swissmedic

Online event

Information on the new medical devices regulation

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Requirements for devices on the Swiss market

Revised Medical Devices Ordinance

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- Product information
  - requirements - benefits - labelling
- Details of the economic operators on the device
  - devices under the new and old legislation
  - transitional periods
- Device identification UDI
- Devices on the market

Disclaimer

- *The applicable medical device provisions of the Therapeutic Products Act (TPA; SR 812.21) and the Medical Devices Ordinance (MedDO; SR 812.213) have been generalised for this presentation.*
- *The current legal provisions apply in all cases.*
- *Specific cases are not covered by this presentation.*

Requirements for devices

- A device may be placed on the market or put into service only if it complies with this Ordinance when duly supplied and properly installed, maintained and used in accordance with its intended purpose.
- Devices must conform to the general safety and performance requirements set out in Annex I MDR, taking account of their intended purpose.

- *Basis:* *Art. 6 paras. 1-2 MedDO*
  Annex I MDR

Requirements for devices

- General Safety and Performance Requirements (GSPR)

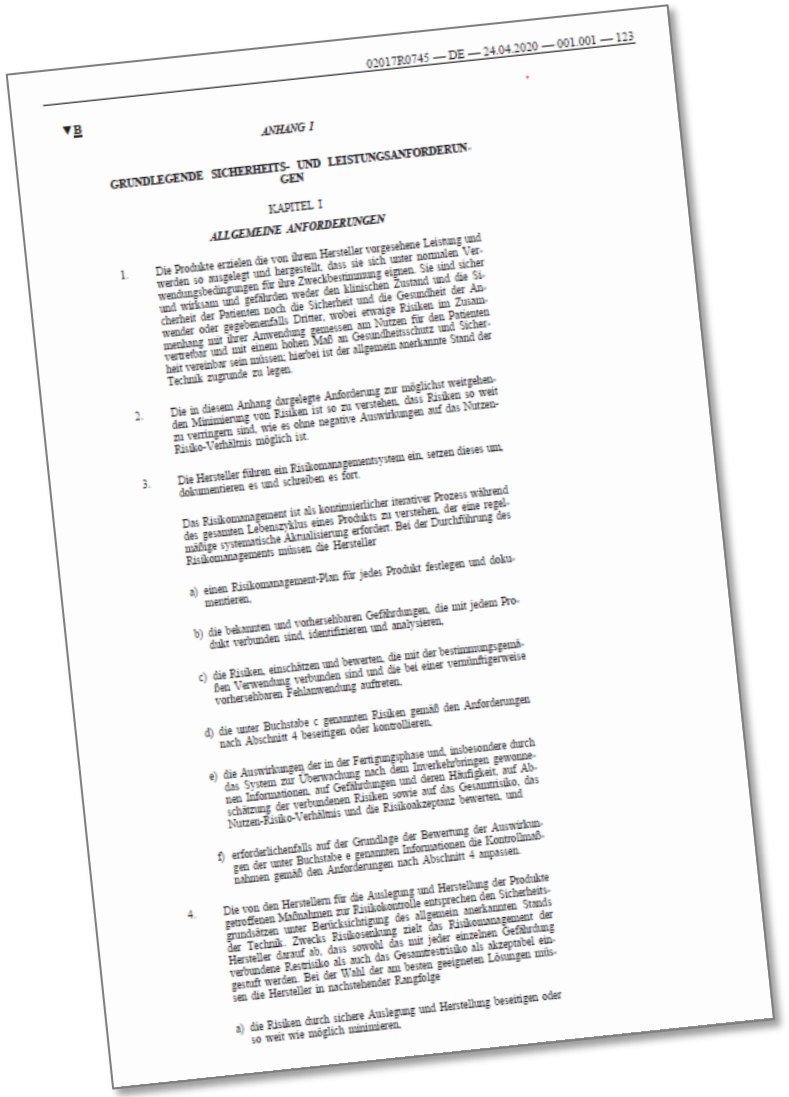
→ **Responsibility of the manufacturer**

Content:

- General requirements (e.g. minimise risks);
- Requirements regarding design and manufacture;
- Requirements regarding **product information**

Additionally:

- Harmonised / designated standards
- Common Specifications (CS)
- **Product information according to MedDO**



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ANHANG I

GRUNDLEGENDE SICHERHEITS- UND LEISTUNGSANFORDERUNGEN

KAPITEL I

ALLGEMEINE ANFORDERUNGEN

1. Die Produkte erzielen die von ihrem Hersteller vorgesehene Leistung und werden so ausgelegt und hergestellt, dass sie sich unter normalen Verwendungsbedingungen für ihre Zweckbestimmung eignen. Sie sind sicher und wirksam und gefährden weder den klinischen Zustand und die Sicherheit der Patienten noch die Sicherheit und die Gesundheit der Anwender oder gegebenenfalls Dritter, wobei etwaige Risiken im Zusammenhang mit ihrer Anwendung gemessen an Nutzen für den Patienten vertretbar und mit einem hohen Maß an Gesundheitsschutz und Sicherheit vereinbar sein müssen; hierbei ist der allgemein anerkannte Stand der Technik zugrunde zu legen.

2. Die in diesem Anhang dargelegte Anforderung zur möglichst weitgehenden Minimierung von Risiken ist so zu verstehen, dass Risiken so weit zu verringern sind, wie es ohne negative Auswirkungen auf das Nutzen-Risiko-Verhältnis möglich ist.

3. Die Hersteller führen ein Risikomanagementsystem ein, setzen dieses um, dokumentieren es und schreiben es fort.

Das Risikomanagement ist als kontinuierlicher iterativer Prozess während des gesamten Lebenszyklus eines Produkts zu verstehen, der eine regelmäßige systematische Aktualisierung erfordert. Bei der Durchführung des Risikomanagements müssen die Hersteller

a) einen Risikomanagement-Plan für jedes Produkt festlegen und dokumentieren.

b) die bekannten und vorhersehbaren Gefährdungen, die mit jedem Produkt verbunden sind, identifizieren und analysieren,

c) die Risiken, einschätzen und bewerten, die mit der bestimmungsgemäßen Verwendung verbunden sind und die bei einer vernünftigerweise vorhersehbaren Fehlanwendung auftreten.

d) die unter Buchstabe c genannten Risiken gemäß den Anforderungen nach Abschnitt 4 beseitigen oder kontrollieren.

e) die Auswirkungen der in der Fertigungsphase und, insbesondere durch das System zur Überwachung nach dem Inverkehrbringen gewonnenen Informationen, auf Gefährdungen und deren Häufigkeit, auf Abschätzung der verbundenen Risiken sowie auf das Gesamtrisiko, das Nutzen-Risiko-Verhältnis und die Risikoakzeptanz bewerten, und

f) erforderlichenfalls auf der Grundlage der Bewertung der Auswirkungen der unter Buchstabe e genannten Informationen die Kontrollmaßnahmen gemäß den Anforderungen nach Abschnitt 4 anpassen.

4. Die von den Herstellern für die Auslegung und Herstellung der Produkte getroffenen Maßnahmen zur Risikokontrolle entsprechen den Sicherheitsgrundsätzen unter Berücksichtigung des allgemein anerkannten Stands der Technik. Zwecks Risikosenkung zieht das Risikomanagement der Hersteller darauf ab, dass sowohl das mit jeder einzelnen Gefährdung verbundene Restrisiko als auch das Gesamtrestrisiko als akzeptabel eingestuft werden. Bei der Wahl der am besten geeigneten Lösungen müssen die Hersteller in nachstehender Rangfolge

a) die Risiken durch sichere Auslegung und Herstellung beseitigen oder so weit wie möglich minimieren.

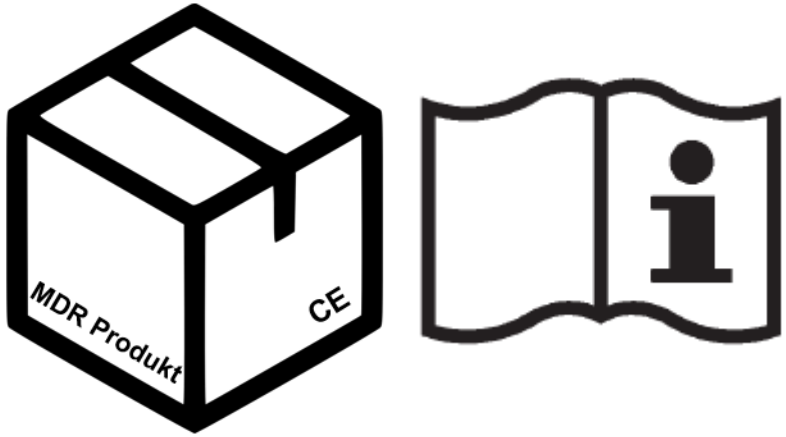
Benefits of product information?

- Information on the safety and performance of the device -> safe use!
- Information on the correct handling of the device (e.g. transport, storage)
- Identifies the device and the economic operators
  - e.g. for reporting incidents, ensuring 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 (Art. 16 MedDO)

- Product information comprises the labelling and instructions for use



- Governed by Chapter III of Annex I MDR

- Three official languages (d, f, i) or symbols
  - Fewer languages possible if supplied exclusively to professionals (Art. 16 para. 3 MedDO)

- Misleading/contradictory information on a device's intended purpose/safety/performance is forbidden (Art. 16 para. 7 MedDO)
  -> also applies specifically to the advertising for these devices! (Art. 69 para. 2 MedDO)

Label

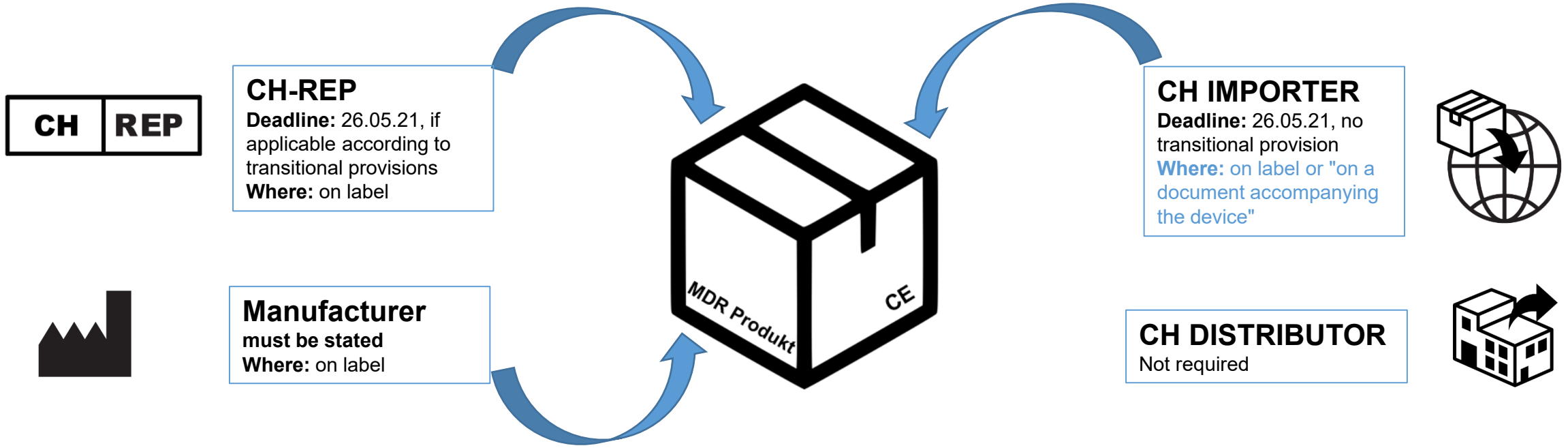
- Written, printed or graphic information appearing either on the device itself, or on the packaging (Art. 4 para. 2 MedDO in conjunction with Art. 2 point 13 MDR)
  - human-readable interpretation supplemented by machine-readable information (e.g.: bar codes or RFID)

Roles of economic operators:

- Provide information about the **manufacturer** and its **authorised representative (device requirement):**
  - MDR: Label (Art. 16 para. 1 MedDO in conjunction with Annex I point 23.2 let. c and d EU-MDR)
  - MDD: Label or instructions for use (Art. 7 para. 1 let. a oMedDO in conjunction with Annex I point 13.3 MDD)
  - AIMDD: Sales packaging and instructions for use (Art. 7 para. 1 let. b oMedDO in conjunction with Annex I points 14 indent 1 and 15 indent 2 AIMDD)

- State the CH importer (Art. 53 para. 2 MedDO)
- Provide the **name** and **address of the place of business**

What roles should be stated "on the MDR device"?

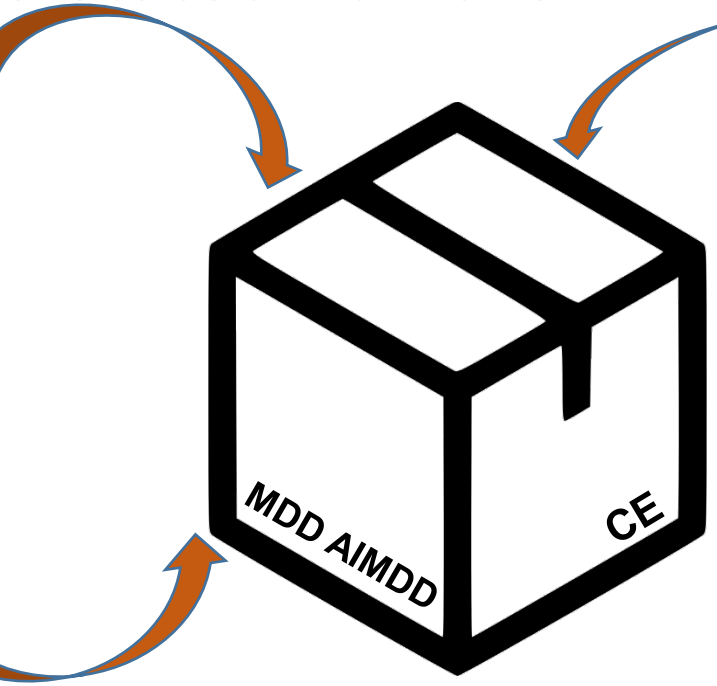


- Importer: What does "on a document accompanying the device" mean? (Art. 16 para. 2 MedDO)
  - Affixed to the device or separately from the device
  - Accompanies the device through the whole supply chain up to the final user
  - Examples: a sticker on the label or the instructions for use.

What roles should be stated "on the MDD/AIMDD device"?

CH-REP
Deadline: 26.05.21, if applicable according to transitional provisions
Where:
MDD -> label or instructions for use
AIMDD -> sales packaging and instructions for use

Manufacturer
must be stated
Where: on label



CH IMPORTER
Deadline: 31.07.2022*,
Swissmedic recommendation, from 26.05.21
Where: on label or "on a document accompanying the device"

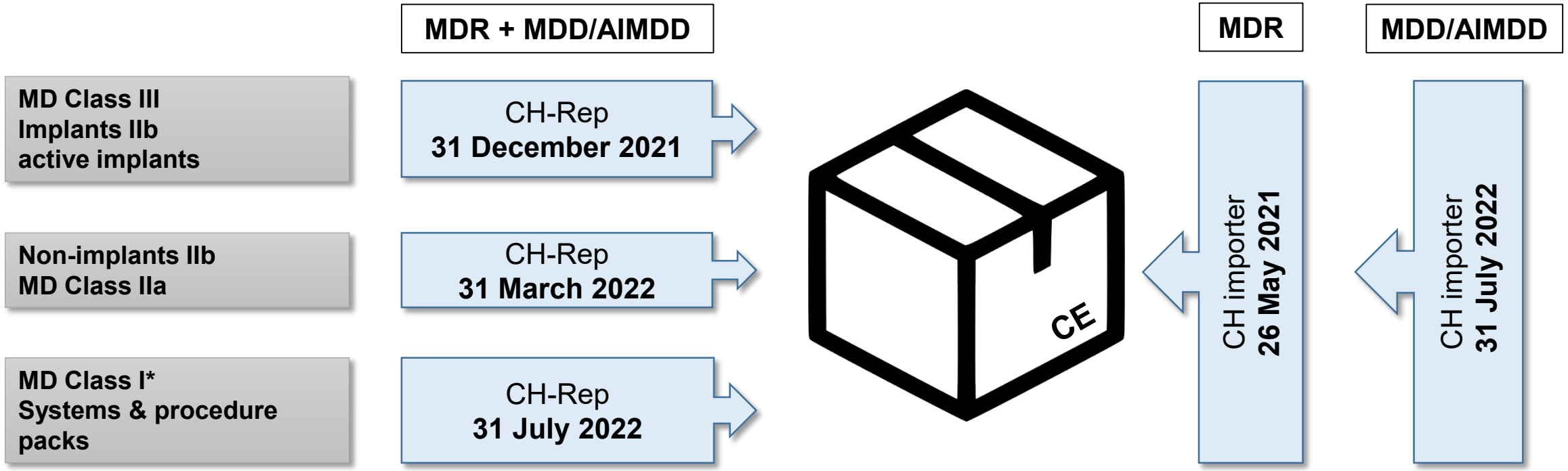
CH DISTRIBUTOR
Not required

*** Deadline:**

- According to published interpretation of the EU (currently not known) -> equivalent implementation
- Swissmedic basically requires the CH importer to be stated
  - From 31.07.2022, if EU interpretation has not been published by then
  - Swissmedic recommendation, implementation from 26.05.21

Label – Overview of transitional provisions

- The key factor is the date of placing on the market (made available for the first time)
- **CH-REP:**
  - Labelling is based on the mandate from the manufacturer
  - From 26.05.21, transitional periods for EU/EEA manufacturers or EC Reps (Art. 104a MedDO)



*Class I per MDD with transitional period (e.g. higher risk classification according to the MDR, sterile, measuring function

Device identification (UDI)

- Any manufacturer or person who assembles systems and procedure packs shall assign the device, system or procedure pack, with the exception of custom-made devices, and all higher levels of packaging, a unique device identifier (UDI) prior to placing it on the market.

- Basis: Art. 17 MedDO
  Art. 27 and 29 MDR
  Annex VI MDR

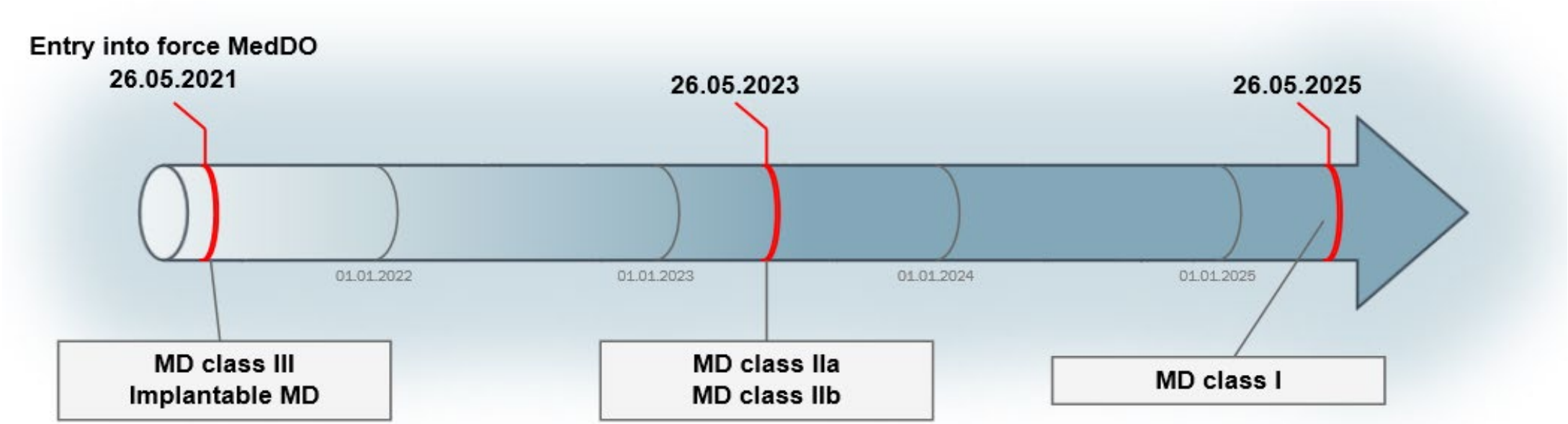
Unique Device Identifier - UDI

- UDI = numeric or alphanumeric code
- Designates
  - Device model (UDI-DI)
  - Production unit (UDI-PI; e.g. lot or serial number)
- On the label of the device, system or procedure pack and all higher levels of packaging (Art. 17 para. 2 MedDO).
- Human Readable Interpretation (HRI) and machine-readable (e.g. bar code)
- Traceability and transparency
- EUDAMED: UDI is the "access key" to publicly available product information
- Affixed by manufacturer, only mandatory for MDR devices

(01)24531543215315 (17)255612(10)ABCD (21)F2445

Label – Product identification (UDI)

- Transitional periods (Art. 104 MedDO):



For reusable devices where the UDI has to be affixed to the device itself:
Two years after the date of the relevant device class

Devices on the market

Devices on the market

- Conformity of the medical device -> with new / old legislation?

- What transitional provisions of the MedDO are applicable?
  - e.g. concerning product information

- Stock items
  - Role of the economic operator in relation to the device?

Questions:

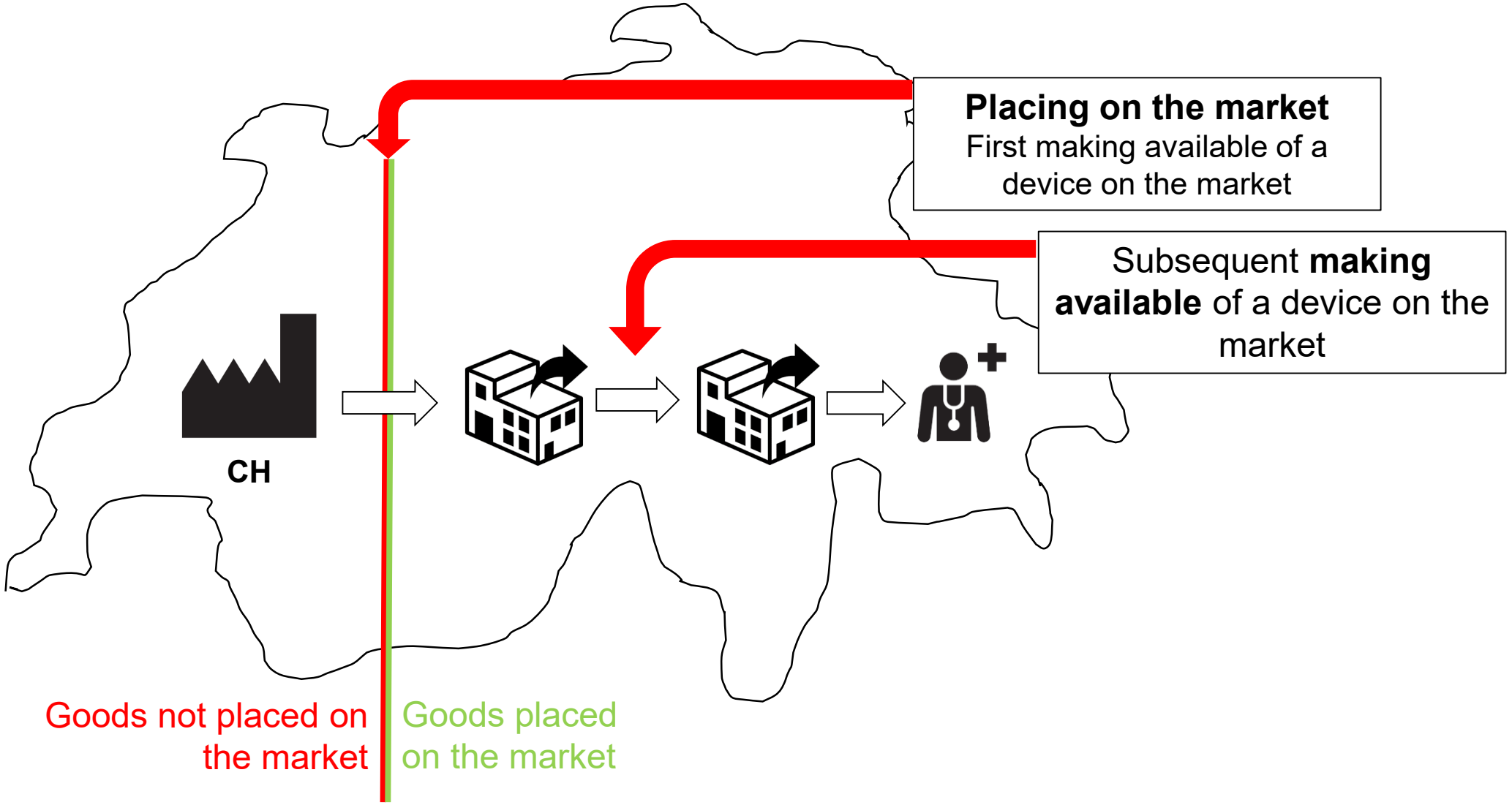
- When is a device considered to be placed on the market?
- Who places it on the market? (e.g. importer)

Placing on the market

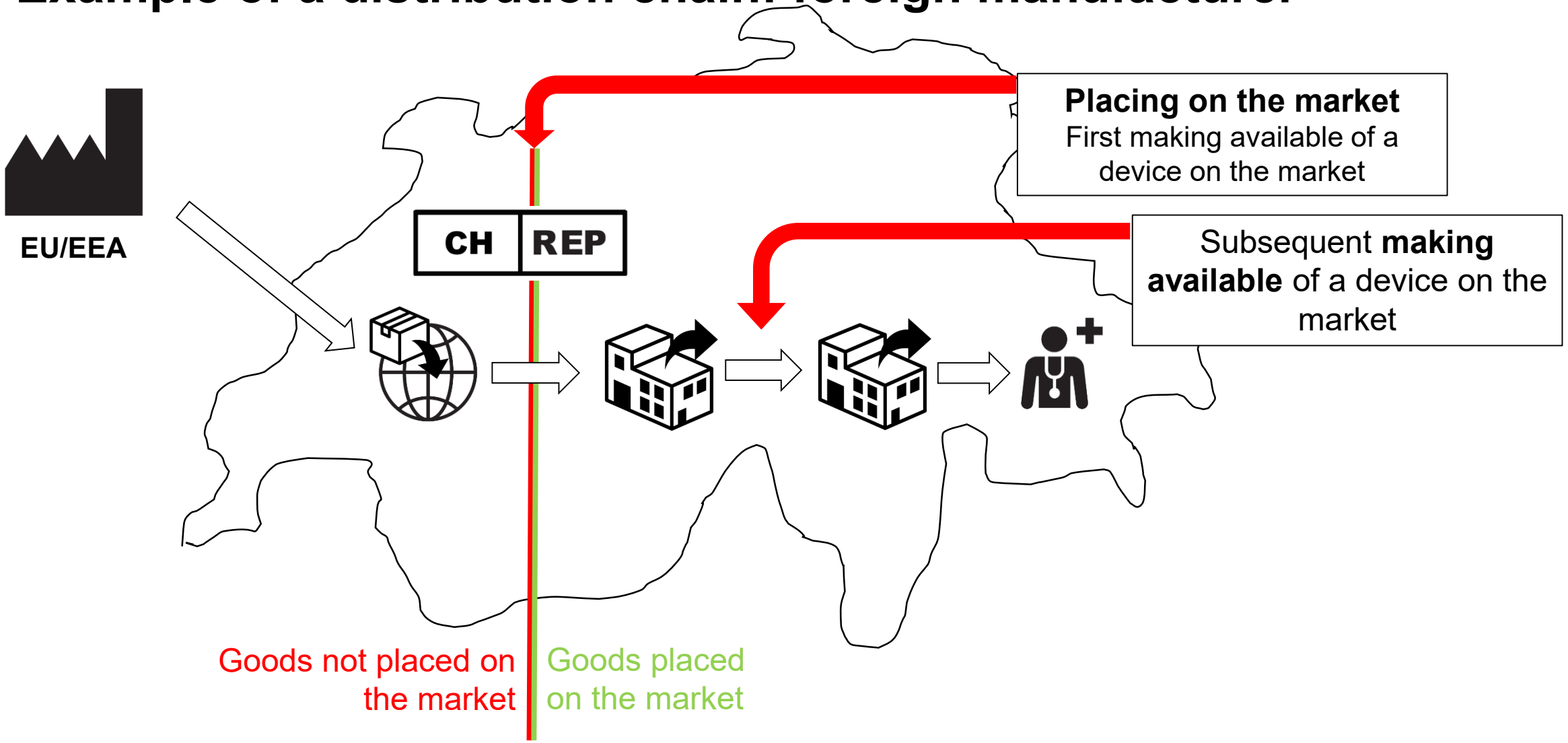
Definition (Art. 4 para. 1 let. b MedDO): first making available of a device on the Swiss market

- First transfer / supply of a medical device in Switzerland
  - between economic operators or
  - from economic operator to a healthcare institution or consumer
- 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

Example of a distribution chain: manufacturer in Switzerland



Example of a distribution chain: foreign manufacturer



Placing on the market of devices that comply with the old legislation (Art. 101 para. 1 MedDO)

Placing on the market or putting into service **until 26 May 2024** possible if:

- Devices continue to comply with the old legislation
  - Devices have not undergone any significant changes in their design or intended purpose
- Valid certificate (EC certificate) acc. to Art 100 MedDO exists
  - issued before 25.05.17 -> valid no later than 25.05.2022
  - issued after 25.05.17 -> valid no later than 25.05.2024
- Devices classified as class I under the old legislation for which a certificate is newly required according to MDR (e.g. devices assigned to a higher risk class under the MDR)

-> All other devices (example: Class I acc. to MDR, custom-made devices, systems and procedure packs under the old legislation) may NO LONGER be placed **on the market** from 26.05.21

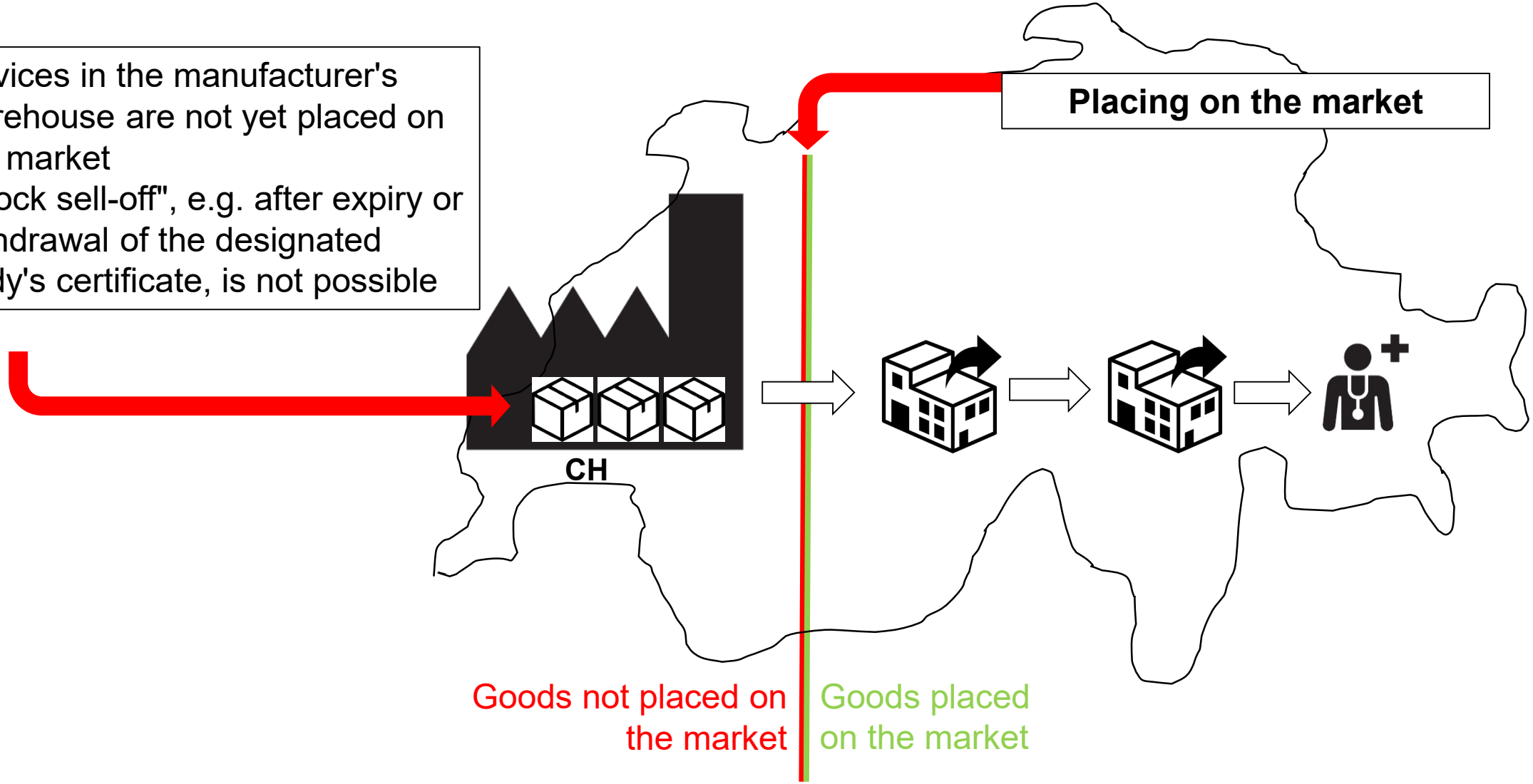
Placing on the market of devices that comply with the old legislation (Art. 101 para. 3 MedDO)

Making available on the market or **putting into service until 26 May 2025** possible for:

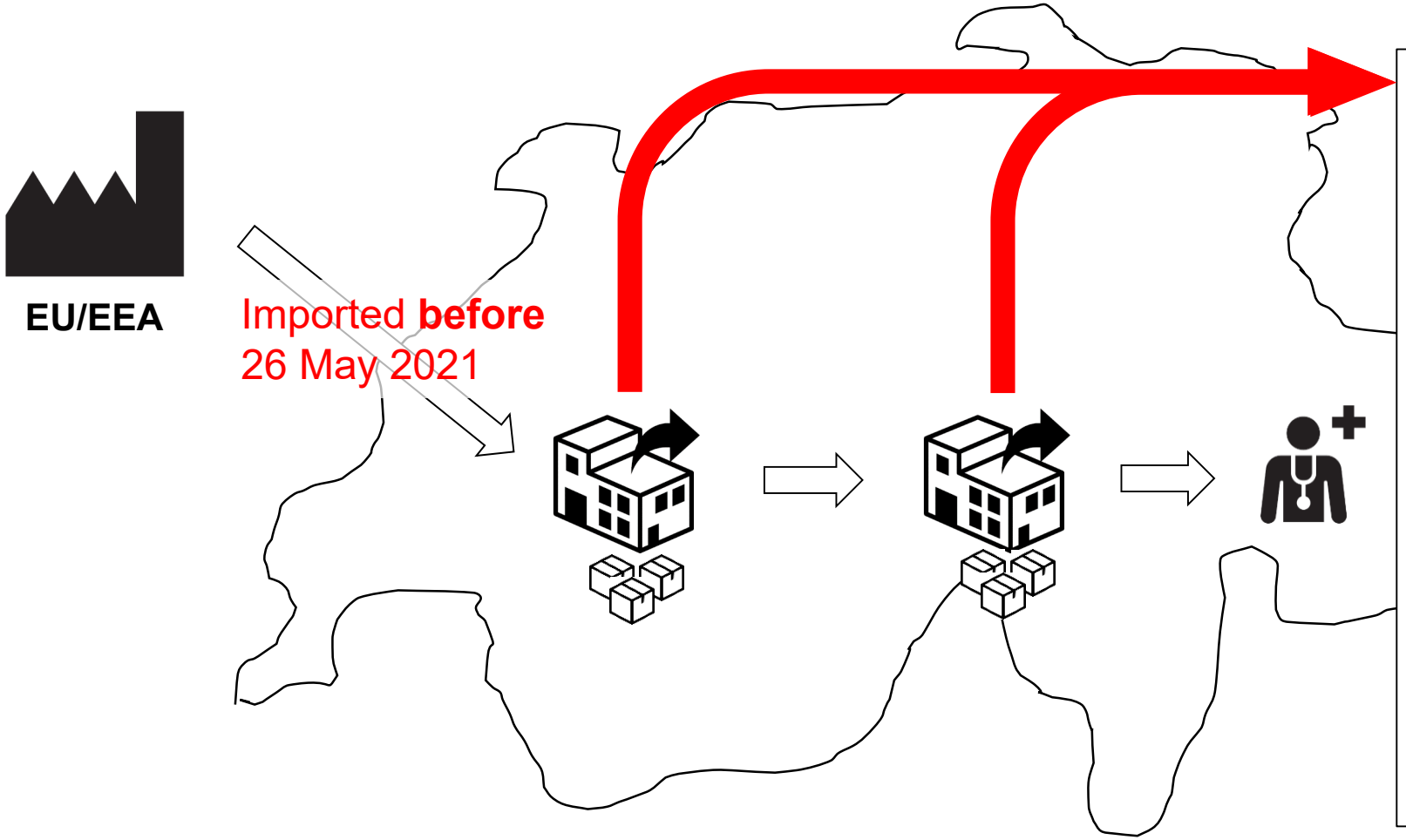
- Devices placed on the market before 26 May 2021 under the old legislation
- Devices placed on the market under the old legislation according to Art. 101 para. 1 MedDO

Devices in the manufacturer's warehouse

- 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 imported before 26 May 2021



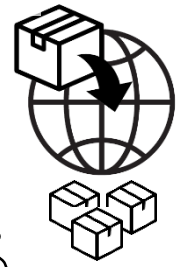
- Imported / at warehouse before the new regulation entered into force (26 May 2021): considered to be placed on the market **in the European context** according to the old legislative provisions
- Devices can continue to be made available on the market (Art. 101 para. 3 MedDO; products compliant with the old legislation may be made available until 26 May 2025 at the latest).
- The importer or CH-REP does **not** need to be stated retrospectively

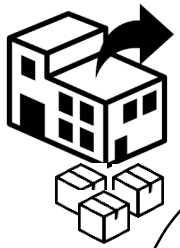
Devices imported after 26 May 2021

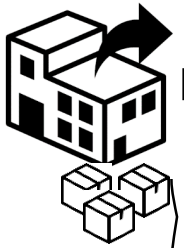
EU/EEA

Imported **after** 26 May 2021

CH REP







Upon expiry of the applicable transitional periods: **place on the market** only if the labelling requirements are satisfied; also applies to devices imported before the end of the periods.

Devices that have been transferred/supplied to the **distributor** are placed on the market. These can therefore continue to be made available on the market although, for devices compliant with the old legislation, only until 26 May 2025 (Art. 101 para. 3 MedDO).

~~Goods~~ not placed on the market

Goods placed on the market

Take-home messages

- Product information
  - Information from economic operators on the device
  - The following are relevant: device status (under the old and new legislation), transitional provisions (CH-REP and importer) and device risk class (CH-REP)
  - Basically, place device information on label or instructions for use

- Device identification (UDI)
  - For MDR devices, to be affixed by the manufacturer

- Determine status of devices on the market:
  - is a device placed on the market?
  - who places/placed the device on the market?

Thank you for your valued attention