SWITZERLAND IVD REGULATORY MAP

A practical orientation for global RA teams entering Switzerland

START HERE: WHAT IS THE PRODUCT IN SWITZERLAND?

1 Confirm Swiss regulatory identity

Confirm the intended use, product family, and whether the item is an IVD reagent, analyzer/instrument, or software/other. Classification and registration depend on the degree of risk to human health under the Swiss IvDO, which is closely aligned with EU IVDR.

IVD reagent | Analyzer / instrument | Software / other

2 Choose the regulatory route

CLASS A	CLASS B	CLASS C	CLASS D
Low risk	Moderate risk	High risk	Highest risk
Self-declaration route	**Third-party / Notified Body route**	**Stronger conformity assessment route**	**Highest scrutiny route**
Lowest risk products with well-established performance and mature technology. Manufacturer self-declaration of conformity.	Moderate-risk products require third-party conformity assesement by a Notified Body.	Higher-risk products require stronger conformity assessment and enhanced performance-evaluation expectations.	Highest-risk / critical products undergo the highest level of scrutiny with the most extensive evidence and control.

3 Build the Switzerland market-access infrastructure

Swiss IvDO conformity / CE-oriented technical foundation
Design and document to the Swiss IvDO, closely aligned with EU IVDR. CE marking under IVDR is the entry ticket.

Swiss Authorized Representative (CH-REP) and importer structure
Non-Swiss manufacturers must appoint a Swiss CH-REP. An importer is required to place the device on the Swiss market.

Swissmedic economic-operator registration and traceability / UDI readiness
Register as manufacturer, CH-REP and importer with Swissmedic. Implement traceability systems and UDI per IvDO.

Swiss language readiness
Product information generally in German, French, and Italian; professional-use flexibility or English may be possible under conditions. Self-testing and near-patient information must be easy to understand and provided in the official languages.

4 Build the evidence stack

Administrative foundation
QMS certificate, technical documentation, risk management, PMS plan, PSUR strategy.

Quality / QMS evidence
ISO 13485 QMS with processes for design, manufacturing, PMS, and CAPA.

Analytical performance
Performance, method comparison, accuracy, precision, reference materials, stability, interference.

Clinical / scientific support
Clinical evaluation report and performance evaluation per Swiss IvDO.

Labeling & IFU package
Swiss-language labeling and IFU per IvDO + UDI, symbols per Swissmedic.

RA TRAP TO AVOID

Do not assume an EU setup alone is enough. Switzerland is not the EU — CH-REP, importer, Swiss registration, and language obligations must be addressed.

STRATEGIC INSIGHT

Switzerland is technically close to EU IVDR but operationally distinct. Plan Swiss market access as a separate workstream.

Training overview — verify current product-specific requirements with Swissmedic and your local CH-REP / importer. Not legal advice.

SWITZERLAND IVD: HOW THE WORK ACTUALLY FLOWS

From classification to commercialization — with the decision points a new RA professional should watch

A Program flow

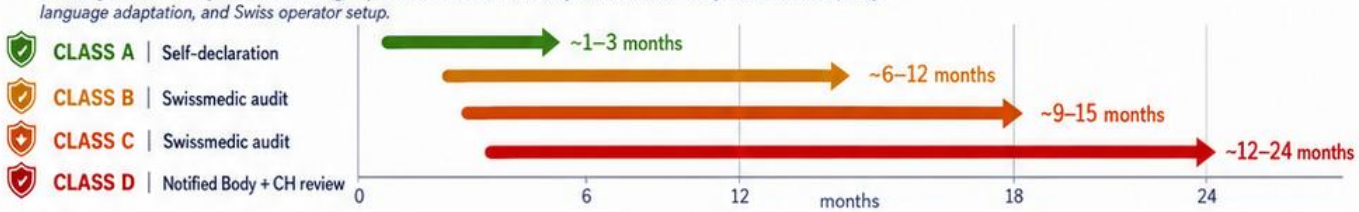
1. **Scope the product** — Define intended use, population and specimen type.
2. **Classify under Swiss IvDO** — Class A–D under the In Vitro Diagnostic Ordinance (IvDO).
3. **Appoint CH-REP / importer where needed** — Appoint a Swiss authorized representative (AR) if required.
4. **Prepare technical documentation & performance-evaluation package** — Compile design, safety, performance, and PMS plans.
5. **Complete conformity assessment route** — Self-declaration (A), Swissmedic audit (B/C), or Notified Body (D).
6. **Complete Swissmedic registration / traceability / labeling setup** — Register devices, set UDI/CHRN, prepare CH labeling.
7. **Launch and maintain PMS / vigilance / change control** — Operate PMS, report incidents, manage changes.

B What gets heavier as the class rises?

Signal	CLASS A	CLASS B	CLASS C	CLASS D
Regulatory pathway	Self-declaration	Swissmedic audit	Swissmedic audit	Notified Body + Swissmedic review
Evidence intensity	Low ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	High ● ● ● ● ○	Very high ● ● ● ● ● ●
Analytical performance	Basic ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	High / comprehensive ● ● ● ● ●	Extensive ● ● ● ● ● ●
Clinical / scientific support	Typically not required ● ○ ○ ○	Limited ● ● ○ ○ ○	Substantial ● ● ● ● ●	Extensive ● ● ● ● ● ●
Quality / QMS readiness	Basic ● ○ ○ ○ ○	Strong ● ● ● ○ ○	Very strong ● ● ● ● ●	Robust ● ● ● ● ● ●
Post-market control	Basic reporting ● ○ ○ ○	Enhanced ● ● ○ ○ ○	Strong ● ● ● ● ●	Intensive ● ● ● ● ● ●

C Indicative route-based planning ranges

Planning estimates only — actual timing depends on evidence maturity, external conformity-assessment capacity, language adaptation, and Swiss operator setup.



Class A self-declaration timelines are typically shortest but still depend on product complexity and evidence.

Classes B–D timelines depend on review workload, conformity assessments, and site inspections.

D Labeling & language essentials

Product information / IFU languages
Product information and IFU are generally required in German, French, and Italian.

Symbols & labeling
Symbols can replace some written statements where permitted by IvDO and standards.

Professional-use flexibility
Professional-use devices may allow English IFU/labeling under conditions.

Near-patient & self-testing
Self-testing and near-patient information must be understandable in the official languages.

Claims control & traceability
Claims must be truthful, verifiable, and evidence-based with UDI/CHRN traceability readiness.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- Swissmedic – In Vitro Diagnostic Medical Devices (IVD) – Information for Manufacturers: www.swissmedic.ch/ivd
- Ordinance on In Vitro Diagnostic Medical Devices (IvDO); SR 812.219 (official legal text)
- Swissmedic – Authorisation and Registration of Medical Devices and IVDs: www.swissmedic.ch/md-autorisation
- Federal Chancellery – Systematic Compilation of Swiss Federal Law (SR): www.fedlex.admin.ch

IMPORTANT: Product-specific requirements, standards, and recent regulatory changes govern. Confirm current requirements before execution.

