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Runs the boutique consultancy and CH-REP Decomplix for 10 years.



Builds and maintains relationships with Swiss importers, manufacturers and institutions of all shapes and sizes.



Helena Lacalle

Regulatory Affairs Director

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➤ Pharmacist by training, with a master's degree in statistics.

➤ 25+ years of regulatory & quality management experience, mainly in MedTech and Pharma.



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Swiss importers: Are you ready for the 2025 Swiss inspection?

Regulatory requirements for medical device importers & Swissmedic's role

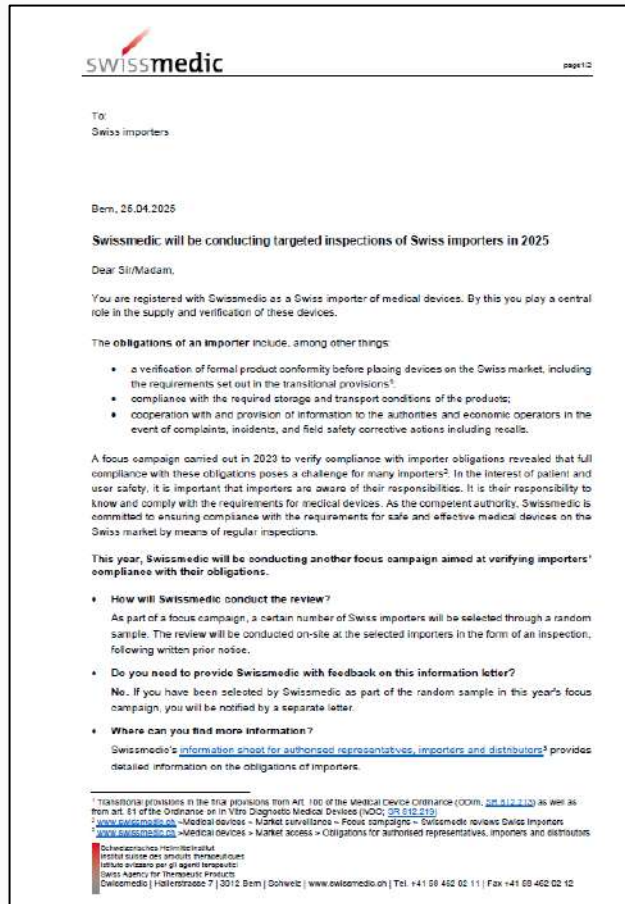
3rd July 2025 | Swiss Medtech Webinar | Beni Hirt & Helena Lacalle

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STARTING POINT



Heads-up: Swissmedic is coming



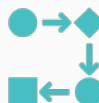
scope

- Obligations of importers under MedDO/IvDO.
- For MDR/IVDR devices & “legacy” devices.
- Also concerns parallel imports.



timelines

- Throughout 2025 (with prior written notice).
- Inspection duration: 0.5 – 1 day.



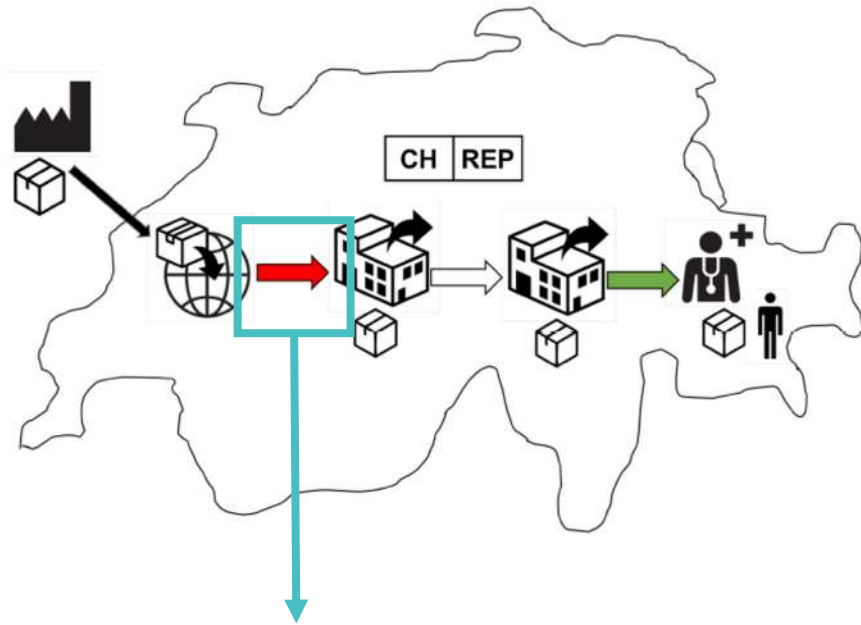
procedure

- On-site inspections (2 inspectors).
- Selection of companies by random sampling.

REGULATORY BASICS



What makes an “importer”?



The action of “placing on the market”:

- 1) “Transfer of ownership” from foreign manufacturer
- 2) Subsequent “transfer of ownership” within Switzerland

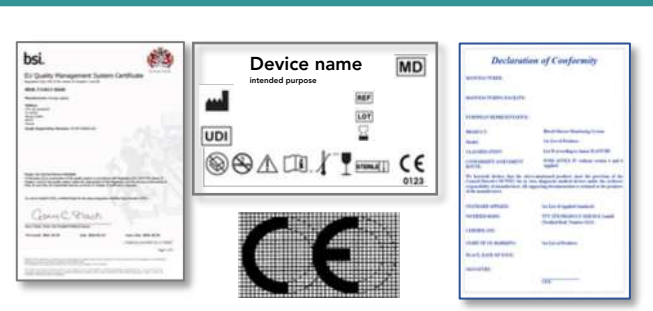
⇨	<p>Making available on the market (Art. 4 para. 1 let. a MedDO, Art. 4 para. 1 let. a IvDO) Collective term referring to the transfer or supply of a device. The use of a product by a professional user (e.g. an implant or dressing material) does not constitute making available on the market. The making available of a product supposes an offer or an agreement (written or verbal) between two or more legal or natural persons for the transfer of ownership possession or any other right concerning the product in question after the stage of manufacture has taken place¹⁰. The transfer does not necessarily require the physical handover of the product. This transfer can be for payment or free of charge.</p>
➔	<p>Placing on the market (Art. 4 para. 1 let. b MedDO, Art. 4 para. 1 let. b IvDO) First making available of a device on the Swiss market (e.g. via a transfer or supply between economic operators or from a Swiss economic operator to a healthcare facility / the consumer). The concept of placing on the market refers to each individual device, not to a type of device¹¹. Consequently, each individual device is placed on the market even if devices of the same model or type have already been placed on the market.</p>
➔	<p>Putting into service (Art. 4 para. 1 let. c MedDO, Art. 4 para. 1 let. c IvDO) The stage at which the device is made available to the final user/healthcare facility for the first time.</p>

Source: Swissmedic’s InfoSheet on the [Obligations of Economic Operators](#)



Flow of goods is NOT indicative of transfer of ownership. They frequently follow different paths.

Swiss importer requirements ([MedDO Art. 53](#) / [IvDO Art. 46](#))




bsi. Quality Management System Certificate
MD
Declaration of Conformity

Device name
intended purpose

CE marking

Check conformity per device unit (CE marking, labelling, CH-REP, UDI)



Ensure right storage/transport conditions (GDP)




UDI
(01)01234567891011|17|200526;10|123456789

UDI
(01)01234567891011
(17)210526
(10)123456789

Keep device traceability ↑↓



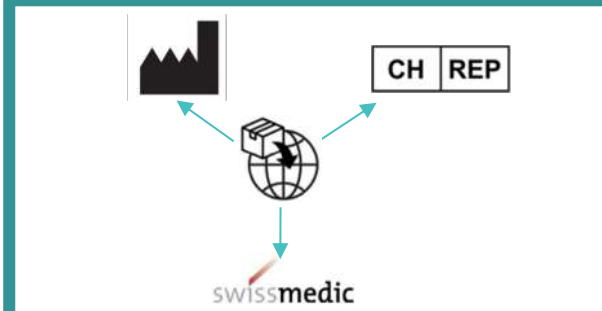
Record complaints, non-conformities, recalls & withdrawals



swissdamed

CHRN - IM - 2xxxxxxx

Register in swissdamed & Indicate importer particulars



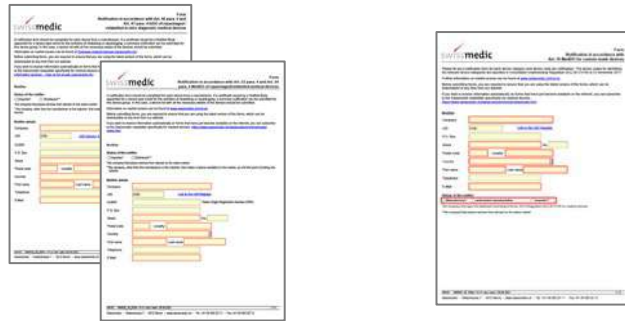
CH REP

swissmedic

Inform & Cooperate with stakeholders

Swissmedic's controls (for Swiss importers)

Mandatory Notifications



Market Surveillance

device inspections



focus campaigns



suspicion reports



Non-conformities

Request for submission of a written CAPA Plan to Swissmedic (various review loops possible).

Insufficient correction

Swissmedic's ruling (administrative procedure), e.g. further CAPA, mandatory product recall, restriction of sales.

Consequence of offences

Fines or prosecution.

Penalties for criminal provisions per chapter 8 of the [TPA](#) (SR 812.21).

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Thank you for your attention!

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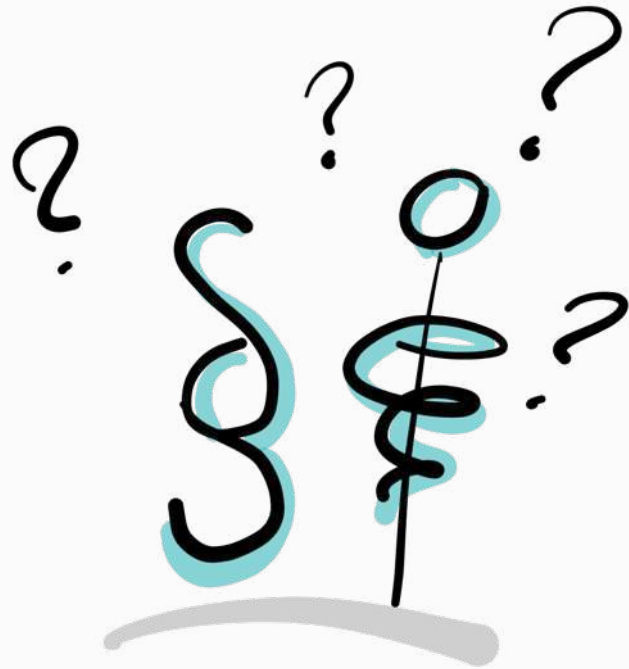
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Recommendations for importers

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What is Compliance?



- Compliance = **conformity with regulations**
- Compliance **requires the use of procedures** that implement the requirements of the regulations
- In Medtech, **compliance must be proven** by meeting 3 conditions:

Documentation

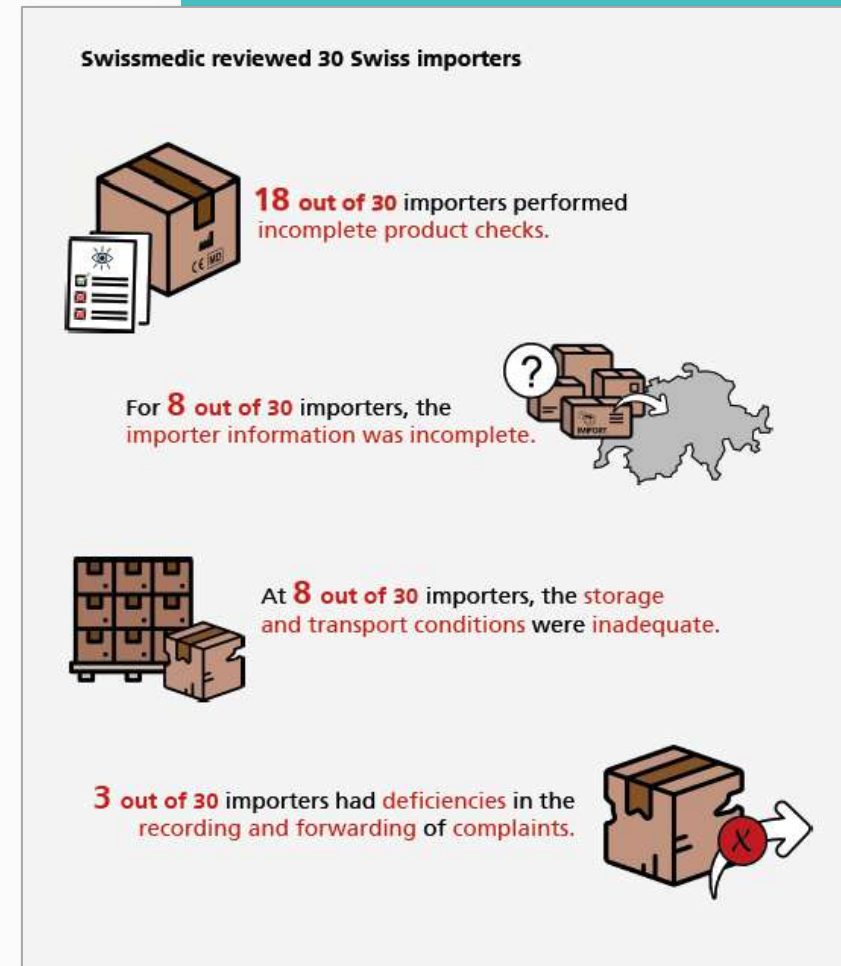
Traceability

Auditability

Swissmedic's expectations on importers

From a previous focus campaign (2023), key points that were checked:

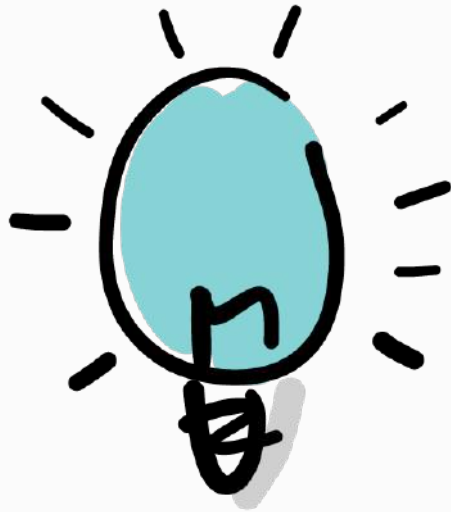
- Correct **device verification** prior to sales
- Indication of **importer's contact details** accompanying the device
- Appropriate **storage and transportation conditions** (per manufacturer's instructions)
- Duly **reporting of problems or complaints** to the manufacturer



**The inspectors focus on
MedDO and IvDO paragraphs.**



Tips for being prepared and compliant



- **Read relevant regulatory references.** Re-read frequently.
- **Review your portfolio** and identify your EO role for each product you bring into the Swiss market.
- Record in your **ERP all relevant regulatory information** about each device
- Have always the following **information ready to share:**
 - Conformity verification record
 - Device's Declarations of Conformity (or CMD statement or PP/S statement)
 - Notified Body's Certificates (and Confirmation Letters for legacy devices)
 - Traceability proof
 - Complaints log (and proof of notification to the manufacturer & CH-REP)

See the inspection as an opportunity to improve quality and efficiency within your company.



How to avoid common pitfalls during the inspection



Ensure a professional welcoming of the inspection team.



Start with a clear presentation of your company and all your product categories.



Ensure consistency between what you say, you show and you have sent in advance.



Have a clear approach to ensure importer and CH-REP particulars on labelling.

Take compliance seriously



Establish the minimum procedures.



Create and save records.



Train your team, prepare your infrastructure and documentation.

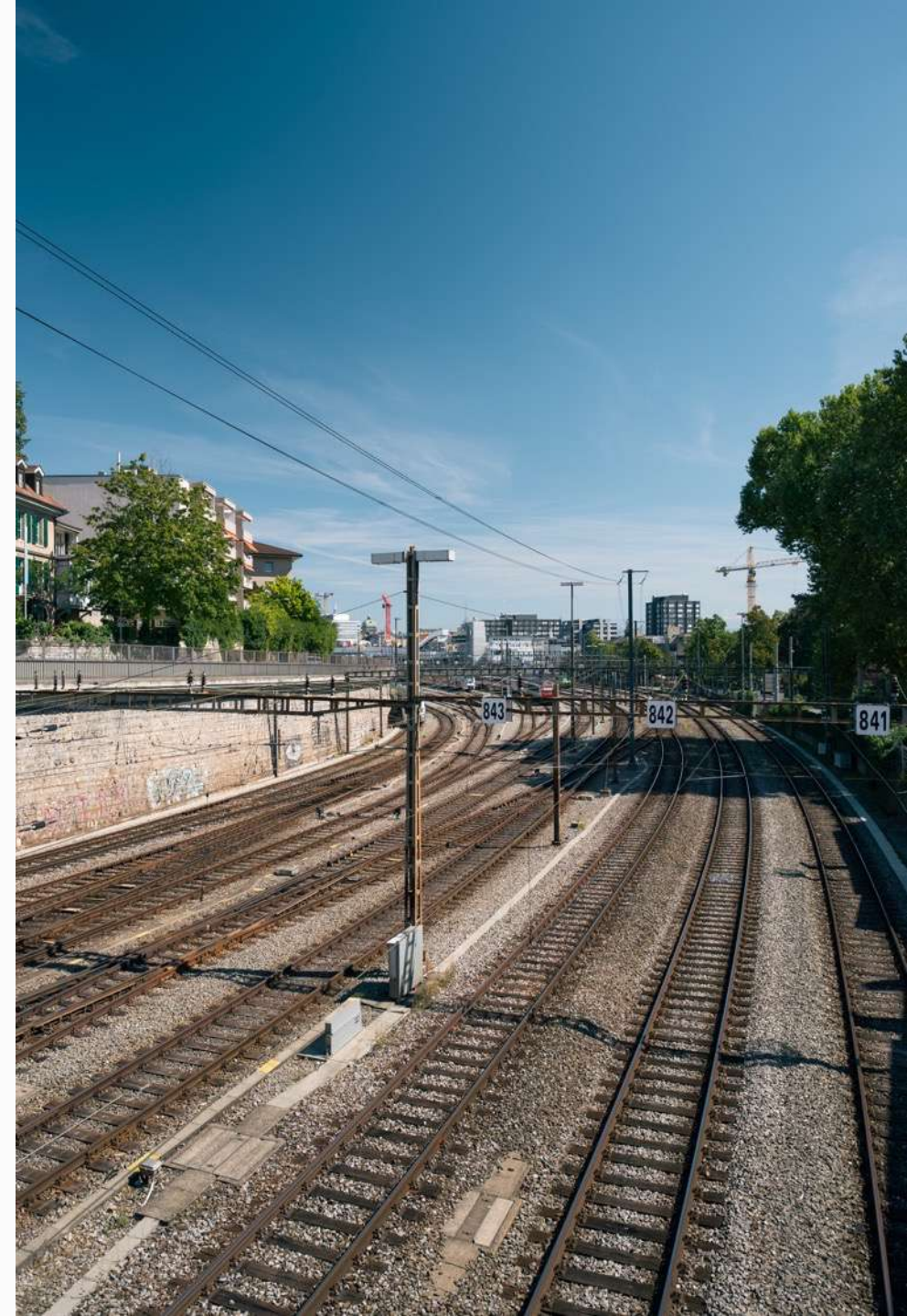


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Questions & Answers

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