Medical Devices
Swissmedic reviewed Swiss importers

Swissmedic, the Swiss supervisory authority for medical devices, has conducted a focus campaign, inspecting importers who bring medical devices from abroad into Switzerland and sell them here.

Medical devices compliant in the EU can also be placed on the market in Switzerland without regulatory approval by Swissmedic. Under the legislation on medical devices in force since 26 May 2021, importers in Switzerland, as in Europe, play an important role. Importers bring foreign medical devices into Switzerland. As "gatekeepers", they are responsible for the initial control of the products before they enter the market.

The revision of the regulation assigned additional duties to importers. They must observe the transitional provisions from the old to the new regulation.

Between March and September 2023, Swissmedic therefore selected a sample of 30 importers and examined them more closely. During this investigation, particular attention was paid to whether these companies were aware of and complied with the legal rules.

Key points that were checked:

- Do importers check the products correctly before they sell them?
- Are the importer's contact details indicated?
- Are the devices stored and transported under the right conditions?
- Does the importer report problems or complaints about a product to the manufacturer?

In general, the importers were aware of the legal obligations. A majority of the companies were also aware of their reporting obligations towards the manufacturer and authorized representative in Switzerland. This is an important prerequisite for continuously improving medical devices and ensuring patient safety.

There were deficiencies at 23 of the 30 inspected importers, in particular:

- the correct verification of the products
- the indication of the importer's contact details
- the storage and transport conditions

Swissmedic has given the importers a deadline to remedy the identified deficiencies. If the deficiencies are not corrected within the deadline, Swissmedic will take appropriate measures.

The focus campaign has shown that the current transition phase is challenging for importers. In the interest of patient safety, it is important that importers are aware of their responsibilities. It is their duty to know and comply with the new regulation for medical devices.

Swissmedic, as the competent supervisory authority, is committed to ensuring compliance with the requirements for safe and effective medical devices on the Swiss market through regular inspections.

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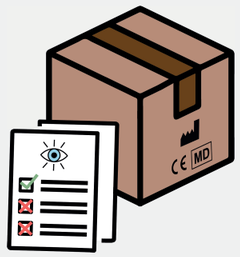
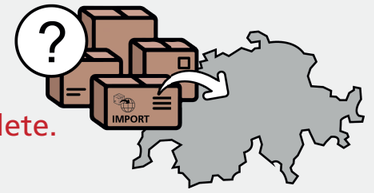
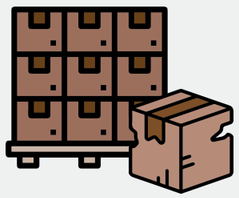


18 out of 30 importers performed incomplete product checks.

For **8 out of 30** importers, the importer information was incomplete.





At **8 out of 30** importers, the storage and transport conditions were inadequate.

3 out of 30 importers had deficiencies in the recording and forwarding of complaints.