

To:
Swiss manufacturers, Swiss authorised representatives

Bern, 23.04.2026

Swissmedic will be conducting a focus campaign of the requirements for post-market surveillance of higher-risk medical devices

Dear Sir/Madam,

You are registered with Swissmedic as a Swiss manufacturer or Swiss authorised representative for medical devices. As such, you play a central role in the post-market surveillance of medical devices.

Manufacturers must:

- establish a post-market surveillance system¹ to collect data on the use of their devices,
- outline their activities in post-market surveillance plans², and
- periodically document the results of their analyses in safety reports³ based on their plan.

For products from foreign manufacturers, the **Swiss authorised representative** is responsible for formal and safety-related matters in connection with the placing on the market of the product⁴.

A focus campaign conducted in 2024 to review post-market surveillance documentation revealed that full compliance with these obligations poses a challenge for many manufacturers⁵. In the interest of patient and user safety, it is important that manufacturers are aware of their responsibilities. It is their duty to be familiar with and comply with the requirements applicable to medical devices. Swissmedic, as the competent supervisory authority, ensures the safety and performance of medical devices on the Swiss market through regular inspections of compliance with the applicable requirements.

This year, Swissmedic will conduct another focus campaign to review post-market surveillance documentation.

¹ Art. 56 MedDO

² Art. 58 MedDO

³ Art. 60-61 MedDO

⁴ Art. 51(2) MedDO

⁵ www.swissmedic.ch > Medical Devices > Market Surveillance > Focus Campaigns > [Swissmedic assessment of post-market surveillance documentation](#)

- **How will Swissmedic conduct the review?**

As part of this focus campaign, a specific number of Class IIa, IIb, and III devices placed on the market in Switzerland will be selected at random. For the purpose of the review, post-market surveillance documentation for these devices will be requested from the Swiss manufacturer or the Swiss authorised representative. Swissmedic will review the submitted documentation.

- **Are you required to provide feedback to Swissmedic on this information letter?**

No, this is not required. If one of your devices has been selected by Swissmedic as part of the sample for this year's focus campaign, you will be informed of this by means of a separate letter.

The results of the [Swissmedic assessment of post-market surveillance documentation](#) in 2024⁶ can be found on the Swissmedic website.

Contribute to the safety of medical devices by fulfilling your obligations as a manufacturer or Swiss authorised representative of medical devices within the scope of your responsibilities and due diligence.

Regardless of the current focus campaign, Swissmedic may carry out further inspections of manufacturers or Swiss authorised representatives at any time⁷.

This information letter is sent to all manufacturers or Swiss authorised representatives registered with Swissmedic and is published on our website⁸.

Kind regards,

Swissmedic, Swiss Agency for Therapeutic Products

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⁶ www.swissmedic.ch > Medical Devices > Market Surveillance > Focus Campaigns > [Swissmedic assessment of post-market surveillance documentation](#)

⁷ [Chapter 9 MedDO](#)

⁸ www.swissmedic.ch