

Information on importing medical devices into Switzerland

Appointment of a Swiss Authorised Representative

Bern, 1st February 2021

Without an update of the Mutual Recognition Agreement (MRA), all foreign manufacturers will need a Swiss authorised representative from May 2021 in order to be able to supply their medical devices to Switzerland.

The MRA between Switzerland and the European Union (EU) regulates the removal of technical barriers to trade. If it is not updated before 26 May 2021 to include the Medical Device Regulation (MDR), Switzerland will lose its barrier-free access to the EU internal market for medical devices, i.e. Switzerland will be treated as a third country. All Swiss manufacturers must appoint an importer and an European authorised representative in a member state to continue to supply medical devices to the EU.

Conversely, the revised Swiss Medical Devices Ordinance (MedDO) provides for equivalent requirements for the import of medical devices, namely the designation of an importer and a Swiss authorised representative, so that foreign manufacturers may continue to supply medical devices to Switzerland. The MedDO, which was published on 1 July 2020, was drafted on the assumption of an updated MRA and must therefore be amended again before May 2021 without an MRA.

Swiss Medtech recommends all Swiss distributors and importers to immediately start planning a scenario without MRA. This includes first and foremost considerations regarding the appointment of a Swiss proxy and the associated organisational procedures. It is urgent to inform the approximately 5'000 affected foreign manufacturers and to start mandate negotiations. The aim is to clarify as quickly as possible which of the currently imported medical devices will continue to be available to patients in Switzerland, which must and can be substituted and which will no longer be available.

Swiss Medtech will actively assist in this important process for the Swiss healthcare system with up-to-date information, guidance and webinars. You will find all the information on our website.

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Swiss Medtech, the Swiss medical technology industry association, represents more than 600 members. With 63'000 employees and a contribution of 16.4% to Switzerland's positive balance of trade, medical technology is an economically important sector. Swiss Medtech advocates an environment in which medical technology can provide top performance for the benefit of first-class medical care.

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