EUDAMED & swissdamed:

What’s Mandatory, What's Different, and How to Be Ready for 2026

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Purpose of Today's Webinar:

- Address major database deadlines approaching in the EU and Switzerland
- Ensure stakeholders are clear on what is mandatory vs optional
- Outline a focused comparison to help prioritize compliance actions

Agenda

- EUDAMED Overview
- swissdamed Overview
- Mandatory vs Optional Requirements
- Key Deadlines in 2026
- Cross-system Alignment / Data Reuse
- Data Quality & Validation Risks
- Roles: Manufacturers, ARs, Importers
- Practical Preparedness Steps
- Q&A

What is EUDAMED?

- **European Union Database on Medical Devices**
- Managed by the European Commission
- Established under:
  - **Article 33 of Regulation (EU) 2017/745 (MDR)**
  - **Article 30 of Regulation (EU) 2017/746 (IVDR)**
- Comprised of six interconnected modules:
  - **Actor Registration** (Article 31 MDR / Article 28 IVDR)
  - **UDI/Device Registration** (Article 29 MDR / Article 26 IVDR)
  - **Notified Body and Certificates** (Article 56(5) MDR / Article 51(5) IVDR)
  - **Clinical Investigations and Performance Studies** (Articles 73–82 MDR / Articles 66–77 IVDR)
  - **Vigilance and Post-Market Surveillance** (Articles 87–92 MDR / Articles 82–87 IVDR)
  - **Market Surveillance** (Articles 93-100 MDR / Articles 88-95 IVDR)

Poll 1

EUDAMED Modules

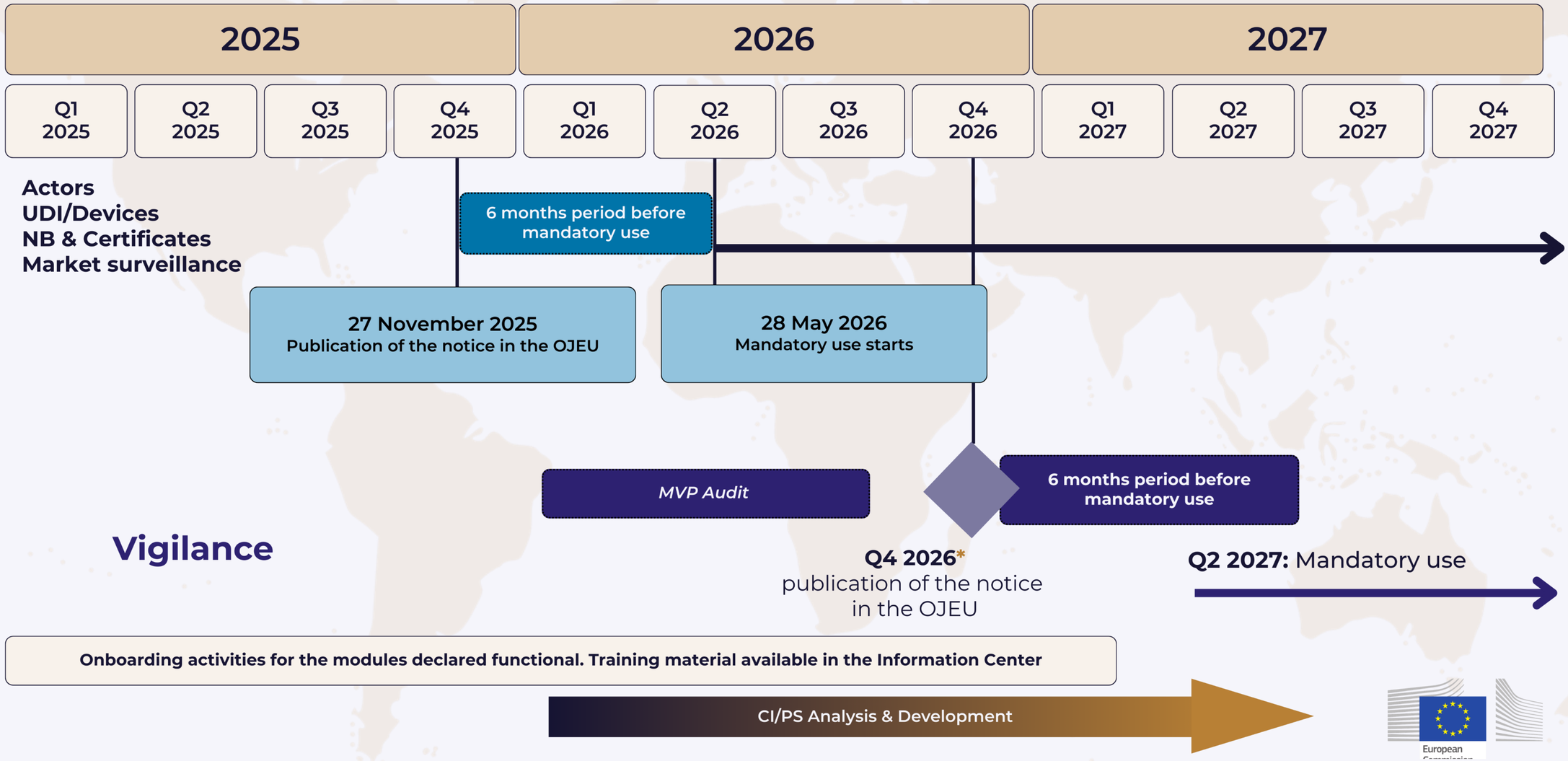
MODULE	RESPONSIBLE PARTY	CURRENT STATUS	MANDATORY USE
Actor module (ACT)	Manufacturer + EU Authorized Representative + EU Importer	Available for voluntary use	28 May 2026
UDI/Device module (UDI/DEV)	Manufacturer + EU Authorized Representative + PP (SPP Producer)	Available for voluntary use	28 May 2026
Notified bodies and certificates module (NB/CRF)	Notified Body + European Commission	Available for voluntary use	28 May 2026
Market surveillance module (MSU)	Competent Authority + European Commission	Available for voluntary use	28 May 2026
Clinical investigations/performance studies module (CI/PS)	Sponsor + Competent Authority	Under development	To be confirmed
Post-market surveillance and Vigilance module (VGL)	Manufacturer + EU Authorized Representative	Under development	To be confirmed

EUDAMED Compliance Timeline

- **2024-2025:** Voluntary use of certain EUDAMED modules (Actor Registration, UDI/Device, and Certificates).
- **27 Nov 2025:** European commission announced that four EUDAMED modules have become fully functional through the official journal **Commission Implementing Decision (EU) 2025/2371**
- **28 May 2026** – Mandatory use (*first four modules*) begins
  - Actor Registration
  - UDI/Device Registration
  - Notified Bodies & Certificates
  - Market Surveillance modules
- **28 November 2026:** Per Regulation (EU) 2024/1860, Article 1(6)(b), the implementation date of EUDAMED for legacy devices is 12 months from date of publication 2025/2371.

EUDAMED Modules Timeline - November 2025

*The timeline for the Vigilance module might be updated depending on the audit results



Source: European Commission, official website - European Commission

Poll 2

What is swissdamed?

- **The Swiss Database on Medical Devices**
- Managed by Swissmedic (Swiss Agency for Therapuetic Products)
- Established under **Articles 62a–62e** of the **Swiss Therapeutic Products Act (TPA)**
- Implemented through:
  - The Swiss Medical Devices Ordinance (**MedDO, SR 812.213**)
  - The Ordinance on In Vitro Diagnostic Medical Devices (**IvDO, SR 812.219**).
- Consists of two modules:
  - **Actor Registration** (Article 62b TPA / MedDO / IvDO)
  - **UDI/Device Registration** (Article 62c TPA / MedDO / IvDO)

swissdamed Modules

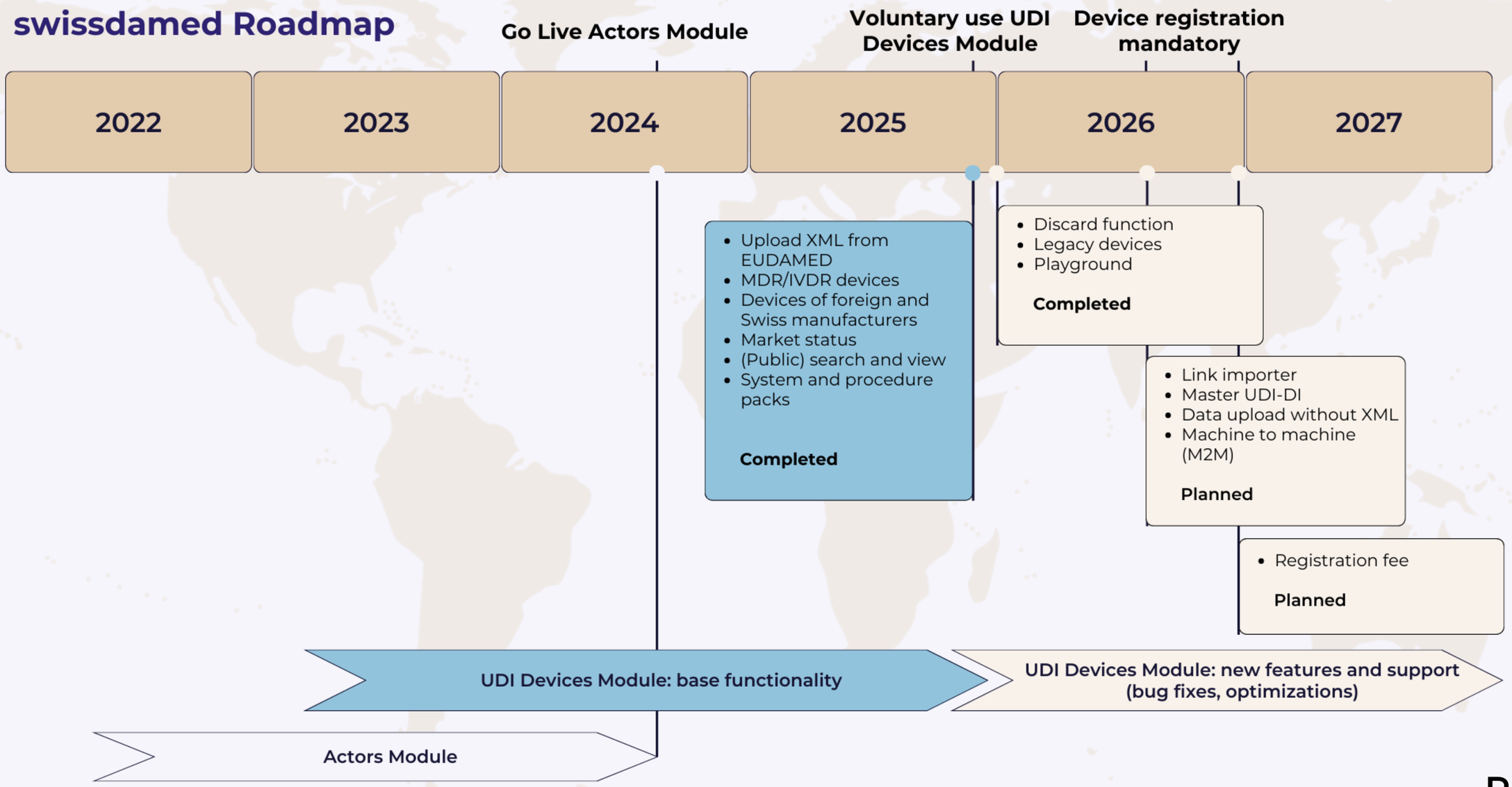
MODULE	RESPONSIBLE PARTY	CURRENT STATUS	MANDATORY USE
Actors module	Swiss Manufacturer + CH Authorized Representative + CH Importer + PP (SPP Producer)	Mandatory	Since 6 August 2024
UDI/Devices module	Swiss Manufacturer + CH Authorized Representative + PP (SPP Producer)	Available for voluntary use	1 July 2026

swissdamed Compliance Timeline

- **August 2024:** Mandatory use of Actors Module since 6 Aug 2024 for all Swiss operators (CHRN).
- **August 2025:** Voluntary use of UDI/Devices Module with base functionality
- **1 July 2026:**
  - Mandatory use of **UDI/Devices Module** with transition to **31 December 2026**.
  - Immediate registration without a transitional period will apply from for devices and systems/procedure packs for which a serious incident, field safety corrective action or trend must be reported to Swissmedic.

swissmedic

swissdamed Roadmap



Source: swissmedic.ch

Poll 3

EUDAMED vs swissdamed Key Differences

Aspect	EUDAMED (EU)	swissdamed (CH)
Jurisdiction	27 EU Member States + EEA (Norway, Iceland, Liechtenstein)	Switzerland only
Legal Basis	EU MDR (2017/745) & EU IVDR (2017/746)	Swiss MedDO (MepV/ODim), updated to align with EU MDR/IVDR
Managing Authority	European Commission (DG SANTE)	Swissmedic (Swiss Agency for Therapeutic Products)
System Access	Via EC EUDAMED portal (eudamed.ec.europa.eu)	Via Swissmedic's swissdamed portal
Authorized Representative	EU AR (EUAR) required for non-EU manufacturers	Swiss AR (CH-REP) required separately for non-Swiss manufacturers — distinct from EUAR
Notified Bodies	EU Notified Bodies (e.g., TÜV SÜD, BSI, SGS) listed in NANDO database	Swissmedic itself acts as conformity assessment body for some devices; EU NBs recognized under MRA
MRA Status	N/A (internal EU market)	Switzerland–EU MRA covers medical devices, but Switzerland is NOT in EUDAMED; separate registration still required
Language Requirements	All EU official languages may apply for labelling/IFU depending on Member State	German, French, Italian required (Switzerland's official languages)
Registration Duplication	Single registration covers all EU/EEA countries	Separate registration in swissdamed required even if already in EUDAMED
Timeline Maturity	More advanced rollout; some modules already mandatory	swissdamed rollout closely follows EUDAMED but on Swiss legislative schedule

Where do EUDAMED & swissdamed Align?

Aspect	What's Similar?
🆔 UDI System	Both adopt the UDI-DI / UDI-PI framework
🏢 Actor Registration	Manufacturers, ARs, importers must register in both
📋 Device Registration	Device data, classification, risk class required in both
📜 Certificate Tracking	Certificates from conformity bodies tracked in both
🌐 Public Transparency	Both have public-facing portals for device lookup
🔗 Regulatory Alignment	Both based on EU MDR/IVDR logic and classifications

UDI Devices Module: Data Elements

swissdamed specific data elements:

- Swiss market status
- Swiss single registration number (CHRN)
- Swiss authorised representative
- versioning of records

Common data elements swissdamed - EUDAMED:

Basic UDI-DI Data

- Basic UDI-DI/EUDAMED DI, issuing entities applicable regulation
- kits, SPP, special device type
- medical purpose
- risk class
- device model/name
- device characteristics (implantable, measuring, reusable surgical instrument, active, administer/remove medicinal product, companion diagnostic, near patient testing, self testing, reagent, instrument, professional testing)
- single registration number (SRN)
- presence of tissues and cells/derivatives

UDI-DI Data

- UDI-DI/EUDAMED ID, unit of use DI, type of UDI-PI, direct marking DI, secondary UDI-DI, Package UDI-DI, issuing entity
- device name, trade name, reference/catalogue number
- product description
- nomenclature code
- intended purpose
- storage/handling warnings/contraindications
- information on sterilization, reuse, single use
- list of substances (CMR, latex, medicinal product, endocrine disruptors)
- clinical sizes
- quantity
- product original manufacturer

EUDAMED specific data elements:

- clinical investigations, performance studies
- certificate information
- market status in EU member states
- member state of placing on the EU market
- device substatus (recalls, field safety corrective actions)
- reprocessed single use
- versioning of records

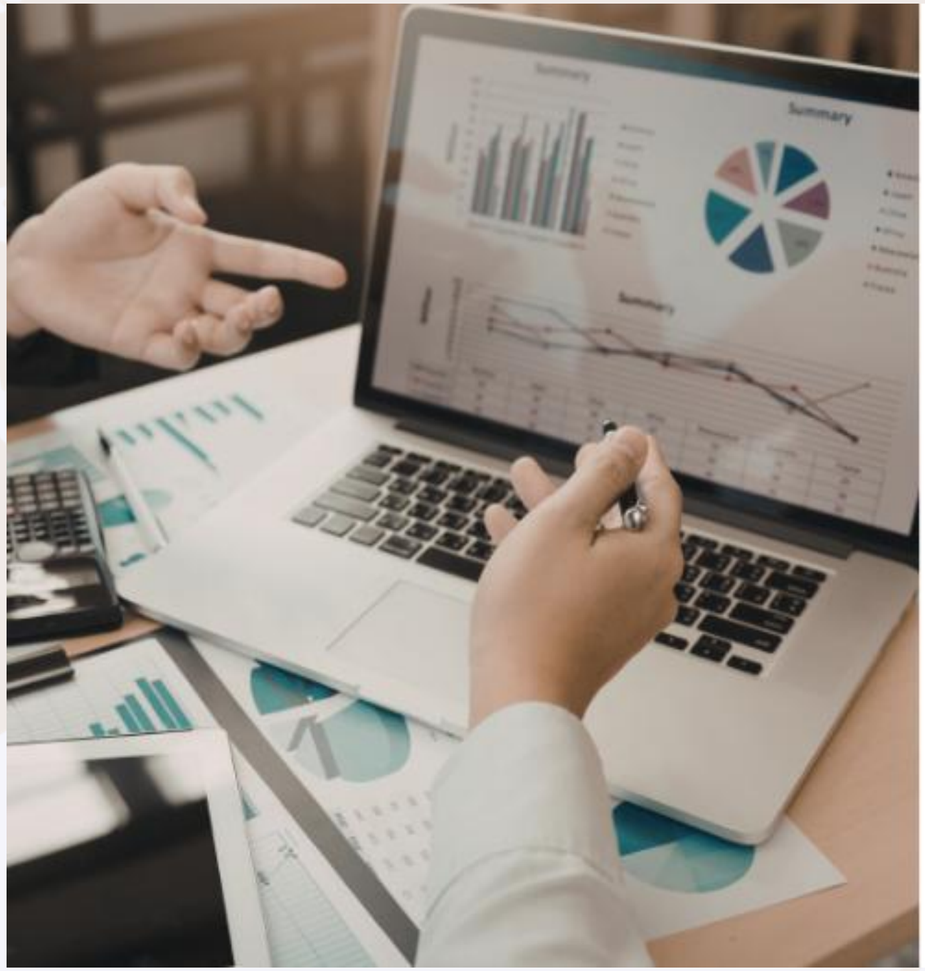
Source: swissmedic.ch

2026 Deadlines Overview

Requirement	EUDAMED (EU)	swissdamed (CH)
Actor Registration	Mandatory by 28 May 2026	Mandatory since August 2024
Device (UDI) Registration	Mandatory 28 May 2026	Mandatory 1 July 2026
Certificate data	Mandatory 28 May 2026	Not applicable (dedicated Swiss field)
Market Surveillance	Mandatory 28 May 2026	Swiss post-market reporting via vigilance system

Data & Registration Pitfalls

- Poor Basic UDI-DI structuring
- Legacy device mapping confusion
- Certificate scope misalignment
- Inconsistent economic operator naming
- Incomplete importer lists
- Wrong risk classification
- Failure to update device status changes
- Weak internal data ownership



Roles & Responsibilities: EUDAMED and swissdamed

Manufacturers

EUDAMED

- ✓ Complete Actor Registration and obtain SRN
- ✓ Assign:
  - ➢ At least two Local Actor Administrators
  - ➢ All required PRRCs
- ✓ Complete UDI/Device Registration (post-CE marking)
- ✓ Ensure:
  - ➢ Accurate Basic UDI-DI & UDI-DI data
  - ➢ Correct EMDN classification
  - ➢ Structured device characteristics
- ✓ Coordinate with Notified Body for certificate linkage
- ✓ Maintain data updates and change control

swissdamed

✓ Register in Actors Module (if Swiss-based entity) or via CH-REP (for foreign manufacturers)

✓ Complete Device Registration (from 1 July 2026)

✓ Upload device data separately (no automatic EUDAMED transfer)

✓ Pay applicable notification fees (proposed CHF 300 per device notification)

✓ Monitor Swiss-specific vigilance or market obligation

Authorized Representatives (ARs)

EUDAMED (EAR)

- ✓ AR must register in Actors Module
- ✓ Digitally verify and accept manufacturer registration
- ✓ Enable SRN issuance through validation workflow
- ✓ Perform due diligence review (not a rubber stamp)
- ✓ Maintain AR data accuracy in Actor module
- ✓ One AR per Generic Device Group (GDG)

swissdamed (CH-Rep)

- ✓ Swiss-based AR must register in Actors Module
- ✓ Ensure manufacturer compliance with Swiss registration requirements
- ✓ Support structured data submission into swissdamed
- ✓ Act as Swiss regulatory liaison

Importers

EUDAMED (EU)

- ✓ Must register in Actors Module
- ✓ Verify:
  - ➢ Manufacturer has valid SRN
  - ➢ Device is properly registered (e.g., Basic UDI-DI where required)
- ✓ Cannot place device on market if registration incomplete (“hard stop” mechanism)
- ✓ Maintain traceability documentation

swissdamed (CH)

- ✓ Must register in Actors Module
- ✓ Verify Swiss device registration before market placement
- ✓ Ensure manufacturer/AR Swiss compliance
- ✓ Prepare for possible enforcement checks tied to Swiss database entries

Practical Preparedness Steps

1. Start with Actor Registration
2. Establish Internal Governance Before Data Entry
3. Prepare Device Data in “Submission-Ready” Format
4. Map Cross-Party Dependencies
5. Use Testing & Rehearsals
6. Budget & Resource Planning

Thank you!

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