SWISSDAMED Readiness

Swissdamed in Switzerland: key deadlines, specifics, and how it differs from EUDAMED

Switzerland is rolling out swissdamed (Swiss Database on Medical Devices), a national database operated by Swissmedic. For medical device and IVD companies, swissdamed introduces a separate Swiss registration track alongside EU MDR/IVDR obligations - particularly relevant for organizations active in both the EU/EEA and Switzerland/Liechtenstein. In practice, this can mean parallel data maintenance, because swissdamed and EUDAMED are aligned in concept but not interchangeable.

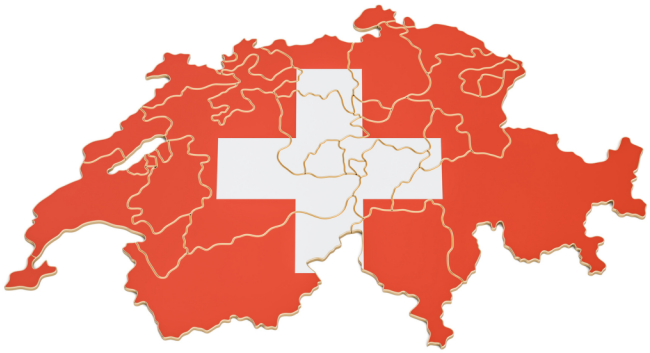
This separation is also reflected in the underlying legal landscape: Switzerland's MedDO and IvDO are the Swiss equivalents of MDR and IVDR, while AIMDD/MDD/IVDD used to be aligned for EU and Switzerland before MDR/IVDR took effect - there is no longer an agreement on a "common medical device market" between the EU and Switzerland. For a current country overview, see the updated list on the p36 website: https://www.p36.io/overview-produkte/udi-platform/#compliance-termine

What is swissdamed (and why it matters)

Swissdamed is Switzerland's national database for medical devices, intended to support transparency, traceability, and regulatory oversight. It also includes a public search website, making selected information accessible beyond restricted regulatory user groups.

For companies, the key point is that Switzerland is not part of EUDAMED. As a result, swissdamed can create an additional registration obligation and, for dual-market portfolios, a risk of duplicate data maintenance:

- Two critical dates: 1 July 2026 **(mandatory product registration)** and 31 December 2026 **(end of transition period)**. These dates define when swissdamed moves from preparation and voluntary submissions to enforceable obligations, and when the transition window closes.
- Swissdamed is modular: Actors registration has been available since August 2024; the Devices (UDI) module since August 2025.
- Not a copy of EUDAMED: swissdamed and EUDAMED are conceptually aligned but technically independent - Reano transfer or synchronization of data.
- Operational impact: additional data governance and process work, especially for companies active in both markets.



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Rollout milestones: Modules and what they cover

Actors module (economic operator registration)

In operation since 6 August 2024.

Focus: economic operators based in Switzerland or Liechtenstein (e.g., Swiss/Liechtenstein manufacturers, Swiss authorized representatives acting for foreign manufacturers, and Swiss/Liechtenstein importers).

After Swissmedic approval, operators receive a CHRN, comparable in purpose to the EU SRN.

Devices module (UDI / product registration)

Available since August 2025.

Scope: registration of medical devices, IVDs, systems, and procedure packs placed on the Swiss market.

Submission approach described: product registration via XML file upload.

Swissmedic is also described as planning machine-to-machine (M2M) interfaces to enable automated exchange and reduce manual effort for large portfolios.

swissdamed vs. EUDAMED: What is different in practise

swissdamed is presented as a Swiss counterpart to EUDAMED and is closely aligned conceptually, but the systems are separate and must be managed independently.

1) Scope and Authority

- EUDAMED: EU and EEA, managed by the European Commission
- Swissdamed: Switzerland (and Liechtenstein), operated by Swissmedic

2) Module Coverage

- EUDAMED: six modules (including certificates/notified bodies, clinical investigations, vigilance, market surveillance)
- Swissdamed: currently focused on Actors and Devices, with further functions planned

3) Actor Registration Rules

- EUDAMED: EU market actors register and receive an SRN. For non-EU manufacturers, the EU AR is appointed by the manufacturer, and the manufacturer maintains its own data after the mandate is confirmed.
- Swissdamed: Registration is handled for Swiss/Liechtenstein actors and results in a CHRN. For non-CH manufacturers, the CH AR selects the manufacturer and - once the mandate is confirmed - maintains the manufacturer data on the manufacturer's behalf.

4) One-way XML re-use from EUDAMED (no sync)

- Both databases use UDI-based, XML-structured data, but they are not synchronized. Swissdamed can import an XML export from EUDAMED (once devices are published there); a small set of Swiss-specific attributes (typically <10) may need to be added manually. Re-use is one-way (EUDAMED → swissdamed), not vice versa. In addition, swissdamed's machine-to-machine (M2M) interface is officially available via a REST API since mid-2026.

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What to prepare now?

- Confirm Actors module registration status and internal ownership (including CHRN handling).
- Prepare for mandatory product registration from 1 July 2026, including UDI readiness, data validation, and XML submission processes.
- Use the transition window up to 31 December 2026 to reduce backlog risk and establish steady-state update routines.
- Set up governance to keep Swiss and EU datasets consistent where possible, acknowledging that submissions remain separate.
- Monitor Swissmedic's planned M2M capabilities if portfolio size makes manual uploads costly.

Summary: What makes swissdamed operationally different (and challenging)

Even for companies already familiar with EU MDR/IVDR data work, swissdamed can require additional coordination:

- Separate regulatory obligation and duplicate maintenance risk: Switzerland is not part of EUDAMED, so companies active in both markets may need to maintain data in parallel.
- UDI-driven data quality requirements: product registration depends on correct UDI implementation and consistent data.
- Process and IT adjustments: internal processes and systems may need adaptation, especially for handling data in the restricted area.
- Public vs. restricted access: swissdamed includes a public search website alongside protected areas, which can affect data governance and review processes.

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