Alignment with Medical Device Regulation (MDR) – duties of Swiss suppliers and manufacturers

29.01.2020

The two new regulations of the EU Commission on medical devices (Medical Device Regulation, MDR; No 2017/745) and the In vitro Diagnostic Medical Devices Regulation (IVDR; No 2017/746) entered into force on 26 May 2017. They are applicable with graduated transition periods of between six months and five years in spring 2020 (MDR) and spring 2022 (IVDR), respectively.

The regulations aim to improve the quality and safety of medical devices, harmonise enforcement in the EU and increase patient safety. Importers and distributors of medical devices produced outside the EU must comply with the new regulations, and this includes Swiss manufacturers of medical devices.

To retain its position as an equal partner in the European single market for medical devices, Switzerland is aligning its legal basis for medical devices with the EU developments. By bringing forward the revision of the Swiss Medical Devices Ordinance (MedDO), Swissmedic can now participate in the EU expert groups that are to be set up. The partial revision of the Swiss Therapeutic Products Act (TPA) with new provisions on medical devices in alignment with the EU regulations, as well as the Swiss Human Research Act (HRA) are expected to enter into force in the first half of 2020. Consultation on the implementing provisions has been completed but the report is still pending.

Christian Roos

Partner
Attorney at law, lic. iur.
Co-head Life Sciences

Pestalozzi Attorneys at Law Ltd
Feldeggstrasse 4
8008 Zurich
Switzerland
T +41 44 217 92 00
christian.roos@pestalozzilaw.com