



Information for Swiss manufacturers of medical devices

Update regarding the Institutional Agreement and the Mutual Recognition Agreement

Bern, 11 December 2019

Over the past few months, Swiss Medtech has communicated intensively with federal administrators and policymakers on how the acute problems and negative consequences of the ongoing legal uncertainty between the European Union (EU) and Switzerland is affecting the Swiss medtech sector. Our association is committed to ensuring that industry players can continue to place products on the EU economic area market - seamlessly and barrier-free. Swiss Medtech also feels a duty to provide manufacturers with all necessary information so they can adapt their business strategy as best possible before 26 May 2020. We would therefore like to inform you about the current state of affairs:

- The legal uncertainty between Switzerland and the European Union (EU) regarding the Institutional Agreement (InstA) is ongoing and is directly affecting the Swiss medtech industry.
- Until the InstA is resolved, no new agreements will be concluded with Switzerland and no existing ones will be modified (Johannes Hahn, European Commissioner for European Neighbourhood Policy and Enlargement Negotiations, press conference of 17 December 2018).
- This also applies to the Mutual Recognition Agreement (MRA), which is particularly relevant for the export-strong Swiss medical technology industry.
- The new EU Medical Devices Regulation (MDR) comes into effect on 26 May 2020 – creating an urgent need for planning and clear legal certainty for the industry.
- The interpretation of the current MRA is therefore of great importance for Swiss manufacturers. Three scenarios are currently conceivable: (1) all medical devices are covered (best case), (2) MDR products are not covered, (3) no medical devices are covered; including both MDR products as well as products with a certificate issued under the old MDD regulation (worst case).
- Last April, Swiss Medtech advised Swiss manufacturers to prepare for Scenario 2; that as of 26 May 2020, they may have to meet third country requirements to export products to the EU in accordance with MDR. This means, among other things, that they must designate a representative with a subsidiary in the EU area and adapt their product labels accordingly.
- Notified Bodies are already demanding that Swiss manufacturers prove compliance with third countries requirements.
- Voices throughout Europe – among others from European Commission members – are increasing supporting Scenario 3 whereby *no* medical devices will be covered under the MRA from May 2020.
- The MDR Corrigendum II adjustment (transitional period extension until May 2024 for higher designated Class I medical devices) does not alleviate the situation regarding third country requirements. Depending on the interpretation of the MRA (specifically Scenario 3) third country requirements must also be fulfilled for products covered in Corrigendum II.

→ We will inform you promptly about further developments.

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