To: European Commission, DG SANTE
Attn.: European Commissioner for Health and Food Safety, Stella Kyriakides
Rue de la Loi 200
1049 Brussels
Belgium

Brussels, October 2024

Subject: Urgent need for action on the medical technology regulations to ensure devices availability and competitiveness of the sector

Dear Commissioner Stella Kyriakides,

On behalf of the European medical technology industry, we would like to thank you for your leadership in healthcare and your attention to the implementation of the medical technologies regulations during the last mandate[1].

As you enter the last months of your office, we would like to call on your leadership once more to make reform of these regulations your priority and urge your successor to do the same to solve their ongoing serious implementation challenges. Action is needed to reverse the exodus of innovation from Europe and to prevent further discontinuations of medical technology intended to protect patient safety and public health.

The medical technology industry has always supported the objectives of the medical technologies regulations, and our members are strongly committed to complying with them. We are facing, however, a critical situation where these two regulations are not delivering on their objectives as originally intended by the EU legislator. The unpredictability, complexity, and burden of the regulations means that many devices on the market today as well as new, innovative medical technologies are not reaching patients in Europe as they should. The competitiveness of the wider industry and even the viability of many small businesses (SMEs) are at risk[2]. These trends must be addressed immediately and before European healthcare is further impacted.

We welcome your targeted evaluation of the medical technology regulations[3] to analyse the root causes of these challenges and explore potential for simplification. We are encouraged that President Ursula von der Leyen's 2024-2029 Mission Letter to your successor mandates action on the implementation of the regulations and possible legislative amendments.

In light of this, the European medical technologies industry proposes three areas of action, **which are outlined in more detail in the Annex to this letter**:

A. *As an immediate outcome of the targeted evaluation running until end-2025* – **a package of legislative reforms for each of the two regulations should be developed** to ensure that these regulations deliver on their original objectives. It is imperative that the improved regulatory systems meet three criteria: being efficient, innovation-friendly and well-governed.

B. *As urgently as possible* – **several 'bridging measures' are needed to support device availability and the viability of the medical technology industry**. These measures cannot wait until the targeted evaluation is concluded and full packages of legislative reforms are written and published into EU law, which will take years. These measures should have sufficient legal weight to achieve the following:
   1. **Time and costs for certifying devices must be significantly reduced and made predictable**. Immediate action here is vital both for helping to halt the ongoing disappearance of today's devices and for attracting investment in bringing innovations to Europe.

1) Medical Devices Regulation (EU) 2017/745 (MDR) and *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR).

2) For example, signs that start-ups smaller & medium-sized business are closing can be found under these surveys: Key takeaways under Dutch IGJ 2023 survey report, Manufacturers, please take timely action to meet IVDR requirements; Also see survey report by the German Chamber of Commerce and Industry (DIHK), the MedicalMountains cluster initiative, and the German industry association SPECTARIS 'Current assessment of the German medical device manufacturers on the effects of the EU MDR, December 2023: while the report did not address business closure specifically, the percentages of planned and reported discontinuations of devices are severe enough especially for smaller companies, to indicate that their business viability is at risk.

3) EU rules on medical devices and *in vitro* diagnostics – targeted evaluation.

2. **Assessment of changes to medical technologies must be made more efficient** to allow the latest technologies to reach patients swiftly.

3. **An accelerated pathway for breakthrough innovation should be put in place** to bring first in class products to Europe first or in parallel with other jurisdictions.

4. **Adapt certification to follow a life-cycle approach**. This would eliminate a major disincentive for manufacturers to certify and maintain devices under the medical technology regulations and help prevent anticipated certification bottlenecks during the transition periods to the regulations.

C. *On an ongoing basis* – **specific measures to improve the implementation of the regulations should continue to be pursued through existing work streams and tools** (including guidance and implementing acts). Examples of needed measures include reducing the technical documentation sampling burden, adopting wide use of electronic instructions for use and having the EU join the Medical Devices Single Audit Program.

Madame Commissioner, at a time when innovation is critical for addressing emerging systemic threats – from antimicrobial resistance to non-communicable diseases, the health impacts of climate change and future pandemics – Europe needs to invest in a regulatory environment that makes speed, coherence and simplification a priority.

President von der Leyen has tasked the next Commissioner-designate for Health and Animal Welfare with ensuring both the availability of medical technologies and the competitiveness of our industry. The actions we are proposing to you will help Europe achieve these important goals.

We ask you once more to act in support of patients and health systems by presenting concrete solutions, based on the actions outlined in this letter, to all European Health Ministers at the upcoming Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council meeting in December 2024. If your successor is already in office at that time, we kindly urge you to encourage and support them to do the same.

The medical technology industry remains ready to collaborate with the Commission on solutions to the identified challenges and get the regulations' implementation back on track. Our vision is to see at last an EU regulatory framework for medical technologies that meets all goals the EU legislator set for it, without in any way compromising device safety, performance, or quality. Only by working together can we achieve this, for the benefit of European patients and health systems.

Yours sincerely,

This letter was sent in digital format with the Director General of the Directorate General for Health and Food Safety, Ms. Sandra Gallina, in copy.

Annex

Three Key Areas of Action are needed to bring critical improvements to the Medical Technology Regulations (Medical Devices and *In Vitro* Diagnostic Medical Devices Regulations (EU) 2017/745 and 2017/746)

A. Legislative package of reforms

As an immediate outcome of the targeted evaluation running until end-2025 – **a package of legislative reforms each for the IVD Regulation and MD Regulation should be developed** to ensure that these regulations deliver on their original objectives and deliver critical and much-needed improvements across the system.

European Commission President Ursula von der Leyen has made "less red tape and reporting, more trust, better enforcement, faster permitting" a priority of her 2nd mandate (2024-2029)[4].

In line with this, it is important that each package of legal reforms for the IVD Regulation and MD Regulation explicitly incorporates principles which will **dramatically enhance efficiency** and **robustly increase Europe's attractiveness for innovation** in medical technologies by:

- Adopting processes which work end-to-end equally for the devices of today and the future – and including for larger unmet needs as for orphan and niche devices,
- Ensuring the system is predictable, 'lean' and able to adapt to changes,
- Realising a net reduction in cost, complexity and administrative burden,
- Incorporating a least-burdensome principle for both pre- and post-market regulatory processes while maintaining a high standard of safety & performance.

To underpin the above, **a single, dedicated governance structure** should be established which oversees and manages the regulatory system, with accountability for ensuring that safe and performing medical technologies can reach patients and health systems in a timely manner. Amongst other tasks, this governance structure also should ensure regulatory coherence with other EU legislation[5].

B. Measures which need to be advanced as a matter of urgency

As urgently as possible – **several 'bridging measures' are needed to support devices availability and the viability of the medical technology industry**. These measures cannot wait until the targeted evaluation is concluded and full packages of legislative reforms are written and published into EU law. The process to realise full legislative packages could take years – time which patients and health systems do not have.

It is critical that devices developed and provided by the wider industry especially Small and Medium Enterprises (SMEs) stay available to patients. Both devices and SMEs are at risk of disappearing due to the current burden of the IVD Regulation and MD Regulation. Innovative medical technologies are not arriving in Europe as they should. These trends must be addressed immediately and before European healthcare is irreversibly impacted. **Several measures are needed as urgently as possible and should have sufficient legal weight (e.g., via implementing acts or legislative amendments) to achieve the following:**

1. **Initial conformity assessment timelines and costs must be significantly reduced and made predictable**. Immediate action here is vital both for helping to halt the ongoing disappearance of today's devices and for attracting investment in bringing innovations to Europe. Manufacturers cite long and unpredictable timelines and costs as principle reasons for not transitioning devices to the IVD Regulation and MD Regulation[6] and for why 1 in 3 manufacturers are launching new innovations only or first outside

4) Political guidelines for the next European Commission, 2024-2029

5) Numerous new requirements arrive for medical technologies every year, some with significant overlaps or misalignments with IVD Regulation and MD Regulation, or which necessitate device re-designs, updates to labelling or have other impacts.

6) For example, see survey report by the German Chamber of Commerce and Industry (DIHK), the MedicalMountains cluster initiative, and the German industry association SPECTARIS '*Current assessment of the German medical device manufacturers on the effects of the EU MDR*', December 2023

of Europe[7]. Notified Bodies consistently should offer dialogues pre-submission and during conformity assessment with the manufacturer to set out timelines and level of evidence expectations, with the outcome described in a formal binding statement. Conformity assessment timelines should be reduced to 6 months for QMS and 3 months for Technical Documentation certification. Notified Bodies should publish ex-post reports on costs and timelines per device type to enable transparency on how much conformity assessment fees cost in total.

2. **Assessments of changes to medical technologies must be made more efficient to allow the latest technologies to reach patients swiftly**. The assessment of changes to medical technologies by Notified Bodies which are CE-marked under the European regulations, needs to be more efficient to ensure patients receive the latest technologies quickly. This is crucial for addressing the current workload of Notified Bodies and reducing the lengthy, unpredictable timelines for updating medical devices. Currently, even urgent device changes are seeing delays, with assessments often taking several months, though they should ideally be completed within 1 month. These delays have a direct impact on patients where they cannot benefit from these updates. To expedite this process, assessments should be limited to only necessary cases and handled promptly. The number of individual change notifications also should be minimized and streamlined through mechanisms like predetermined change controls.

3. **An accelerated pathway for breakthrough innovation should be put in place.**
   A clear regulatory pathway with an accelerated timeline of 120 days is needed to allow rapid uptake of breakthrough technologies. Today there is uncertainty over what is the appropriate level of evidence and what is acceptable to be provided pre- and post-market for groundbreaking, breakthrough and disruptive technologies. A well-defined, holistic approach to support innovation within our system will attract medical technology innovations to come to Europe faster and address unmet or undertreated medical needs of patients that are waiting for diagnosis, treatment, and care.

4. **Adapt certification to follow a life-cycle approach.**
   There is an immediate need for aligning certification with the lifetime of medical technologies. Removing the limited validity of certificates would eliminate a major bureaucratic burden and disincentive for manufacturers to bring and maintain devices under the IVD Regulation and MD Regulation and at the same time, help prevent anticipated Notified Body assessment bottlenecks during the transition periods to the regulations. Today, recertification for medical technologies is required every 5 years, which represents a high bureaucratic effort and re-investment burden without resulting in additional safety benefits. This is because the Notified Body already is required to continually assess devices and quality systems after their certification on an annual and ongoing basis. On that basis, Notified Bodies have today at their disposal sufficient mechanisms to allow for suspension of certificates where there is justification for doing so.

C. Specific measures to be pursued within the regulatory framework

On an ongoing basis – **specific measures to improve the implementation of the regulations should continue to be pursued through existing work streams and tools foreseen under the IVD Regulation and MD Regulation** (e.g. guidance, implementing acts, etc.).

While these should not be considered as a substitute for a package of legislative reforms – since the latter is needed to ensure a holistic approach is taken to addressing system deficiencies – there are many specific measures which can bring measurable improvements in the short-term.

The European medical technologies industry recognizes the considerable ongoing and important work of the European Commission and the Medical Devices Coordination Group[8] to improve the implementation of the IVD

7) For examples, see survey report by MedTech Europe '*Transition to the IVD Regulation - MedTech Europe Survey Results for October 2022*', October 2022. See survey report by MedTech Europe 'Analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation', April 2022

8) Including for example, to improve the framework for performance studies & clinical investigations, support pilot programs for orphan and niche devices, drive clarity on methodological frameworks for clinicals, put in place a framework for mandatory use of the European medical devices database and many other work streams.

Regulation and MD Regulation across many work areas. Amidst these needed work streams, we highlight the following areas which are essential to support a smoother transition of devices to the regulations, reduce the burden of the regulations and help new innovations arrive in Europe, and ask that the European Commission in its capacity as chairing the Medical Devices Coordination Group:

- **Speed up and deliver on implementation of the 19 point action plan (see MDCG guidance 2022-14) to support the transition to the regulations**, in particular to
    - Realize more concrete measures to enable structured dialogues before and during conformity assessment,
    - Provide clear principles for leveraging evidence based on a 'no duplication of evidence review' principle,
    - Reduce the technical documentation sampling burden for both IVDs and MDs.

- **Work towards enabling electronic Instructions for Use (e-IFU) for all medical technologies**, following a risk-based assessment by the manufacturer.

- **Promote global convergence of regulations, in particular in the context of the International Medical Devices Regulators Forum (IMDRF) and their Medical Device Single Audit Program (MDSAP) initiative.** We call for the EU to join the MDSAP program as a Full Member and to enable recognition of MDSAP certificates for the purpose of CE marking medical devices and *in vitro* diagnostic medical devices.