swissmedic
20 Jahre 2002 - 2022

Authorised representatives, importers and distributors: Obligations of economic operators in Switzerland

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Any person handling **therapeutic products** must take all measures necessary according to the state of the art to ensure that **human** or animal **health** is not endangered.

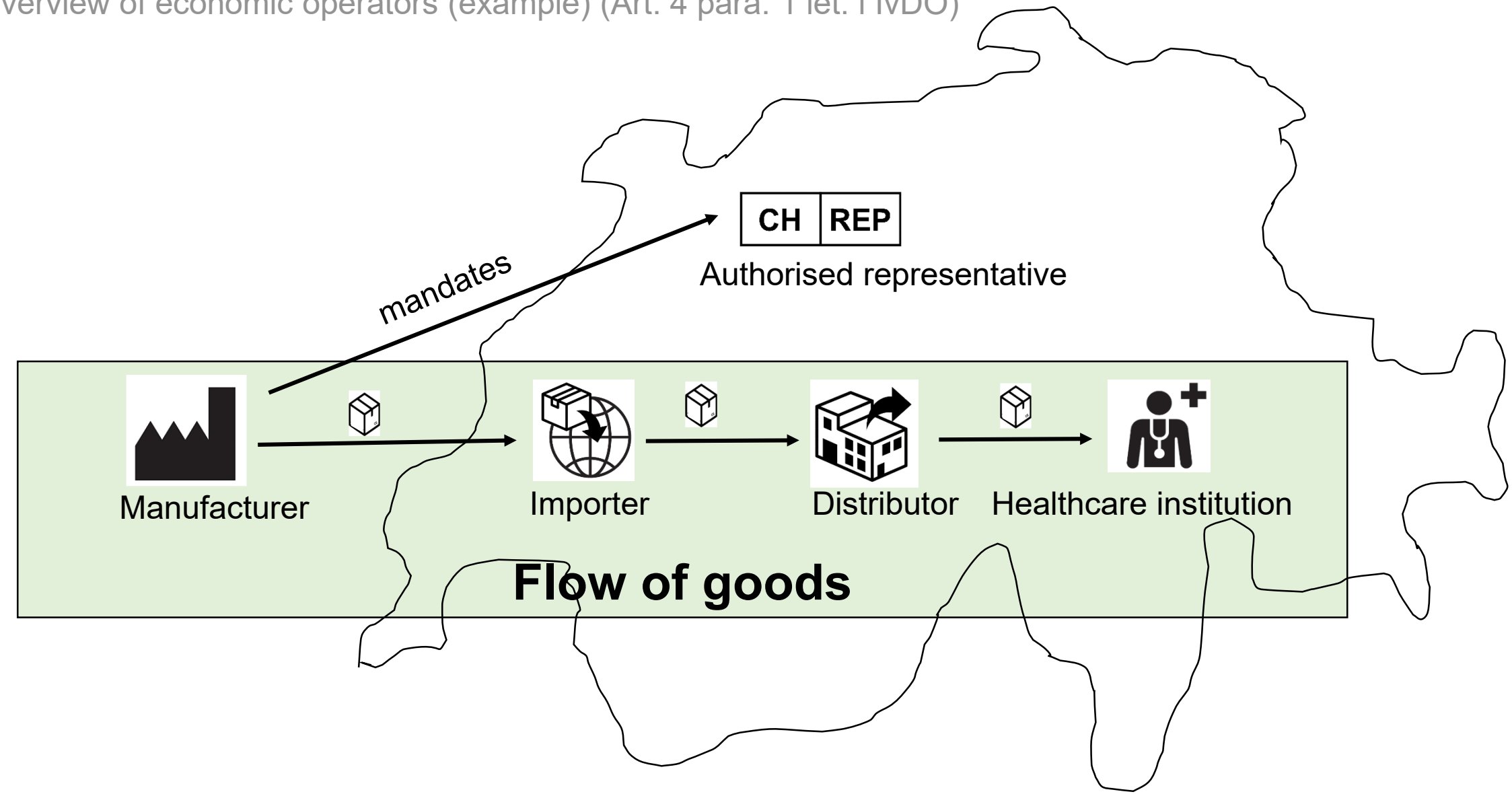
Disclaimer

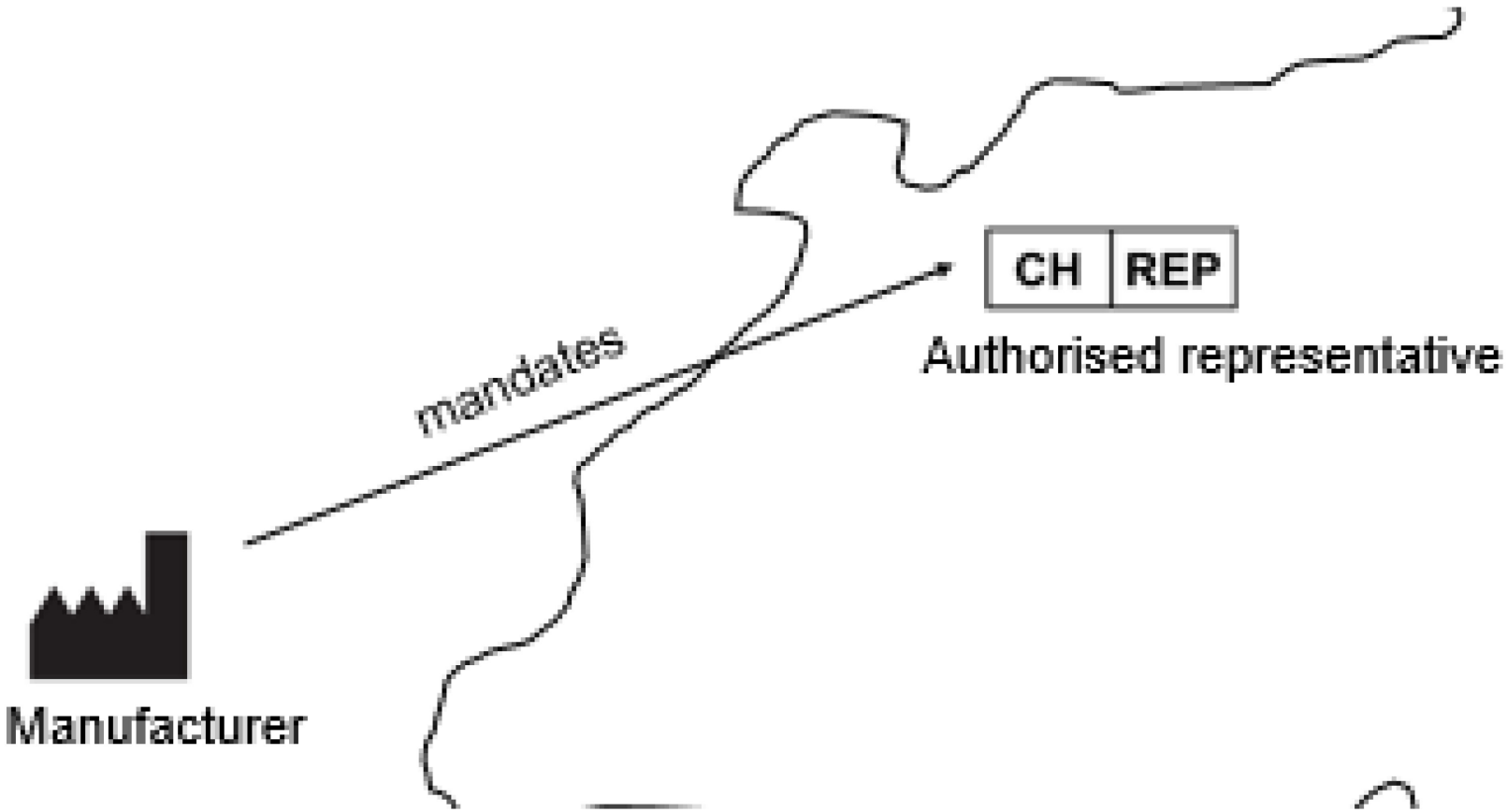
- *The applicable provisions of the Therapeutic Products Act (TPA; SR 812.21) and the Ordinance on In Vitro Diagnostic Medical Devices (IvDO; SR 812.219) have been generalised for this presentation.*
- *The current legal provisions apply in all cases.*
- *Specific cases are not covered by this presentation.*

Economic operators (Art. 4 para. 1 let. i IvDO)

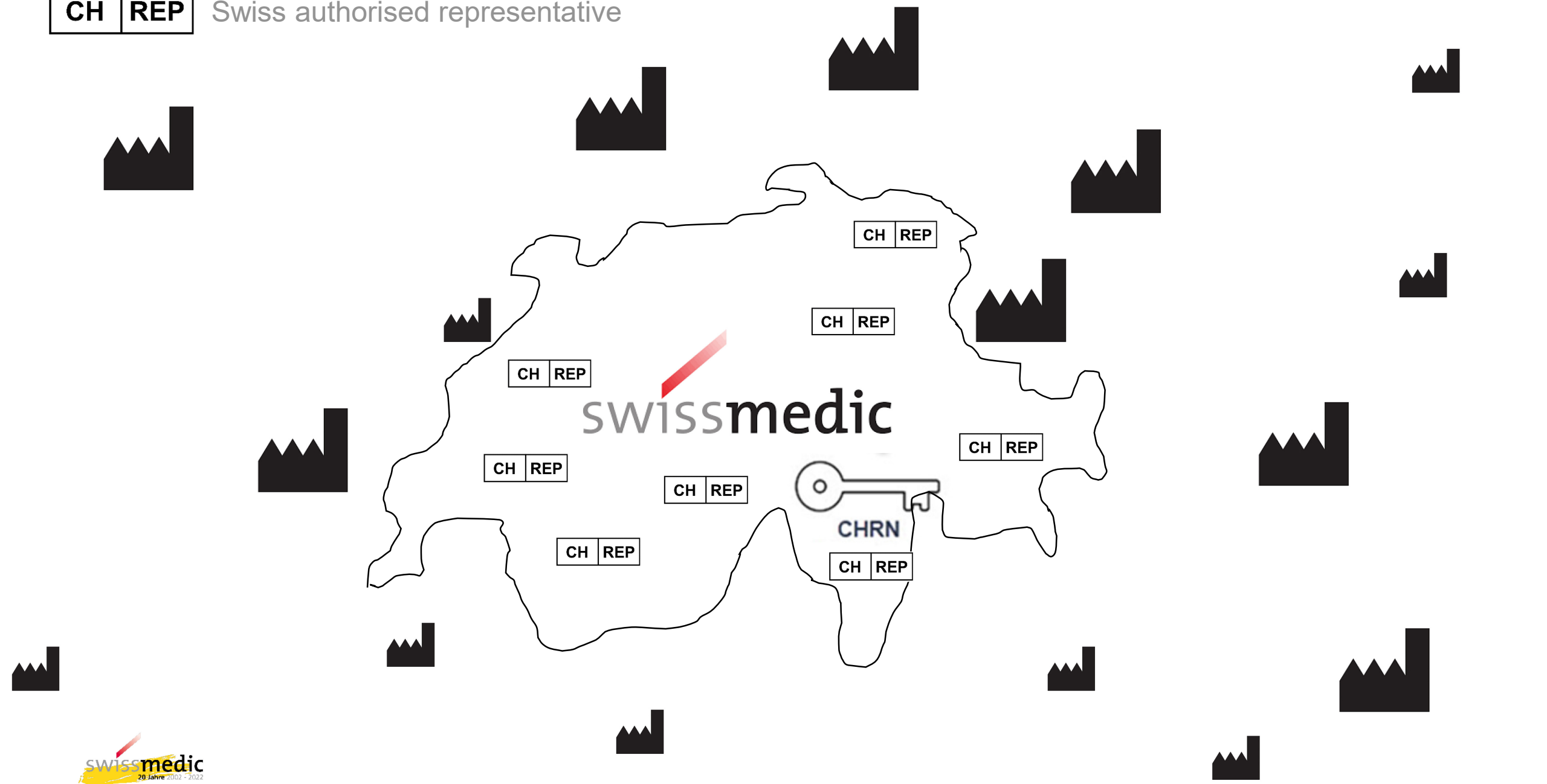
 Manufacturer and  Authorised representative	Responsible for complying with the general safety and performance requirements
 Importer	Places devices from abroad on the Swiss market (part of the supply chain)
 Distributor	Makes devices available on the Swiss market (part of the supply chain)

Overview of economic operators (example) (Art. 4 para. 1 let. i IvDO)




CH REP
Authorised representative
mandates
Manufacturer

CH REP Swiss authorised representative



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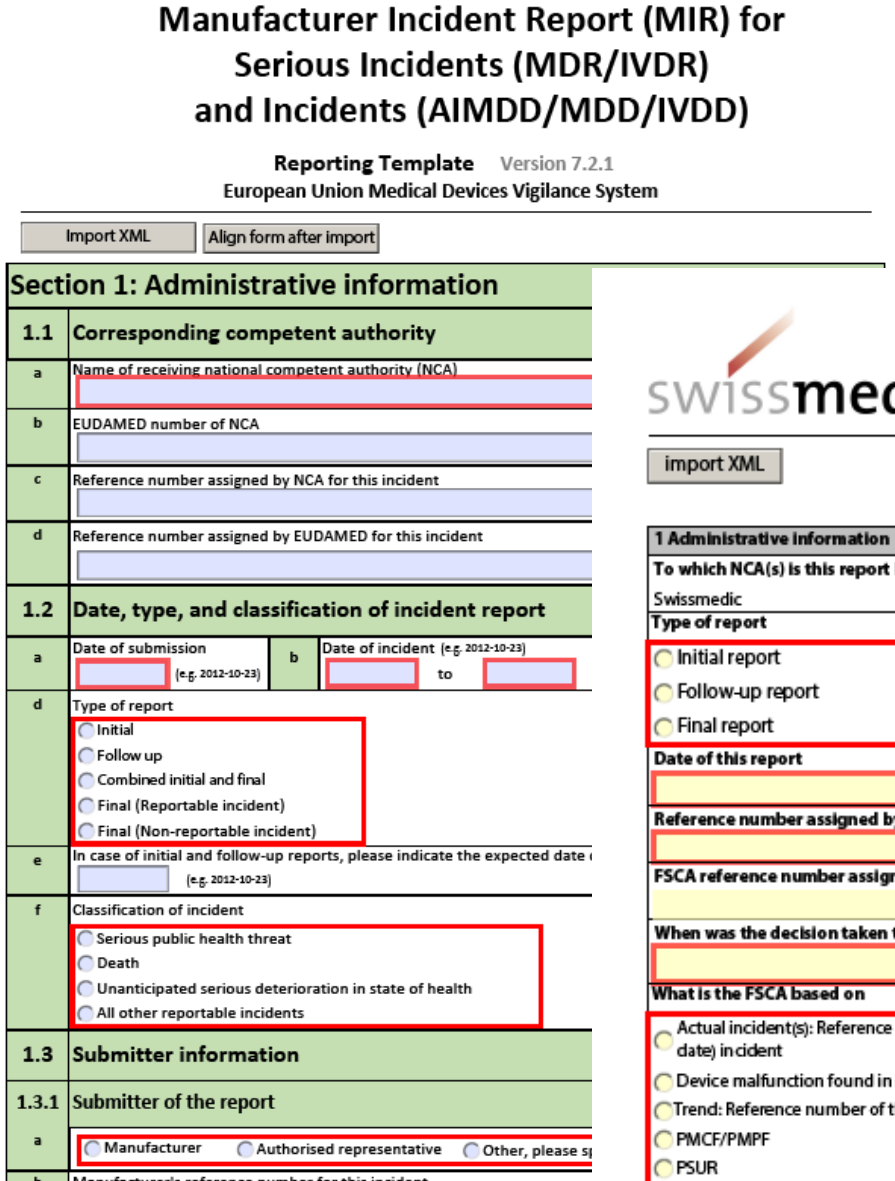
Authorised Representative (Art. 44 and 45 IvDO)

- If the manufacturer is **not domiciled in Switzerland**, it must designate an authorised representative by means of a **written mandate** (including manufacturers from the EU/EEA)
- Any natural or legal person **domiciled in Switzerland** can act as an authorised representative
- **The manufacturer's authorised representative** is **responsible**, in Switzerland, for the safety and performance of the devices on the Swiss market
- It is one of the **most important contact persons** for the authorities in Switzerland
- Authorised representatives must be **registered** with Swissmedic

The transfer of these obligations from the manufacturer to the authorised representative should be agreed in **writing** in the mandate



Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR) and Incidents (AIMDD/MDD/IVDD)

Reporting Template Version 7.2.1
European Union Medical Devices Vigilance System

Import XML | Align form after import

Section 1: Administrative information

1.1 Corresponding competent authority

a Name of receiving national competent authority (NCA)

b EUDAMED number of NCA

c Reference number assigned by NCA for this incident

d Reference number assigned by EUDAMED for this incident

1.2 Date, type, and classification of incident report

a Date of submission (e.g. 2012-10-23) | b Date of incident (e.g. 2012-10-23) to

d Type of report
- Initial
- Follow up
- Combined initial and final
- Final (Reportable incident)
- Final (Non-reportable incident)

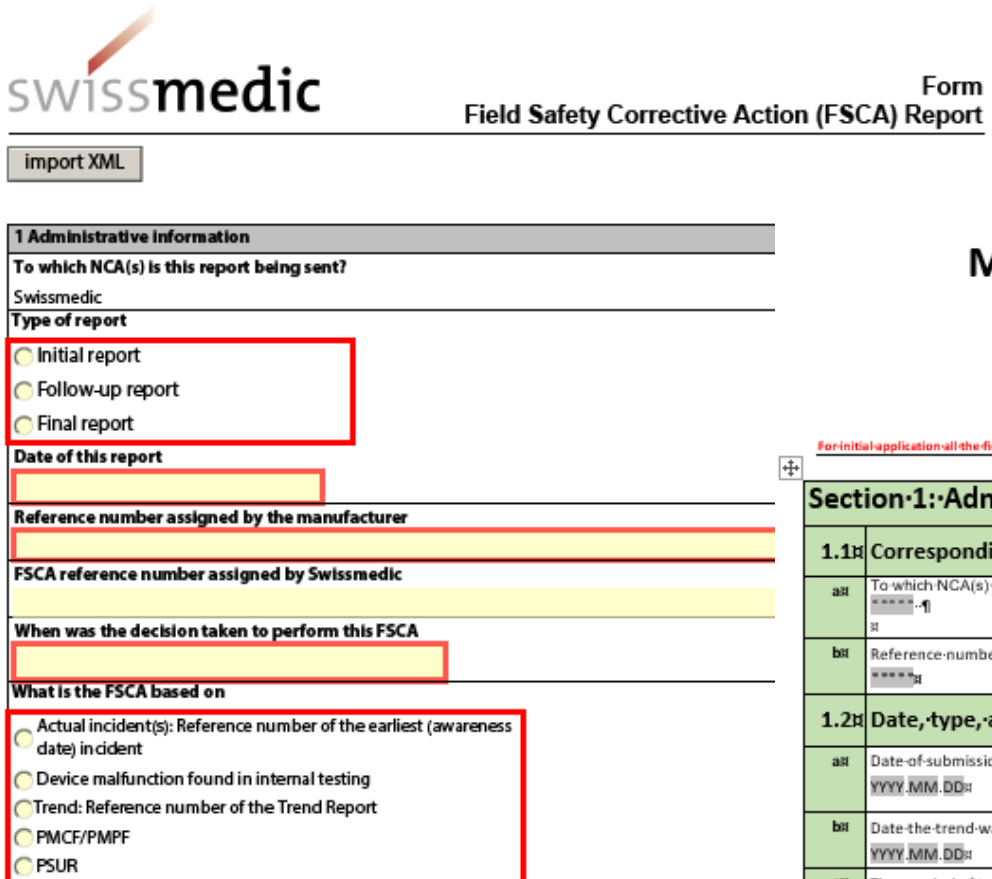
e In case of initial and follow-up reports, please indicate the expected date (e.g. 2012-10-23)

f Classification of incident
- Serious public health threat
- Death
- Unanticipated serious deterioration in state of health
- All other reportable incidents

1.3 Submitter information

1.3.1 Submitter of the report

a Manufacturer | Authorised representative | Other, please sp



swissmedic Form
Field Safety Corrective Action (FSCA) Report

import XML

1 Administrative information

To which NCA(s) is this report being sent?
Swissmedic

Type of report
- Initial report
- Follow-up report
- Final report

Date of this report

Reference number assigned by the manufacturer

FSCA reference number assigned by Swissmedic

When was the decision taken to perform this FSCA

What is the FSCA based on
- Actual incident(s): Reference number of the earliest (awareness date) incident
- Device malfunction found in internal testing
- Trend: Reference number of the Trend Report
- PMCF/PMPF
- PSUR

Manufacturer's Trend Report (TrendR)

Reporting Template Version 1.0

Medical Devices Vigilance System

For initial application all the fields should be completed except 4.2 analysis update.

Section 1: Administrative information

1.1 Corresponding competent authority

a To which NCA(s) is this report being sent?
*****

b Reference number assigned by NCA for this TrendR
*****

1.2 Date, type, and classification of Trend Report

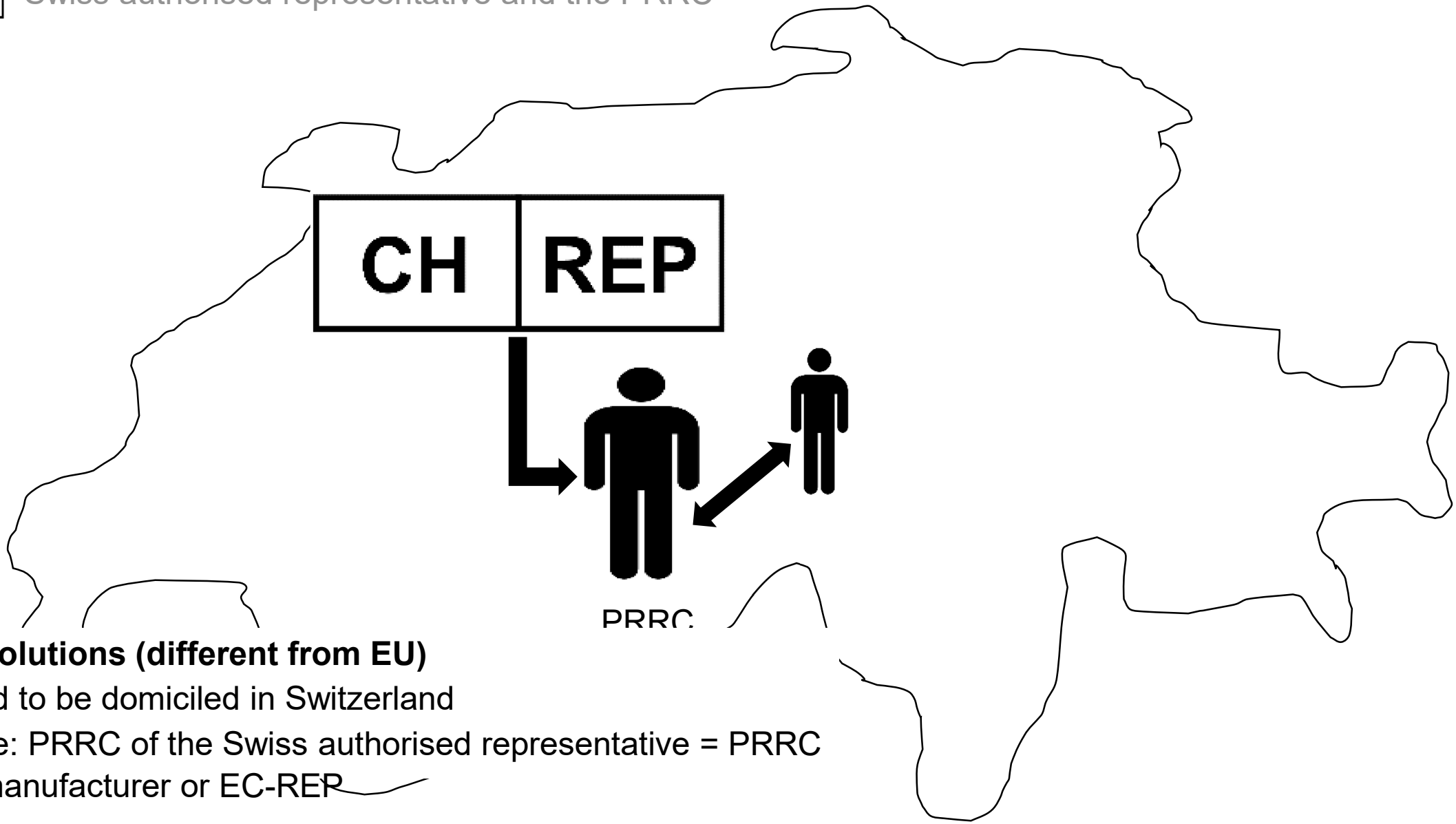
a Date of submission
YYYY.MM.DD

b Date the trend was identified
YYYY.MM.DD

Vigilance reporting obligation for the CH-REP (Art. 59 IvDO)

- **CH-REP is responsible** for reporting serious incidents as soon as it becomes aware of them, and for the field safety corrective actions (FSCA) undertaken in Switzerland.
- **CH-REP** submits **trend reports** concerning incidents in Switzerland and abroad to Swissmedic without being requested to do so
- **CH-REP** submits final reports on FSCA to Swissmedic
- **The transfer of these obligations** from the manufacturer to the authorised representative should be agreed in **writing** in the mandate

CH REP Swiss authorised representative and the PRRC



Specific solutions (different from EU)

- No need to be domiciled in Switzerland
- Possible: PRRC of the Swiss authorised representative = PRRC of the manufacturer or EC-REP

CH REP Swiss authorised representative and the PRRC

Authorised representatives must have permanently and continuously at their disposal a **Person Responsible for Regulatory Compliance** (Art. 45 para. 1 IvDO)

- **A deputy** must be designated
- If several persons are jointly responsible: Establish their areas of responsibility **in writing**

General qualifying requirements for the PRRC

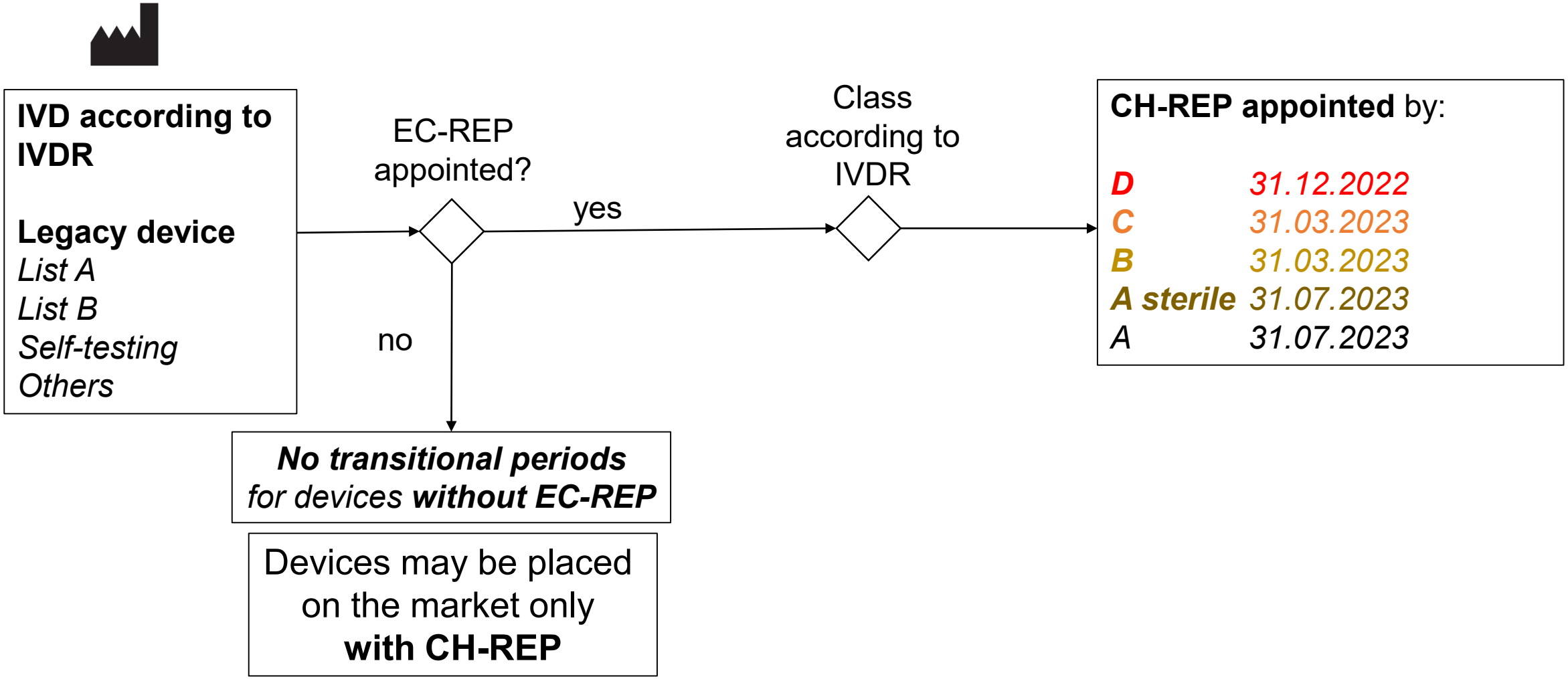
a) Either a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree […] in **law, medicine pharmacy, engineering** […] and **at least one year of professional experience** in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices;

b) Or **four years of professional experience** in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices

Specific solutions (different from EU)

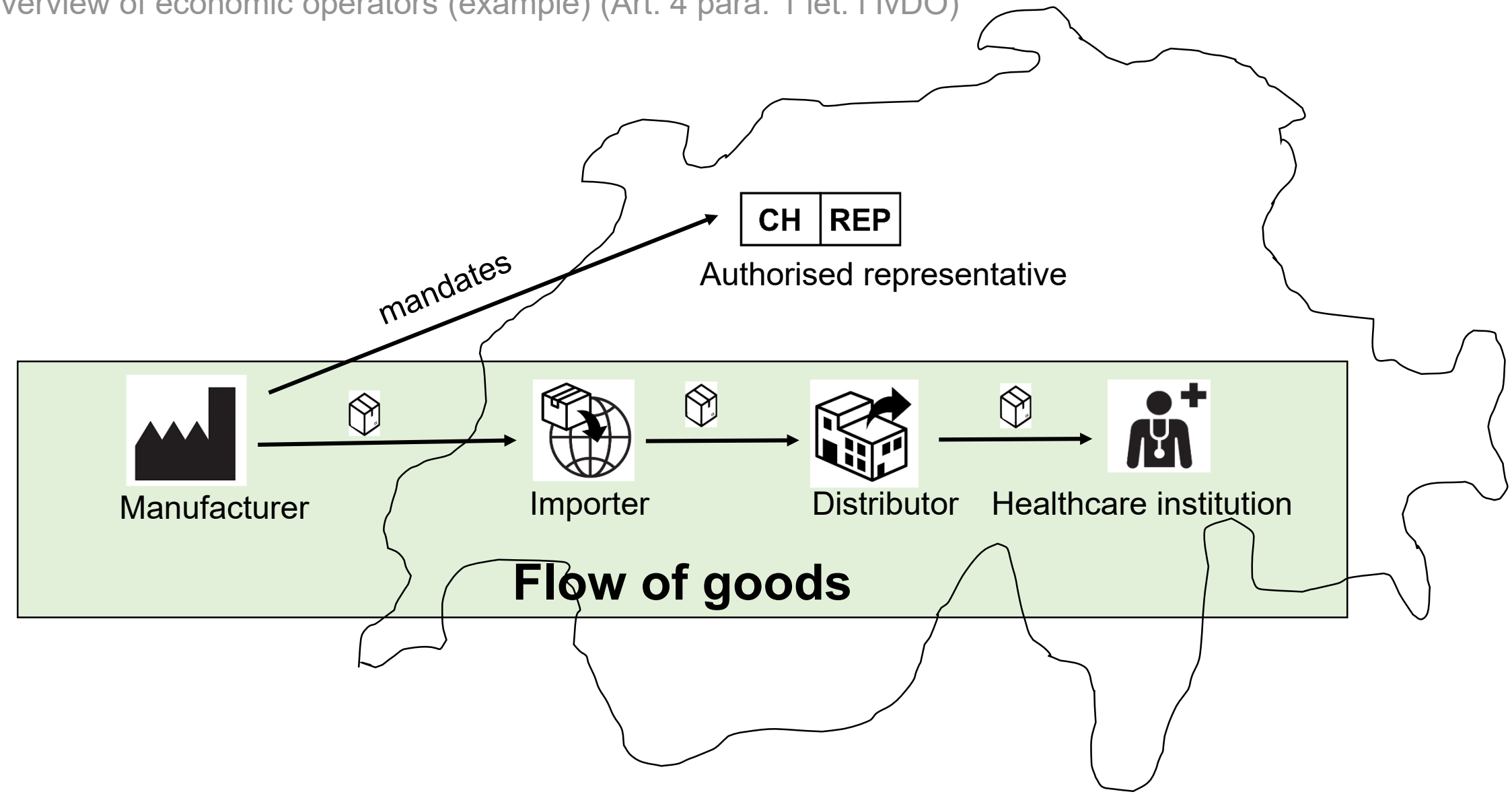
- No need to be domiciled in Switzerland
- Possible: PRRC of the Swiss authorised representative = PRRC of the manufacturer or EC-REP

CH REP Swiss authorised representative



Art. 89 IvDO

Overview of economic operators (example) (Art. 4 para. 1 let. i IvDO)



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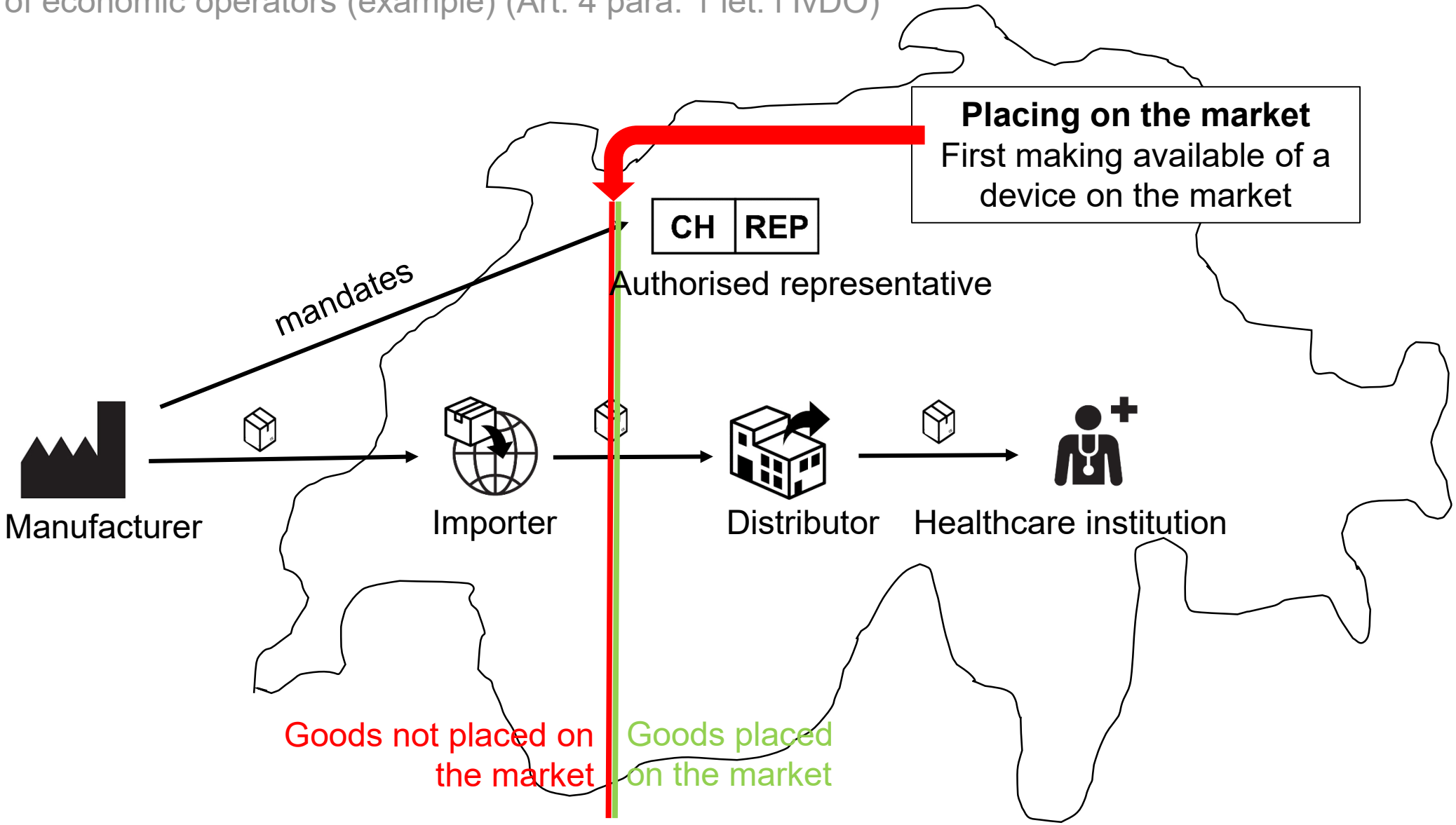
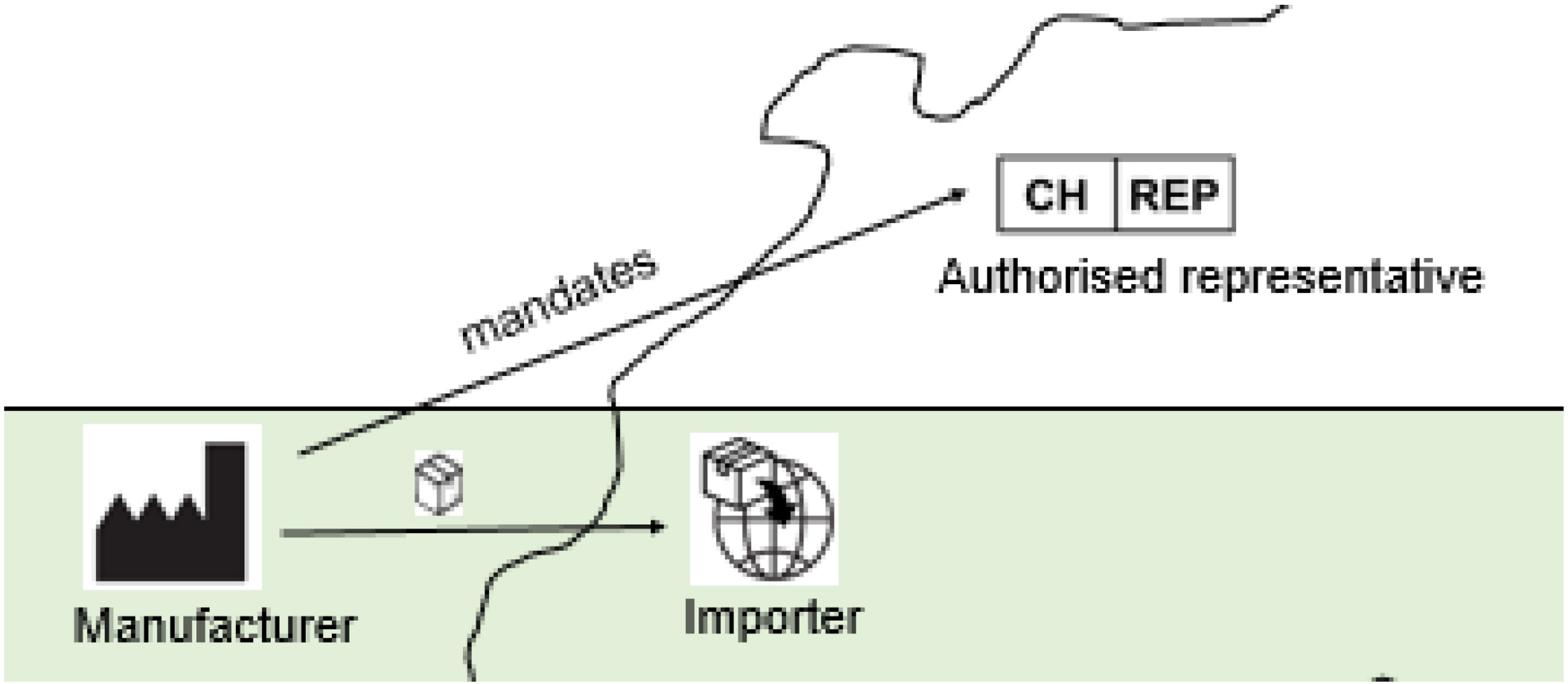


Importers


CH REP
Authorised representative
mandates
Manufacturer
Importer

Importers (Art. 46 IvDO)

- Natural or legal person that **places** a device **from abroad** on the Swiss market
  - **Placing on the market:** first making available of a device on the Swiss market

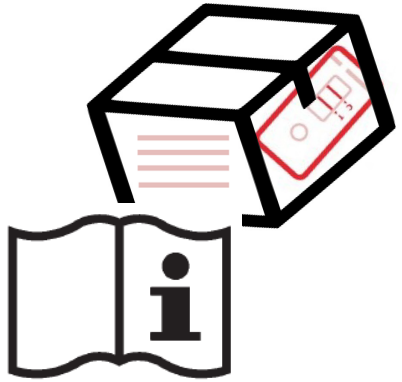
- Before placing on the market, check that:

CE

CE XXXX

CH REP

DE / FR / IT



UDI

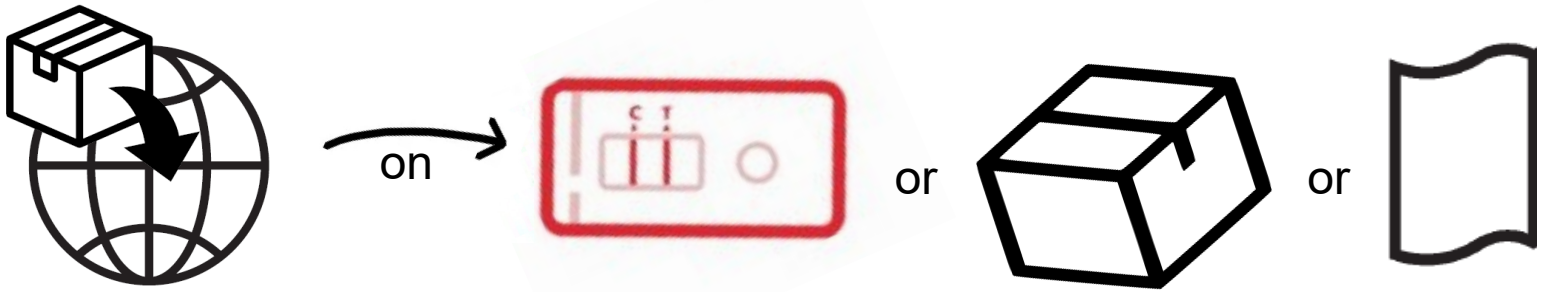
Importers (Art. 46 IvDO)

- Natural or legal person that **places** a device **from abroad** on the Swiss market
  - **Placing on the market:** first making available of a device on the Swiss market

- Before placing on the market, check that:
  - The **conformity marking** is present
  - The **declaration of conformity** exists
  - The **manufacturer is known**
  - An **authorised representative** is appointed
  - **Trilingual labelling:** the device is labelled in all three languages and the instructions for use are available in all three languages
  - Where required, a **UDI** is assigned

Importers (Art. 46 IvDO)

- Traceability in the market



- Gatekeeper for the Swiss market
  If the importer has doubts about its conformity, the device may **not** be placed on the market

- Registration obligations

Importers

Legacy device
List A
List B
Self-testing
Others

98/79/EC certificate?

yes

Placing on the market (PoM)
*Expiry of certificate, no later than 26.05.**2025***

Further making available on the market
Deadline PoM + 1 year

no

Class according to IVDR, newly with NB

Placing on the market (PoM) until:

D	*26.05.**2025***
C	*26.05.**2026***
B	*26.05.**2027***
A sterile	*26.05.**2027***

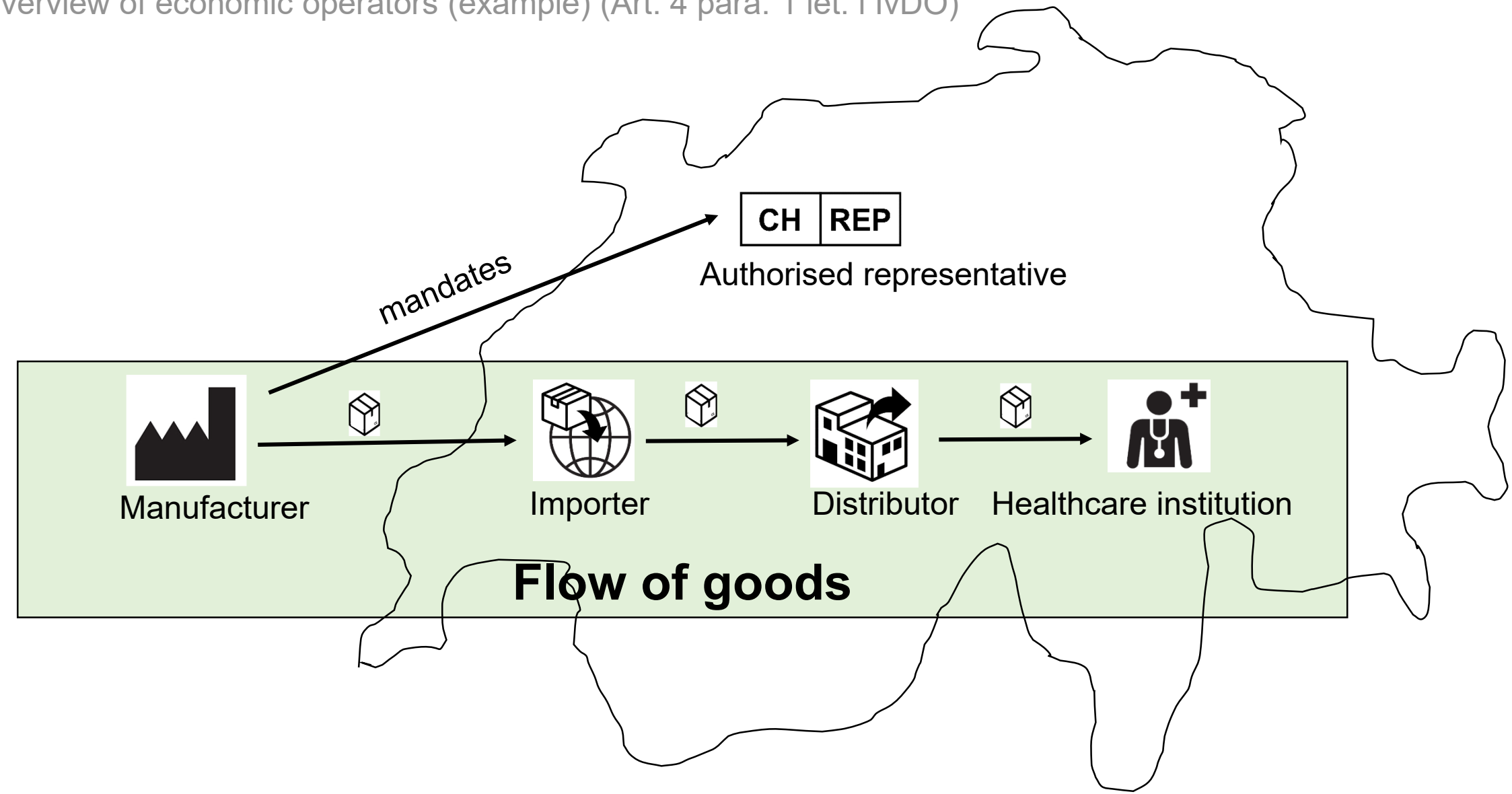
Further making available on the market
Deadline PoM + 1 year

Authorised representative appointed until:

D	*31.12.**2022***
C	*31.03.2023*
B	*31.03.2023*
A	*31.07.2023*

Art. 82 IvDO
Art. 86 IvDO

Overview of economic operators (example) (Art. 4 para. 1 let. i IvDO)



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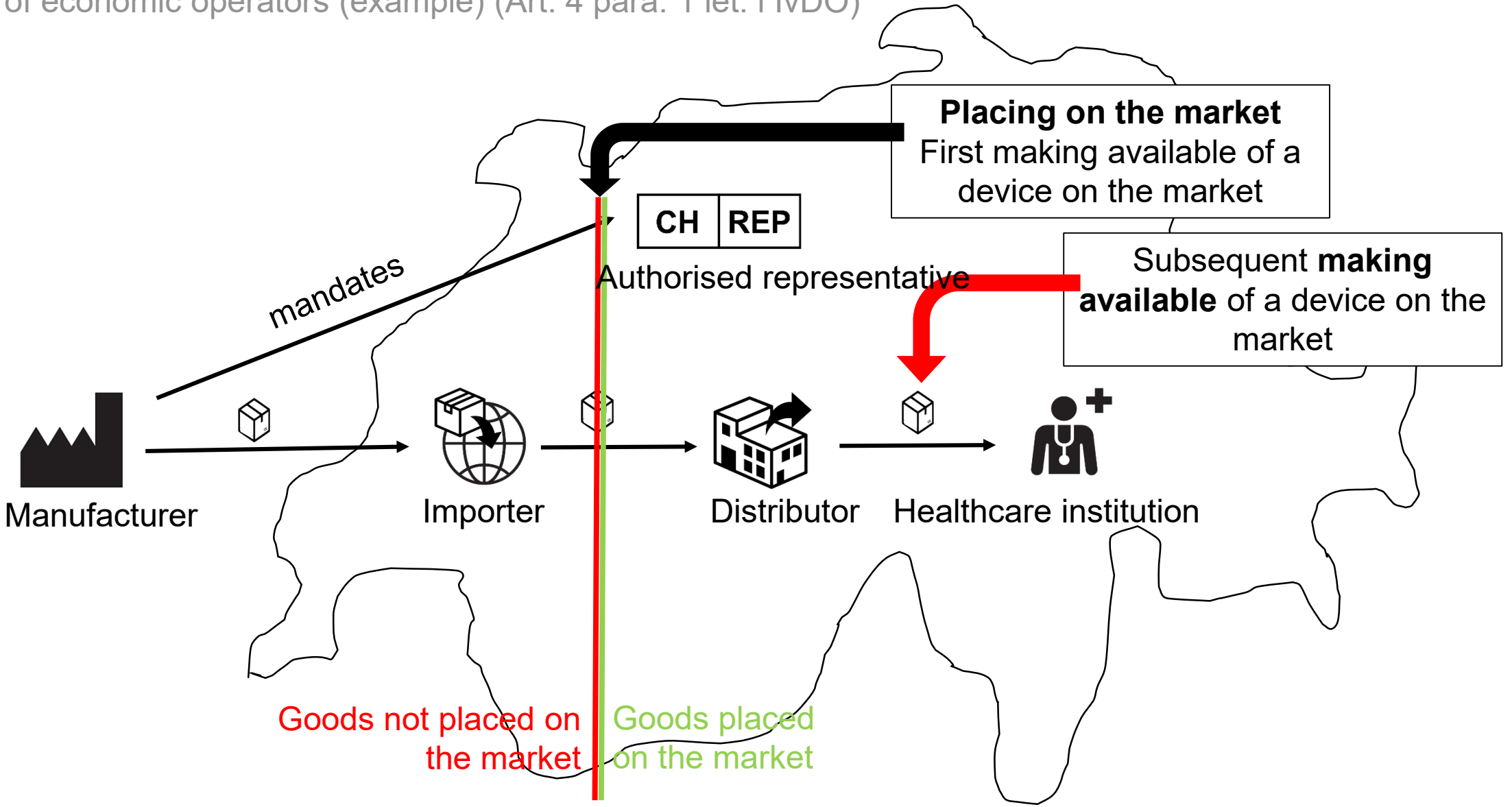


Distributor (Art. 74 IvDO)

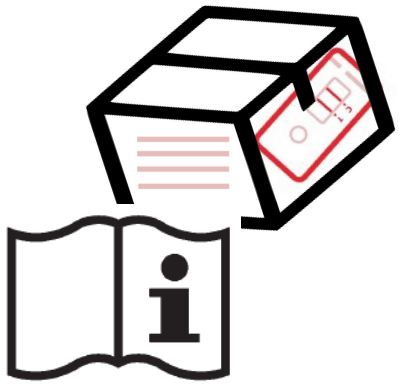
- Natural or legal person that **makes a device available on the Swiss market** up until the point of putting into service
  - **Making available:** transfer or cession of a device for distribution, consumption or use on the Swiss market in the course of a commercial activity

- Before making available on the market, check that:

CE

CE xxxx

DE / FR / IT



UDI

Distributor (Art. 74 IvDO)

- Natural or legal person that **makes a device available on the Swiss market** up until the point of putting into service
  - **Making available:** transfer or cession of a device for distribution, consumption or use on the Swiss market in the course of a commercial activity

- Before making available on the market, check that:
  - The device carries the conformity marking
  - The declaration of conformity exists
  - The product information exists
  - For imported devices: Importer is noted
  - Where required, a UDI is assigned

Distributor (Art. 74 IvDO)

- Traceability in the market
  General principle: Devices must achieve an appropriate level of traceability
  - Economic operators shall disclose the following to Swissmedic on request:
    - All economic operators from whom they have acquired a device and
    - All economic operators, healthcare institutions and healthcare professionals to whom they have supplied a device.

- Duty of care
  If the distributor has doubts about its conformity, the device may **not** be made available on the market

- Registration obligations
  Distributors do **not** need to register.

Any person handling **therapeutic products** must take all measures necessary according to the state of the art to ensure that **human** or animal **health** is not endangered.

Further information on our website and especially in the information sheets

- **for economic operators**
  https://www.swissmedic.ch/swissmedic/en/home/medizinprodukte/marktzugang/pflichten-bevollmaechtigte.html

- **for healthcare institutions**
  https://www.swissmedic.ch/swissmedic/en/home/medical-devices/reprocessing---maintenance/beschaffung.html