

## MedTech Europe statement on EPSCO Meeting – June 2019

MedTech Europe recognizes the outcome of the Member States' debate on the preparedness status of MDR/IVDR implementation held during the EPSCO Council meeting on 14 June. MedTech Europe welcomes the attention given by Member States to the serious consequences these challenges can cause to the quality of care for European patients.

Many Member States highlighted the potential impact that a late system readiness could mean for European patients and for their national healthcare systems. It was widely recognized that the implementation faces severe system challenges and, despite the European Commission remarks, will not be ready on time to guarantee continued delivery of medical devices.

A clear call for immediate action was directed towards the European Commission to find solutions without delay, with some Member States specifically calling for solutions to happen before the end of 2019. The Romanian Council Presidency, furthermore, stressed that solutions must be European solutions. MedTech Europe warns that national un-coordinated solutions, such as relying on national derogations, would not serve as the best result for European patients as this would create serious disruption and inequalities in the access to care in Europe.

MedTech Europe continues to reiterate its call on the European Commission and Member States to accelerate the implementation of the regulatory system's most critical infrastructure. [Click here](#) for the industry's seven concrete proposals for achieving this. Also, serious thoughts should be given to improve the "Grace Period" to enlarge its scope to more categories of Medical Devices.

Industry supports the regulation and its objectives. The sector will continue to heavily invest to meet all new requirements in due time (once these are finalized by the Commission). Now the system needs to be able to receive and process the CE-marking files on time. Considering the lengthy certification process (6 to 9 months) and the thousands of files to certify, the deadline is now, not at the end of 2019 and definitely not in May 2020 MDR date of application.