ARAZY GROUP CONSULTANTS INC.

2021 Swiss Medical Device Legislation

Upcoming Changes that Manufacturers Need to Know

Important Date: May 26th, 2021

The Federal Council, the Federal Office of Public Health (FOPH) will put into force the amended Medical Devices ordinance ("Contingency MedDO") if the Mutual Recognition Agreement between Switzerland and the European Union (EU) is not updated by this date to include the Medical Device Regulation (MDR). This would result in Switzerland as a third country requiring changes and additional measures for foreign manufacturers to supply their medical and in-vitro diagnostic devices to Switzerland.

How can you prepare?

The adaptation of the Swiss medical device law is occurring in coordination with the transition periods in the EU. Manufacturers should be aware that the Mutual Recognition Agreement (MRA) between Switzerland and the European Union (EU) will most likely not be updated by 26 May 2021. To prepare, manufacturers must designate an importer and a Swiss authorized representative to supply devices to Switzerland. The Contingency MedDO (not yet passed) provides transitional periods for the appointment of a Swiss representative, including corresponding labelling, staggered according to risk classes:

Until 31 December 2021

- Class III devices
- Class IIb implantable devices
- All active implantable devices

Until 31 March 2022

- Non-implantable class IIb devices and class IIa devices

Until 31 July 2022

- Class I devices, systems and procedure packs

Economic operators who have already placed products on the market before 26 May 2021 must complete their registration by 26 November 2021, in accordance with the MDR and IVDR.

How Arazy Group can Assist You

Arazy Group is readily available to act as your Swiss representative to ensure your compliance through the transitional periods in the likely case that the Mutual Recognition Agreement is not passed by 26 May 2021.

Our regulatory compliance solutions can provide the following for the Swiss market:

- device-specific Technical File checklist for each line of products
- easy and simple upload of compliance documents
- gap analysis report for each Technical File*
- real-time document viewing and sharing
- consultation to amend non-conformities*

*at an additional cost

Email us at info@arazygroup.com to learn more about our Swiss representative services and to speak with one of Regulation Experts.