swissmedic

Guidance document
Service Agreement Export Certificates MEP

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Service agreement for the issue of Export Certificates

1 General

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

2 Services, entitlements and obligations of the Agency

2.1 Service description

Certain countries do not recognise the European CE conformity marking for medical devices, and, for the purposes of authorisation and distribution, demand an export certificate issued by the competent authority at the registered place of business of the exporting company. The Agency can issue export certificates of this type for manufacturers in Switzerland or authorised representatives (from foreign manufacturer) in Switzerland who wish to export medical devices to third countries[1] on provision of appropriate supporting documentation.

Export certificates (Free Sales Certificates (FSC)) certify the formal conformity of the medical devices in question with the legal requirements in Switzerland and thus their fundamental capacity for being marketed in Switzerland at the time the certificate is issued.

2.2 Delimitation

Export Certificates are issued solely for products that are defined as medical devices[2] under the terms of the Swiss legislation and for which a certificate of conformity is available, making them marketable in Switzerland. The marketability of DEVIT products (devices derived from devitalised human tissue, or which incorporate such tissue) is certified only for Switzerland.

Swissmedic does not issue Export Certificates for veterinary medical devices or products that are defined as medical devices only in the country of destination, e.g. toothbrushes, instruments for dental technicians, general laboratory equipment etc.

The Agency does not contact authorities in Third countries in order to perform its services; this is the responsibility of the exporting persons.

[1] Art. 50 para. 2 of the Federal Act on Medicinal Products and Medical Devices (TPA; SR 812.21)

[2] Definition according to Art. 4 para. 1 let. b TPA

2.3 Services provided by the Agency

2.3.1 Service trigger

Application form completed in full and submitted electronically via the eGov Service “eMessage” (hereafter referred to as the Swissmedic Portal), accompanied by certificates of conformity and a product list.
Applications submitted in paper form will not be accepted.

2.3.2 Scope of service provided

Incoming applications for Export Certificates are captured electronically and checked for form.
The supporting documents required to verify the situation are checked formally for validity. If all the criteria are fulfilled, an Export Certificate is issued.
If the submitted supporting documentation is not sufficient to verify the formal conformity of the medical devices or the existence of a certified quality management system, the application is cancelled.
Export Certificates are issued **in English only**.

2.3.3 Deliverables

The original document (Export Certificate) and attachment (applicant’s product list) are sent to the applicant by post.

2.3.4 Deadlines

The Agency requires a processing time of 30 days from the date on which all the information and documents needed to provide the service are present. The deadline ends after the certificate has been sent to the applicant.

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 [3]. In order to obtain the certificate in this case, a completely new order must be made with all the necessary information and documents.

2.3.5 Validity of Export Certificates

An Export Certificate is issued with a period of validity of three years. Export Certificates for Thailand form an exception; they are valid for five years.

[3] Annex 2 of the Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic; SR 812.214.5)

2.4 Special conditions

In justified cases, the Agency may attach special conditions to the issue of a certificate[4]. For example, it may require additional supporting documents to be submitted, or limit the period of validity of an Export Certificate.

2.4.1 Minimum remaining validity of supporting documents

All documents submitted in support of an application that have a limited period of validity, e.g. EU certificates, must have a **minimum remaining validity of three months** if they are to be accepted by the Agency and an Export Certificate is to be issued with the full period of validity.
If the remaining period of validity of supporting documents with a limited period of validity is **less than three months**, Export Certificates are issued for the full period of validity requested, but **on condition** that a renewed supporting document is submitted to the Agency within 3 months of the currently valid document expiring.
If the new supporting document is not submitted in time, the corresponding Export Certificate will be revoked.

2.5 Revocation of Export Certificates

The Agency revokes an Export Certificate if[5]:

a) it was issued on the basis of false documentation;
b) the devices listed are no longer covered by the necessary declarations of conformity and the corresponding certificates, or if they are subject to an import or export embargoes;
c) the medical devices represent a danger to the health of users, patients or third parties.

If an Export Certificate is revoked by the Agency, the Agency may inform affected Third countries of this revocation.

3 Obligations and responsibility of the beneficiaries

3.1 Authorised applicants

Manufacturers and authorised representatives domiciled in Switzerland[6]. The applicant must also state an invoicing and delivery address in Switzerland.

3.2 Reporting obligation

Relevant changes or events that could affect the use or continued provision of this service, e.g. the restriction or withdrawal of an EU certificate, must be reported to the Agency as soon as the applicant becomes aware of them.

The applicant also undertakes to inform the relevant target countries about the relevant change on its own initiative and, where appropriate, to withdraw Export Certificates that have become invalid.

[4] Art. 50 para. 2 TPA (SR 812.213)

3.3 Agreement of the applicant

By accepting this agreement, the applicant consents to the Agency informing Third countries about Export Certificates that it has issued, without first consulting the applicant and at the Third countries' request, e.g. in order to check their authenticity or validity if there is a suspicion that the certificates are counterfeit.

Non-conformities of medical devices that are discovered during the provision of the service may be reported to the Market Control section of the Division Medical Devices for verification in the frame of the market surveillance activities of the Agency[4] , which may lead to administrative proceedings. If procedure for measures are ongoing, the Agency may issue for example Export Certificates with a limited period of validity or certificates to which special conditions are attached or refuse to delivery of the certificate.

3.4 Responsibility

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

3.5 Formal requirements

In order to make use of the service, the applicant must submit the electronic application form completed in full, including certificates of conformity and, where appropriate, product list, via the Swissmedic Portal. All the formal requirements stated in the guidance document, particularly those referring to the structure and organisation of the certificates and product lists, must be observed in full. If the formal requirements are not complied with, a short deadline is set for improvement. If the formal requirements are not improved or complied with, the application will not be considered and removed from the business directory.

4 Fees/costs

The applicant will be invoiced the flat rate[5] of CHF 200.00 for issuing an Export Certificate[7].

4.1 Corrections

Corrections for which the Agency is responsible will not be charged.
If the applicant subsequently requires changes to be made to an Export Certificate that has been issued correctly by the Agency, the effort required will be charged to the applicant in full.

[4]Art. 58 TPA and Art. 75 ff. of the Medical Devices Ordinance (MedDO; SR 812.213)
[5] Art. 4 para. 1 and Annex 2 of the Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic; SR 812.214.5)
[7] Art. 4 FeeO-Swissmedic
[7]Art. 10 der Allgemeinen Gebührenverordnung (AllgGebV, SR 172.041.1)

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 certificate 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[8].

6 Data protection

The Agency processes data in accordance with the Swiss data protection legislation and the relevant legal standards and protects data generated in the course of handling applications against unauthorized access.

7 Acceptance by the country of destination and exclusion of liability

The Agency is not familiar with the registration requirements in individual countries of destination. The Agency takes the information from the application form, and the applicant therefore bears responsibility for acceptance of the Export Certificate by the country of destination.

In issuing the Export Certificate, the Agency certifies no material conformity (neither the efficacy nor the safety) of the products in question. The Agency is thus not liable for any damage that may arise from their use.

Liability for damage resulting from negligence is excluded (For example that the wrong product name is written on the certificate). 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.

8 Modifications

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.

9 Applicable law and place of jurisdiction

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

10 Final provisions

Modifications of or additions to the agreement must be made in writing. Modifications not made in writing shall be invalid.
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.

Change history

Version	Change	sig
1.4	New layout, no content adjustments to the previous version.	hem
1.3	Point 2.3.4 was made more precise	ler
1.1	Adaptation of the ordering process, deadlines for incomplete applications	ler
1.0	Doc newly created owing to revision of MD regulatory provisions; old doc ID: BW540_00_002f_MB	pej