SWISS MEDTECH

Bern, 12 May 2021

Information for the Swiss Medical Technology Industry

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

In two weeks – on 26 May 2021 – the new EU Medical Device Regulation (MDR) will come into force. The present situation is:

Third country requirements for all MDR products

Barring a last-minute political solution between the European Union (EU) and Switzerland, the Swiss medtech industry will be downgraded to third country status on 26 May 2021. The amended Swiss Medical Devices Ordinance (Contingency MedDO – the essential components of which we sent the industry on 1 April 2021: Industry information on the Contingency MedDO) is expected to come into force on the same day. For the Swiss medtech industry, this means:

- **Exports**: Swiss manufacturers must fulfil third country requirements in order to gain authorization to export MDR products (all products with MDR certificate as well as all Class I products) to the EU. This primarily necessitates the designation of a European Authorized Representative, and the corresponding adapted labelling.
- **Imports:** Swiss importers must fulfil the Contingency MedDO requirements in order to gain authorization to import MDR products into Switzerland. This primarily necessitates the designation of a Swiss Authorized Representative by the manufacturer, and the corresponding adapted labelling.

Transitional solution for MDD products not yet secured

At the end of March 2021, the EU Commission announced that the transitional period (Grace Period) until 2024 would also apply – under certain conditions – to MDD products from Swiss manufacturers. The risk of a medical devices supply shortage has accelerated talks between the EU and Switzerland. This progress is encouraging, but no reason to give the «all-clear» as long as the negotiating partners have not reached a binding agreement on clear transitional provisions. Swiss Medtech is working to ensure that the May 2024 transition period applies to the movement of goods in both directions; namely that MDD products can be transferred from Switzerland to the EU and from the EU to Switzerland until May 2024 without the need to designate an authorized representative.

The ongoing negotiations between Switzerland and the EU for a transitional solution for MDD products have not yet been concluded, and have not yet resulted in any agreement. **We therefore urgently draw the attention of the Swiss medtech industry to the following situation: Only those MDD products made available on the market in the EU area before 26 May 2021 *are sure* to be distributed as before without a European Authorised Representative in the EU until 26 May 2025 (Grace Period plus one year of sales).** This is due to continuing uncertainty if Switzerland and the EU will agree to guarantee mutual market access for MDD products until May 24, 2024; even if this would be a pragmatic and responsible decision with regard to patient care in Europe and in Switzerland.

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Support from Swiss Medtech
Swiss Medtech actively supports its member companies in implementing the regulatory requirements. We offer concrete assistance such as training seminars, guidelines, and sample contracts. You will find all information on our website.

→ MDR portal
→ MDR calendar of events

Swiss Medtech represents more than 600 members in its role as industry association for Swiss medical technology. With 63,000 employees and a contribution of 16.4% to the positive trade balance, medical technology is an economically significant sector in Switzerland. Swiss Medtech advocates for conditions that enable the medtech industry to perform at peak capacity and provide first-class medical care.