Regulatory Update for Switzerland

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Key changes to regulatory framework

Revision of MedDO and IvDO*

The new provisions in the Medical Devices Ordinance (MedDO, SR 812.213) and the Ordinance on In Vitro Diagnostic Medical Devices (IvDO, SR 812.219) entered into force on 1 November 2023. The changes align the Swiss provisions with the EU requirements, restoring equivalence with the EU-MDR and EU-IVDR.

- **Extension of transitional provisions for medical devices and lifting of deadlines**
  To ensure continuity of medical device supplies in Switzerland, the transitional period for medical devices certified under the former directives 93/42/EEC and 90/385 EEC can be extended under certain conditions from 26 May 2024 to 31 December 2027 or 31 December 2028. The deadlines for putting into service and placing on the market were lifted.

- **Product groups without an intended medical purpose**
  (e.g. cosmetic implants, contact lenses without visual correction, or brain stimulation devices), fall under the scope of the MedDO and have to meet the common specifications set out in the EU Implementing Regulation.

- **Reclassification of certain active products**
  without an intended medical purpose, such as equipment for liposuction or hair removal, are reclassified according to the EU Implementing Regulation and have to comply with higher safety standards.

Key changes to guidance documents

Market access
- BW617_00_003e MB Derogation MEP (revised - 15.12.2023)
- MU600_00_016e MB Obligations Economic Operators CH (revised - 01.11.2023)

Provisions governing special medical devices
- MU600_00_007e MB Products without an intended medical purpose (new - 08.12.2023)
- BW630_30_007e Information sheet Medical Device Software (revised - available soon)

Clinical Trials
- BW600_00_015e MB Clinical investigations with medical devices (revised - 27.12.2023)
- BW600_00_016e MB Performance studies with IVD (revised - 27.12.2023)

Healthcare institutions
- "Checklist the annual validation reports of instrument for washer disinfectors and trolley washer disinfectors" * (new - 08.01.2024)
- "Checklist for the verification of a report on the performance qualification (PQ) of a steam steriliser" * (new - 25.10.2023)
- "Swiss guideline for the transport of contaminated and reprocessed medical devices for reprocessing units" * (new - 25.09.2023)
- MU600_00_006e MB Procurement of medical devices in health institutions (revised - 01.11.2023)

*not available in English
Swissmedic sets the course for the future

New organisational structure with separate Medical Devices Surveillance Sector.

For the strategy period 2023-2026, Swissmedic’s objectives include making legal responsibilities for medical devices more visible and stepping up international collaboration in this area.
Market surveillance

Focus campaign on economic operators
Swissmedic inspected 27 medical device manufacturers in Switzerland

Implementation of the new medical device requirements and market surveillance for medical devices in the lowest risk class

11 % of the products did not have proof of compliance with the new requirements and therefore could not be marketed.

39 % of the devices and 14 % of the manufacturers were not correctly registered.

70 % of the documentation on surveillance of the devices on the market did not meet the new requirements.

Link: Announcements on market control issues
Swissmedic inspected 20 Swiss authorised representatives

70% of CH-REPs with NCs

65% NC - Mandate requirements

55% NC - Vigilance reporting obligations

Link: Announcements on market control issues
Swissmedic reviewed 30 Swiss importers

18 out of 30 importers performed incomplete product checks.

For 8 out of 30 importers the importer information was incomplete.

At 8 out of 30 importers, the storage and transport conditions were inadequate.

3 out of 30 importers had deficiencies in the recording and forwarding of complaints.

Link: Announcements on market control issues
Product conformity under the Medical Devices Ordinance

Risk classification

Classification is subject to Annex VIII EU-MDR, taking account of the implementing acts listed in Annex 5a MedDO, which define specific rules of classification for the (active) product groups 4 to 6 in Annex 1 MedDO.

Furthermore, the “Borderline Manual” must be observed, which places facial and other dermal and mucous membrane fillers under the highest risk class of III.

Table: Classification in accordance with the EU Commission’s implementing acts listed in Annex 5a MedDO:

<table>
<thead>
<tr>
<th>Group</th>
<th>Description (short form)</th>
<th>Class</th>
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<tbody>
<tr>
<td></td>
<td>Reduction, removal or destruction of adipose tissue</td>
<td>IIb</td>
</tr>
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</table>

Actions required of the manufacturer*

- Determine whether your device falls under one of the six product groups listed in Annex 1 MedDO[1] and whether you are thus affected by the new requirements.
- Familiarise yourself with the legal requirements under the MedDO, the EU-MDR and the common specifications for product groups without an intended medical purpose. See also the Explanatory report [not available in English] of the FOPH for background information on the MedDO.
- Make a note of 1 May 2024. The devices must have been marketed in Switzerland by this date in order to benefit from the transitional rules.
- Based on the intended purpose, determine the risk class (Art. 15 MedDO) for your devices under Annex VIII EU-MDR, taking account of the exceptions for the active product groups under Annex 5a MedDO.
- Prepare technical documentation in accordance with Annexes II/III EU-MDR to provide evidence of conformity with the general safety and
New explanatory clips available (Link)

More clips:
- What is a medical device?
- How do medical devices come onto the market?
- What are the tasks of Swissmedic in the area of medical devices?

...more to come soon
Development

- ACT module (Release 1.1) has been completed in functional terms.

- UDI module is underway.
## Swissmedic’s commitment to IMDRF WG's

<table>
<thead>
<tr>
<th>Topic</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Adverse Event Terminology</strong></td>
<td>Harmonize terminology for reporting adverse events related to medical devices, and further harmonize adverse event reporting datasets to improve signal detection.</td>
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<tr>
<td><strong>Artificial Intelligence/Machine Learning-enabled</strong></td>
<td>Seeking to harmonize international best practices to help promote the development of safe and effective AI/ML enabled medical devices.</td>
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<tr>
<td><strong>Good Regulatory Review Practices</strong></td>
<td>Develop good review practices for pre-market reviews and evaluations.</td>
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<tr>
<td><strong>Software as a Medical Device</strong></td>
<td>Promote consistency in regulatory assessment for Software as a Medical Device to make patients more efficiently.</td>
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<tr>
<td><strong>Personalized Medical Devices (PMD)</strong></td>
<td>Harmonize the regulatory requirements for medical devices that are intended for a particular individual, considering unique characteristics and risks associated with each type of device.</td>
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<tr>
<td><strong>Quality Management Systems</strong></td>
<td>Ensure alignment of IMDRF QMS and risk management documents with current international standards.</td>
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<tr>
<td><strong>Regulated Product Submission</strong></td>
<td>Harmonize the format and content of regulatory submissions.</td>
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IMDRF AE WG F2F Meeting in Bern, CH

Venue

International Medical Device Regulators Forum (IMDRF)
AET WG F2F Meeting
23 to 26 April 2024, Bern, Switzerland

It is an honour for Swissmedic, the Swiss Agency for Therapeutic Products, to host this next meeting as a new, young member of the AET WG. We are very much looking forward to it.

The meeting will be at Swissmedic's headquarters, Hallenstrasse 7, Bern, Switzerland. We are looking forward to welcoming you.
<table>
<thead>
<tr>
<th>Date</th>
<th>Organiser</th>
<th>Event, venue</th>
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<tbody>
<tr>
<td>27. Sep. 2023</td>
<td>Medtech &amp; Pharma Platform (MPP)</td>
<td>MPP Annual Conference, Basel, CH</td>
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<tr>
<td>18. Oct. 2023</td>
<td>University of Bern</td>
<td>Master of Science in Pharmacy, University of Bern (M Sc Pharm) As part of the curriculum, Swissmedic teaches the organisation and operation of pharmacovigilance and Materiovigilance, Bern, CH</td>
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<tr>
<td>18. Oct. 2023</td>
<td>Swiss Medical Technology Association (Swiss Medtech)</td>
<td>National Regulatory Conference, Bern, CH</td>
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<td>13. Nov. 2023</td>
<td>Swissmedic</td>
<td>Roundtable on Medical Technology (RTMT), Bern, CH</td>
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<tr>
<td>02. Feb. 2024</td>
<td>Clinical Trial Unit Basel, Department of Clinical Research, University of Basel</td>
<td>CAS Clinical Research I (Clinical Trial Planning and Conduct) Certificate of Advanced Studies, Module 1, Basel, CH</td>
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<td>02. Feb. 2024</td>
<td>«Swiss Association for the Supply of Sterile Goods” (SSSH/SGSV)</td>
<td>Training day: Swissmedic’s requirements for hospital sterilisation centres and its strategic objectives on reprocessing of reusable medical devices, followed by a Q&amp;A session, Lausanne, CH</td>
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<tr>
<td>12. Feb. 2024</td>
<td>Swissmedic</td>
<td>Roundtable on Medical Technology (RTMT), Bern, CH</td>
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