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Information for all Swiss manufacturers of medical devices

Third country compliance for all products (MDR and MDD) from 26 May 2020 is currently the realistic «worst case scenario»

Bern, 20 January 2020

As indicated in the information bulletin from Swiss Medtech dated 11 December 2019 concerning the Mutual Recognition Agreement (MRA)[i], the interpretation of the current MRA is key for Swiss manufacturers. Since last December, EU Commission lawyers have been interpreting the MRA in the most unfavourable way possible for Switzerland. Their position assumes that the MRA will no longer apply to medical devices after 26 May 2020.

The worst case scenario – that Swiss manufacturers will have to meet third country requirements for all medical devices (MDR and MDD) from 26 May 2020 – is realistic from today's perspective.

Swiss Medtech recommends that Swiss manufacturers consider the technical interpretations of the MRA that the EU Commission have made since last December, and adjust their business strategy accordingly. Please note that a last minute political solution is also conceivable before the 26 May 2020 deadline.

→ We will keep you up to date about any new developments.
→ Questions: Peter Studer, Head Regulatory Affairs, peter.studer@swiss-medtech.ch, 031 330 97 74
→ MDR News Ticker at www.swiss-medtech.ch
→ Instructions on how to designate an authorised representative (in German; the April 2019 version must be extended to all products; a revision will follow shortly)

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[i] Information for Swiss manufacturers of 11 December 2019