



Switzerland

Medical Device Regulatory Intelligence Report

Regulatory Body	Swissmedic (Swiss Agency for Therapeutic Products)
Primary Legislation	Medical Devices Ordinance (MedDO, SR 812.213); IvDO (SR 812.219); TPA (SR 812.21)
EU Alignment	Aligned with EU MDR 2017/745 & EU IVDR 2017/746 (cross-reference model)
MRA Status	CH–EU MRA for medical devices lapsed May 2021 — independent Swiss regime applies
Report Date	July 09, 2026
Tiles Covered	Classification Rules, Obligations, Notified Body, Battery Requirements, Shelf-Life Requirements, REACH, RoHS, Change Control Requirements, OTC Requirements, Export Certificates, Transportation & Storage, Waste Management, AI Medical Device

Disclaimer: This report is prepared for regulatory intelligence purposes based on publicly available Swiss legislation and Swissmedic guidance as of July 09, 2026. It does not constitute legal advice. Verify current requirements directly with Swissmedic before making regulatory decisions.



1. Classification Rules

SUMMARY

Switzerland uses the same risk-based classification system as the EU. Devices are classified by the manufacturer using classification rules incorporated by cross-reference into MedDO/IvDO. The same four-class system applies for medical devices (Class I, IIa, IIb, III) and IVDs (Class A, B, C, D).

KEY REQUIREMENTS

- Medical Devices (MedDO):** Four classes — Class I, IIa, IIb, III — per classification rules in **Annex VIII of EU MDR 2017/745**, incorporated by reference into MedDO. Class I = lowest risk; Class III = highest risk (implantable, long-term contact).
- IVDs (IvDO):** Four classes — Class A, B, C, D — per classification rules in **Annex VIII of EU IVDR 2017/746**, incorporated by reference into IvDO.
- Products without intended medical purpose** (e.g. coloured contact lenses, IPL hair removal, subdermal fillers): Regulated within the scope of MedDO per Art. 1 para. 1 let. b and para. 2 MedDO, as listed in Annex 1 MedDO.
- Classification is performed by the **manufacturer** as part of conformity assessment; Swissmedic may challenge classification under its market surveillance powers.
- Custom-made devices:** Subject to specific requirements under Art. 10 MedDO and Annex XIII EU MDR.
- In-house / health institution-manufactured devices:** Art. 9 MedDO (MD) and Art. 9 IvDO (IVD).

Swiss-Specific Note: Since May 2021, EU CE marking alone is NOT sufficient for Swiss market access — the manufacturer must also comply with Swiss MedDO requirements including appointing a Swiss Authorised Representative (CHrep).

LEGAL BASIS

Reference	Description
Art. 1 MedDO (SR 812.213)	Scope and product categories
Art. 4 MedDO	Definitions (custom-made device, system, procedure pack)
Annex 1 MedDO	Products without intended medical purpose
Annex VIII EU MDR 2017/745	Classification rules for MDs (cross-referenced in MedDO)
Annex VIII EU IVDR 2017/746	Classification rules for IVDs (cross-referenced in IvDO)
Art. 2 TPA (SR 812.21)	Overarching definition of therapeutic products

2. Obligations

SUMMARY

All economic operators placing medical devices on the Swiss market have defined obligations under MedDO/IvDO, covering QMS, technical documentation, UDI, PMS, vigilance, and registration in swissdamed.

MANUFACTURER OBLIGATIONS

- Establish and maintain a **Quality Management System (QMS)** per Art. 8 MedDO and Annex IX/X/XI EU MDR requirements
- Prepare and maintain **Technical Documentation** (Annex II & III EU MDR)
- Issue a **Declaration of Conformity** and affix CE mark (Switzerland unilaterally accepts CE marking)
- Implement **UDI** per Art. 17 MedDO (mirrors EU MDR Art. 27)
- Conduct **Post-Market Surveillance (PMS)** per Art. 32–34 MedDO
- Report serious incidents and FSCAs (vigilance) to Swissmedic per Art. 66 MedDO
- Register in **swissdamed** — mandatory from **1 July 2026** for economic operators (Art. 108 MedDO, as amended November 2024)

SWISS AUTHORISED REPRESENTATIVE (CHREP)

- Non-Swiss manufacturers must appoint a **CHrep** established in Switzerland or Liechtenstein (Art. 51 MedDO); deadline was 31 July 2022 (Art. 104a para. 2 MedDO)
- CHrep must register in swissdamed per Art. 55 MedDO

IMPORTER & DISTRIBUTOR OBLIGATIONS

- **Importers (Art. 52 MedDO):** Verify CE marking, manufacturer identity, correct labeling, registration in swissdamed; notify for repackaged/relabelled devices (Art. 53–54 MedDO)
- **Distributors (Art. 53–54 MedDO):** Storage, traceability, complaint handling

LEGAL BASIS

Reference	Description
Art. 8 MedDO	QMS requirement for manufacturers
Art. 17 MedDO	UDI requirements
Art. 18 MedDO	Notification of in-house devices
Art. 20 MedDO	Implant card obligation
Art. 32–34 MedDO	Post-market surveillance
Art. 51 MedDO	Obligations of authorised representatives (CHrep)
Art. 52–54 MedDO	Obligations of importers/distributors
Art. 55 MedDO	Registration in swissdamed
Art. 66 MedDO	Vigilance / serious incident reporting
Art. 108 MedDO	Device registration obligation (swissdamed) — mandatory from 1 July 2026
GebV-Swissmedic (SR 812.214.5)	Notification fees (CHF 300 per notification)



3. Notified Body

SUMMARY

Switzerland uses its own "**Designated Bodies**" (**Anerkannte Stellen**) — the Swiss equivalent of EU Notified Bodies. Since the MRA lapsed in May 2021, EU Notified Bodies are not recognized for Swiss market access purposes. CE marking issued by EU Notified Bodies is unilaterally accepted by Switzerland but the manufacturer must still comply with all MedDO requirements.

KEY REQUIREMENTS

- Mandatory conformity assessment by a Designated Body for Class IIa, IIb, III (MDs) and Class B, C, D (IVDs) before placing on market
- Switzerland unilaterally accepts CE marking issued by EU Notified Bodies; the device must still comply with MedDO (CHrep, labeling, registration in swissdamed)
- Swiss Designated Bodies are designated and supervised by Swissmedic under Art. 22 MedDO
- For Class I devices (non-sterile, non-measuring): self-certification — no third-party body involvement
- Swissmedic acts as the national authority overseeing designated bodies, market surveillance, and vigilance (not as a premarket approval body)

CONFORMITY ASSESSMENT ROUTES (BY CLASS)

Device Class	Required Route
Class I (non-sterile, non-measuring)	Manufacturer self-declaration — no Designated Body
Class Is / Im (sterile / measuring)	Designated Body involvement required
Class IIa	Designated Body: Annex IX or XI (EU MDR)
Class IIb	Designated Body: Annex IX, X, or XI (EU MDR)
Class III	Designated Body: Annex IX or X (EU MDR) — highest scrutiny

LEGAL BASIS

Reference	Description
Art. 22 MedDO	Designation and supervision of conformity assessment bodies
Art. 23–26 MedDO	Requirements for conformity assessment procedures
Annex VII EU MDR 2017/745	Requirements for designated/notified bodies (cross-referenced)
Annex IX–XI EU MDR 2017/745	Conformity assessment procedures (cross-referenced)
Art. 12 TPA (SR 812.21)	Delegation to conformity assessment bodies

Swiss-Specific: Swiss manufacturers needing EU market access must work with an EU Notified Body. Swiss designated bodies issue certificates only for the Swiss market. Swissmedic maintains an up-to-date list of designated bodies on its website ([swissmedic.ch](https://www.swissmedic.ch)).

4. Battery Requirements

SUMMARY

There is no standalone Swiss medical device battery regulation. Battery requirements are addressed through: (1) GSPR under MedDO/EU MDR, (2) Swiss product safety legislation, and (3) chemical/environmental legislation for disposal.

KEY REQUIREMENTS

- **Safety & Performance:** Devices with batteries must meet the GSPR under Annex I EU MDR 2017/745 (cross-referenced by MedDO), including Section 8 (electrical hazards) and Section 13.6 (battery life disclosure in IFU)
- **Harmonized Standards:** IEC 60601 series (medical electrical equipment safety); IEC 62133 (lithium battery safety) — compliance creates presumption of conformity
- **Warning symbols and labeling** per Art. 16 MedDO and Annex I Chapter III EU MDR (e.g., low battery indicator, charging instructions)
- **Lithium Battery Transport:** ADR/IATA regulations apply to shipment of devices containing lithium batteries (see Transportation & Storage section)
- **Disposal:** Batteries in medical devices are subject to the Ordinance on the Return, Taking Back and Disposal of EEE (VREG, SR 814.620) — see Waste Management section

- **Chemical restrictions:** Battery materials must comply with Swiss chemical legislation (ChemV, ChemRRV) for restricted/prohibited substances

LEGAL BASIS

Reference	Description
Annex I EU MDR 2017/745 §8	GSPR — electrical and mechanical safety
Annex I EU MDR 2017/745 §13.6	IFU battery information requirements
Art. 16 MedDO	Labeling requirements including battery warnings
SR 814.620 (VREG/ORDEE)	Battery and EEE end-of-life disposal
IEC 60601 series	Medical electrical equipment general safety (harmonized standard)
IEC 62133	Lithium battery safety for portable devices (harmonized standard)



5. Shelf-Life Requirements

SUMMARY

Switzerland does not have a standalone shelf-life regulation for medical devices. Shelf-life requirements are derived from the GSPR (General Safety and Performance Requirements) under MedDO/EU MDR and apply wherever the device's safety and performance are time-limited.

KEY REQUIREMENTS

- **GSPR obligation:** If a device has a defined shelf life (e.g. sterile devices, single-use devices, reagent kits), the manufacturer must determine, validate, and declare it in the technical documentation and on the device label/IFU per **Annex I EU MDR 2017/745, Section 23.2(w)** (expiry date or manufacture date)
- **Labeling:** The expiry date (where applicable) must be indicated on the label using the standardized symbol (ISO 15223-1) per **Art. 16 MedDO** and **Annex I Chapter III EU MDR §23.2(w)**
- **Sterile devices:** Shelf-life of the sterile barrier system must be validated per EN ISO 11607 as referenced in applicable GSPR and harmonized standards
- **IVD reagents and kits:** Shelf-life requirements under IvDO — expiry date mandatory on label per **Art. 16 IvDO** and **Annex I EU IVDR 2017/746**
- **Storage conditions:** Storage conditions that affect shelf life must be disclosed in IFU and labeling (temperature, humidity, light exposure)

LEGAL BASIS

Reference	Description
Art. 16 MedDO (SR 812.213)	Labeling requirements — expiry date, manufacturer date
Annex I EU MDR 2017/745 §23.2(w)	Label must include expiry date (GSPR — cross-referenced)
Art. 16 IvDO (SR 812.219)	IVD labeling requirements including shelf-life
Annex I EU IVDR 2017/746	IVD GSPR — shelf-life labeling (cross-referenced)
EN ISO 11607	Sterile barrier packaging — shelf-life validation (harmonized standard)
ISO 15223-1	Symbols for medical devices including expiry date symbol

6. REACH

SUMMARY

Switzerland has adopted chemical legislation substantially equivalent to the EU REACH Regulation (EC 1907/2006) through the **Swiss Chemicals Act (ChemG, SR 813.1)** and the **Swiss Chemicals Ordinance (ChemV, SR 813.11)**. The **Ordinance on Risk Reduction for Chemicals (ChemRRV, SR 814.81)** implements restrictions on specific hazardous substances.

KEY REQUIREMENTS

- **Registration / notification:** Substances manufactured in or imported into Switzerland in quantities ≥ 1 tonne/year must be notified to the Swiss notification authority (Anmeldestelle Chemikalien) per ChemG Art. 48
- **SVHCs (Substances of Very High Concern):** Switzerland maintains its own candidate list of SVHCs aligned with the EU ECHA list. Medical devices containing SVHCs above 0.1% w/w require communication in the supply chain per ChemV Art. 69
- **Restrictions:** Substances restricted under ChemRRV (including CMR substances, endocrine disruptors, persistent substances) must not be used in excess of permitted concentrations
- **CMR substances in medical devices:** GSPR Annex I §10 EU MDR (cross-referenced by MedDO) restricts use of CMR (carcinogenic, mutagenic, reprotoxic) and endocrine-disrupting substances — justification required when present above 0.1% w/w
- **SVHC Article Communication:** Manufacturers/importers must provide SVHC information to professional users within 45 days of request (equivalent to EU REACH Art. 33)
- Switzerland updates its SVHC list and restriction list to track EU ECHA decisions, though updates may lag slightly

LEGAL BASIS

Reference	Description
ChemG (SR 813.1)	Swiss Chemicals Act — overarching framework

Reference	Description
ChemV (SR 813.11)	Swiss Chemicals Ordinance — notification, SVHC communication
ChemRRV (SR 814.81)	Ordinance on Risk Reduction for Chemicals — substance restrictions
Annex I EU MDR 2017/745 §10	GSPR restriction on CMR/endocrine-disrupting substances in MDs (cross-referenced by MedDO)
EU REACH Regulation (EC) 1907/2006	Referenced as equivalent standard; Switzerland tracks EU ECHA SVHC candidate list

Note: Switzerland is not part of the EU and does not directly apply REACH. However, exporters to Switzerland must comply with ChemG/ChemV/ChemRRV, which are substantively equivalent. Companies selling into both the EU and Switzerland typically satisfy both regimes simultaneously since ChemRRV tracks EU restrictions closely.



7. RoHS

SUMMARY

Switzerland implements equivalent restrictions to EU RoHS 2 Directive (2011/65/EU) through the **Ordinance on the Return, Taking Back and Disposal of Electrical and Electronic Equipment (VREG, SR 814.620)** and the **Ordinance on Risk Reduction for Chemicals (ChemRRV, SR 814.81)**. Medical devices (Class IIb and III, and IVDs) are within scope.

KEY REQUIREMENTS

- **Restricted substances:** Medical devices that are electrical/electronic must not contain the following substances above maximum concentration values (MCVs): lead (Pb) >0.1%, mercury (Hg) >0.1%, cadmium (Cd) >0.01%, hexavalent chromium (Cr(VI)) >0.1%, polybrominated biphenyls (PBB) >0.1%, polybrominated diphenyl ethers (PBDE) >0.1%, DEHP >0.1%, BBP >0.1%, DBP >0.1%, DIBP >0.1%
- **Scope:** Medical devices (Class IIb and III) and IVDs (all classes) are in scope for Swiss RoHS-equivalent restrictions. Class I and IIa medical devices are currently subject to lighter requirements but must comply with GSPR chemical restrictions under MedDO
- **Exemptions:** Switzerland tracks EU RoHS exemptions (Annex III and IV of EU RoHS 2) for medical devices; specific use cases may be exempt (e.g., lead in specific solder applications)
- **Declaration of Conformity:** Manufacturer must declare RoHS compliance as part of the broader CE/conformity assessment documentation
- **GSPR overlap:** Annex I §10 MedDO/EU MDR GSPR restricts CMR and hazardous substances independently of RoHS — both must be satisfied

LEGAL BASIS

Reference	Description
SR 814.620 (VREG/ORDEE)	Ordinance on EEE — restricts hazardous substances (RoHS equivalent)
ChemRRV (SR 814.81)	Ordinance on Risk Reduction for Chemicals — substance MCVs
Annex I EU MDR 2017/745 §10	GSPR restriction on hazardous chemical substances (cross-referenced)
EU RoHS 2 Directive 2011/65/EU	Referenced as equivalent standard (Switzerland tracks EU exemption lists)

8. Change Control Requirements

SUMMARY

Switzerland does not have a separate standalone change control regulation for medical devices. Change control obligations are embedded within the QMS, technical documentation, and post-market surveillance requirements of MedDO, mirroring EU MDR requirements for managing changes to CE-marked devices.

KEY REQUIREMENTS

- **QMS requirement:** Manufacturers must establish documented change control procedures within their QMS per Art. 8 MedDO (incorporating EU MDR Annex IX and ISO 13485:2016 Section 7.3.9 / 8.3.6)
- **Significant changes to approved devices:** Changes that could affect the safety, performance, or intended purpose of the device must be assessed. Significant changes require re-evaluation of the conformity assessment and may require Designated Body involvement per Art. 23 MedDO
- **Technical Documentation update:** Any design or manufacturing change must be reflected in updated technical documentation (Annex II & III EU MDR, cross-referenced by MedDO)
- **Post-Market Surveillance linkage:** PMS data that triggers a corrective action or design change must flow through the change control process per Art. 32–34 MedDO
- **FSCA (Field Safety Corrective Actions):** Changes made in response to a safety risk must be reported to Swissmedic as a vigilance event per Art. 66 MedDO
- **UDI update:** Significant changes may require issuance of a new UDI-DI per Art. 17 MedDO (mirrors EU MDR Art. 27 and EUDAMED guidance)
- **Swissmedic notification:** Changes requiring an update to the swissdamed registration (e.g., new UDI-DI, new CHrep, change in device name/intended purpose) must be updated per Art. 108 MedDO

LEGAL BASIS

Reference	Description
Art. 8 MedDO	QMS — change control procedures
Art. 23 MedDO	Conformity assessment re-evaluation for significant changes
Art. 17 MedDO	UDI — new DI required for significant changes
Art. 32–34 MedDO	PMS — change control triggered by surveillance data
Art. 66 MedDO	Vigilance — FSCA reporting
Art. 108 MedDO	swissdamed registration update obligation
Annex II & III EU MDR 2017/745	Technical documentation requirements (cross-referenced)
ISO 13485:2016 §8.3.6	Design & development changes — change control in QMS (harmonized standard)



9. OTC (Over-the-Counter) Requirements

SUMMARY

Switzerland does not use the term "OTC" for medical devices in the same way as pharmaceuticals. However, Class I and certain Class IIa medical devices may be sold directly to consumers (self-use/home-use devices) without a prescription. The applicable requirements focus on labeling, IFU clarity, and safe use by lay persons.

KEY REQUIREMENTS

- **Consumer/lay user devices:** Devices intended for use by lay persons (e.g., home blood pressure monitors, self-test IVDs) must include Instructions for Use (IFU) in German, French, and Italian (Switzerland's three official languages) and English (optional but common per Art. 16 MedDO)
- **Labeling language:** Mandatory label information must appear in at least the official Swiss languages (German, French, Italian) per Art. 16 MedDO and Annex I §23.4 EU MDR
- **IFU content for lay users:** IFU must be written in non-technical language, include warnings for contraindications, and explain safe use per GSPR Annex I §23.1(d) EU MDR
- **Self-test IVDs:** Must be specifically intended and validated for self-testing; Class C IVDs for self-testing require Designated Body involvement per IvDO; IFU requirements under Art. 16 IvDO and Annex I EU IVDR §20
- **Point-of-care IVDs:** Specific requirements under Annex I EU IVDR §20 for IVDs intended for near-patient testing (cross-referenced by IvDO)
- **Advertising restrictions:** Advertising of medical devices to the public is regulated under the Swiss Therapeutic Products Act (TPA Art. 31–32) — claims must not be misleading and must align with the device's intended purpose as documented in technical files
- **Pharmacy/retail channel:** No Swiss regulatory pre-authorization is required for retail sale of compliant Class I/IIa devices, but cantonal health regulations may apply to specific products or settings

LEGAL BASIS

Reference	Description
Art. 16 MedDO (SR 812.213)	Labeling in Swiss official languages
Annex I §23.4 EU MDR 2017/745	Language requirements on labels (cross-referenced)
Annex I §23.1(d) EU MDR 2017/745	IFU for lay users — plain language requirement
Art. 16 IvDO (SR 812.219)	IVD labeling — self-test devices
Annex I EU IVDR 2017/746 §20	IVD IFU requirements for near-patient and self-test devices
TPA Art. 31–32 (SR 812.21)	Advertising restrictions for therapeutic products

10. Export Certificates

SUMMARY

Switzerland (Swissmedic) issues export certificates for medical devices manufactured in Switzerland that are intended for markets outside Switzerland. These certificates are commonly required by importing countries' regulatory authorities to confirm the device is legally marketed in Switzerland and meets applicable standards.

KEY REQUIREMENTS

- **Certificate of Free Sale (CFS):** Swissmedic issues a CFS confirming that the device is legally marketed in Switzerland. The certificate is based on the manufacturer's Declaration of Conformity and CE marking. Applications are submitted to Swissmedic with supporting documentation.
- **WHO Certificate of Pharmaceutical Product (CPP) equivalent:** Not applicable to medical devices — for pharmaceuticals only. Medical devices use the CFS.
- **Apostille:** Swiss export certificates may require apostille authentication (via the Swiss cantonal authorities or Federal Chancellery) for use in countries party to the Hague Convention.
- **Application requirements:** Manufacturer must submit: Declaration of Conformity, CE certificate (if applicable), device description, intended purpose, and labeling/IFU samples to Swissmedic.
- **Fee:** Export certificate fees are set by GebV-Swissmedic (SR 812.214.5). Fees vary by document type and number of devices covered.

- **Custom-made and in-house devices:** Export certificates may also be issued for custom-made devices registered with Swissmedic under Art. 10/19 MedDO.

LEGAL BASIS

Reference	Description
Art. 62 TPA (SR 812.21)	Swissmedic authority to issue export certificates
Art. 88 MedDO (SR 812.213)	Export documentation for medical devices
GebV-Swissmedic (SR 812.214.5)	Fee schedule for export certificate issuance
Hague Convention (1961)	Apostille authentication for international recognition

Practical Note: Certificate of Free Sale applications should be submitted via the Swissmedic online portal. Processing typically takes 10–15 business days. Certificates are issued in English, German, French, or Italian upon request. Swissmedic's website provides the current application form and fee schedule.



11. Transportation and Storage

SUMMARY

Transportation and storage requirements for Swiss medical devices are governed by a combination of the GSPR under MedDO, the Swiss dangerous goods transport ordinances (ADR/RID/IATA), and specific cold-chain requirements for temperature-sensitive devices.

KEY REQUIREMENTS

- **Storage conditions in IFU/labeling:** Manufacturers must specify storage conditions (temperature, humidity, light) on the device label and in the IFU per Art. 16 MedDO and Annex I §23.2(z) EU MDR — conditions that must be met to preserve safety and performance throughout shelf life
- **Cold-chain devices:** Devices requiring cold-chain transport (e.g., certain IVD reagents, biological implants) must be transported under validated conditions; distributors must maintain cold chain per Art. 53–54 MedDO importer/distributor obligations
- **Dangerous goods — road transport (ADR):** Medical devices classified as dangerous goods (UN3373 biological substances, UN1845 dry ice, lithium battery devices UN3090/UN3091/UN3480/UN3481) must comply with **Swiss SDR Ordinance (SR 741.621)** which adopts the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR)
- **Rail transport (RID):** International rail transport of dangerous medical device materials is governed by the RID (Regulations Concerning the International Carriage of Dangerous Goods by Rail), adopted by Switzerland under SR 742.401.6
- **Air freight (IATA DGR):** Air shipment of medical devices containing dangerous goods (lithium batteries, biological substances, dry ice) must comply with IATA Dangerous Goods Regulations (DGR) — operators must be IATA DGR certified
- **Sterile packaging integrity:** Transportation must not compromise the sterile barrier — manufacturers must validate transport packaging per EN ISO 11607-1 and consider transport conditions (vibration, pressure, temperature) per ASTM D4169 / ISTA protocols
- **Radioactive devices:** Devices incorporating radioactive materials must comply with the Swiss Radiological Protection Ordinance (StSV, SR 814.501) for transport and use

LEGAL BASIS

Reference	Description
Art. 16 MedDO	Labeling — storage conditions on label/IFU
Annex I §23.2(z) EU MDR 2017/745	GSPR — storage/transport conditions disclosure (cross-referenced)
Art. 53–54 MedDO	Importer/distributor obligations — maintain storage conditions
SR 741.621 (SDR)	Swiss Dangerous Goods Road Transport Ordinance (implements ADR)
SR 742.401.6 (RID)	Rail transport dangerous goods regulations
IATA DGR (current edition)	Air freight dangerous goods — lithium batteries, biologicals
EN ISO 11607-1	Sterile packaging validation including transport (harmonized standard)
SR 814.501 (StSV)	Radiological Protection Ordinance — radioactive device transport

12. Waste Management

SUMMARY

Medical device waste management in Switzerland is governed by environmental legislation including the **Ordinance on the Return, Taking Back and Disposal of Electrical and Electronic Equipment (VREG, SR 814.620)**, the **Technical Ordinance on Waste (TVA, SR 814.600)**, and the **Ordinance on Movements of Waste (VeVA, SR 814.610)** for special/hazardous waste.

KEY REQUIREMENTS

- **EEE (Electrical and Electronic Equipment):** Medical devices that are electrical/electronic equipment are subject to VREG (SR 814.620). Manufacturers/importers must: register with SENS eRecycling or SWICO (producer responsibility organizations), pay advance recycling contributions (VRG), and ensure take-back at end of life for recycling
- **Take-back obligation:** Retailers and distributors must accept end-of-life EEE medical devices from consumers free of charge per Art. 9 VREG
- **Hazardous/special waste:** Certain medical devices (devices contaminated with biological/chemical agents, devices containing hazardous substances) are classified as special waste under VeVA (SR 814.610). They must be collected, transported, and treated by licensed waste management companies. Accompanying document (Begleitschein) required for special waste movements per Art. 8 VeVA

- **Clinical/biological waste:** Medical devices contaminated with infectious biological material (e.g., used single-use devices in clinical settings) are regulated as clinical waste under TVA (SR 814.600) and must be treated by approved facilities (typically incineration)
- **Labeling for waste:** Manufacturers must provide information in IFU on safe disposal procedures per Annex I §23.1(d) EU MDR (cross-referenced by MedDO), especially for devices with batteries, CMR substances, or biological components
- **Mercury-containing devices:** Subject to strict disposal requirements per ChemRRV (SR 814.81) — mercury thermometers, sphygmomanometers being phased out

LEGAL BASIS

Reference	Description
SR 814.620 (VREG/ORDEE)	EEE take-back, recycling, advance recycling contribution (VRG)
SR 814.600 (TVA)	Technical Ordinance on Waste — clinical/biological waste treatment
SR 814.610 (VeVA)	Ordinance on Movements of Waste — special/hazardous waste tracking
ChemRRV (SR 814.81)	Mercury-containing device disposal restrictions
Annex I §23.1(d) EU MDR 2017/745	IFU must include disposal instructions (cross-referenced)



13. AI Medical Device (Software as a Medical Device / AI-SaMD)

SUMMARY

Switzerland regulates AI-driven Software as a Medical Device (AI-SaMD) under MedDO/IvDO, applying the same framework as EU MDR/IVDR for software classification and conformity. There is no separate Swiss AI medical device regulation; requirements are embedded in the general MedDO framework supplemented by Swissmedic guidance and EU-level reference documents (MDCG guidance papers).

REGULATORY CLASSIFICATION OF SOFTWARE

- Software as a Medical Device (SaMD):** Software that qualifies as a medical device under Art. 2 MedDO must comply with MedDO. The definition aligns with EU MDR Art. 2(1) — software with a medical intended purpose is a medical device
- MDCG 2019-11 Classification:** Swissmedic accepts and applies the **MDCG 2019-11 guidance on qualification and classification of software** as a reference document. Software primarily driving or influencing clinical decisions is typically Class IIa or above
- AI/ML classification factors:** Intended purpose, decision criticality (informing vs. driving clinical decision), and patient risk level drive classification. High-risk AI-SaMD (e.g., diagnostic AI for cancer detection) typically falls in Class IIb or III

KEY REQUIREMENTS FOR AI-SAMD

- GSPR for software (Annex I §17 EU MDR):** AI-SaMD must meet software-specific GSPR requirements including: repeatability, reliability, and performance specifications; clinical validation of algorithm outputs; performance reporting (sensitivity, specificity, AUC); robustness against adversarial inputs; cybersecurity per IEC 81001-5-1 and Art. 16 MedDO
- Technical documentation:** Must include the algorithm description, training/validation data set characteristics, performance metrics across defined sub-populations, and change management plan for continuous learning models (Annex II & III EU MDR cross-referenced by MedDO)
- Cybersecurity:** As of 2023, cybersecurity is an explicit requirement under updated MDCG guidance (MDCG 2019-16 Rev.1). Swissmedic aligns with this — AI devices must address cybersecurity in design and have an update/patch management process per Art. 8 MedDO (QMS) and GSPR §17.4
- Continuous learning / adaptive AI:** Post-deployment algorithm changes in continuously learning AI-SaMD may constitute "significant changes" requiring conformity assessment re-evaluation per Art. 23 MedDO. A pre-specified change protocol (PSCP) approach, consistent with MDCG 2020-1 Annex, is recommended
- Clinical evaluation:** AI-SaMD requires clinical evaluation per Annex XIV EU MDR (cross-referenced by MedDO), demonstrating clinical performance of the AI outputs — not just technical performance of the software
- Post-Market Surveillance:** PMS plan must include specific AI performance monitoring in real-world deployment. Retrospective performance drift is a vigilance-relevant finding per Art. 66 MedDO if it affects patient safety
- Swiss AI Act alignment:** Switzerland is developing its own framework for AI regulation in alignment with the EU AI Act (2024/1689). High-risk AI systems used in medical devices may fall under both MedDO and future Swiss AI legislation. Swissmedic is actively monitoring EU AI Act implementation; manufacturers should ensure MedDO compliance today and monitor Swiss AI Act developments (expected transposition 2025–2027)
- IVD AI software (AI-IVD):** AI-driven IVD software must comply with IvDO (SR 812.219) and IVDR GSPR per Annex I EU IVDR. MDCG 2019-11 also applies to IVD software qualification/classification

LEGAL BASIS

Reference	Description
Art. 2 MedDO (SR 812.213)	Definition — software as a medical device (adopts EU MDR Art. 2(1))
Annex I §17 EU MDR 2017/745	GSPR for software — performance, reliability, cybersecurity (cross-referenced)
Annex II & III EU MDR 2017/745	Technical documentation — algorithm description, validation data (cross-referenced)
Annex XIV EU MDR 2017/745	Clinical evaluation requirements for AI-SaMD (cross-referenced)
Art. 23 MedDO	Conformity assessment re-evaluation for significant changes (adaptive AI)
Art. 32–34 MedDO	PMS — AI performance monitoring in real-world deployment
Art. 66 MedDO	Vigilance — performance drift reporting if patient safety affected
MDCG 2019-11	Qualification and classification of software as a medical device
MDCG 2019-16 Rev.1	Cybersecurity guidance for medical devices (applied by Swissmedic)

Reference	Description
MDCG 2020-1 Annex	Pre-specified change protocol for continuously learning AI
IEC 81001-5-1	Health software cybersecurity (harmonized standard)
EU AI Act 2024/1689	High-risk AI systems — Switzerland tracking for future transposition (2025–2027)
IvDO (SR 812.219)	AI-IVD software regulatory framework (IVD classification + GSPR)

Watch Point — EU AI Act: The EU AI Act (entered into force August 2024) classifies AI systems used as medical devices or in their function as high-risk AI. Switzerland is actively aligning its legal framework. Manufacturers placing AI-SaMD in Switzerland should monitor Swissmedic's official communications on Swiss AI Act transposition — expected to be confirmed by 2026/2027.