

As the Swiss authorisation and supervisory authority for therapeutic products, Swissmedic is responsible for medical devices surveillance. In 2025, it conducted a focus campaign inspecting importers supplying medical devices from abroad for the Swiss market.

Between March and November 2025, Swissmedic carried out announced on-site inspections of a sample of 30 importers.

The focus was mainly on devices for daily use in health-care facilities (e.g. catheters, cannulas, surgical instruments and diagnostic instruments). A high standard of quality and safety must be ensured at all times in order to guarantee safety and health protection for patients and users.

When reviewing the devices, particular attention was paid to whether the importers

- correctly verify device conformity before placement on the market in Switzerland and comply with the requirements in the transitional provisions¹,
- ensure their details are indicated as importer and
- comply with the required storage and transport conditions.

Results – Importers

For 43 percent, there were no deficiencies (13/30 importers).

For 57 percent, there were deficiencies in the correct verification of devices, the importer information and/or the storage and transport conditions (17/30 importers).

It was notable that 30 percent (9/30 importers) were unable to ensure indication of their details as importer on the devices or an accompanying document.

Results – Devices

A transitional period has been in effect since Directive 93/42/EEC (“MDD”) was replaced by Regulation EU 2017/745 (“MDR”) on 26 May 2021. During this period, to ensure supply, legacy² “MDD” devices are permitted on the market under certain conditions via transitional provisions¹ in addition to “MDR” devices.

Of the 232 devices reviewed, 57 percent were legacy “MDD” devices (133/232 devices) and 43 percent were “MDR” devices (99/232 devices). On a positive note, sufficient evidence of compliance with the transitional provisions could be provided for 93 percent of the legacy “MDD” devices (124/133 devices).

Swissmedic identified deficiencies in 22 percent of the total number of devices reviewed (51/232 devices). While deficiencies were identified in 26 percent of the legacy “MDD” devices (34/133 devices), this was the case for only 17 percent of the “MDR” devices under the new regulatory framework (17/99 products). Fewer deficiencies were therefore found for “MDR” devices.

¹ Transitional provisions in the final provisions from Art. 100 of the Medical Devices Ordinance ([MedDO, SR 812.213](#))

² Medical devices for which a declaration of conformity and, if applicable, certification according to Directive 93/42/EEC concerning medical devices or Directive 90/385/EEC on active implantable medical devices has been issued and for which the conformity assessment procedure according to MedDO requires the involvement of a designated body (Art. 101 para. 1 let. a and b MedDO).

Conclusion

Compared to the focus campaign carried out in 2023, the current results show only minor improvements for importers.

Swissmedic is taking these findings into account in its ongoing market surveillance activities to further strengthen patient protection. Market surveillance will therefore continue to inspect importers on an ongoing basis.

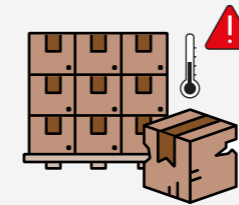
Deficiencies for 57% of inspected importers and 22% of reviewed devices



47% (14 out of 30) incomplete verification of devices

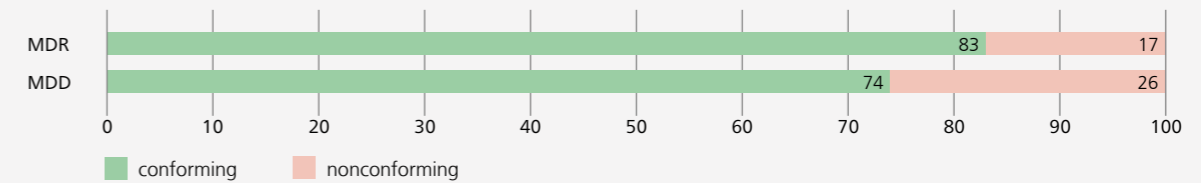


30% (9 out of 30) incomplete importer information



13% (4 out of 30) inadequate storage and transport conditions

Share of compliant and non-compliant MDD and MDR devices



Publisher

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