1. CAMD recognise the significant and urgent challenges that remain in ensuring sufficient capacity and a readiness across all stakeholders with an appropriate regulatory infrastructure with in time for May 2024. The data gathered to date indicate there are multiple causes and no single solution. Finding solutions is a shared responsibility.

2. CAMD recognise that these challenges, left unaddressed, may lead to disruption to supply of essential medical devices to health systems and patients and may alter the access of innovative medical devices to the European market.

3. CAMD also believe that it is important in addressing the immediate challenges associated with capacity that we examine and address underlying causes.

4. CAMD are committed to work together, with the EU Commission, the MDCG and our leadership, to urgently seek and consider all potential solutions to address this and mitigate supply disruption and a lack of system readiness. These discussions will necessitate close collaboration with notified bodies and other relevant stakeholders.

5. CAMD strongly agree that solutions to the capacity challenges should not involve a reduction, removal or unnecessary reinterpretation of the Regulation's requirements, to ensure that the intended high level of protection and safety is achieved and that safe medical devices are available to citizens in Europe.

6. CAMD agree that solutions should ensure that manufacturers are on the road to compliance rather than providing further delay of compliance or deferral of their applications for conformity assessment under the Regulations.

7. CAMD consider that derogations from conformity assessment issued by national competent authorities are not suitable as a general solution. CAMD recognise the need to deploy derogations, as an exception rather than a rule, on the grounds of public health protection only rather than on the basis of commercial or market factors. Derogations cannot replace or substitute the assessment completed by notified bodies.

8. CAMD propose that work on solutions is progressed urgently centred at the Medical Device Coordination Group. These discussions will necessitate close collaboration with notified bodies and other relevant stakeholders.