Information sheet
Derogation MEP

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1 Aim of this information sheet

This information sheet provides information on the options for the placing on the market and putting into service of medical devices[1] in Switzerland, which do not fully comply with the requirements of the Medical Devices Ordinance (MedDO, SR 812.213) / Ordinance on In Vitro Diagnostic Medical Devices (IvDO, SR 812.219).

2 Exemption authorisation for the placing on the market and putting into service of non-conforming medical devices

Any manufacturer that places a device on the market in Switzerland must carry out an assessment of its conformity in accordance with the valid conformity assessment procedure[2] before the device is placed on the market. The manufacturer and importer must be able to prove that such an assessment of conformity has been carried out and that the product is conforming[3]. MedDO and IvDO also specify requirements for the languages of the product information[4].

However, there are certain situations in which, in the interests of public health or patient safety or health, a device is placed on the market and put into service even though the relevant conformity assessment procedure has not been carried out (e.g. because the device has not undergone a complete conformity assessment procedure or the certificate for a device was subsequently declared invalid, etc.), or the language requirements are not met. In such cases Swissmedic, as the competent authority, may grant an authorisation on the basis of Art. 22 para. 1 MedDO / Art 18 para. 1 IvDO, subject to a corresponding justified application and after checking the facts.

[1] In vitro diagnostic medical devices are classed as a subgroup of medical devices (Art. 3. para. 1 and 2 MedDO and Art. 3 para. 1 IvDO). Therefore, provisions that apply separately to IVD are referred to explicitly as such in this information sheet.
[2] Art. 23 MedDO / Art. 19 IvDO
[3] Art. 21 para. 2 MedDO / Art 17 para. 2 IvDO
[4] Art. 16 para. 2 and 3 MedDO / Art 15 para. 2 IvDV

2.1 Requirements to be met by the applicant

An application for an exemption authorisation can be submitted by anyone who is responsible for placing the device on the market – or putting it into service – in Switzerland and who is prepared to accept the corresponding obligations (see para. 2.2 of this information sheet).

The applicant must be based in Switzerland. Any of the following parties based in Switzerland, for example, can apply for an exemption authorisation:

- Manufacturer[5]
- Authorised representative[6]
- Importer[7]
- Distributor[8]

2.2 Responsibilities of the applicant

MedDO and IvDO specify obligations for the placing on the market and putting into service of medical devices. These include the following:

- Devices that are made available on the market or put into service must satisfy the general safety and performance requirements specified in Annex I of EU-MDR[9] (Art. 6 para. 2 MedDO) / Annex I of EU-IVDR[10] (Art. 6 para. 2 IvDO).
  The applicant also remains responsible for the performance and safety of the devices at all times, and must be able to provide the required evidence.
- The applicant must fulfil its responsibility in respect of its obligation to report incidents and hazards connected with the devices (Art. 51 para. 3 MedDO, Art. 53 para. 4 MedDO, Art. 54 para. 4 MedDO, Art. 66 MedDO / Art. 44 para. 3 IvDO, Art. 46 para. 4 IvDO, Art. 47 para. 4 IvDO, Art. 59 IvDO).
- If the applicant is a manufacturer, according to Art. 56 MedDO / Art. 49 IvDO it must maintain a post-market surveillance system so that information about the safety, quality and performance of its medical devices during use can be collated and analysed. On the basis of this information, it must be possible to identify any problems and implement required corrective or safety actions (Art. 57 para. 2 MedDO / Art. 50 para. 2 IvDO).
- The applicant shall co-operate with the other economic operators (manufacturer, authorised representative, importer, distributor) to achieve an appropriate level of traceability of devices (Art. 64 para. 1 MedDO / Art. 57 para. 1 IvDV).

2.3 Requirements for applying for an exemption

The application submitted must include the following information:

1. Details of the applicant: name of company, address, contact person.
2. Details of any role(s) held by the applicant as economic operator with regard to the devices to be exempted.

[5] Art. 4 para. 1 let. f MedDO / Art. 4 para. 1 let. e IvDO
[6] Art. 4 para. 1 let. g MedDO / Art. 4 para. 1 let. f IvDO
[7] Art. 4 para. 1 let. h MedDO / Art. 4 para. 1 let. g IvDO
[8] Art. 4 para. 1 let. i MedDO / Art. 4 para. 1 let. h IvDO
[9] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
[10] 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, OJ L 117 of 5.5.2017, p. 176; most recently amended by Regulation (EU) 2022/112 OJ L 19 of 28.1.2022, p. 3.

3. Details of the manufacturer (name, address).
4. Description of the device, incl. figures, model types, usage, intended purposes (according to manufacturer information), defined user group and intended patient population.
5. Instructions for use (IFU).
6. Justification as to why the conformity assessment procedure has not been completed.
7. Details, including proof, of the planned completion of the conformity assessment procedure.
8. Evaluation of potential alternative devices and/or therapeutic procedures **in Switzerland**, taking into account the use of the device/therapeutic procedure according to current scientific and technological standards.
9. Justification, including proof, as to why no other conforming device/therapeutic procedure can be used.
10. Justification as to why the placing on the market and putting into service of the devices are in the interests of public health or patient safety or health.
11. Number of devices placed on the Swiss market each year in the last 3 years (in the case of different devices: number per year for each device).
12. Estimated number of devices expected to be to be placed on the Swiss market under the exception authorisation (in the case of different devices: number for each device).
13. List of customer for the device(s) in question.
14. Proof of the benefit-risk analysis, including information on known or foreseeable risks, adverse reactions, contraindications and warning and the conclusions drawn therefrom.
15. Proof that the devices satisfy the general safety and performance requirements (e.g. “general safety and performance requirements checklist”) taking into account their intended purpose. Individual exceptions must be justified.

If no information is available on individual points (nos. 1–12), clear justification should be submitted in each case.

It should be noted that the evaluation of the application by Swissmedic will be delayed if full documentation and proof are not submitted. Swissmedic reserves the right to request further information and proof while processing the application.

2.4 Fees

Swissmedic charges fees for its administrative activities in accordance with Art. 65 para. 1 of the Therapeutic Products Act (TPA; SR 812.21) and Art. 1 and Art. 3 para. 1 of the Ordinance of the Swiss Agency for Therapeutic Products on its fees (GebV-Swissmedic; SR 812.214.5). The hourly rate for the time-based fees is CHF 200.00 in accordance with Art. 4, para. 2 GebV-Swissmedic.

3 Placing on the market and using medical devices without a valid certificate in an individual case without an exemption authorisation from Swissmedic

Art. 22 para. 2 MedDO and Art 18 para. 2 IvDO permit the placing on the market and use of individual devices without valid certificates **in an individual case** if all the conditions stated in Art. 22 para. 2 MedDO / Art 18 para. 2 IvDO are fulfilled:

a) the devices serve to avert life-threatening conditions or to resolve the permanent impairment of a bodily function or, in the case of in vitro diagnostic medical devices (IVD), are used to test samples with the aim of averting or treating life-threatening conditions or permanent impairments of a body function;

b) no conforming device is available for a specific intended purpose;

c) they are used by healthcare professionals on individual persons only or are used exclusively in the laboratory to investigate samples from an individual person (IVD);

d) the healthcare professional using the device or providing treatment (for IVD) has informed the individual person concerned about the non-conformity of the medical device and the related risks; and

e) the individual person concerned has consented to the use of the device.

The decision to use a product without proof of conformity must be made after assessing the benefits and risks associated with the specific case. An authorisation from Swissmedic is not needed in such cases.

Restricting the exemption to the placing on the market and use of the device is designed to highlight the fact that such devices are not allowed to be traded and made more widely available on the market. The exemption is intended to benefit only the manufacturer or importer that makes the devices available to the user for the first time, as well as the users themselves. The group of individuals that may use the device is restricted to healthcare professionals as defined Art. 2 para. 1 of the Federal Act on University Courses for Medical Professions (Medical Professions Act, MedPA; SR 811.11).

In order to demonstrate compliance with the provisions of Art. 22 para. 2 MedDO / Art 18 para. 2 IvDO, the responsible healthcare professional must record the evidence for compliance with the aforementioned preconditions a) – e) and retain the corresponding documentation.

4 Contact

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Change history

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2.0	Amendments due to entry into force of IvDO	mea
1.1	Insertion of section 2.3 V1.1 in German is valid as of 08.04.2022	mea
1.0	Document newly created owing to revision of MD regulatory provisions; old doc ID: BW617_00_004e_MB Authorisations for non-conforming medical devices	mea