President Ursula von der Leyen

Commissioner Stella Kyriakides

European Commission

24.03.2020

Re: Medical Device Regulation

Dear President,

Dear Commissioner,

Firstly, thank you both for your considerable efforts to respond to this unprecedented public health crisis and its wide-ranging impacts on European citizens.

We, the undersigned, urge the European Commission to give greater flexibility regarding the implementation of the Medical Device Regulation and possibly come forward with a proposal to extend the implementation deadline via the ordinary legislative procedure, in light of the current crisis.

The Medical Device Regulation contains very important elements to improve patient safety and it is important that these changes can be implemented as soon as possible.

However, in light of the current situation, healthcare systems across Europe are diverting resources to meet the demands posed by the COVID-19 crisis, including the provision of sufficient safe medical devices such as ventilators.

Fewer resources are available to ensure the implementation of the regulation, for example, the approval of clinical studies, the designation and auditing of notified bodies and in manufacturing.

We propose to maintain the current system and postpone the implementation deadline of 26 May 2020 to allow the industry focus on the essential and urgent work of tackling COVID19.

We are also open to proposals by the Commission to make changes to the current Directive 93/42EEC.

Patient safety and ensuring continuity of supply of medical devices must be guaranteed at this time.

Yours sincerely,

Mairead McGuinness MEP

Peter Liese MEP

Nils Torvalds MEP

Jytte Guteland MEP

Biljana Borzan MEP

Claudia Gamon MEP