swissmedic

Information sheet

FAQ on in vitro diagnostic medical device notifications

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1 Which in vitro diagnostic medical devices must be notified to Swissmedic and by whom?

- In vitro diagnostic medical devices (IVDs) according to IVDR[1] that are placed on the market in Switzerland for the first time by manufacturers must, according to Art. 90 para. 1 IvDO[2] in conjunction with Art. 6 oMedDO[3], be notified to Swissmedic.
  The notification obligation applies only to manufacturers based in Switzerland. Swiss authorised representatives are not subject to the notification obligation according to Art. 90 IvDO.
- According to Art. 46 and Art. 47 IvDO, repackaged or relabelled devices must be notified to Swissmedic.
  The notification obligation applies to persons (importers and distributors) domiciled in Switzerland.
- According to Art. 10 IvDO, IVDs that are manufactured and used in healthcare institutions (in-house IVDs) must be notified to Swissmedic.
  The notification obligation applies to healthcare institutions in Switzerland before the IVDs are put into service.

For the notification of medical devices and products containing devitalised human tissue, please refer to the following websites: Notification of medical devices (swissmedic.ch) and Notification of devitalised human tissue (swissmedic.ch)

2 Should in vitro diagnostic medical devices from a manufacturer in the EU/EEA be notified to Swissmedic if they are placed on the market in Switzerland?

No. IVDs from a manufacturer in the EU or European Economic Area do not need to be notified in Switzerland, see Art. 90 para. 1 IvDO. However, the IVDs must be compliant. Where the manufacturer of an IVD is not domiciled in Switzerland, the IVD may only be placed on the

[1] 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
[2] Ordinance of 4 May 2022 on In Vitro Diagnostic Medical Devices (SR 812.219)
[3] Medical Devices Ordinance of 17 October 2001 (SR 812.213)

market in Switzerland if it has authorised a person domiciled in Switzerland (Art. 44 para. 1 IvDO).

3 Should in vitro diagnostic medical devices from third countries (outside the EU/EEA) be notified to Swissmedic?

No. IVDs from a manufacturer from a third country do not need to be notified in Switzerland, see Art. 90 para. 1 IvDO. However, the IVDs must be compliant. Where the manufacturer of an IVD is not domiciled in Switzerland, its IVD may only be placed on the market in Switzerland if it has authorised a person domiciled in Switzerland (Art. 44 para. 1 IvDO).

4 Do devices that have been placed on the market and notified according to Art. 6 para. 2 oMedDO on the basis of IVDD[4] need to be notified to Swissmedic again if these devices are newly placed on the market according to IVDR?

Yes. IVDD devices that were notified to Swissmedic according to Art. 6 oMedDO and that now satisfy the requirements of IVDR must be renotified to Swissmedic.

5 Do devices that satisfy the requirements of IVDR and that were already notified as IVDR devices according to Art. 6 para. 2 oMedDO need to be notified to Swissmedic again?

No. An in vitro diagnostic medical device that was notified as an IVDR device before 26 May 2022 does not need to be notified again according to Art. 90 para. 1 IvDO.

6 Does a manufacturer that has already placed IVDR devices on the market before 26 May 2022, but has not yet notified these, still need to notify these devices to Swissmedic?

Yes. If these IVDR devices continue to be marketed, the manufacturer must notify these to Swissmedic according to Art. 90 para. 1 IvDO.

7 Can an IVDD device still be notified after 26 May 2022?

No. After 26 May 2022, IVDD devices can no longer be notified.

[4] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

8 Can a notification of change for a notified IVDD device be submitted after 26 May 2022?

No. Significant changes to IVDD devices are no longer possible after 26 May 2022.

9 Does a manufacturer domiciled in Switzerland and that has already placed IVDD devices on the market need to notify a change of address?

Yes. Swiss manufacturers must report changes of address to notifications.devices@swissmedic.ch unless the changed address has been registered according to Art. 48 IvDO.

10 Does notification according to Art. 90 para. 1 IvDO satisfy the registration obligation stipulated in Art. 16 and Art. 48 IvDO?

No. The notification according to Art. 90 para. 1 IvDO does not replace the obligation to register in vitro diagnostic medical devices in accordance with Art. 16 para. 5 IvDO (after this article enters into force) or the obligation to register in accordance with Art. 48 IvDO (registration of manufacturer, authorised representative and importer). According to Art. 90 para. 2 IvDO, in vitro diagnostic medical devices must be registered at the latest by six months after the entry into force of Art. 16 para. 5 IvDO.

11 Do in-house IVDs that have already been notified at an earlier date according to Art. 6 para. 2bis oMedDO need to be notified to Swissmedic again if these in-house IVDs are newly put into service according to IvDO?

Yes. In-house IVDs that were notified to Swissmedic at an earlier date according to Art. 6 para. 2bis oMedDO and that now satisfy the requirements of IvDO need to be renotified to Swissmedic according to Art. 10 IvDO.

12 Can a healthcare institution still notify an in-house IVD according to Art. 6 para. 2bis oMedDO after 26 May 2022?

No. After 26 May 2022, in-house IVDs can no longer be notified according to Art. 6 para. 2bis oMedDO. However, for healthcare institutions that manufacture and put into service in-house IVDs based on IvDO, the IvDO defines transitional periods relating to the fulfilment of the requirements and the notification obligation.

13 When do the requirements specified in Art. 9 IvDO start to apply for in-house IVDs?

According to Art. 83 IvDO, the relevant requirements apply from the following dates:

a) the requirements set out in Art. 5 para. 5 let. b, c and e-i IVDR: from 26 May 2024

b) the requirements set out in Art. 5 para. 5 let. d IVDR: from 26 May 2028

c) the requirements set out in Art. 5 para. 5 let. a IVDR are applicable from 26 May 2022.

14 By when do in-house IVDs need to be notified to Swissmedic according to Art. 10 IvDO?

According to Art. 90 para. 3 IvDO, the notification obligation for in-house IVDs apply from the following dates:

a) for class D in-house IVDs: from 1 July 2024

b) for class B and C in-house IVDs: from 1 January 2025

c) for class A in-house IVDs: from 1 July 2025

15 What is the procedure for completing the notification form for in-house IVDs?

What follows is a proposal for a possible procedure for completing the notification form:

1. Specify the test for which the in-house IVD is used (the list of tests[5] can be consulted as a guide)
2. Check which EMDN code (https://webgate.ec.europa.eu/dyna2/emdn/) can be used to code this test (IVDs are coded under the letter W)
3. Classify the test (Class A, B, C, or D; according to the Classification rules in Annex VIII IVDR). MDCG 2020-16 can be consulted to help with the classification (Guidance - MDCG endorsed documents and other guidance (europa.eu))
4. Decide whether an individual or joint notification is to be submitted. A joint notification is possible if several tests have the same classification and the same EMDN code.
5. When completing the notification form and providing details of the device, first state whether an individual device notification or joint notification is involved.
6. State the EMDN code in the notification form (when submitting a joint notification, make use of the option to enter a non-terminal EMDN code; the minimum length of the EMDN code is specified in the notification form)
7. State the classification of the device in the notification form
8. Complete the rest of the notification form

Example: The healthcare institution has developed its own method for the qualitative detection of *Chlamydia trachomatis* serotypes in genital swabs by PCR. Various reagents (e.g. Mastermix,

[5] List of tests according to Art. 52 para. 1 let. a no. 1 of the Federal Act of 18 March 1994 on Health Insurance (SR 832.10)

controls, etc.), the individual steps of the test method and the calculation of the results were developed by the laboratory itself. The detection method is implemented on a standard commercial PCR instrument.

The proposed procedure for completing the notification form for this example:

1. This method can be considered as a test (a corresponding position can be assigned in the list of tests)
2. This test can be coded with the EMDN code W0105010117
3. Classify the test, e.g.: Class C
4. A joint notification can be submitted for all tests in Class C and with an EMDN code of W0105010117, W01050101 or W010501.
5. State in the notification form whether the notification concerns an individual device or is a joint notification
6. Enter the EMDN code W0105010117 in the notification form (for a joint notification make use of the option to enter an EMDN code W01050101 or W010501)
7. Enter the classification, e.g.: C
   Enter classification rule no., e.g.: 3c
8. Complete the rest of the notification form (and Excel list for a joint notification), e.g.:
   - Generic name (term name acc. to EMDN), e.g. for EMDN code W0105010117: *Chlamydia trachomatis* detection by NA reagents
   - Intended use: Qualitative detection of *Chlamydia trachomatis* serotypes in genital swabs by PCR

Additional note on this example: The PCR instrument, individual reagents and any software used in this test method to detect *Chlamydia trachomatis* by PCR are included in this type of notification and do not need to be notified separately.

16 As stated in the notification form for in-house IVDs, the declaration according to Art. 5 para. 5 let. f of Regulation (EU) 2017/746 on in vitro diagnostic medical devices needs to be submitted: what is this declaration and how should it be drawn up?

In the declaration according to Art. 5 para. 5 let. f IVDR, the healthcare institution declares that the in-house IVDs meet the general safety and performance requirements set out in Annex I IVDR. The declaration is drawn up by the healthcare institution and signed by the responsible person of the healthcare institution.

The declaration according to Art. 5 para. 5 let. f IVDR includes the following:

i) the name and address of the healthcare institution that manufactures the in-house IVDs;
ii) the details necessary to identify the in-house IVDs;
iii) the declaration that the in-house IVDs meet the general safety and performance requirements set out in Annex I of Regulation (EU) 2017/746 on in vitro diagnostic medical devices and, where applicable, information on which requirements are not fully met, together with a reasoned justification therefor;

Annex A of the document MDCG 2023-1 (Guidance - MDCG endorsed documents and other guidance (europa.eu)) provides a template for the declaration according to Art. 5 para. 5 let f IVDR.

A copy of the signed declaration according to Art. 5 para. 5 let. f IVDR should be submitted, together with the completed notification form.

17 Who has access to Eudamed?

The link https://ec.europa.eu/tools/eudamed/#/screen/home leads to Eudamed. All entries relating to manufacturers and in vitro diagnostic medical devices in Eudamed are made by the company.

18 Where can a device code be obtained (EMDN/GMDN)?

The new EMDN nomenclature is issued by the European Commission:
https://webgate.ec.europa.eu/dyna2/emdn/
The GMDN codes are issued by the GMDN Agency (www.gmdnagency.org).

19 Does the device code (EMDN/GMDN) absolutely have to be stated in the notification?

Yes. The device code (EMDN or GMDN) is required for a notification according to Art. 90, Art. 46 and Art. 47 as well as Art. 10 IvDO.

20 How much does a notification cost?

A fee is charged (CHF 300 per notification) for all notifications according to Art. 10, Art. 46 and Art. 47 as well as Art. 90 IvDO. A fee is not charged for changes to a notification.

A notification form must be completed for each in vitro diagnostic medical device or each group of in vitro diagnostic medical devices. The respective notification form shows whether several in vitro diagnostic medical devices can be notified as a device group in a joint notification, and for which joint notifications a device list needs to be submitted.

21 Does a CHRN need to be applied for before a notification is submitted?

No, although economic operators must register for a CHRN within three months of placing an in vitro diagnostic medical device on the Swiss market for the first time.

The registration obligation of economic operators is processed by Swissmedic independently of the notification obligation for in vitro diagnostic medical devices. Please proceed according to the corresponding requirements and take into account any transitional periods.

22 How long does it take to process a notification?

Processing a notification takes approximately one month from receipt. This assumes that the notification contains all the necessary information and documentation. However, the statutory notification obligation is fulfilled with the submission of the notification.

23 When must a notification of change be submitted?

Changes only need to be notified to Swissmedic if the name or address of the economic operators, the intended purpose, qualification, classification, the details of certificates (EC certificates), the details of performance or name of the in vitro diagnostic medical device changes, or if a submitted device list changes in respect of the intended purpose, qualification, classification or name of one or more in vitro diagnostic medical devices.

24 Fees

The ordinance of the Swiss Agency for Therapeutic Products on its fees (GebV-Swissmedic) specifies the following fees:

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 a notification after work has already been carried out, requests for information or the correction of a notification as a result of a mistake made by the notifying company.

Please note that, as the supervisory authority for medical devices and in vitro diagnostic medical devices, Swissmedic does not provide any advice regarding the development, qualification, classification, registration, certification or placing on the market of medical devices or in vitro diagnostic medical devices. Please contact a private consultant directly for such advice.