MedTech Europe Recommendations for the Upcoming Danish Presidency of the Council of the European Union

May 2025

1. Executive Summary

In an era of growing geopolitical uncertainty and increasing global competition, Europe must act decisively to secure its economic resilience and technological leadership. The life sciences sector—anchored by medical technologies, biotechnology, and health innovation—offers one of the most promising avenues to achieve this. However, without swift and coordinated action, Europe risks falling behind.

The upcoming Danish Presidency of the Council of the European Union (from 1 July to 31 December 2025) comes at a critical juncture. It presents a unique opportunity to drive forward a policy agenda that ensures Europe remains an attractive hub for life sciences investment and innovation. Denmark's proven leadership and recent national initiatives in life sciences position it to catalyse real progress at EU level. At the same time, this is also a moment to prioritise patients across Europe. Ensuring that innovation in medical technologies translates into timely, equitable access for patients must be at the heart of the EU life sciences strategy. By fostering an environment that supports the development and availability of life-saving and life-transforming technologies, Europe can strengthen public health, improve outcomes, and deliver on its promise of high-quality care for all.

MedTech Europe calls on the Danish Presidency to provide strong political leadership in ensuring continued, timely access to medical technologies for patients, healthcare professionals and health systems across Europe. To this end, it is crucial that medical technologies are free from any tariffs. Removing unnecessary barriers, such as tariffs on medical technologies, is essential to maintain Europe's health and economic resilience.

As Denmark sets its priorities for its upcoming role as Presidency of the Council of the European Union, and in light of its recent work on the national *Danish Life Sciences Strategy* from November 2024 and the inspiring proposals from the Danish Life Science Council towards the upcoming European Life Sciences Strategy, we look forward to collaborating with the Danish Presidency towards building a strong and comprehensive **EU Life Sciences Strategy**. This strategy must strengthen European competitiveness, ensure availability of and access to high-quality medical technologies, drive digital transformation, and support healthcare systems resilience and sustainability. By championing these priorities, Denmark has the opportunity to drive meaningful progress for patients, healthcare providers, and the broader European life sciences ecosystem.

This is not merely an opportunity—it is a necessity. The time to act is now.

In order to build a strong **EU Life Sciences Strategy**, we recommend:

- **Enhancing Competitiveness** – Streamline and better align compliance with legal requirements across different policy domains to enable the timely creation and launch of top-tier innovations.

- **Ensuring an efficient, innovative, and well-governed regulatory framework for the medical technology sector** – Address the structural issues in the EU Regulations for Medical Devices (MDR) and *In Vitro* Diagnostic Medical Devices (IVDR), to improve predictability and ensure timely and continuous availability of safe and innovative medical technologies to patients across Europe.
- **Advancing Digital Transformation** – Facilitate harmonised implementation of the European Health Data Space (EHDS) and the AI Act to ensure equitable, timely and affordable patient access to care.
- **Supporting Joint Decarbonisation and Competitiveness Planning** – Integrate environmental and economic goals to bridge Europe's sustainability and growth ambitions.
- **Harnessing partnerships and ensuring a fair national, EU and global level playing field for companies.**

MedTech Europe looks forward to supporting the Danish Presidency in pursuing these priorities during its upcoming mandate. Together, we can build a stronger, more innovative, and competitive European health ecosystem that benefits patients, healthcare professionals, and healthcare systems alike.

2. Detailed Recommendations and Open Files

2.1 Introduction

The EU's Life Sciences Strategy provides a unique opportunity to enhance competitiveness, digital transformation, sustainability, and regulatory efficiency. As the next Council Presidency, Denmark can play a key role in ensuring policies reflect the needs of patients and healthcare systems.

2.2 Policy priorities and recommendations

2.2.1 Enhancing competitiveness

Context and challenges:

- **Fragmented Regulatory Pathways:** Diverse regulatory requirements across EU Member States — including inconsistent interpretation of horizontal legislation such as the General Data Protection Regulation (GDPR), the Artificial Intelligence (AI) Act, as well as digital and sustainability legislations — can delay the introduction of innovative medical technologies, hindering Europe's competitiveness.

- **Adoption of Innovation:** There is a need to accelerate the adoption of cutting-edge medical technologies to meet evolving healthcare demands and ensure Europe maintains its global leadership in healthcare innovation. However, recent policy and legislative developments — including the European Health Data Space (EHDS), the new litigation environment (revised Product Liability Directive), and the interpretation of competition law — risk diluting key incentives for innovation by weakening the protection of intellectual property (IP) and trade secrets.

- **National Cost-containment Pressures:** Member State initiatives to contain healthcare costs — such as payback systems — are increasing legal, financial, and operational burdens on medical technology companies. These measures risk undermining the long-term competitiveness and attractiveness of the European market.

Recommendations:

- **Ensure Better Alignment and Simplification of Regulatory Requirements across policy areas:** Align regulatory pathways across EU Member States — including a more consistent application of horizontal legislation such as the GDPR, Public Liability Directive, and digital and sustainability legislations — to reduce legal uncertainty and market fragmentation to facilitate access to cutting-edge care, especially for small and medium-sized enterprises (SMEs) and start-ups.
- **Support Research, Development and Innovation:** Increase funding and incentives for research, development and innovation in medical technologies to stimulate innovation and ensure the EU remains at the forefront of medical advancements.

- **Foster access to innovation, including through Value-based Procurement**: Effectively address Member States' healthcare budget challenges, exploring alternative solutions that do not hinder investment, innovation, or patient access to medical technologies is essential (e.g. reimbursement of innovation).

- **Recognise the importance of intellectual property and trade secrets:** Ensure that ongoing and future legislative initiatives uphold robust protection of IP rights and trade secrets, which are essential enablers of innovation, investment, and Europe's competitiveness.

2.2.2 Ensuring an efficient, innovative and predictable regulatory framework

Context and challenges:

- **Slow, unpredictable, costly and complex regulatory system:** The existing regulatory landscape for medical devices and *in vitro* diagnostics (i.e., MDR and IVDR) is complex, leading to unpredictability and delays in the availability and access to medical technology. Access to innovative products will also be heavily

impacted, with ~50% of medical technology manufacturers reporting a significant decline in new device developments and 30-40% of large companies moving 1st launches outside EU.

Recommendations:

- **Ensure timely availability of safe and performing medical technologies:** Address structural issues in the existing Medical Devices and *In Vitro* Diagnostic Medical Devices Regulations to create a more agile, innovative and predictable framework. More specifically, by:
    - **Ensuring efficiency** – establish clear, lean, dedicated and predictable processes for conformity assessment and across the product lifetime, removing the mandatory 5-year recertification requirements across all risk classes and making the framework for product updates more predictable.
    - **Embracing innovation** – incorporate an innovation principle, such as a fast-track procedure for breakthrough innovation, to ensure the latest medical technologies swiftly reach patients and health systems.
    - **Effective governance** – ensure ownership through an accountable structure which is responsible for driving a healthy ecosystem for medical technologies, taking system-level decisions, managing the decentralised network of Notified Bodies and representing the system both within Europe and globally.

2.2.3 Advancing digital transformation

Context and challenges:

- **Data silos:** Fragmented health data systems hinder the seamless exchange of information, limiting the potential of digital health solutions.
- **Cybersecurity:** As healthcare becomes more digital, protecting sensitive patient data and ensuring the integrity of healthcare systems is an imperative

Recommendations:

- **Facilitate Harmonised Implementation of EHDS and AI Act:** Promote consistent adoption of the European Health Data Space (EHDS) and the AI Act across Member States to ensure smarter, safer, and more connected care for patients.
- **Facilitate and accelerate the creation of EHDS governance structures, such as the EHDS Board and the Stakeholder Forum:** Establishing those structures as soon as possible at the outset of the planning and implementation phase is key to ensuring an effective and future-proof functioning of the EHDS.
- **Strengthening the overall cyber-resilience of the European health system:** ensuring harmonised transposition of the NIS 2 Directive to avoid fragmentation among Member States will be key to strengthening healthcare systems' cybersecurity. Additionally, increasing the level of cybersecurity through multistakeholder collaboration, such as public-private partnerships, will bolster resilience against constantly increasing cyber threats and help maintain trust in digital health technologies and healthcare overall.

2.2.4 Supporting joint decarbonisation and competitiveness planning

Context and challenges:

- As climate, health and competitiveness are intrinsically linked, **joint decarbonisation and competitiveness planning is key for a successful sustainability transition and implementation of the EU Green Deal in Healthcare**: MedTech Europe promotes accelerating the roll out of clean energy and infrastructure, designing a supportive sustainable framework, leveraging the synergies with digitisation for efficiency and enabling increased circularity in healthcare. The design of realistic, patient-centric and economically viable

transition pathways for medical technology manufacturers and their supply chains will ensure that patients and practitioners can rely on uninterrupted access to medical technologies during the transition.

Recommendations:

- **Accelerate the rollout of clean energy and infrastructure:** Continuous access to renewable energies and heat in sufficient quantities and affordable prices are a precondition for decarbonising healthcare, including the medical technology sector.
- **Allocate strategic investments for building more efficient, sustainable and resilient healthcare systems**, supported by digital health and medical technologies: The European Union plays a crucial role in creating a supportive environment that enables the rapid transition, deployment and scaling of sustainable solutions in healthcare. These efforts need to be supported by sufficient funding and investment support.
- **Support simplification and reduction of administrative burden of EU sustainability regulation:** Reporting requirements should be streamlined so that they are workable and fit for purpose. In particular, ensure that future environmental legislation is consistent with sector-specific regulatory requirements and enhances the sustainability performance of medical technologies both, from a life cycle and care continuum perspective.
- **Strengthen the EU Single Market:** A fully functioning and harmonised Single Market is vital to ensure the effective deployment of sustainable and circular medical technologies across Europe**.** Truly harmonised rules are needed to complete the European Single Market, the EU's strongest asset and prerequisite for a high level of environmental protection and a competitive medical technology industry in Europe.

3. Conclusions

The upcoming Danish Presidency offers an opportunity to reinforce the EU's leadership in life sciences. By implementing these recommendations, the EU can maintain a robust, innovative, and sustainable medical technology ecosystem. MedTech Europe remains committed to supporting policymakers in achieving these shared goals.

4. Annex

4.1 Enhancing Competitiveness

Please find below supporting documents:

- MedTech Europe's response to Call for Evidence on the Life Sciences Strategy (here)
- Open Letter: MedTech Europe Calls for Prioritising Life Sciences in EU Competitiveness Strategy
- MedTech Europe Calls for Recommitment to and Strengthening of the EU Single Market (here)
- Europe's Attractiveness For Innovation (here)

4.2 Ensuring and efficient, innovative and predictable regulatory framework

Please find below supporting documents:

- Joint paper on Future governance of medical technologies in Europe
- Results of MedTech Europe 2024 Regulatory Survey results
- Report on Administrative Burden
- MedTech Europe's responses to targeted evaluation call for evidence (here) and public consultation (here)
- Paper on the Future of our Regulatory System (here)
- Position on "Smooth transition to the mandatory use of EUDAMED"

4.3 Advancing Digital Transformation

Please find below supporting documents:

- Together with 38 other European health stakeholders, MedTech Europe has shared key recommendations on the implementation of the EHDS

- Vision for Strengthening Cybersecurity in Europe's Future Healthcare Systems
- Medical technology industry perspective on the final AI Act
- Stakeholder coalition calls for legislative refinement of the EHDS

4.1 Implementing joint decarbonisation and competitiveness planning

Please find below supporting documents:

- MedTech Europe recommendations on the Clean Industrial Deal
- Circular Economy Act: MedTech Europe recommendations, January 2025
- Chemicals Industry Act: MedTech Europe recommendations, January 2025
- MedTech Europe position paper on EU Prosperity and Competitiveness: Implementing the EU Green Deal in Healthcare