STATEMENT from the 51st meeting of the EU Competent Authorities for Medical Devices (CAMD)

The European Competent Authorities for Medical Devices (CAMD) met for its 51st meeting in Prague on the 20th – 21st October 2022 under the Czech Presidency of the Council of the European Union.

The CAMD recognises that much work has been done at the Medical Device Coordination Group (MDCG) and in other fora to try and address the critical system issues relating to certification capacity and to promote readiness of manufacturers to avoid disruption to supply of essential medical devices to patients and health systems across Europe.

The CAMD is committed to working together with stakeholders to ensure that a harmonised, effective and sustainable solution to this immediate issue can be found as a priority.

At its 51st meeting, the CAMD recognised that while contingency measures are required to solve these immediate short term issues, it is crucial to undertake a broader, critical appraisal of the underlying causes and factors which led to the capacity challenges.

The CAMD emphasised the urgent need to commence an appraisal of the practical application and operation of the regulatory system using the core objectives of the Regulations as key measures, which are to:

- establish a robust, transparent, predictable and sustainable regulatory framework for medical devices
- ensure a high level of safety and health for the public
- support innovation within Europe
- ensure smooth functioning of the internal market.

While measures to improve the efficiency of application of the regulatory requirements to address the capacity bottleneck are currently in the process of being implemented, a focussed European discussion should also be conducted involving experts and decision makers from the Member State authorities, the EU Commission and including, when appropriate, relevant stakeholders, identifying how best to support and deliver on the implementation and practical application of the MDR and IVDR for the benefit of European citizens.

The CAMD will continue to work and collaborate with key stakeholders to ensure the long term objectives of the regulations are achieved.