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EU Medical Devices Regulation is Postponed

The European Commission has postponed by one year the date of application of the Medical Devices Regulation (MDR) till 26 May, 2021, "to allow member states, health institutions and economic operators to prioritise the fight against the coronavirus pandemic."

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The coronavirus crisis has created extraordinary circumstances that require substantial additional resources and an increased availability of vitally important medical devices. As is noted in the EU Commission's statement, none of this could reasonably have been anticipated at the time of adoption of the MDR.

Previously, there has not been a single EU-wide policy on the reuse of SUDs. The MDR seeks to ensure that remanufactured devices meet certain standards. Currently, the in-house reuse of single-use devices (SUDs) is allowed, but under the MDR must have ceased by 26 May, 2020, and use of professionally remanufactured (CE marked) single-use medical devices adopted instead. The latter practice has been implemented in the U.S., Germany, Canada, the UK and other countries. In Europe, it is under review in Ireland, Germany, Portugal, Spain and Sweden.

The current postponement, however, will allow increased availability of vitally important medical devices across the EU whilst continuing to ensure patient health and safety until the new legislation becomes applicable, the EU Commission stated.

According to Stella Kyriakides, EU Commissioner for Health and Food Safety, the priority is "to support Member States to address the coronavirus crisis and protect public health as powerfully as possible – by all means necessary." The Commissioner pointed out that as the COVID-19 crisis increased demands for certain vital medical devices, any potential market disruptions regarding the availability of safe and essential medical devices must be avoided. Therefore, the current rules will continue to apply for one more year.

It is noted that the date of application of the In Vitro Diagnostics Medical Devices Regulation, which becomes applicable from 26 May 2022, is not affected.

UPDATE:
Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context , 3 April 2020
IMDRF Standards Checklist modified in scope of COVID-19 , 3 April 2020

Source: European Commission

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Published on : Sun, 5 Apr 2020