MEDTECH INSIGHT
CITELINE COMMERCIAL

16 Jul 2020 | **Analysis**

Device Week, 16 July 2020: The EU's MDR & IVDR Deadlines – Can They Be Met?

by Amanda Maxwell

In this week's podcast, *Medtech Insight*'s Amanda Maxwell reviews the EU regulatory outlook for device companies against the backdrop of COVID-19 and consequent delay in the MDR application date, the knock-on effects on the IVDR, and the pressures being felt by notified bodies.

The one-year delay to the full application of the EU's Medical Device Regulation has been generally welcomed. Industry has long been lobbying for it.

But the European Commission only agreed to this concession because of the impact of COVID-19, and to allow the sector to address the urgent need for products for the pandemic above all else.

Now it seems that it will be no less a struggle for the medical devices industry to be ready for the new MDR application date of 26 May 2021, and notified bodies are under enormous pressure too. Nor is the challenge restricted to medical devices alone; IVDs are equally impacted.

Themes addressed and their (minute/second) start times in the podcast are shown below.

	Questions	Time
1	The real impact of the pandemic been on the medtech sector – and the MDR's one-year postponement	0.44
2	Notified body numbers under the MDR and IVDR	4.42
3	Notified body coverage of industry's needs under the MDR and IVDR – and the realistic value of the MDR's postponement	5.58

4	Will there be a steady flow of products certified against the MDR over the next year?	9.53
5	Or will companies still opt to use the “grace period”?	11.37
6	Impact of COVID-19 on the IVDR	12.06

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