Joint industry supports postponement of MDR to respond to COVID-19 and ready to help on next steps

We support the European Commission's announcement to propose a one-year postponement of the Medical Device Regulation's Date of Application. This important initiative will allow the industry's efforts to continue supporting patients, healthcare professionals, and hospitals in their fight against COVID-19.

Since the publication of the Medical Device (MDR) and In Vitro Diagnostic (IVDR) Regulations, companies have invested significant efforts in meeting the regulatory requirements. However, the current COVID-19 crisis creates a clear and unprecedented disruption to these preparations. We thus ask Member States and European Parliament to support the European Commission's initiative and we encourage swift adoption of the postponement. In addition, the European Union should consider similar postponement for the IVDR since the crisis also affects the implementation of this Regulation.

We would like to attract your attention to three critical points to ensure continuity:

1. Until the new Date of Application of the Regulations, the current Directives must remain valid in their entirety. This may require changes of not only European but also national legislation and administrative procedures that have already been adapted to the new Regulations. Sufficient capacity needs to be in place for new certification and changes to existing devices.
2. During the COVID-19 crisis, additional exceptional non-legislative measures may need to be taken. This includes but should not be limited to the proposed draft guidance on Notified Body audits during COVID-19 quarantine orders and travel restrictions as well as European derogations based on the Directives for certain product categories.
3. Continuous dialogue between regulators and stakeholders is critical in this difficult time, so we hope that the postponed meeting of the Medical Device Coordination Group with stakeholders is soon re-scheduled even through web-meeting. It is necessary to monitor the situation in the European market and be able to react in a flexible manner.