MEDTECH INSIGHT
CITELINE COMMERCIAL

24 Apr 2020 | **News**

EU's MDR One-Year Delay Now Official As Amending Regulation Is Published In EU Official Journal

by Amanda Maxwell

The EU medtech industry's hard-fought battle for a one-year delay to the Medical Device Regulation is now reality. While COVID-19 was the deciding factor in the EU decision, it is what the industry has been lobbying for over the past year.

26 May 2021 is now the official date of full application of the EU's Medical Device Regulation (MDR).

The amending regulation, which delays the start date by one year, was published in the Official Journal of the EU on 24 April.

The document also grants the European Commission immediate powers to grant exceptions ("derogations") to meeting full conformity assessment requirements for medical devices that are urgently needed, for example in the context of the COVID-19 emergency.

> ***Postponing the date of application gives more time for the new MDR regulatory system to be more solidly established and brought to full functionality.***

An oversight in the original commission document – which would have meant only up-classified class I devices with certificates predating 26 May 2020 could benefit from the grace period, and

which was corrected by the Council of EU – has been changed so the deadline for up-classified class I devices is now 26 May 2021, in line with all the other one-year delay amendments.

The EU is not known for passing new laws at such speed. But when it came to the crunch and the impact of COVID-19, it was able to move all the previous legal obstacles to delay the EU MDR by a year within just four weeks. Only a month ago, the commission had reiterated that the 26 May 2020 MDR deadline would go ahead despite the then-growing COIVD-19 crisis. (Also see "*European Commission Churns Out EU MDR Documents, Including On 'Significant Changes'*" - Medtech Insight, 23 Mar, 2020.)

Postponing the date of application gives additional time for the new MDR regulatory system to be more solidly established and brought to full functionality. There is an urgent need for a greater number of notified bodies and guidance documents.

Meanwhile, the 26 May 2022 IVD Regulation deadline has not been changed despite outcry that the MDR delay will further exacerbate problems implementing the IVDR on time.