

Medical devices

2020/0060(COD) - 17/04/2020 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a legislative resolution on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) 2017/745 on medical devices as regards the dates of application of certain of its provisions.

The European Parliament adopted its position at first reading under the ordinary legislative procedure by means of an urgent procedure.

Parliament supported the proposal to defer for one year (until 26 May 2021) the application of certain provisions of Regulation (EU) 2017/745 on medical devices in order to allow Member States, health establishments and economic operators to give priority to the fight against the coronavirus pandemic by continuing according to current procedures.

Medical devices, such as medical gloves, surgical masks, equipment for intensive care and other medical equipment, play a crucial role in the context of the COVID-19 outbreak and the associated public health crisis to ensure the health and safety of Union citizens and to enable Member States to give necessary medical treatment to patients who are urgently in need of such treatment.

Given the unprecedented magnitude of the current challenges related to COVID-19, it is very likely that Member States, health institutions, economic operators and other relevant parties shall not be in a position to ensure the proper implementation and application of that Regulation from 26 May 2020 as laid down therein.

By way of derogation from Directives 90/385/EEC and 93/42/EEC, it is specified that conformity assessment bodies which comply with this Regulation may be designated and notified prior to 26 May 2021. Notified bodies which are designated and notified in accordance with this Regulation may carry out the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation prior to 26 May 2021.