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MedTech Europe Diabetes Sector Group's Position on Quality Standards for Diabetes Technology

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The MedTech Europe Diabetes Sector Group is dedicated to improving access for people with T1 and T2 diabetes to safe, accurate, and high-performing medical technologies across Europe.

We acknowledge the ongoing discussions within the diabetes community and among standardisation bodies regarding quality standards for continuous glucose monitoring (CGM) technologies. Innovation in CGM and other medical devices has transformed diabetes management, benefiting people with diabetes, care teams, and health systems alike. The CE marking system under the EU regulatory framework (EU Medical Devices Regulation, MDR, and In Vitro Diagnostic Regulation, IVDR) ensures the safety and performance of these technologies, providing a solid foundation for considering additional quality standards. To deliver real value, such standards must be evidence-based, consistent with existing regulations, foster continued innovation, and ensure inclusive, transparent, and coordinated stakeholder engagement.

The MedTech Europe Diabetes Sector Group supports the development of standards as a complement to the existing regulatory framework when there is a well-defined need to specify minimum criteria, including setting clear expectations for supporting evidence.

- The medtech sectoral regulations (MDR / IVDR) have clearly designated harmonised standards or Common Specifications as the means of setting specific performance standards where necessary. These standards should provide clear, objective criteria that have already proven valuable for other technologies (such as blood glucose monitoring (BGM) for diabetes mellitus) once a sufficient level of standardisation and maturity has been reached.

- Our ambition is to see the development of a standard for CGM that is harmonised against MDR and IVDR, takes into account the diversity of CGM technologies and their intended uses, and effectively safeguards the next generation of CGM technologies – including emerging, breakthrough, and iterative innovation. Such innovation may include sensor types, glucose measurement sites and biofluids, wear time, and integration approaches, among a range of others. Minimum criteria for CGM should take the range of innovations into account as this dynamic class of technologies continues to evolve.

- The development of CGM standards must also balance scientific rigor with participant safety and practical feasibility, utilise robust comparator methods accepted by regulators, and reflect the diversity of CGM users, including non-insulin-treated and paediatric populations.

- In this context, we welcome the ongoing work at the International Standardisation Organisation (ISO), whose efforts are making a significant contribution to developing globally relevant technical standards. The

forthcoming harmonised standard against MDR / IVDR for CGM systems will set a new benchmark, similar to the one that already exists for self-testing of diabetes mellitus.

- For these standards to be of maximum value, it is important for all key stakeholders - patient groups, medical societies (such as the European Association for the Study of Diabetes, EASD), healthcare professionals (e.g., diabetologists), industry representatives, and forums such as the European Diabetes Forum (EUDF) - to be actively engaged in the ISO process. This ensure the full range of perspectives and expertise is reflected and that standards are practical and implementable. MedTech Europe encourages all these stakeholders to contribute to the process.

- While ISO standards are being developed, it should be noted that other jurisdictions have already issued, or are in the process of issuing, guidance for CGM systems – such as but not limited to, the U.S. FDA's integrated CGM (iCGM) framework, as well as various guideline initiatives from the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and British Standards Institution (BSI) – which operate within their respective regulatory domains. This underscores the need for harmonised and comprehensive (ISO) guidance applicable internationally, for adoption in the EU, which we strongly support.

Considerations and guiding principles for the development of standards for diabetes medical technology

1. Medical technologies have revolutionised the management of diabetes for individuals and their care teams.

Medical technologies play a crucial role in supporting effective diabetes management. These include insulin delivery systems (including pumps, pens and pods), glucose monitoring systems (such as BGM and CGM), apps that prompt action, inform and educate, and the algorithms that support these technologies.

Better diabetes management and care support, enabled by medical technologies, has meaningfully improved the lives of people with diabetes:

- Improved health outcomes and higher quality of life
- Fewer health emergencies
- Better decision-making support for care teams and health professionals
- Reduced strain on individuals, care teams, health systems and society

Medical technologies that today support millions of people living with diabetes in managing their condition are the result of both breakthrough and iterative innovation. As such, the future of diabetes care rests on ongoing innovation.

Companies developing, producing, and maintaining diabetes technologies play a key role, alongside healthcare professionals, patient representatives and people living with diabetes in driving high-quality innovation that benefits patients.

The MedTech Europe Diabetes Sector Group shares the goals of ensuring that people in Europe have access to safe, accurate and performant diabetes technologies, and recognises the importance of a multistakeholder process to achieve these objectives.

2. The CE marking system within the existing regulatory framework (EU MDR / IVDR) ensures the safety and performance of medical technologies in Europe. This provides a robust foundation for any additional quality standards considerations.

Patient safety is a cornerstone of the current EU regulatory framework for medical technologies.

In the European Union, medical technologies are tightly regulated by laws that govern the safety and performance of devices across their lifetime, before and after they are placed on the market.

Medical devices CE-marked under the EU MDR and IVDR must comply with strict patient safety requirements and controls to verify that those requirements are met. At present, these requirements and controls are among the most stringent and comprehensive globally.

Medical technologies in the EU must comply not only with MDR / IVDR, but also with a broader framework of EU legislation. These additional regulatory requirements include those related to cybersecurity, artificial intelligence, environmental sustainability (including chemicals), and data protection. This layered compliance

landscape aims to ensure that medical technologies are not only safe and effective but also ethically, digitally, and environmentally responsible.

For many medical device product groups, the CE marking is supported and further clarified by internationally recognised standards, such as those developed by the International Organisation for Standardisation (ISO), which provide criteria that support the assessment of the quality, performance, and safety of medical devices. An example is ISO 15197:2013 for Blood Glucose Monitoring (BGM) systems.

3. Innovation is also crucial to continue improving diabetes management for the benefit of patients, care teams and health systems.

Innovation in medical technology has led to improved health outcomes and quality of life for people living with diabetes and their care teams.

Medical technology continuously improves through innovation to meet the needs of patients and society. 'Innovation' refers to breakthrough and disruptive technologies, as well as iterative changes which enhance functionality and performance of existing technologies, such as software updates, improved service time, more interoperable services, and offering a technology used in a clinical setting for home or point of care use.

This range of innovation is the result of continued research and development investment by the industry, in close cooperation with healthcare professionals, patients and health systems to identify unmet needs.

4. Any development and application of quality standards in diabetes technologies should follow several key principles to ensure they bring value to the diabetes community.

It is essential that the development of any technology-specific standards is evidence-based and inclusive, and that their application in Europe aligns with the established EU regulatory framework, guided by a clear and accurate understanding of said framework. This will help ensure such standards serve as a tool to support – and not hinder – innovation and patient access.

- **Evidence-based: All quality standards should be grounded in scientific evidence and objective assessments** to ensure that any requirements for diabetes technologies are robust, credible, and focused on delivering real benefits to patients and care teams. Prioritising evidence-based criteria supports the development of standards that maintain high levels of patient safety and device performance, while fostering trust among healthcare professionals, patients, and regulators.

- **Aligned with regulations: The application of quality standards should be fully harmonised with existing regulatory frameworks and processes.** The EU regulatory framework and its high standards of safety and performance should serve as the foundation of any additional requirements in order to prevent inadvertently delaying patient access to beneficial innovations. By extension, any consideration of quality or performance standards should be undertaken in a manner that complements – rather than duplicates or conflicts with – existing EU regulations such as the CE marking, the Medical Devices Regulation (MDR), and the In Vitro Diagnostic Regulation (IVDR).

- **Innovation-focused: The use of standards should support and enable continued access to the next generation of technologies, including emerging, breakthrough, and iterative innovation.**

- As the next generation of medical technologies will benefit patients, care teams and broader health systems, it is crucial to **avoid unnecessary barriers** that could limit innovation or restrict market entry for both established and emerging technologies.

- As such, any additional standards should set meaningful benchmarks that support device performance and reliability **without imposing overly prescriptive or narrowly defined technical criteria.**

- Looking forward, **any proposed EU-specific quality standards should be future-proofed** to ensure that, in the event they are either superseded by or used in conjunction with future internationally approved standards (such as from the International Standardisation Organisation - ISO), manufacturers do not face duplicative requirements that could slow innovation and limit access.

- **Transparent and inclusive: The development and establishment of quality standards should ensure inclusive, transparent, and coordinated stakeholder engagement.**

  - The MedTech Europe Diabetes Sector Group is **committed to open and constructive engagement** with the full diabetes community, including healthcare providers, patient groups, academic researchers, policymakers, diabetes experts, and a broad range of industry players.

  - **Active industry participation in the development of quality standards is essential alongside healthcare professionals, patient representatives, and other stakeholders,** to ensure that emerging standards are patient-centred, practical, scientifically sound, and aligned with the broader medtech landscape. Such collaboration is vital to ensure that standards development reflects diverse perspectives and addresses the needs of all stakeholders.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
www.medtecheurope.org.