

Press release

Medical technology sector suffers from legal uncertainty

Swiss Medtech gives recommendation to Swiss medical device manufacturers

Berne, 25th April 2019 – The legal uncertainty in connection with the Institutional Agreement between Switzerland and the European Union (InstA) directly affects the medical technology sector. Swiss Medtech recommends that Swiss manufacturers' business considerations should also include the scenario of having to meet the requirements of a third country.

Barrier-free access to the EU single market can only be achieved by updating the Mutual Recognition Agreement (MRA) between Switzerland and the European Union. Such updating of the MRA is not assured owing to the legal uncertainty in connection with the InstA. Today, Swiss Medtech gives a recommendation to all Swiss medical device manufacturers.

The Association recommends that manufacturers' business considerations should include that they may have to meet the requirements of a third country in order to be permitted to export products to the EU in accordance with the new EU Medical Device Regulation (MDR). In concrete terms, this means that they would have to appoint an authorised representative with a domicile in the EU, in addition to adapting all product labels. "Depending on the complexity and scope of the product range, meeting these two requirements can take two years," says Beat Vonlanthen, President of Swiss Medtech.

According to the Association, business considerations should also cover the possibility that the Federal Council will, in principle, voice its support for the InstA in the course of 2019. According to statements by the EU Commission, this would fulfil the prerequisite for updating the MRA. It is also conceivable that Brexit is accompanied by a Europe-wide supply bottleneck and that exemptions will apply.

"The decision whether to prepare for meeting the third-country requirements now or rather wait, is left up to each company. As an Association, we are always ready to give advice," says Vonlanthen.

Contact media enquiries

Anita Holler

Head of Communication and Public Affairs

+41 76 527 35 54

anita.holler@swiss-medtech.ch

Further documents on www.swiss-medtech.ch → access focus topics

- Recommendation from Swiss Medtech to Swiss medical device manufacturers
- Guidance for appointing an authorised representative