Product information and devices on the Swiss market

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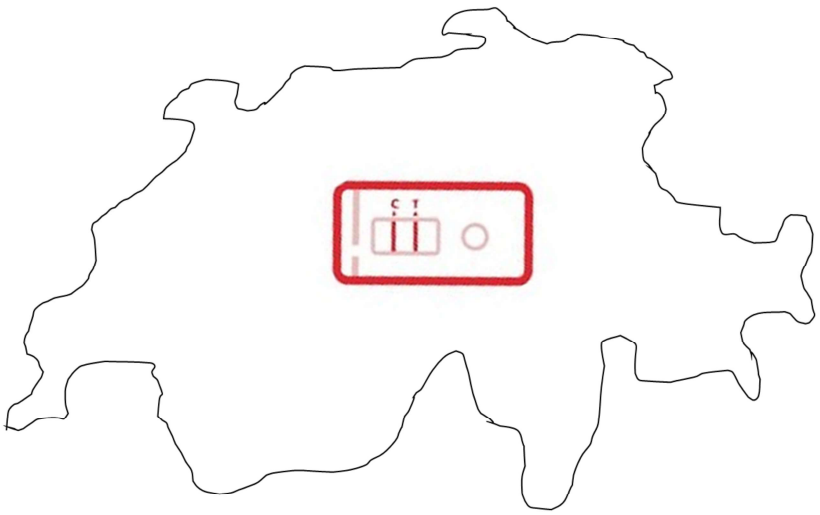

Disclaimer

- *The applicable medical device provisions of the Therapeutic Products Act (TPA; SR 812.21) and the Ordinance on In Vitro Diagnostic Medical Devices (IvDO; SR 812.219) have been generalised for this presentation.*
- *The current legal provisions apply in all cases.*
- *Specific cases are not covered by this presentation.*

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- Transitional periods for placing on the market of devices that comply with the old legislation
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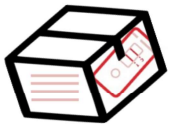
Product information

Labelling 

Instructions for use 

→ Annex I Chapter III EU-IVDR

Art. 15 IvDO Product information

- Product information comprises the labelling and instructions for use. It is governed by Chapter III of Annex I to EU-IVDR.
- It must be written in all three official languages of Switzerland. Symbols established by means of technical standards may be used to replace written statements.
- The product information may be provided in fewer than the three official languages of Switzerland or in English, provided that:
  a. the device is supplied exclusively to healthcare professionals or concerns a device in accordance with Article 9 IvDO;
  b. it is certain that the user meets the necessary professional and linguistic requirements and qualifications, and is in agreement;
  c. the protection of patients, users and third parties is ensured; and
  d. the efficacy and performance of the medical device are not placed at risk.
- If requested, additional information must be provided to users in one of the official languages of Switzerland.
- Misleading or contradictory information on a device's intended purpose, safety and performance is forbidden.
- For devices for self-testing or for near-patient testing, the information stated in Chapter III of Annex I to EU-IVDR should be easily understandable and written in the three official languages.

Definitions:
"**Label**" means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices;
“**Instructions for use**” means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken;

Product information – What for?

Safe use

Correct handling

Identification of device and operators

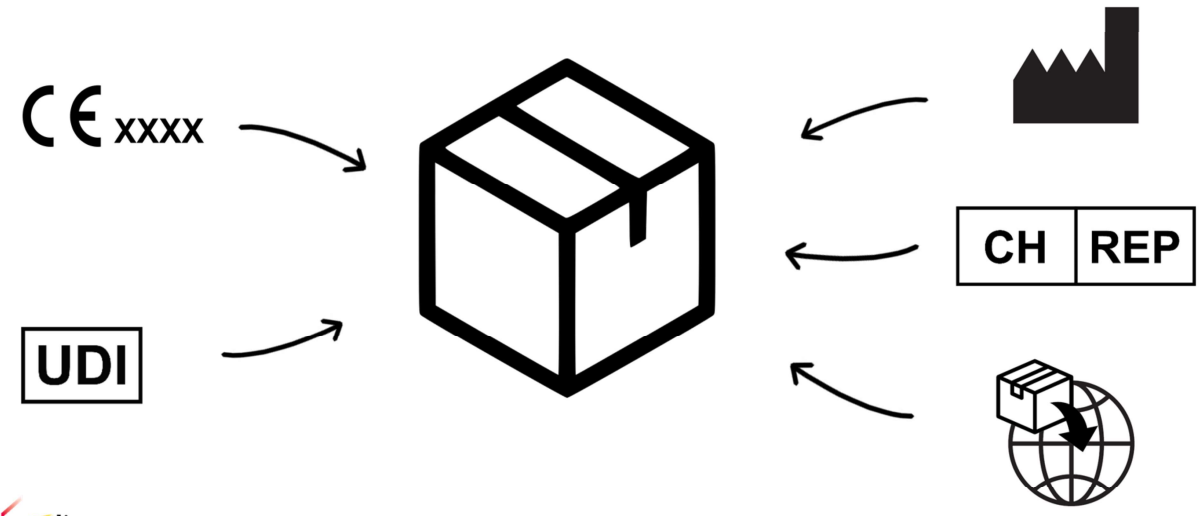
Information for surveillance in order to protect patient safety

Benefits of product information

- Information on the safety and performance of the device -> safe use!
- Information on the correct handling of the device (e.g. transport, storage)
- Identifies device and economic operators
  - Examples: Reporting of incidents, ensure traceability in the event of field safety corrective actions
- Relevant information for official market surveillance in order to protect patient safety

→ Basically promotes transparency for all parties involved

Product information – Key elements



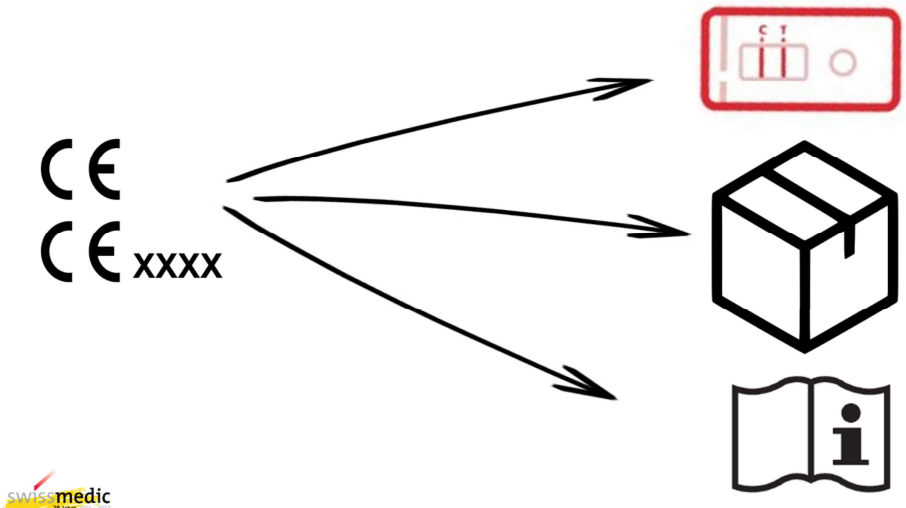
Key elements

- Conformity marking (with identification number)
- Unique Device Identifier (UDI)
- Manufacturer

Additionally for manufacturers abroad:

- Swiss authorised representative (CH-REP)
- Importer

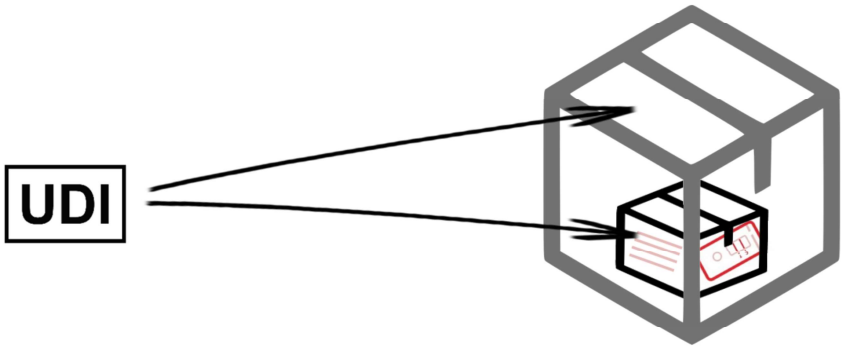
Conformity marking and identification number



Art. 13 IvDO Affixing of conformity markings and identification numbers

- The conformity marking and, where necessary, the associated identification number shall be affixed to the device itself or its sterile packaging.
- Where this is not possible or practicable owing to the nature of the device, the conformity marking and, where necessary, the associated identification number must be displayed on the packaging.
- The conformity marking shall also appear in the instructions for use and on the sales packaging.
- The requirements of Article 18 paragraphs 3–6 EU-IVDR and the general principles stated in Article 30 of Regulation (EC) No. 765/2008 must also be observed when affixing the conformity marking.

UDI – Unique device identification



Art. 16 Unique device identification

- The manufacturer shall assign to the device and all superordinate packaging layers a unique device identifier (UDI) prior to placing it on the market.
- The manufacturer must state the UDI on the labelling of the device and all higher levels of packaging. Shipping containers are not considered as a higher level of packaging.
- The manufacturer shall maintain a list of all the UDIs it has assigned. This list is part of the technical documentation specified in Annex II to EU-IVDR. It must be kept up-to-date at all times.
- The obligations and modalities associated with device identification and registration are governed by Articles 24 and 26 and Annex VI to EU-IVDR, taking account of the amendments to this Annex adopted by the European Commission by means of delegated acts.

- UDI = numeric or alphanumeric code
- Designates
  - Device model (UDI-DI)
  - Production unit (UDI-PI; e.g. lot or serial number)
- On the labelling of the device and all higher levels of packaging (Art. 16 para. 2 IvDO).
- Human Readable Interpretation (HRI) and machine-readable (e.g. bar code)

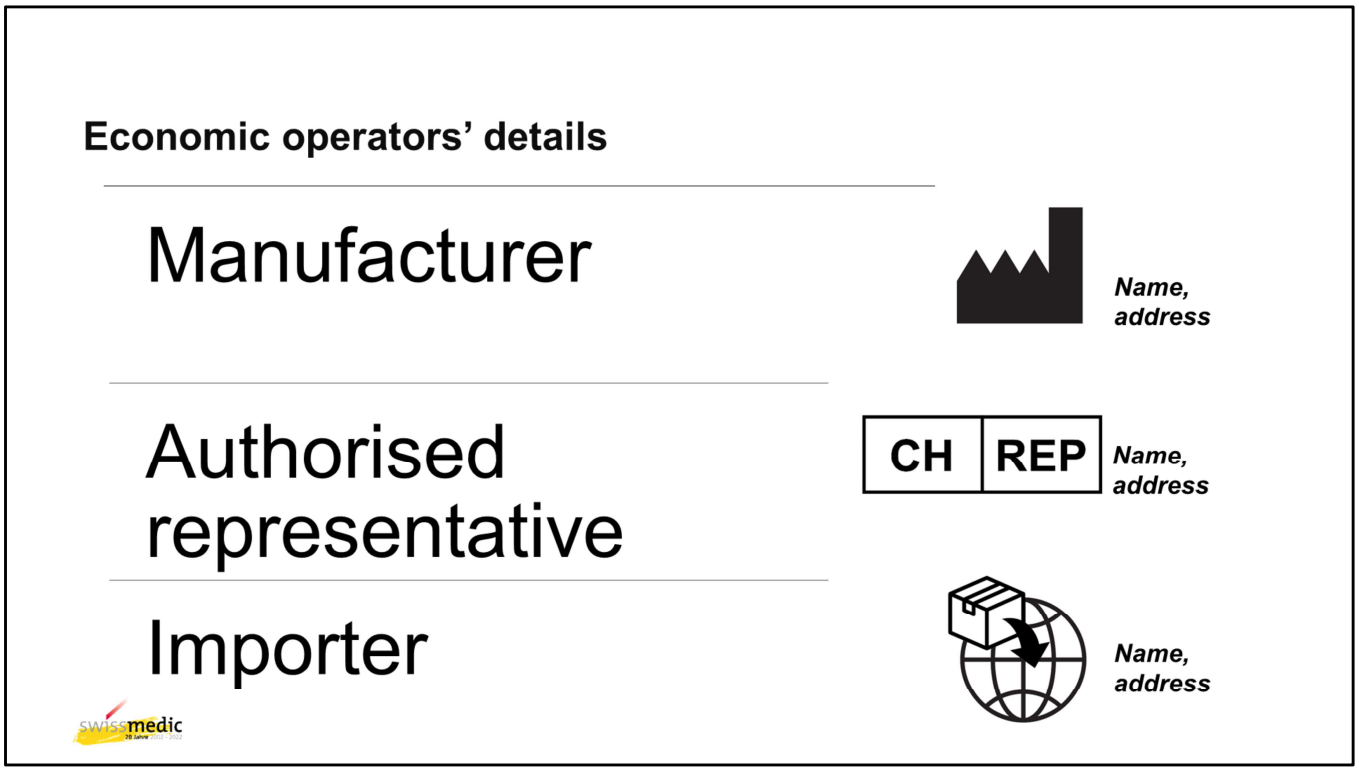
- Traceability and transparency
- swissdamed / EUDAMED: UDI is the "access key" to publicly available product information
- Affixed by the manufacturer, only mandatory for IVDR devices

UDI – Deadlines for affixing

UDI

IVD	
D	from 26 May 2023
C	from 26 May 2025
B	from 26 May 2025
A	from 26 May 2027

Art. 85 IvDO Affixing the UDI
The UDI must be affixed in accordance with Article 16 paragraph 2:
a. for class D devices: from 26 May 2023;
b. for class B and C devices: from 26 May 2025;
c. for class A devices: from 26 May 2027.



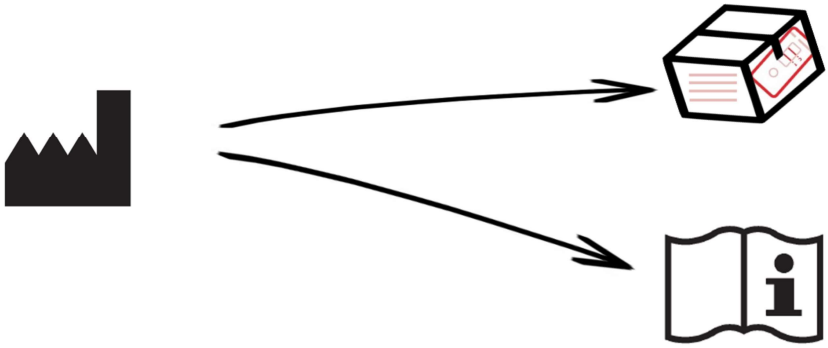
Economic operators' details

- The manufacturer of the device must always, without exception, be defined and indicated on the label.

- The label bears the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;

- For imported devices, the CH-REP and the importer must also be indicated.
    - Name and address of the authorised representative's registered place of business;
    - Importers must state their name, their registered trade name or their registered trade mark, their registered place of business and the address at which they can be contacted on the device, on its external packaging or in a document accompanying the device so that their actual location can be determined. They must ensure that any additional labelling does not obscure the information on the label affixed by the manufacturer.

Manufacturer's details

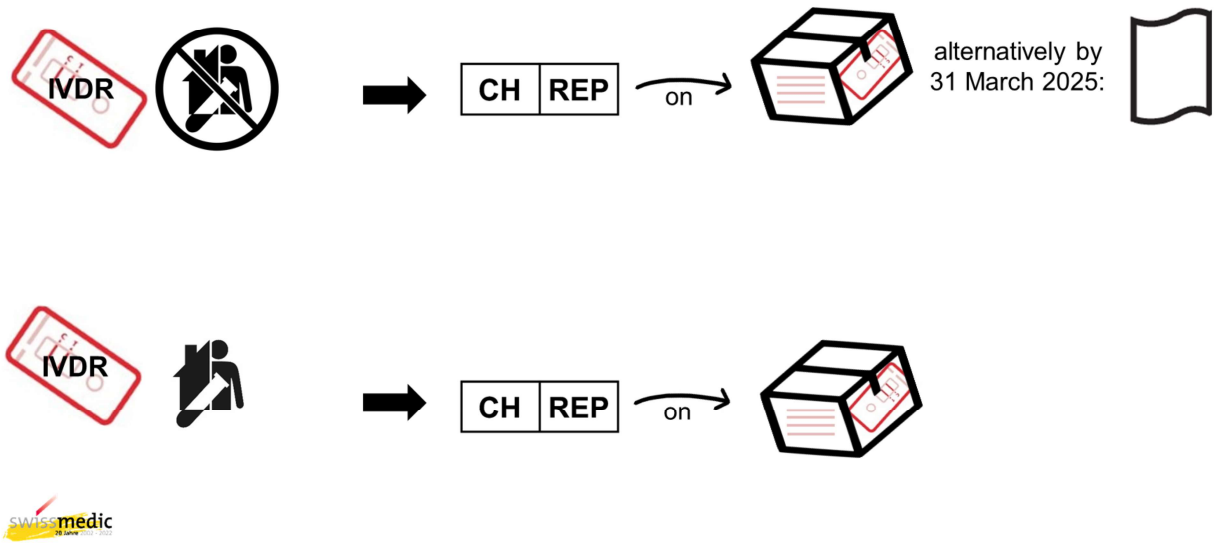


- The label bears the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business.

- Stated:
  - On the label
  - In the instructions for use

- It is mandatory to indicate the manufacturer (no deadlines).

Authorised representative's details – IVDR device



Art. 87 IvDO Placing information about the authorised representative

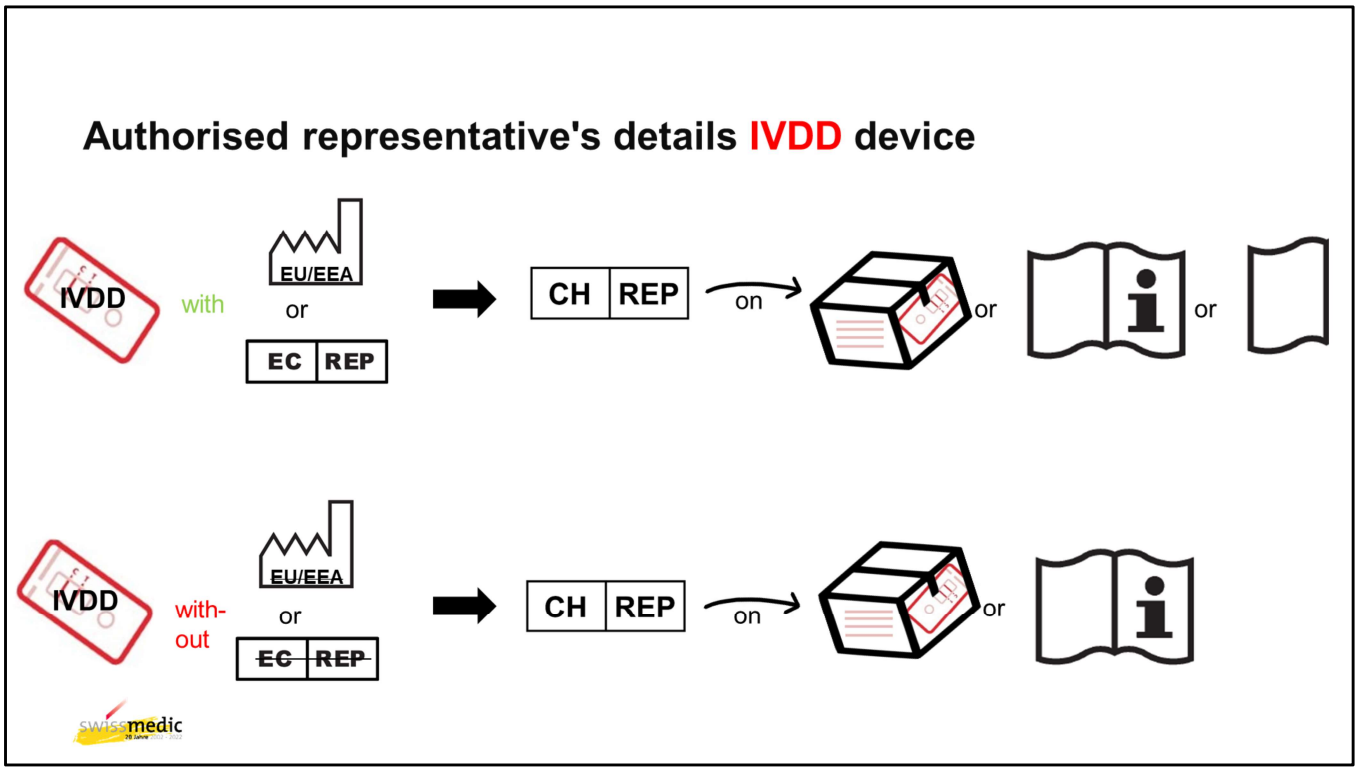
- For devices which are not intended for self-testing and are placed on the market according to the new legislation, the information specified in Annex I Chapter III Section 20.2 letter d EU-IVDR about the authorised representative according to Article 44 paragraph 1 of the MedDO may be included in a document accompanying the device until 31 March 2025.

- The "document accompanying the device" can be affixed to the device or be separate from the device.
    - Examples of documents accompanying the device include: delivery note, guarantee certificate, customs documents, invoice, a sticker on the packaging or the instructions for use.

- Such documents must accompany the devices through the supply chain so that distributors are able to fulfil their verification obligation stated in Art. 54 para. 1 let. d MedDO or Art. 47 para. 1 let. d IvDO (information about the importer). Therefore, the "document accompanying the device" does not necessarily need to reach the end user. The aim and purpose of the information is to allow rapid and unambiguous identification of the economic operators responsible for the relevant devices (importer and, if applicable, CH-REP), e.g. for implementing product recalls, reporting incidents, reporting dangerous devices or non-conformities, and in the context of

enforcement.

Note: This is the Swiss interpretation of the term "document accompanying the device", which differs from the European interpretation (MDCG 2021-27 of December 2021, question 8) for supply-related reasons.



Information about the authorised representative

- IVDD devices with EU/EEA manufacturer or EC-REP: On the label or in the instructions for use or in a document accompanying the device.
- IVDD devices without EU/EEA manufacturer or without EC-REP: On the label or in the instructions for use.

Authorised representative – Deadlines for affixing – IVDR device

CH REP

IVD	
D	until 31 December 2022
C	until 31 March 2023
B	until 31 March 2023
A	until 31 July 2023

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Deadlines for mandating the CH-REP

- **IVDR devices:**
  - Class D: 31 December 2022
  - Classes C and B: 31 March 2023
  - Class A: 31 July 2023

Authorised representative – Deadlines for affixing – IVDD device

CH REP

IVD	
D	until 31 December 2022
C	until 31 March 2023
B	until 31 March 2023
A	until 31 July 2023

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Deadlines for mandating the CH-REP

- **IVDD devices with EU/EEA manufacturer or EC-REP:**
  - Class D: 31 December 2022
  - Classes C and B: 31 March 2023
  - Class A: 31 July 2023

Authorised representative – Deadlines for affixing – IVDD device

CH REP

*from **26 May 2022***

Deadlines for mandating the CH-REP

- **IVDD devices without EU/EEA manufacturer or without EC-REP:**
  - From 26 May 2022

Importer's details

The regulations for **indicating the importer** are the same for all IVDR and IVDD devices:

- On the device or on the packaging or in a document accompanying the device.

Importer – Deadline for affixing

*from **26 May 2022***

The regulations for **indicating the importer** are the same for all IVDR and IVDD devices:

- from 26 May 2022.

Devices on the Swiss market

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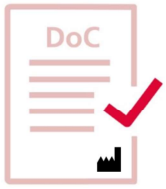
Provisions for placing on the market of devices that comply with the old legislation = IVDD devices



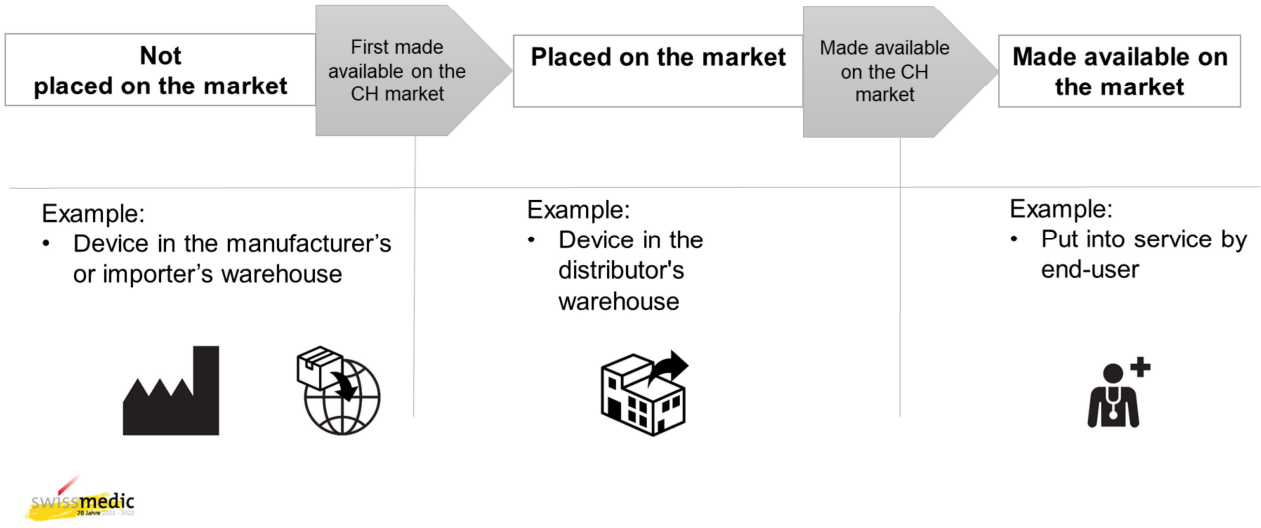
Before
26 May 2022

As old legislation

Art. 82 IvDO Placing on the market of devices that comply with the old legislation

- Provided the following devices **continue to comply with the old legislation** as of 26 May 2022 and **have not undergone any significant changes in their design or intended purpose**, they may be placed on the market or put into service temporarily:
  - Devices with a certificate valid under Article 81.
  - Devices that did not require the involvement of a designated body in connection with the conformity assessment procedure according to the old legislation, but which is now required by this Ordinance, and for which **a declaration of conformity was issued before 26 May 2022 under the old legislation**.

Placing & making available on the market



Making available on the market; Definition (Art. 4 para. 1 let. a IvDO): any transfer or cession of a device, other than a device for performance study, for distribution, consumption or use on the Swiss market in the course of a commercial activity, whether in return for payment or free of charge.

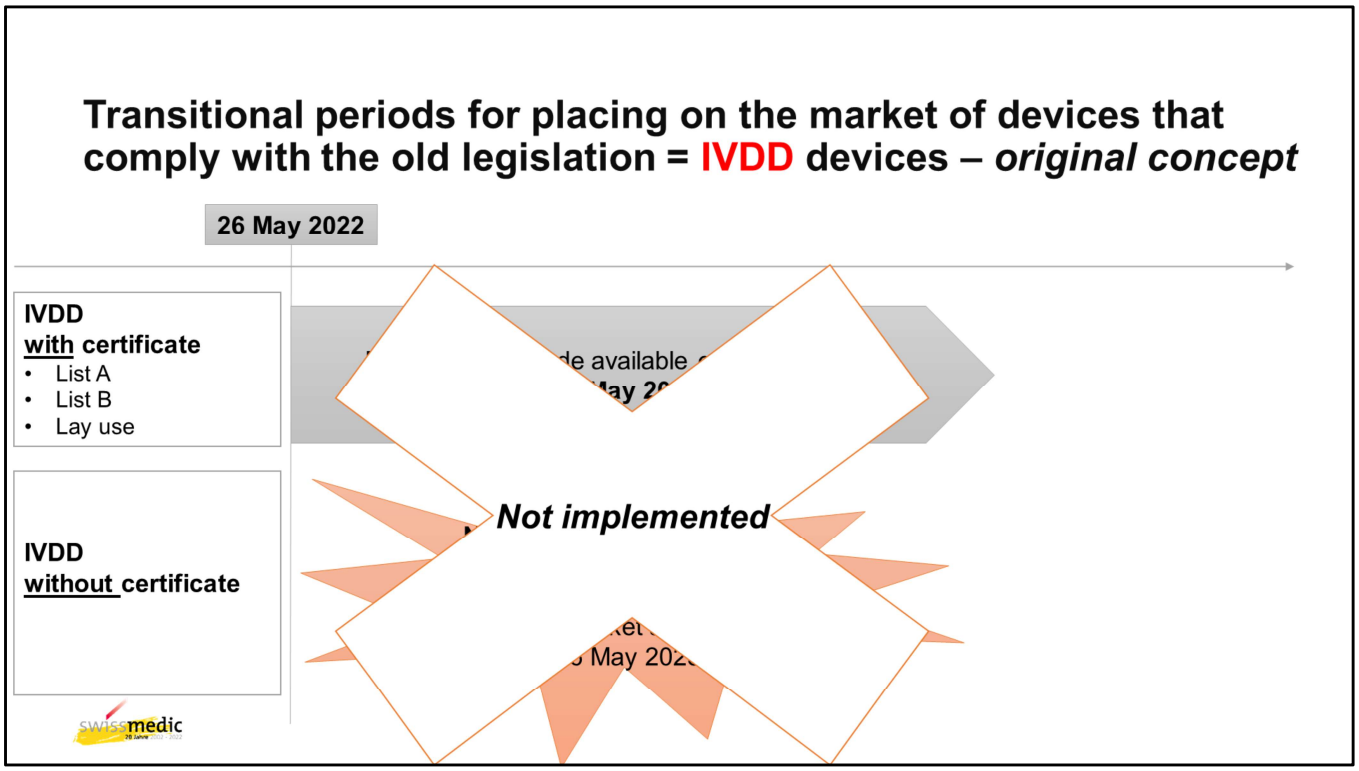
Placing on the market; Definition (Art. 4 para. 1 let. b IvDO): first making available of a device on the Swiss market.

- First transfer / cession of a device in Switzerland
  - for distribution,
  - for consumption or
  - for use

  on the Swiss market in the course of a commercial activity
- Each individual device is placed on the market
- Date of first transfer / supply is relevant
- Transfer can be for payment or free of charge
- Physical handover of the device is not essential

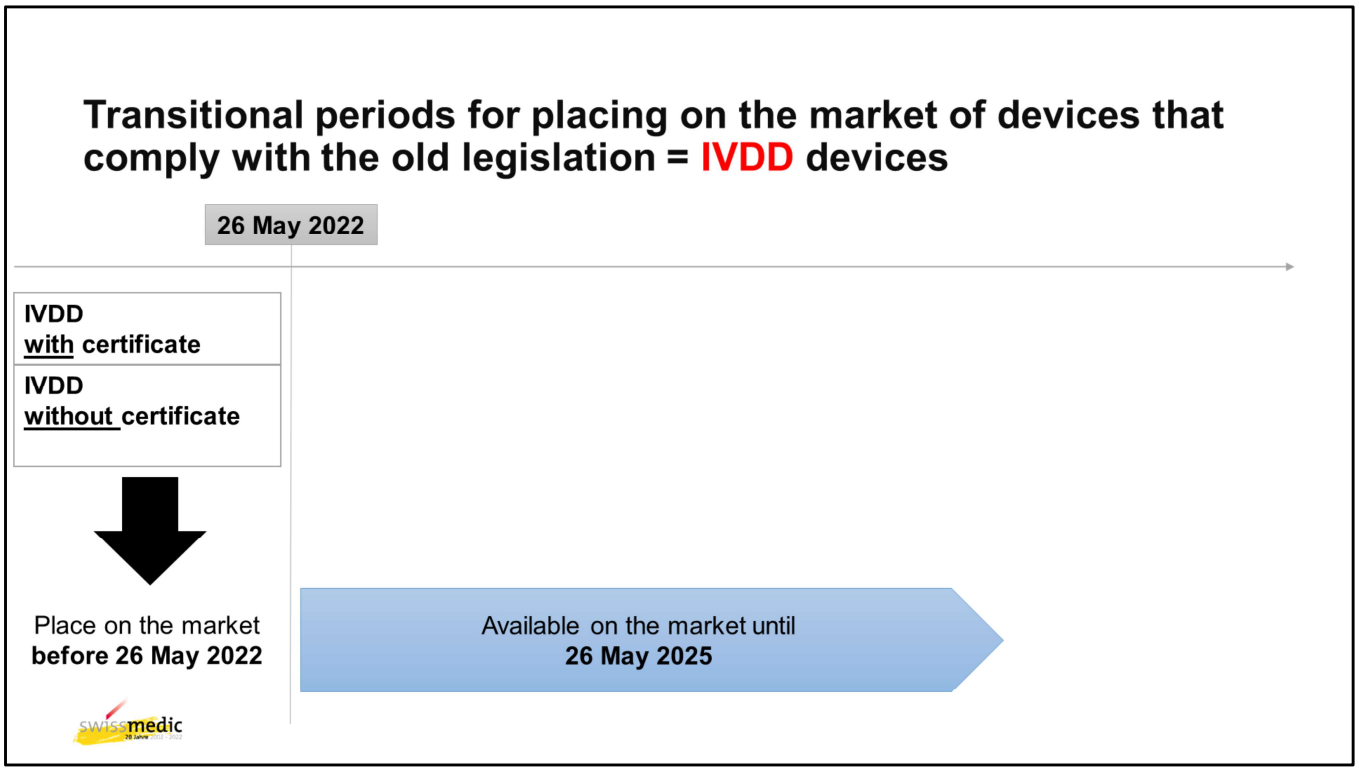
- Devices in the manufacturer's warehouse are not yet placed on the market
  - "Stock sell-off", e.g. after expiry or withdrawal of the designated body's certificate, is not possible

- Devices that have been transferred/supplied to the distributor have been placed on the market.



- Art. 110 IVDR originally defined transitional provisions only for IVDD devices with a certificate.
- However, no transitional provisions were foreseen for IVDD devices without a certificate; in other words, these devices would have had to comply with the provisions of the IVDR from 26 May 2022. It became clear that this could have put the security of the supply of IVD devices at risk.

-> **The transitional provisions were modified in Regulation (EU) 2022/112**.



Art. 82 para. 3 Placing on the market of devices that comply with the old legislation

- Devices legally placed on the market prior to 26 May 2022 under the old legislation may continue to be made available on the market or put into service until 26 May 2025.

Art. 82 para. 1 IvDO Placing on the market of devices that comply with the old legislation

- Devices with a certificate valid under Article 81: until 26 May 2025;
- Devices that did not require the involvement of a designated body in connection with the conformity assessment procedure according to the old legislation, but which is now required by the IvDO, and for which a declaration of conformity was issued before 26 May 2022 under the old legislation:
    - Class D devices: until 26 May 2025,
    - Class C devices: until 26 May 2026,
    - Class B devices: until 26 May 2027,
    - Class A devices placed on the market in a sterile condition: until 26 May 2027.
- No transitional period for IVDD without a certificate that are now in Class A.

Art. 14 IvDO Classification

- Devices shall be divided into classes A, B, C and D, taking into account the intended purpose of the devices and their inherent risks. This classification must comply with the provisions of Annex VIII to EU-IVDR.

Take-home messages

- Product information
  - Details of the economic operators on the device
  - Device identification (UDI) for IVDR devices
  - Deadlines for affixing UDI and CH-REP by product risk class

- Placing on the market and devices on the market
  - Determine regulatory status!
  - Classification according to IvDO (EU-IVDR): which rules – particularly transitional provisions – apply?
  - Has a device been placed on the market?

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