



## Medical Devices Regulation: Commission welcomes Council support to prioritise the fight against coronavirus

Brussels, 23 April 2020

The European Commission welcomes the adoption by the European Parliament and the Council of the proposal to postpone by one year the date of application of the [Medical Devices Regulation](#). This will allow all key players - Member States, health institutions and economic operators to give priority to the fight against the ongoing coronavirus pandemic, forming a key position in the timing of the lifting of confinement measures as Member States return to the road of recovery.

The adopted amendment takes into consideration the need for an increased availability of vitally important medical devices across the EU, and at the same time continues to guarantee patient health and safety until the new legislation becomes applicable.

Vice-President for Promoting our European Way of Life, Margaritis **Schinus**, said: *"I welcome the adoption in record time by the European Parliament and the Council of the proposal to postpone by one year the date of application of the Medical Devices Regulation. We are determined to have our medical industries pouring all their energy into what we need them to be doing: helping fight the pandemic. The European Union will do whatever it takes to support our health systems in their hour of need."*

Stella **Kyriakides**, Commissioner for Health and Food Safety, said: *"Yesterday's adoption will allow us all, in this time of crisis, to maintain our focus on the most critical issues and to ensure the continued availability of vitally important medical devices. This is clear proof of our ongoing determination to tackle the pandemic through all possible means, while always maintaining the safety of patients as our utmost objective. I thank the Parliament and Council for the record time approval, cooperation and efficient handling of this urgent proposal."*

The coronavirus crisis increases demand for certain vital medical devices. It is therefore important to avoid any further difficulties or risks of potential shortages or delays in the availability of such devices that could be caused by the limited capacity of authorities or conformity assessment bodies related to the implementation of the Medical Devices Regulation.

The adopted amendment therefore postpones the application of the Medical Devices Regulation by one year - until 26 May 2021. The currently applicable rules will continue to guarantee patient health and safety.

### Background

The coronavirus pandemic and the public health crisis resulting from it is putting Member States, together with national authorities, health institutions and economic operators, under extreme pressure. These circumstances demand substantial additional resources, and the need for an increased availability of vitally important medical devices has considerably increased. At the time of adoption of the Medical Devices Regulation none of the above could have been foreseen.

The present situation strongly impacts upon the different areas covered by the Medical Devices Regulation. It is therefore highly probable that it would not have been possible for Member States, health institutions, economic operators and other relevant parties to implement and apply the Regulation from its foreseen date of application on 26 May 2020.

In order to ensure an effective regulatory framework for medical devices, the present amendment also postpones the date of repeal of the [Directive](#) on active implantable medical devices and the [Directive](#) on medical devices by one year.

The present adoption will not have impact on the date of application of the In Vitro Diagnostics Medical Devices Regulation, which becomes applicable from 26 May 2022.

The amendment of the Medical Devices Regulation complements other important measures in the area of medical devices, which the Commission continues to adopt in its fight against the coronavirus pandemic.

The Commission adopted the proposal on 3 April, and this was followed by the support of the European Parliament on 17 April. As a final step, yesterday the Council has voted to adopt the proposal and it will enter into force upon publication in the Official Journal of the European Union.

### **Useful links**

[Medical devices](#)

[Dedicated Commission webpage on the EU's response to the COVID-19 outbreak](#)

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Press contacts:

[Stefan DE KEERSMAECKER](#) (+32 2 298 46 80)

[Darragh CASSIDY](#) (+32 2 298 39 78)

General public inquiries: [Europe Direct](#) by phone [00 800 67 89 10 11](#) or by [email](#)