

Brussels, 28 April 2025

OPEN LETTER TO EUROPEAN COMMISSION PRESIDENT URSULA VON DER LEYEN

Dear President von der Leyen,

The undersigned associations are urgently calling for your decisive leadership, at a pivotal and perilous moment for Europe's continued health, wealth and security,

The medical technology industry, which we collectively represent, stands among Europe's most innovative and critical sectors. Home to more than 37,000 companies, 90% of which are Small and Medium-Sized Enterprises (SMEs), this industry has a significant economic footprint and directly employs more than 880,000 people across Europe.

But more importantly, the medical technologies which this industry delivers to Europe's healthcare systems, are essential to save and improve people's lives each and every day. Medical technology products, services and solutions – such as implants, imaging equipment, *in vitro* diagnostics, radiotherapy, surgical instruments and personal protective equipment – are constantly transforming global healthcare, through earlier disease detection, less invasive procedures and more effective treatments. Without them, public health would be impossible.

The United States is Europe's most important trading partner for medical technologies. However, recent trade tensions and the threat of tariffs now pose an existential threat, both to our industry, and to the patients, healthcare professionals and to health systems who depend on seamless, timely access to the technologies we provide.

We therefore urgently call for a direct dialogue with you to address this impending crisis.

Our industry strongly supports your proposal for "Zero-for-Zero" tariffs on trade in industrial goods between Europe and the United States, and urges you in the strongest possible terms to protect public health, by promoting an extension of the Zero-for-Zero proposal to all medical technologies, and to the essential components needed to produce them.

There are more than 2 million different medical technologies in Europe, and many of them are highly complex and rely on intricate, globally-integrated supply chains. Tariffs can lead to higher costs for the many components, spare parts, and raw materials used in production of medical technologies, and this in turn can directly threaten availability. Substitution (where possible) of critical raw materials or components necessitates validation to ensure the technology remains safe and performs as intended. Unlike with many other jurisdictions around the world, European rules for medical technologies¹ can mandate **re-certification** in cases where these materials/components need to be changed. This can prevent or delay patient access to needed technologies.

¹ E.g., the EU Regulations for Medical Devices 2017/745 and *In vitro* Diagnostic Medical Devices 2017/746

The threat of tariffs also comes at a time when Europe's medical technology sector is already experiencing shortages, an innovation drain, and the risk of SMEs closing business due to European regulatory frameworks – which are excessively costly, time-consuming and unpredictable when compared to medical technology regulatory pathways in other jurisdictions. For example, 1 in 2 healthcare professionals in Europe are already reporting issues with availability of medical devices² and 30-40% of large manufacturers have started launching their innovations in other jurisdictions³. Tariffs will only further exacerbate these substantial challenges which are already facing the companies who supply Europe with medical technologies.

Moreover, tariffs increase production and distribution costs. Most medical technologies reach hospitals, laboratories or other health institutions, via multi-year agreements with minimal price flexibility. Since price increases cannot be easily mitigated by manufacturers – and particularly by SMEs – increased operating costs from tariffs could easily result in closures, the ceding of innovation to foreign competitors and, ultimately, decreased availability of medical solutions for patients, healthcare professionals and health systems.

The medical technology industry stands ready to jointly tackle these above challenges with you. What is at stake is not merely the defence of one of Europe's most dynamic industries. The task before us is to collectively do all we can, to safeguard the high standards of patient care on which people in Europe depend each and every day.

Yours sincerely,



² See [survey report](#) by Biomedical Alliance in Europe 'Clinicians concerned about limited availability of medical devices', January 2023

³ See MedTech Europe [Survey report IVDR/MDR 2024](#)