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20 Jahre 2002 - 2022

In-house IVD

Requirements for devices and obligations of healthcare institutions

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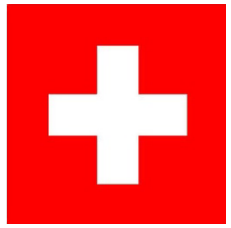
Overview of applicable legislation



TPA
Therapeutic Products Act

EpidA
Epidemics Act

HRA
Human Research Act

HGTA
Federal Act on Human Genetic Testing

TBA
Federal Act on Technical Barriers to Trade

MedDO
Medical Devices Ordinance

IvDO
Ordinance on In Vitro Diagnostic Medical Devices

Ordinance on Microbiology Laboratories

ClinO
Clinical Trials Ordinance

ClinO-MD
Ordinance on Clinical Trials with Medical Devices

HGTO
Ordinance on the Genetic Testing of Human Beings

AccDO
Accreditation and Designation Ordinance

EU MDR
Regulation (EU) 2017/745 on medical devices

EU IVDR
Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Cantonal provisions

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What is an IVD?

- Art. 3 IvDO
- (Simplified) definition:

  In vitro diagnostic medical device (IVD) = Medical device that generates medical information ***in vitro*** from specimens taken from humans

Specimen → 

→ Medical information

Disclaimer

- *The applicable provisions of the Ordinance on In Vitro Diagnostic Medical Devices (IvDO; SR 812.219) have been generalised for the purposes of this presentation.*
- *The current legal provisions apply in all cases.*
- *Specific cases are not covered by this presentation.*

What are in-house IVDs?

- Devices manufactured and used in healthcare institutions
- Designates devices according to Art. 9 IvDO and Art. 5 para. 5 EU IVDR
- Art. 9 IvDO:
  - Devices that are **manufactured and used solely within** healthcare institutions
    - Devices: In vitro diagnostic medical devices and associated accessories
    - **Healthcare institutions** comprise **hospitals** and **laboratories**
- In-house IVDs are also known as laboratory-developed tests (LDTs)
- General term; not used in this form in laws and ordinances
- MDCG 2022-10:
  - In-house IVD: IVD manufactured and used within the same health institution as outlined in IVDR Article 5 (5).

Examples of in-house IVDs

- Analytical tests developed for medical purposes by a healthcare institution
  - A PCR test for detecting a particular analyte
- Standard analytical medical tests that use an institution’s proprietary devices (e.g. reagents that are not CE-marked)
- IVD test equipment manufactured in-house
- IVD software developed in-house

Examples of devices that are not IVDs

- Test procedures with CE-marked IVDs that are implemented according to the directions of the IVD manufacturers
- Products for general laboratory use
- Products intended for research use only

In-house IVDs

- Are deemed to have been put into service
- But are not deemed to have been placed on the market
- May not be supplied to any other legally autonomous entity
- May not be produced on an industrial scale

Requirements for in-house IVDs

The following requirements must be fulfilled (Art. 9 and 10 IvDO):

- The relevant general safety and performance requirements according to Annex I of EU IVDR
- The requirements set out in Art. 5 para. 5 EU IVDR
- In-house IVDs have to be notified to Swissmedic before they are put into service

Other requirements of EU IVDR do not have to be fulfilled.

That means, for example:

- Certification by a designated body is not required
- A UDI does not have to be assigned and affixed to the device
- In-house IVDs may not carry a conformity marking

Obligations of healthcare institutions 1/3

Art. 5 para. 5 EU IVDR

a. Devices must not be supplied to any other legally autonomous entity

b. Devices must be **manufactured** and **used** under appropriate quality management systems

c. The healthcare institution's laboratory must comply with EN ISO 15189 or national provisions, including national accreditation provisions

d. Written evidence that no equivalent device is on the market must be provided

e. Healthcare institutions must provide information upon request on the use of such devices to the competent authority

Art. 83 IvDO => applicable from: **26 May 2022** **26 May 2024** **26 May 2028**

Obligations of healthcare institutions 2/3

f. Healthcare institutions must produce a **publicly accessible declaration** showing:
   i. Name and address of the healthcare institution
   ii. Identifying details for the in-house IVD
   iii. Declaration that the in-house IVD fulfils the general safety and performance requirements. => Any requirements that are not fulfilled must be identified and reasons for non-compliance must be given.

g. Healthcare institutions must produce detailed documents that facilitate understanding of the manufacturing facility, manufacturing process, device design and performance data, including intended purpose.
   - Documents must demonstrate that the general safety and performance requirements are fulfilled

Art. 83 IvDO => applicable from: **26 May 2022** **26 May 2024** **26 May 2028**

Obligations of healthcare institutions 3/3

h. All necessary steps must be taken to ensure that all devices are manufactured in compliance with the documents referred to in **g** above

i. Experience gained while using the device in clinical practice must be assessed and all necessary corrective actions must be implemented

Art. 83 IvDO => applicable from: **26 May 2022** **26 May 2024** **26 May 2028**

Further obligations of healthcare institutions 1/3

Vigilance Art. 59 and 60 IvDO

- “Any **professional** who becomes aware of a **serious incident** when using devices must **report** this to **Swissmedic**” Art. 59 para. 4 IvDO
- “Hospitals must set up an internal reporting system within the framework of an established quality management system for the purpose of reporting under Article 59 paragraph 4 IvDO” Art. 60 para. 1 IvDO.

Maintenance Art. 64 IvDO

- “Any professional using devices must ensure that the devices are maintained and tested in accordance with the regulations” Art. 64 para. 1 IvDO

Cyber security Art. 65 IvDO

- “Healthcare institutions must put in place all technical and organisational resources required by the state of the art to ensure that network-compatible devices are protected against electronic attack and unauthorised access” Art.65 para. 1 IvDO.
- “Hospitals must identify, evaluate and document the measures taken under paragraph 1 in accordance with the principles of a risk management system. This system forms an integral **part of the hospitals' quality management system**” Art. 65 para. 2 IvDO.

Market surveillance

- Principle is defined in Art. 66 IvDO
- Responsibilities according to Art. 69 IvDO
  - Swissmedic is responsible for **monitoring**:
    a. devices and **device conformity**;
    b. vigilance;
    c. the maintenance of devices that are intended for use in hospitals.
  - The Cantons are responsible for monitoring:
    a. .. ;
    b. the maintenance of devices by the professionals using them and in healthcare institutions with the exception of hospitals.

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Note:

- The Cantons are generally responsible for monitoring compliance with cantonal provisions
- Enforcement of EpidA/Ordinance on Microbiology Laboratories => Authorisation by Swissmedic
- Enforcement of HGTA/HGTO (laboratories conducting genetic testing) => Responsibility of FOPH, Swissmedic conducts inspections in a supporting role

Notification requirement in accordance with Art. 10 IvDO

In-house IVDs have to be notified to Swissmedic before they are put into service.
The notification requirement for in-house IVDs applies from the following dates (Art. 90 para. 3 IvDO):

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

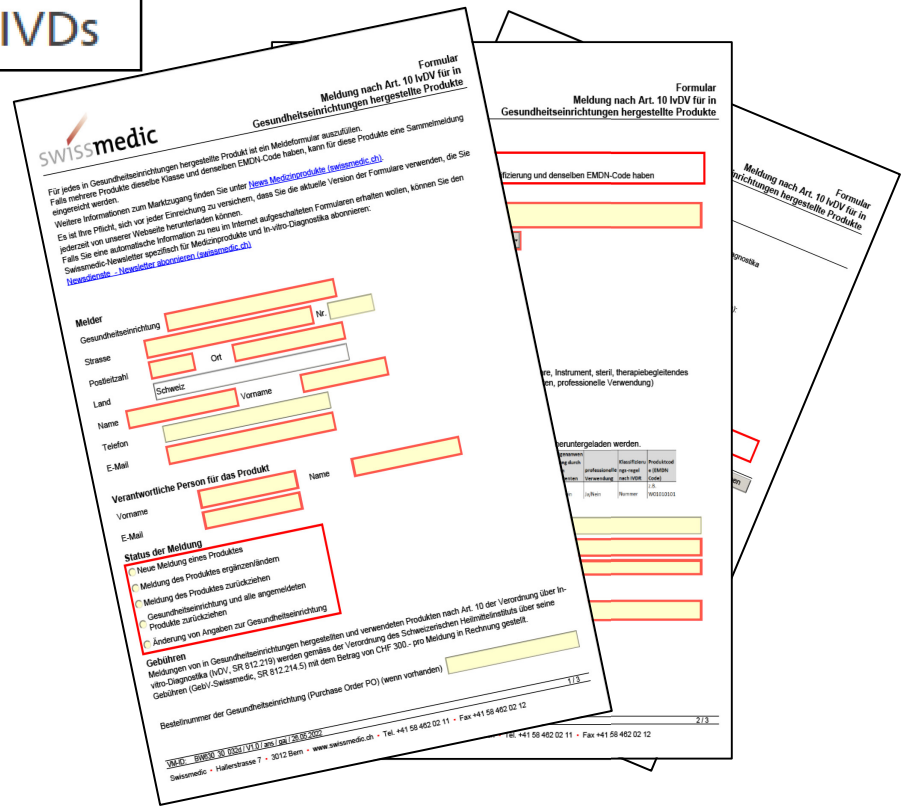
b) for class B and C in-house IVDs: from 1 January 2025

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

How should in-house IVDs be notified?

Forms available on Swissmedic's website www.swissmedic.ch

Home › Medical devices › Market access › Notification of IVDs



The following form must be sent to Swissmedic:

PDF BW630_30_032e FO Notification form acc. to Art. 10 IvDO for an in-vitro diagnostic medical device (IVD) manufactured in house (PDF, 2 MB, 26.05.2022)

The product list template for notifying a device group can be downloaded here:

Product list template Art. 10 IvDO (XLSX, 11 kB, 26.05.2022)

What are the main details that have to be provided?

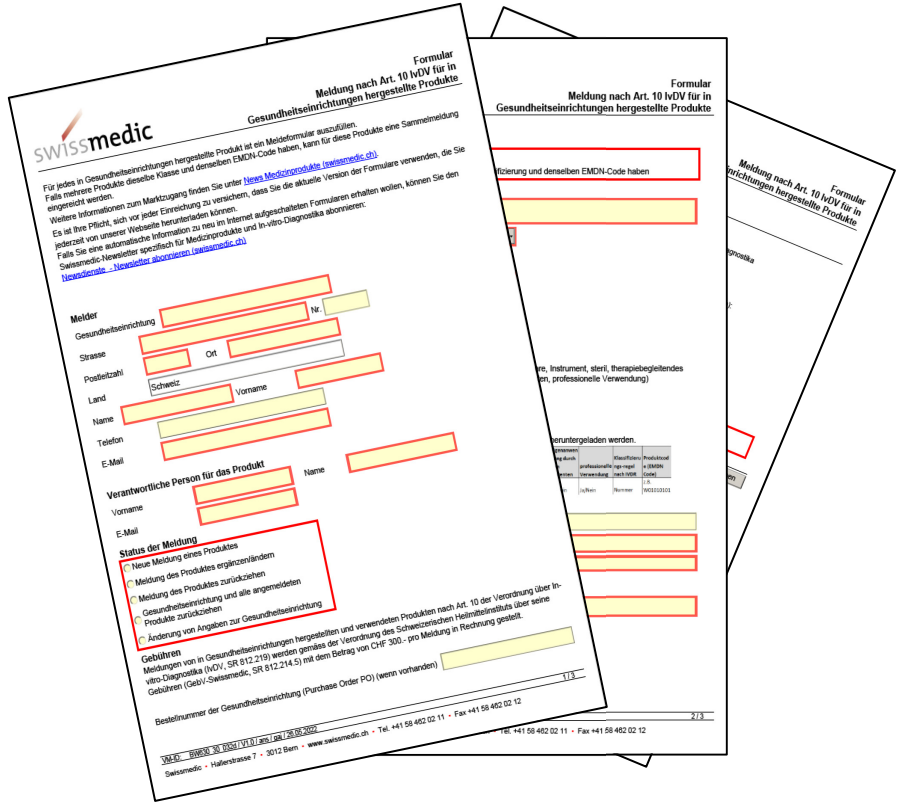
a. Name and address of the healthcare institution
b. Name and intended purpose of the device
c. Device risk class
d. Classification rule number acc. to Annex VIII EU IVDR
e. EMDN code

Changes to the information required in letters a–c must be notified to Swissmedic within 30 days

Criteria for notifying a device group (joint notification):

- Same healthcare institution
- Same risk class
- Same EMDN code

All criteria must be fulfilled

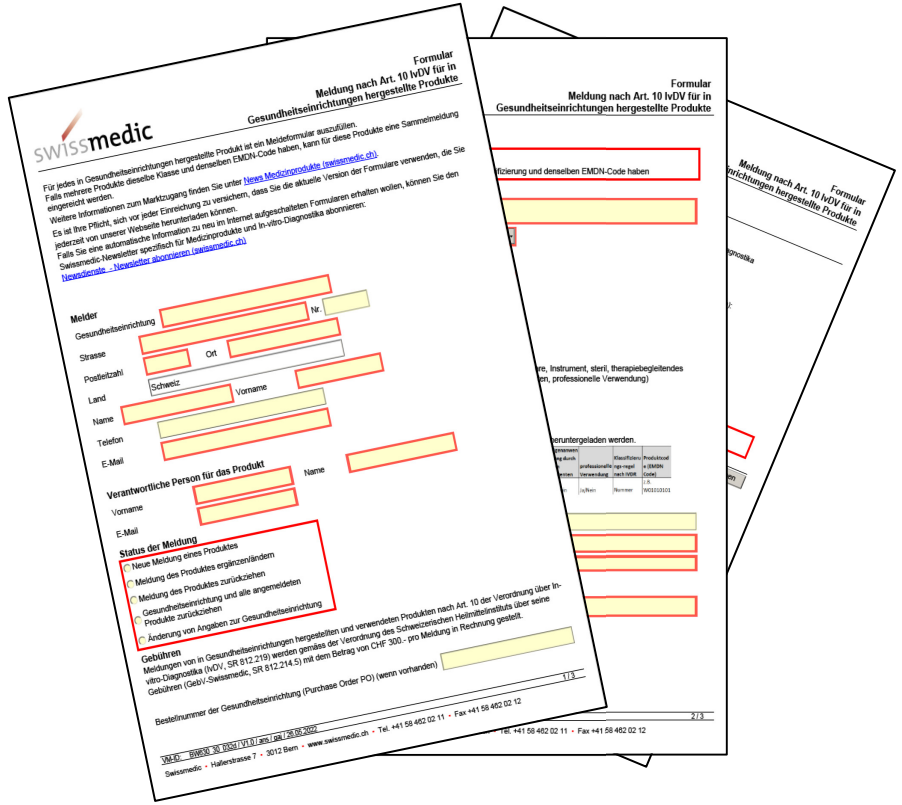


Associated documents

Documents to be submitted:

- Declaration according to Art. 5 para. 5 let. f EU IVDR
- List of devices in the case of a joint notification

Notifiers must confirm that the documents according to Art. 5 para. 5 let. g EU IVDR are available.



Notifying in-house IVDs

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.

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 Ordinance defines transitional periods relating to the fulfilment of the requirements and the notification obligation.

Take-home messages

- Requirements of Art. 9 IvDO and Art. 5 para. 5 EU IVDR must be observed
  - Date of applicability in Art. 83 IvDO
- From 26 May 2028: Written evidence that no equivalent device is on the market (Art. 5 para. 5 let. d EU IVDR)
- In-house IVDs must be notified to Swissmedic.
  - Date of applicability in Art. 90 para. 3 IvDO
- EU: Publication of MDCG Guidance on *In-house devices* planned