Access to the Swiss medical device market

Basel (Switzerland) / Münster (Germany), 21 September 2021.
Diapharm has set up a branch office in Switzerland, allowing it to act as a Swiss authorised representative for registration procedures and safety-related matters for the marketing and distribution of medical devices within the country's borders.

Procedural changes were made in May 2021 in relation to the marketing and distribution of medical devices in Switzerland. According to the Swiss Medical Devices Ordinance (MedDO), only Swiss companies are permitted to register medicinal products and medical devices with Swissmedic, the Swiss regulatory and authorisation body. The rules apply to products newly placed on the market and legacy devices already on the market prior to May 2021, albeit with a transitional period in the latter case.

Manufacturers of medical devices based in the European Union and other third countries must appoint a Swiss authorised representative (CH-REP) to register products with Swissmedic. As a European authorised representative (EC-REP) and newly certified Swiss authorised representative (CH-REP), Diapharm has been facilitating third-country manufacturers' access to the European market for a number of years already.

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