**To:** National Ministers of Health [Member State]
**Subject:** MDR/IVDR Implementation – Urgent need for interim measures

**Dear Minister [Name],**

On behalf of [National AmCham Name], and in coordination with AmCham EU and other national AmChams across Europe, we are writing to express our strong support for the European Commission’s efforts to reform the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR).

While we support the Commission’s ongoing comprehensive evaluation process, tangible outcomes are not anticipated before 2028. In the interim, targeted short-term bridging measures - including, where appropriate, legislative instruments - are urgently needed to sustain the EU MedTech ecosystem. Member States play a crucial role in enabling these actions, and we welcome ongoing efforts to keep this issue prominent on the Council’s healthcare agenda.

Delays in implementing targeted regulatory relief risk restricting patient access to medical devices while also reducing Europe’s attractiveness for innovation and investment. Without timely action, ongoing regulatory uncertainty may lead companies to deprioritise the EU market.

**We therefore request your support for including MDR/IVDR on the agenda of the 19 June 2025 Employment, Social Policy, Health and Consumer Affairs Council (EPSCO).** Member State political backing at EPSCO will be critical to empower the Commission to move forward with targeted implementing or delegated acts that could be adopted as early as this year.

Specifically, we encourage consideration of the following measures:

1. Accelerate and streamline initial product approvals.
2. Improve efficiency and predictability in change notification procedures.
3. Establish an expedited pathway for breakthrough innovations.
4. Adopt lifetime risk-based certification to reduce duplication and address notified body capacity constraints, while ensuring a level playing field across the sector.

These measures will help sustain availability of safe, effective medical technologies and ensure continuity of care for patients, while giving space for the broader reform process to conclude.

**AmCham remains strongly committed to the long-term success of the MDR/IVDR framework and to safeguarding Europe’s position as a global leader in patient care and medical innovation**. Our shared objective is to ensure patients’ continued access to the most advanced healthcare solutions. We appreciate your attention to this matter and stand ready to support your Ministry in advancing this important discussion.

[Insert Signature]