MEDDEV SAFETY SIGNALS · ISSUE 02

Which medical devices appeared most often in safety notices?

An analysis of public field safety corrective action and recall notices in Switzerland shows which device groups most often required a manufacturer response.

H1 2026 Published: 24 July 2026 Data snapshot: 2026-07-24

EXECUTIVE SUMMARY

Surgical, laboratory and medical-imaging devices appeared most often.

The 250 Swissmedic publications listed 339 device entries. Among clearly defined groups, surgery and endoscopy, laboratory diagnostics and medical imaging were the largest. This measures public regulatory activity, not manufacturer safety performance.

Surgery and endoscopy: 56 entries.

The group included robotic instruments, endoscopic equipment, electrodes and procedure accessories.

Laboratory diagnostics: 47 entries.

Notices covered analysers, reagents and in-vitro diagnostic test kits.

Medical imaging: 40 entries.

Digital angiographic X-ray systems were the largest exact class. The group also included MRI, CT and other imaging systems.

PUBLICATIONS	DEVICE ENTRIES	SOFTWARE
250	339	24
unique Swissmedic references	one publication may list several devices	entries whose description mentions software

PUBLICATION TIMING

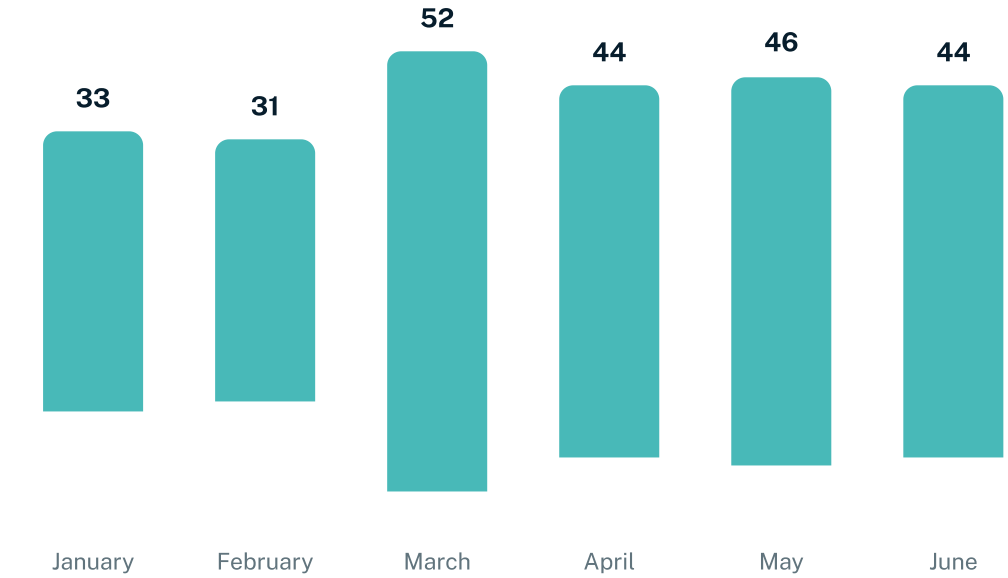
March recorded the largest number of new publications.

Monthly publication volume ranged from 31 to 52. The March peak does not establish that market safety deteriorated; timing also reflects manufacturer actions, document updates and authority publication practice.

Publications by month

Source: Swissmedic

Swissmedic, January–June 2026; original publication date.



How to read: the chart shows publication timing, not incident date, corrective-action start or defect onset.

DEVICE GROUPS

Three groups accounted for 42.2% of classified device entries.

Surgery and endoscopy, laboratory diagnostics and medical imaging represented 143 of 339 device entries. “Other” contains unrelated devices and is excluded from the ranked chart.

Most frequent device groups

Source: Swissmedic

Device entries listed in publications; each entry assigned to one dictionary-based group.



Meaning: higher volume may reflect a large installed base, broad portfolios or one action covering several models. It does not provide a failure rate.

RECURRING CLASSES

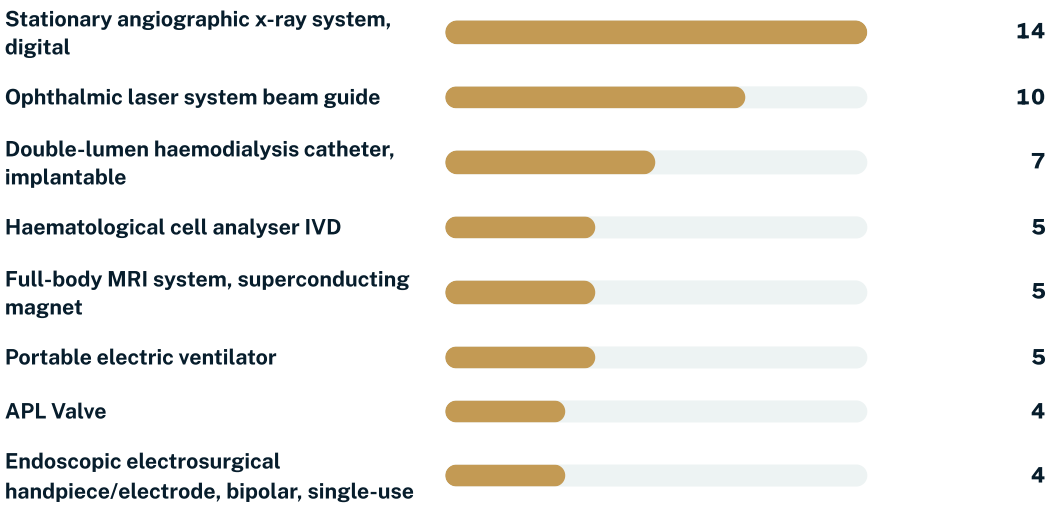
Angiography systems and ophthalmic laser beam guides recurred most often.

At the exact-class level, digital angiographic X-ray systems and ophthalmic laser beam guides appeared most often. Implantable haemodialysis catheters followed, then haematology analysers, whole-body MRI systems and portable ventilators.

Most frequently listed device classes

Source: Swissmedic

Exact class descriptions from the Swissmedic public list; unit: device entry.



This is not a risk ranking: the data do not provide installed units, procedure volume or patient exposure.

WHAT MANUFACTURERS SHOULD DO

A safety notice starts the work; it does not close it.

A public notice should trigger a documented review of the manufacturer's portfolio, distribution records and post-market surveillance evidence. Shared components, software and multi-configuration devices deserve particular attention.

01 Confirm the affected scope
Match names, models, lots, software versions and identifiers against the portfolio and supplied devices.

02 Test for a shared failure mode
Determine whether the same architecture, component, supplier or process exists in other devices.

03 Connect the signal to evidence
Review risk management, complaints, literature, periodic reports and post-market surveillance data.

04 Close the action loop
Document the decision, corrective action, distributor and user communication, and effectiveness check.

> **Important:** 24 entries mentioned software, but digital issues may also sit inside other device classes. Software version and system configuration should form part of device traceability.

SCOPE AND LIMITATIONS

A credible European-market sample, but not a complete picture of the European Union.

Swissmedic publishes notices concerning devices supplied in Switzerland or Liechtenstein. Many actions have broader international scope, but this report is not an EU-wide incident database. EUDAMED's vigilance module remains under development.

What we counted

- 250 unique publications in H1 2026.
- 339 device entries listed in those publications.
- Publication month, class description and device group.

What the data cannot show

- How often the issue occurred among devices in use.
- Whether a notice involved patient harm.
- Which manufacturer or device was “most dangerous”.

Why countries were not added together

The same action may be published by several authorities, while national systems use different update and display rules. Simple addition would create duplicates.

Comparison sources

The scope was also reviewed against public communications from Germany's BfArM, the UK's MHRA and the European Commission's EUDAMED status information.

> **Primary caveat:** a field safety corrective action or recall is not evidence of poor device quality by itself. It may also demonstrate effective detection and an appropriate manufacturer response.

Prepared by the MEDDEV specialist team. This report is informational and is not a safety assessment of a specific device, legal advice or medical advice.