MedTech Europe
from diagnosis to cure

Brussels, 07 May 2021

To the European Commission
Executive Vice-President Dombrovskis and
Commissioner Kyriakides

Open Letter

Re: Call to action to ensure continued supply of medical technologies between the EU and Switzerland after 26 May 2021

Dear Executive Vice-President Dombrovskis,
Dear Commissioner Kyriakides,

MedTech Europe calls on you for urgent action to ensure that the transition to the new regulatory framework for medical devices and the continued supply of medical technologies to patients beyond the deadline of application on 26 May 2021 are not cut short due to the pending discussions on the rules and agreements between the EU and Switzerland.

We would urge you to ensure that all manufacturers, including those currently located in Switzerland, that hold a valid Notified Body certificate issued under Directive 90/385/EEC or Directive 93/42/EEC, including those certificates issued by the Swiss Notified Body, to benefit in full from the transitional provisions known as the “grace period” outlined in article 120(3) of Regulation (EU) 2017/745.

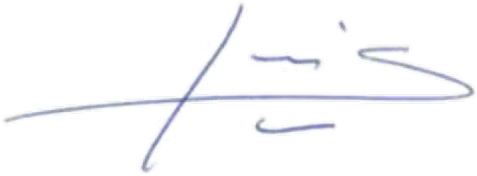
Specifically, with less than 20 days to go to the date of application for most of the provisions of the new EU Medical Devices Regulation, it is imperative that the situation around the status of the Mutual Recognition Agreement (MRA) between the European Union and Switzerland is clarified. The announcement by the European Commission on 31 March to amend the MRA has unfortunately not yet led to a situation where there is clarity on the transitional provisions or on the collaboration between the European Union and Switzerland to ensure the safety and availability of medical technologies.

Details with regards to the procedures to be followed by manufacturers both in the EU and Switzerland are urgently needed. The current uncertainty around the application and interpretation of the new EU Medical Devices Regulation vis-à-vis Switzerland risks compromising a smooth transition to the new Regulation and the continued supply of certain medical technologies.

MedTech Europe, as the trade association representing the medical technology industry, remains committed to the transition to the new EU Medical Devices Regulation. It is because of this that we urge you again, to ensure that the necessary steps are taken to overcome the remaining uncertainties before the deadline of application on 26 May 2021.

We remain at your full disposal for further discussion.

Yours sincerely,



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