

Dear colleagues,

The situation we find ourselves in is indeed truly exceptional. It requires exceptional actions which would not have been taken under normal circumstances.

Directly related to MDR implementation and taking stock of the MDCG discussions on 11 March, the Commission has carefully evaluated the impact of COVID-19 on the implementation of the Joint Implementation Plan and on the MDR, including looking into the implementation deadline of the MDR. The COVID-19 situation has added a lot of pressure to an already challenging situation for all actors involved (national competent authorities, notified bodies, industry and the Commission).

As such, today (25 March 2020), and with patient health and safety as a guiding principle, the **Commission announced that work on a proposal to postpone the date of application of the MDR for one year is ongoing.** “We are working to submit this proposal early April and we call on Parliament and Council to adopt it quickly as the deadline for entry into force is end of May.” This will relieve pressure from national authorities, notified bodies, manufacturers and other actors and will allow them to focus fully on urgent priorities related to the coronavirus crisis.

We **remain fully committed** to the effective implementation of the new medical device legislation and will proceed with this important work – together with all actors involved. The European Commission has been facilitating strong collaboration between competent authorities of Member States and relevant economic operators for a smooth transition to the new legislative framework. The extraordinary situation caused worldwide by COVID-19 calls for extraordinary measures. The new legislation is key to ensure patient health and safety and increase transparency on medical devices across the EU. The proposal for postponement seeks to temporarily alleviate the burden on available resources **but work done until now will not be lost, it will be used for a longer upgrade and transition of the system.**

We call on all actors to **ensure that this is additional year is used appropriately** and consciously and that all incomplete work leading up to the originally foreseen date of application is this time around appropriately completed.

Wishing you all good health during these difficult times,

Best regards,

SANTE B6 – Medical Devices Unit