

MedTech Europe Statement on EU Commission intention to postpone MDR deadline

We welcome the announced intention of the European Commission to propose the postponement of the date of application for the Medical Devices Regulation by 12 months, and we also welcome the support that the European Parliament has expressed for this.

Once adopted, this measure would enable healthcare stakeholders to maintain focus on fighting the COVID-19 pandemic while keeping healthcare systems running. Rest assured that our industry is putting all its efforts to deliver needed medical technologies to patients and healthcare professionals during these difficult weeks.

For the In Vitro Diagnostic Regulation, we remain convinced that a similar solution is needed. Although this Regulation has a longer implementation time, diagnostic manufacturers and authorities alike must prepare for major changes and requirements to adapt to the new regulatory framework. Right now, their capacity is focused on the critical task of keeping diagnostic tests available, despite the challenges the pandemic is creating for their production and distribution. By providing the same solution for the in vitro diagnostics and medical devices sectors, the EU would be doing even more to keep health systems up running effectively in times of the COVID-19 pandemic.