SWISS MEDTECH

# Information to the Swiss medical technology industry

## The date of application of the MDR has been postponed by one year to the 26th of May 2021

Berne, 17th of April 2020

On the 17th of April 2020, the EU Parliament adopted a proposal to postpone the date of application of the Medical Devices Regulation (MDR) by one year to the 26th of May 2021. The regulation shall enter into force on the day of its publication in the Official Journal of the European Union. According to the EU Parliament, the postponement aims to give national authorities, notified bodies, manufacturers and others time to prioritise the fight against the coronavirus pandemic.

We now wish to provide you with information about the consequences for the Swiss medical technology industry as follows:

- The new date of application of the MDR is the 26th of May 2021.
- Up until the 26th of May 2021, medical devices may be placed on the market within the EU single market under the current European and national regulatory framework.
- The present Mutual Recognition Agreement (MRA) between Switzerland and the European Union (EU) also falls within the current regulatory framework.
- Consequently, **MDD products** and **MDR products** are therefore able to be placed on the market within the EU single market up until the **26th of May 2021** as before, without non-member country requirements having to be fulfilled.
- Under the current regulatory framework, **EC certificates and EU certifications** issued by Swiss conformity assessment bodies will remain in full force and effect until at least the 26th of May 2021.
- The public announcement on the functioning of the central database **Eudamed** (Art. 34 MDR) is scheduled to be made on the 26th of March 2021, meaning that Eudamed will not be operational until the 26th of May 2021 at the earliest.

Swiss Medtech recommends that Swiss companies take into account the fact that the MRA might not have been updated in a year's time either. Should this be the case, all products (MDD and MDR) would have to satisfy non-member country requirements from the 26th of May 2021 onwards. The

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association recommends using the thirteen months until the new date of application to prepare in the best way possible for such an eventuality.

- If you have any questions, please contact Dr. Daniel Delfosse, designated Head of Regulatory Affairs
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- We will keep you informed on the latest developments via the MDR News Ticker at
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**Swiss Medtech** is an industry association which represents the interests of the Swiss medical technology sector and has over 550 members. Employing 58,500 individuals and accounting for 13.5% of Switzerland's positive trade balance, medical technology is a major economic industry. Swiss Medtech is committed to an environment in which medical technology can deliver top performance for the benefit of first-class medical care.

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