SWISS MEDTECH

Dear Swiss Medtech Members,
Ladies and Gentlemen of the Swiss Medtech Industry

On behalf of the Federal Council, the Federal Office of Public Health (FOPH) has prepared an amendment to the Medical Devices Ordinance («Contingency MedDO») as a precautionary measure, which will be put into force by the Federal Council on 26 May 2021 if the Mutual Recognition Agreement (MRA) between Switzerland and the European Union (EU) has not been updated by that date.

Swiss Medtech is in regular contact with the FOPH regarding the Contingency MedDO. Due to the time pressure under which the Swiss medical technology industry is operating, we would like to inform you in this letter about some important contents of the Contingency MedDO. Please note that an update of the MRA before 26 May 2021 is not excluded. In that case, the Contingency MedDO would not enter into force.

Important contents of the Contingency MedDO (not yet passed)

The Contingency MedDO provides **transitional periods** for the appointment of a Swiss representative, including corresponding labelling, staggered according to risk classes:

- **Until 31 December 2021** for class III devices, class IIb implantable devices, and all active implantable devices.
- **Until 31 March 2022** for non-implantable class IIb devices and class IIa devices.
- **Until 31 July 2022** for Class I devices, systems and procedure packs.

- **Registration and notification obligations** do not run via EUDAMED, but via Swissmedic. Economic operators who have already placed products on the market before 26 May 2021 in accordance with the MDR and IVDR must complete their registration by 26 November 2021.
- Access to the **technical documentation** may be provided either by keeping a copy available at the authorised representative or by contractually guaranteeing that it will be handed over to Swissmedic upon request within 7 days.
- The **validated Summary of Safety and Clinical Performance (SSCP)** is not uploaded by the Notified Body in EUDAMED, but published by the manufacturer, for example on its website.

Support by Swiss Medtech

The transition periods are very tight. Swiss Medtech actively supports its member companies in implementing the regulatory requirements within the transition periods. We offer assistance such as training seminars, guidelines and contract templates. You will find all the information on our website.

→ MDR Portal

→ Events

Notification of any delivery stops

Regardless of the transition periods, there is an inherent risk that certain foreign companies will no longer be willing to supply their products for the small Swiss market. We ask you to notify us of any supply stoppages. Your report will be added to the list of potentially missing medical products in Switzerland which we will periodically send to the Federal Council in anonymised form. This will happen for the first time in October 2021.

→ Notification form for delivery stops (in German)