1 Purpose and objective of this fact sheet

This fact sheet gives an overview of the registration process for in vitro diagnostics (IVDs). Please note that the information provided might be incomplete. It is therefore well suited to refer to the relevant legislation.

On January 1rst 2002 the regulations for IVDs compatible with the legal requirements in the European Union came into force in Switzerland. The applicable legal requirements are laid down in the Federal Law on Medicinal Products and Medical Devices[1], and the revised Ordinance on Medical Devices[2]. IVDs are medical devices. Before their placement on the market, IVDs must comply with the essential requirements of the European Directive on In Vitro Diagnostics[3] and have undergone an evaluation of compliance process foreseen therein. The European CE label or the Swiss MD label (only for Switzerland) constitute the compliancy marks. In addition IVDs first placed on the market must be notified to the competent authorities according to Art. 6 Par. 2 MedDO at the latest at the time they are first placed on the market (see point 4).

2 Who has to register where?

The regulations laid down in Directive 98/79/EC principally also apply for Switzerland. Any individual or organization (legal entity) placing an IVD on the market or in a treaty country[4] for the first time is subject to mandatory registration. In the European context, the country in which the manufacturer placing the device on the market for the first time has its registered offices must be taken into account.

Mandatory registration is primarily with the competent authorities of each treaty country in which the legal entity placing the medical device on the market for the first time has its registered offices. Manufacturers who have their registered offices neither in Switzerland nor in a treaty country must designate an authorised representative in the EC or EFTA countries or in Turkey, who handles the mandatory registrations with the respective competent authority.

There are two basic possibilities with regard to the country where the legal entity who puts an IVD for the first time on the market has its place of business:

2.1 The legal entity who places an IVD on the market for the first time has his registered offices in Switzerland

Those placing IVDs on the market for the first time as manufacturers or their representatives and whose registered offices are in Switzerland are required to register with Swissmedic. The originals of the standardized registrations forms and any other necessary documentation must be provided to Swissmedic (see point 3). Mandatory registration with Swissmedic is also required if the product is only distributed in the treaty companies.

2.2 The legal entity who places an IVD on the market for the first time doesn't have his registered offices in Switzerland

Those placing IVDs on the market and whose registered offices are not in Switzerland are primarily required to register with the competent authorities of the country in which they, as manufacturers, or their representatives, have registered offices. The originals of the registration forms must be sent to the said competent authorities when IVDs are placed on the market for the first time. Example: The manufacturer of the IVD who has its registered office in an Asian country and his authorised representative in France has to notify the French authorities. In this case, the manufacturer will not notify Swissmedic.

[1] Law on therapeutic products of 15 December 2000; HMG, SR 812.21
[2] Ordinance on medical devices of 17 October 2001; MedDO, SR 812.213
[3] Directive 98/79/EC of the European parliament and of the council on in vitro diagnostic medical devices
[4] Treaty countries are those countries with which Switzerland has ratified an agreement on the mutual recognition of the respective conformity assessments and their procedure (EC and EFTA countries).

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3 Which products must be registered, which documents must be submitted to Swissmedic?

IVDs that are to be placed on the market for the first time must be registered. The registration must be in one of the official Swiss languages (French, German, Italian) or in English.

The forms listed are standardized on a European level. They can be downloaded from the Medical device tab of the Swissmedic website: www.swissmedic.ch/md_market_access (> Notification of IVD medical devices).

Swissmedic must be notified once a year of any changes to the information registered. For these notifications the same forms must be used as those for the original registrations.

Swissmedic reserves the right to request additional information if the data submitted in the registration documentation are not complete.

3.1 IVDs according to Annex II of the Directive 98/79/EC and IVDs for self-testing

IVDs according to Annex II (Lists A and B) of the Directive 98/79/EC and IVDs for self-testing must be registered individually and with detailed information. A separate registration is requested for each product. The following documents must be submitted to Swissmedic:

- *"Form for the registration of manufacturers and devices, In Vitro Diagnostic Medical Devices Directive, Art. 10";*
- *"Form for the registration of information relating to the certification of in vitro diagnostic medical devices (Annexes III to VII), In Vitro Diagnostic Medical Devices Directive ";*
- the certificates regarding the conformity assessment procedures performed (EC-certificates); and
- the instructions for use as well as — in case of an IVD for self-testing — the layout of the external packaging

3.2 "Other" IVDs

All other products may be registered individually or as product groups: In addition, the following form must be submitted to Swissmedic:

- *"Form for the registration of manufacturers and devices according to Directive 98/79/EC on in vitro diagnostic medical devices, Art. 10".*

3.3 IVDs manufactured in house

IVDs manufactured in house are medical devices that are developed and produced by a laboratory and only intended for its own use (Art. 3 Para. 1, Let. bbis MedDO).

The document "Information sheet for in house IVD manufacturers" is a comprehensive description of the requirements regarding in-house manufacturers of IVDs. It can be downloaded from the Medical device tab of the Swissmedic website: www.swissmedic.ch/md_market_access (> Notification of IVD medical devices).

In accordance with Art. 6 Para. 2 Let. a of the revised MedDO, mandatory registration consists of the following:

For IVDs manufactured in house, registration is only required in the case that the item is a medical device in accordance with Annex II (List A and List B) to Directive 98/79/Executive Committee. For List A medical devices, a confirmation of accreditation, licensing or recognition must be provided in addition to the documents specified in Art. 6 Para. 2, Let. c MedDO if:

a) the manufacturer is a designated national reference laboratory or a laboratory with an equivalent qualification, and

b) no common technical specifications exist for the medical device concerned.

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The registration form “Notification form for an in-vitro diagnostic device (IVD) manufactured in house” can be downloaded from the Medical device tab of the Swissmedic website: www.swissmedic.ch/md_market_access (> Notification of IVD medical devices).

4 When must be registered?

IVDs must be registered with Swissmedic at the latest at the time they are first placed on the market. This first placing on the market means the first making available in return for payment or free of charge of a device other than a device intended for performance evaluation with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished.

5 Contact

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Change history

Version	Valid and binding as of:	Modified without version change	Description, comments (by author)	Author’s initials
02	**29.06.17**		**Cancel the word „new“ in the first chapter.**	**ans**
01	**28.11.16**		**New QM ident: BW530_00_002e_MB** **Old QM ident: MU107_00_002e_MB** **Link corrected** **The remaining content of the document was not reviewed and stays unchanged.**	**wkn**
01	**08.04.15**		**New document**	**dsa**