

MedTech Europe calls for a pause on IVDR and MDR implementation to facilitate the fight against COVID-19 and to safeguard Healthcare Systems

23 March 2020, Brussels – The medical technology industry is fully engaged with all other healthcare stakeholders in the fight against COVID-19 outbreak, one of the worst pandemics in the past 100 years. The industry is working relentlessly to provide personal protective equipment (PPEs), diagnostics, respiratory devices and other critical medical equipment to patients, healthcare workers, and hospitals on the COVID-19 frontline.

At the same time as fighting COVID-19, it is critical to maintain the seamless availability of **all other** medical technologies needed daily to diagnose, treat and monitor patients suffering from other critical or chronic health conditions.

Currently and for the next few months, helping healthcare systems to overcome this outbreak is and will be in everyone's top priority and focus. Manufacturers are striving to keep needed medical technologies available to healthcare systems while managing the effects of the pandemic on their organisations.

This severely disrupts healthcare stakeholders' efforts to implement the new Medical Devices Regulation (MDR) and *In Vitro* Diagnostics Regulations (IVDR) within the fixed transition timelines, which expire on 26 May 2020 and 26 May 2022 respectively.

MedTech Europe therefore calls on the European Institutions to postpone implementation of these Regulations and resume it six months after the present crisis has passed. The crisis could be considered passed when, for instance the World Health Organization or other relevant authority (where critical preparedness activities are ongoing) declares the pandemic to be over.