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COVID-19 – Delay to the EU Medical Device Regulation

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Given concerns over the ongoing coronavirus disease 2019 (COVID-19) pandemic, the EU has published Regulation 2020/561 (Regulation) to defer the date of application of certain provisions of Regulation 2017/745 (MDR) by one year and introduce other measures.

The Regulation was published 24 April 2020 through an EU accelerated procedure.

The Regulation recitals state that the COVID-19 outbreak and the associated public health crisis presents an unprecedented challenge to member states and constitutes an immense burden for national authorities, health institutions, Union citizens and economic operators. The public health crisis has created extraordinary circumstances that demand substantial additional resources, as well as an increased availability of vitally important medical devices, that could not reasonably have been anticipated at the time of adoption of Regulation (EU) 2017/745.

The Regulation effectively provides considerable regulatory easement for the medical device industry, notified bodies and EU regulators, and with a view to allow more directed action against the pandemic.

Importantly, the Regulation acts to reduce the chances of shortages or delays in the supply of vitally important medical devices to the market due to the COVID-19 pandemic, and postpones the application of certain provisions of the MDR from 26 May 2020 to 26 May 2021.

The Regulation amends the MDR by deferring the repeal of the current Medical Device Directives (Directive 90/385 and Directive 93/42) thus ensuring the continuity of current conformity assessment procedures.

The Regulation also amends the MDR to defer requirements relating to the functionality of EUDAMED, which has impacts for manufacturers, importers and others in the medical device supply chain.

The Regulation also delays requirements in respect of single-use devices but notably does not impact the separate regime for in-vitro diagnostic devices.

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