

Swiss Medical Devices Regulation: Federal Council Issues Last-Minute Changes

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The European Medical Devices Regulation (MDR) finally becomes applicable on May 26, 2021. By then, Switzerland will have left the common market for medical devices it shared with the European Union (EU) for the last 20 years. Until now, the manufacturers of medical devices in Switzerland and abroad were uncertain what the Swiss regulation would look like as of May 26.

Barely a week before this crucial date, the Swiss Federal Council has issued the last changes of the draft for a Medical Devices Ordinance (draft MedDO). An earlier version of this ordinance was issued on July 1, 2020, but will only come into force, including the latest changes, on May 26, 2021, thus forming the new medical devices regulation for Switzerland.

The latest changes to the draft MedDO are mostly due to the fact that Switzerland will become a “third country” with regard to MDR (i.e., it will no longer participate in a common market for medical devices) and that the Swiss authorities will have no access to the European databases for medical devices.

The most important changes are these:

- Manufacturers from outside of Switzerland need a Swiss-authorized representative (CHRep). Manufacturer and CHRep need to define their contractual relationship in a written agreement along the lines of the EU-authorized representative according to Art. 27 MDR. In contrast to Art. 27 MDR, the parties may conclude that instead of the CHRep being obligated to keep copy of the technical documentation at its premises, the manufacturer will, upon request, send the documentation directly to Swissmedic.
- The following transitional periods for the appointment of a Swiss representative, including corresponding labeling, are foreseen:
 - until December 31, 2021, for class III devices, class IIb implantable devices, and all active implantable devices
 - until March 31, 2022, for non-implantable class IIb devices and class IIa devices
 - until July 31, 2022 for Class I devices, systems, and procedure packs
- The CHRep has to comply with the vigilance obligations according to the MedDO. This obligation has to be included in the agreement between the manufacturer and the CHRep.

- Either the manufacturers, their CHRep, or the importer has to register a product put on the Swiss market within 30 days with Swissmedic, providing the information according to Annex VI, part A, section 1 MDR. Economic operators that have put products complying with MDR or the EU Medical Devices Directive on the Swiss market before May 26, 2021, need to register these products with Swissmedic until November 26, 2021.
- Declarations of conformity according to EU law issued by accredited notified bodies in a member state of the EU or European Economic Area will be equal to declarations issued by Swiss notified bodies.
- A Unique Device Identifier (UDI) is needed for all medical devices, including systems and procedure packs (excluding custom-made products). At a later date (not yet defined), the information on the UDI has to be reported to Swissmedic in accordance with the provisions of Art. 27 and 29 and Annex VI MDR.