (sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)

4.6.3 Special Case: Ordering Export Certificates for Systems and Procedure Packs (Sections 2-4 of the Form)

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

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

Supporting documents to be submitted with the order: The supporting documents according to section 4.6 of this guidance document need to be submitted for the medical devices that are part of the systems and procedure packs. 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. If the systems or procedure packs contain medical devices according to the old legislation, the documents indicated in section 4.6.1 must be submitted.

Furthermore, for each system and each procedure pack, either **a declaration according to Art. 12 of Directive 93/42/EEC** or **a declaration 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 list of products 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.

Order form: Please indicate the address of the **system assembler** in the field “legal manufacturer”.

4.6.4 In Vitro Diagnostic Medical Devices (IVD) According to Old Legislation (Directive 98/79/EC)

With orders for export certificates for IVD devices according to the old legislation, their classification according to the old legislation and the current legislation must be provided (e.g. on the list of products).

For in vitro diagnostic medical devices, the certificates under the old legislation expired on 26 May 2025 at the latest. In order for these devices to remain marketable, the requirements of the transitional provisions stated in Art. 82 para. 1 and 1bis IvDO must be met.
The **plausibility of the conformity of in vitro diagnostic medical devices under the old legislation and the correct application of the transitional periods** can be verified using the following evidence:

- A declaration from the manufacturer that the requirements for placing devices under the old legislation on the market are met (see template Manufacturer's Declaration in relation to Regulation (EU) 2024/1860 - MedTech Europe);
- A confirmation letter from the designated/notified body stating that the manufacturer has submitted an application for a conformity assessment / has signed a written agreement with a designated/notified body (see Team-NB-IVDConfirmationLetterTemplate-V2-20240710.pdf))

An application for a conformity assessment procedure must be completed by:

- 26 May 2025 for old legislation devices with a certificate of conformity and old legislation devices in the "Other" class that now belong to Class D according to IVDR
- 26 May 2026 for old legislation devices in the "Other" class that now belong to Class C according to IVDR
- 26 May 2027 for old legislation devices in the "Other" class that now belong to Classes B or A sterile according to IVDR

The conclusion of the contract for a conformity assessment procedure must be completed by:

- 26 September 2025 for old legislation devices with a certificate of conformity and old legislation devices in the "Other" class that now belong to Class D according to IVDR
- 26 September 2026 for old legislation devices in the "Other" class that now belong to Class C according to IVDR
- 26 September 2027 for old legislation devices in the "Other" class that now belong to Classes B or A sterile according to IVDR

Type of medical device	Legislation	Class	Declaration of conformity (valid on 25 May 2022)[15]	Certificate of EC conformity
Invitro diagnostics (IVD)	Dir. 98/79/EC	Other	X	An export certificate cannot be issued for old legislation devices in the "Other" class that now belong to Class "A" according to IVDR.
	Dir. 98/79/EC	Self-testing	X	Annex III (6), *or* Annex IV excluding (4), *or* Annex V + Annex VI, *or* Annex V + Annex VII (3)
	Dir. 98/79/EC	List B	X	Annex IV excluding (4), *or* Annex V + Annex VI, *or* Annex V + Annex VII (3)
	Dir. 98/79/EC	List A	X	Annex IV excluding (4) + Annex IV (4) *or* Annex V + Annex VII (3) / VII (5)

[15] Declaration of conformity must have been signed **prior to** 26 May 2022 (according to Art. 82 IvDO)

4.6.5 In Vitro Diagnostic Medical Devices (IVD) under the Current Legislation (IvDO)

Type of medical device and legislation	Class	Declaration of conformity[16]	Certificate of conformity
In vitro diagnostic medical devices according to IvDO in conjunction with IVDR[17] (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 Annex IX Chapter II Section 4 (EU technical documentation assessment 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 Annex IX Chapter II Section 4 (EU technical documentation assessment 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 5.1 and 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 and III (EU quality management certificate) and Annex IX Chapter II [excluding Section 5] (EU technical documentation assessment 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 5.1 and 5.2 (EU technical documentation assessment certificate) *or* Annex X (EU type-examination certificate) and Annex XI (EU product quality assurance certificate)

[16] 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

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

4.6.6 Transitional Provisions (Directive – MedDO/IvDO)

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 issuance 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.

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

4.6.7 Notifications

Certain medical devices and in vitro diagnostic medical devices must be notified. MD-DEVIT products in accordance withArt. 1, para. 3 letter c number 2 MedDO and in accordance with Art. 1 para. 3 letter d MedDO are also subject to notification. Details regarding notifications can be found on the «Market access» website. The confirmation of notification does not need to be enclosed with the order for the export certificate.

4.7 Countries of Importation and Number of Certificates (Section 5 of the Form)

In general, 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, these are listed.
If the country of importation is not yet known, as many lines as necessary can be added , stating "unspecified country".

4.7.1 Entity Responsible for Placing on the Market in the Country of Importation (Section 5 of the Form)

The details of the entity responsible for placing on the market in the country of importation must be provided when ordering an export certificate for Algeria, Saudi Arabia, Libya or Turkey. In this case, one export certificate is issued for each entity responsible for placing on the market in the country of importation.

4.7.2 Period of Validity

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

5 Language Used on Export Certificates

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 requesting company 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 submitted are incomplete or incorrect, Swissmedic will not accept the application and will mark the order as closed. 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 [18]. In order to obtain the certificate in this case, a 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[19] specifies the following fees:

- Issue of an export certificate (Art. 4, para. 1 and annex 2 FeeO-Swissmedic): CHF 200 per certificate.
- In accordance with Art. 4 FeeO-Swissmedic (SR 812.214.5), an additional fee will be charged for export certificate orders containing extensive product lists (over 100 pages), due to the additional resources required for processing.
- Swissmedic can reduce the fees if an application cannot be accepted (Art. 8, para. 1 FeeO-Swissmedic).
- If an order is cancelled or an application is withdrawn, a reduced fee of CHF 100 will be charged for the services already provided by Swissmedic (Art. 8 para. 1 FeeO-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 and IVD», go to: www.swissmedic.ch/md-fsc-en.

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

[18] Annex 2 of the Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic; SR 812.214.5)
[19] 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
4.1	Revision of section 3 – Note concerning device registration Revision of section 7 – Cancellation	ler
4.0	Clarification of section 4.6.5 Clarification of the CHRN in section 4.5	lao
3.10	Clarification of the section 4.3, 4.6.2 and 7 Removal DEVIT products	sch
3.9	There are spaces missing in Tables 4.6.1, 4.6.2, 4.6.4, and 4.6.5.	sch
3.8	Correction link	lao
3.7	Clarification of sections 4.5.1, 4.6, 4.6.1, 4.6.2, 4.6.3, 4.6.4, 4.6.5, 4.6.7 Separation of sections relating to medical devices and in vitro diagnostic medical devices	lao
3.6	Clarification of the CHRN in section 4.5 and 4.5.1	sch
3.5	Clarification of the section 4.8	sch
3.4	Clarification of the section 4.6.1 and 4.8	sch
3.3	Clarification of the section 4.6.1	sch
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