

Message

From : DG SANTE B6 Medical Devices & DG TRADE

The Commission services would like to inform that, to mitigate the risk of possible disruptions of supply of medical devices on the EU market, and to provide legal certainty to companies, the European Union will propose to Switzerland a limited modification to the current Mutual Recognition Agreement. An amendment is currently under preparation, aimed at granting certificates already issued in Switzerland for existing medical devices under the Swiss legislation equivalent to existing EU Directives the same transitional validity as the new EU Medical Devices Regulation grants to certificates issued in the EU.

If agreed by EU and Switzerland, this small amendment to the Mutual Recognition Agreement will enter into force on 26 May 2021.

The Mutual Recognition Agreement will not be updated with regard to new certificates under the new Regulation pending any substantial progress on the Swiss side towards signature of the EU-Switzerland Institutional Framework Agreement.