MedTech Europe
from diagnosis to cure

# The medical technology industry's views on simplification of EU digital legislation

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# Executive Summary

Digital medical technologies, including connected devices, diagnostic software, and AI-enabled solutions, are at the forefront of Europe's healthcare transformation, enabling early diagnosis, personalised care, and improved patient outcomes. These benefits hinge on a regulatory environment that is clear, coherent, predictable and compatible with the specific needs of the medical technology sector.

Medtech Europe welcomes the European Commission's drive towards simplification and calls for a digital policy framework that supports innovation while remaining firmly aligned with existing sectoral legislation such as Europe's Medical Devices Regulation 2017/745 (MDR), *In Vitro* Diagnostic Medical Devices Regulation 2017/746 (IVDR), and the European Health Data Space (EHDS) Regulation. These frameworks have been cautiously designed to ensure high standards of device safety while also upholding fundamental principles of data protection and privacy. Building on these robust frameworks, it is essential to avoid duplicative or conflicting obligations that would create unnecessary complexity and regulatory and administrative burden.

The European medical technology industry urges EU policymakers to ensure coherent implementation and alignment of horizontal digital legislation, including the AI Act, with sector-specific requirements. This also includes a proportionate and sectoral approach to health data sharing via the EHDS, that takes into account the unique sensitivity of data generated in healthcare settings and prioritises patient safety, in particular when it relates to data generated by the use of connected medical devices. Sectoral data sharing approaches should come with clear legal definitions, and safeguards that protect both patients and the ability of manufacturers to contribute meaningfully to Europe's health and digital objectives.

**Artificial Intelligence (AI) Act**
MedTech Europe calls for targeted adjustments and continued dialogue among EU lawmakers and stakeholders with the goal of ensuring that new AI requirements complement, and add value to, existing frameworks for medical technologies and data protection. Unnecessary complexity and regulatory burden for AI manufacturers and notified bodies must be reduced.

**Cybersecurity**
MedTech Europe calls for greater harmonisation of national transpositions and reporting obligations under instruments such as the Network and Information Security Directive II (NIS2) and the Cybersecurity Act, to prevent further fragmentation of the Single Market and ensure that critical medical technologies remain secure, interoperable, and accessible across the EU.

**Data Act**
MedTech Europe calls for greater clarity within the Data Act, specifically urging that data sharing requirements be made voluntary for manufacturers of medical technologies, ensuring that the EHDS remains the primary data sharing ecosystem for health-related data and providing for greater guarantees to user-generated data and patient cybersecurity. We also advocate for greater coherence with the General Data Protection Regulation (GDPR), increased trade secrets protections, a clear exemption for legacy products and an extension of the Data Act's application timeline to September 2029, providing the necessary space for compliance preparation.

**European Health Data Space (EHDS)**
On the EHDS, MedTech Europe calls for a clear and comprehensive regulation of Electronic Health Record (EHR) Systems, specifically characterised by the primary intended purpose as indicated by the manufacturer.

This will ensure that the EHDS' definition of EHR system does not unnecessarily include devices primarily and already covered under the MDR or IVDR, increasing the potential of duplicative and double regulation.

MedTech Europe stands ready to work with EU policymakers to ensure that digital legislation supports innovation, strengthens patient care, and upholds Europe's global leadership in medical technology.

# Introduction

Digitalisation is reshaping how healthcare is delivered, and medical technologies — including medical devices, *in vitro* diagnostics, and digital health solutions — are at the centre of this shift. When effectively integrated, digital medical technologies can support earlier diagnosis, remote monitoring, personalised treatment, and improved continuity of care. They enable patients to play a more active role in managing their health while also helping healthcare professionals to optimise their time, workflows and improve patient outcomes.

To realise these benefits, the European Union (EU) regulatory environment must support digital innovation while remaining coherent with existing sectoral legislation. Fragmented or duplicative requirements risk delaying access to essential technologies and discouraging investment in Europe. MedTech Europe has long advocated for a coherent digital legislative framework that enables safe, effective, and sustainable deployment of digital medical technologies.

An innovation-friendly and collaborative environment to deliver lifesaving medical technologies to patients in the EU is urgently needed, as well as a mind-shift towards regulation simplification and integration of the Single Market. The European Commission's 2025 Work Programme focused on competitiveness and simplification is a good step in that direction.

We propose key recommendations to ensure that EU digital legislation supports innovation, maintains high standards for patient care, and avoids regulatory overlap — ultimately fostering a healthcare system that is more resilient, efficient, and responsive to citizens' needs, and supporting the European Commission's overall objective for regulatory simplification and clarity.

# Artificial Intelligence Act

The Artificial Intelligence (AI) Act entered into force in August 2024 and will apply in full to AI-enabled medical technologies as of 2 August 2027. From that date, AI-enabled medical technologies will need to comply with the AI Act alongside either the *In Vitro* Diagnostic Medical Devices Regulation (IVDR) or the Medical Devices Regulation (MDR).

The current approach and timeline risk overlooking the unique safety, performance, and clinical integration requirements already addressed under IVDR and the MDR. The regulatory situation risks leaving Europe behind global competitors who are rapidly advancing AI integration in healthcare. Without swift, targeted action to address areas of regulatory overlap and legal uncertainty, the EU will miss a critical window to lead in medical innovation and digital health.

MedTech Europe encourages EU policymakers and regulators to address key regulatory and legal inconsistencies outlined below in a Digital Omnibus before end-2025. The EU must also accelerate its efforts both to ensure a coherent and effective implementation of the AI Act and create a forward-looking framework for AI which fosters trust in innovation.

We believe that, with targeted adjustments and continued dialogue among stakeholders, the novel aspects of artificial intelligence can be safely regulated in a way that complements existing frameworks for medical technologies and data protection, thereby reducing unnecessary complexity and regulatory burden for AI manufacturers and notified bodies.

## Extend the application date of the AI Act to 2 August 2029

### Issue

The industry is significantly concerned that the current application timeline of the AI Act is not sustainable:

- Medical technology manufacturers and the entire regulatory ecosystem are in transition to the existing sectoral legislation (IVDR/MDR).
- Independent auditing bodies ("Notified Bodies") are needed to certify AI-enabled medical technologies. TeamNB, the association of Notified Bodies, has raised concerns that delays in national implementation may lead to a shortage of designated NBs, risking bottlenecks (in certification) when the high-risk provisions become mandatory in 2027.
- There is no clear way for Notified Bodies under the IVDR and MDR to be designated under the AI Act to certify AI-enabled medical technologies.
- There is lack of guidance and alignment about how to apply the AI Act requirements which could lead to compliance delays for medical technology manufacturers and fragmentation of application among EU member states.
- There are delays in the availability of harmonised standards needed to implement the AI Act – now expected only in 2026, which is too short to implement them in time for the 2027 end of transition deadline.
- Legal uncertainty about the application of key provisions of the AI Act to pre-market clinical and performance evaluation prior to affixing CE marking creates major uncertainty for pre-market generation of clinical evidence.

## Impact on the medical technology sector

Without the necessary compliance support mechanisms in place and the necessary regulatory and legal clarity, the original application date of 2 August 2027 risks disrupting the medical technology development cycle. This risks delaying access to safe and effective AI-enabled medical technologies for hospitals, healthcare professionals and patients. Manufacturers may be forced to prematurely re-engineer compliance pathways without clear guidance or applicable harmonised standards, stalling innovation and market entry.

## MedTech Europe's proposed solution

MedTech Europe calls on the European Commission to extend the application date of the AI Act to 2 August 2029 for AI systems already regulated by the IVDR/MDR. This extension would not only ensure that AI regulation complements, rather than complicates, the existing IVDR/MDR frameworks, and leverages the domain expertise already embedded in those systems. It would also provide the necessary time to allow the entirety of the ecosystem to prepare to comply with the requirements of the AI Act. We call on the European Commission to put this extension in place prior to the end of 2025.

The proposed extension of the AI Act's application timeline is not merely a request for more time. It reflects the deep complexity and critical importance of the medical technology sector, and the unique challenge to be effectively governed by horizontal rules. It is critical that additional time given be used by the European Commission, and specifically the AI Office, to put in place a coherent and accessible regulatory infrastructure for AI-enabled medical technologies, support development of timely harmonised standards, and conduct operational readiness including capacity-building across notified bodies and national enforcement authorities. In the interim, the safety and performance of AI medical technologies would continue to be expertly governed under the IVDR/MDR and other applicable EU legislation, as it is already happening today.

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# Ensure a clear designation pathway for Notified Bodies under the AI Act

## Issue

There are significant concerns as to what extent IVDR/MDR-designated Notified Bodies will also be designated under the AI Act. With reports of a proportionally low number of Notified Bodies planning to seek designation under the AI Act, and misalignment among regulators as to whether full AI Act designation or specific technology codes are required, the system lacks the clear, harmonised designation pathway needed for manufacturers, healthcare systems and patients.

The IVDR and MDR implementation deadlines have been extended four times due to bottlenecks in the transition process – largely due to no or slow designation of Notified Bodies. More time was needed to ensure that enough Notified Bodies were available to certify medical technologies so that manufacturers could continue to make them available to Europe's patients and health systems.

It is critical both that there are sufficient Notified Bodies with designation under the AI Act and that those Notified Bodies have the capacity to certify AI-enabled medical technologies in a swift and predictable way (given the dynamic nature of these products).

## Impact on the medical technology sector

Without an adequate capacity of notified bodies and streamlined process, manufacturers face delays and bottlenecks in conformity assessment, efficient placing of AI-enabled medical technologies on the market. This will ultimately stifle the availability of AI-enabled medical technologies offered to patients and healthcare systems in the EU.

## MedTech Europe's proposed solution

MedTech Europe urges the European Commission to enable the use of existing IVDR/MDR technology codes for Notified Bodies designated under the AI Act. We also encourage the publication of clear guidelines which are accessible and understandable for any size of manufacturer and Notified Body. They should confirm that conformity assessment for AI-enabled medical technologies can be conducted under the existing IVDR/MDR procedures by appropriately scoped Notified Bodies.

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# Provide a clear legal avenue to perform pre-market clinical testing

## Issue

Unlike the legal pathways enshrined in the sectoral MDR and IVDR, the AI Act does not explicitly exempt investigational devices (per the MDR) or devices for performance studies (per the IVDR) from being "placed on the market" or "put into service" under the AI Act. This omission raises concerns that such devices – despite not being placed on the market or put into service, or interacting with end-users/patients – could be inappropriately subject to the full breadth of AI Act obligations. Such studies are foundational aspects in the pursuit of a CE-mark under the sectoral MDR and IVDR, and as such, are critical pre-market elements to demonstrate that the future device would perform safely in a clinical setting.

As a result of this legal discrepancy, an AI-enabled medical device or IVD that is required to undergo a clinical investigation or performance study under the MDR and IVDR respectively could therefore be considered "placed on the market" or "put into service" under the AI Act – while not yet being "placed on the market" or "put into service" under the IVDR/MDR. While the Medical Device Coordination Group (MDCG) has considered this regulatory incoherence in its AIB 2025-1 MDCG 2025-6 on the interplay between the AI Act and IVDR/MDR, the necessary legal certainty is neither reflecting the official position of the European Commission, nor is it legally binding.

## Impact on the medical technology sector

This regulatory friction risks significantly hampering the ability of AI medical technology manufacturers to conduct essential pre-market clinical investigations and performance studies. Such delays in generating the data required to demonstrate safety and effectiveness under the IVDR/MDR may, in turn, postpone CE-marking and ultimately slow patient access to innovative technologies. Moreover, imposing AI Act obligations on devices not yet placed on the market, without any added safety or performance benefit, could introduce unnecessary regulatory hurdles to research and development activities, with no positive impact on safety and performance of devices.

## MedTech Europe's proposed solution

MedTech Europe asks the European Commission to explicitly exempt investigational devices and devices for performance studies from the AI Act's legal obligations, provided they operate in compliance with the IVDR/MDR framework and respect fundamental rights such as patient safety and data protection. Such an exemption will ensure continuity of evidence generation without compromising regulatory safeguards, patient safety, and continued innovation in medical technology development.

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# Clarify terminology on "substantial modification" and "significant change" for AI in medical devices and IVDs

## Issue

The AI Act introduces the concept of "substantial modification" which may result in the requirement to undergo re-certification. However, this concept is not aligned with existing definitions under IVDR/MDR or associated guidance, which employ the concepts of "substantial change" and "significant change" as a benchmark for either pre-approval of the change by the Notified Body or triggering a new conformity assessment for the device. This misalignment creates regulatory uncertainty for AI-enabled medical technology manufacturers, particularly in cases involving regular algorithmic updates or learning cycles.

## Impact on the medical technology sector

Without a clear and harmonised definition of "substantial modification", AI medical technology manufacturers risk being faced with a lack of level playing field due to inconsistent regulatory interpretations across EU Member States or among Notified Bodies, who may be required to make arbitrary decisions on how to interpret and apply these cross-regulatory terms. This could result in redundant conformity assessments for routine software updates, adding administrative burden, reducing efficiency for Notified Bodies, delaying product improvements benefit healthcare systems, and increasing costs for manufacturers.

## MedTech Europe's proposed solution

MedTech Europe asks the European Commission to ensure clear and comprehensive alignment of the AI Act's definition of "substantial modification" with the IVDR/MDR legal texts and associated guidance related to "significant change". These classifications should be articulated to be very clear around the management of adaptative learning algorithms (i.e., how to define whether self-learning algorithm evolution requires additional submission if the fundamental function is not affected). Sectoral expert groups, such as the Medical Device Coordination Group (MDCG), should be consulted to develop joint implementation guidance that avoids duplication and supports agile, iterative innovation in AI systems. Based on previous discussions within the MDCG,, one possible approach could be to address this within a revised rendition of AIB 2025-1 MDCG 2025-6 on the interplay between the AI Act and IVDR/MDR.

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## Avoid duplication in risk management requirements across the AI Act and IVDR/MDR

### Issue

The AI Act requires the development of a risk management system, while IVDR/MDR already mandates comprehensive risk analysis for medical technologies. The pending horizontal AI harmonised standards (e.g., by the European standards bodies CEN and CENELEC) may conflict with vertical risk standards already used in medical technology compliance frameworks.

### Impact on the medical technology sector

The potential duplication of risk management requirements between the AI Act and the IVDR/MDR is part of a wider concern regarding regulatory incoherences between the two legal frameworks. Duplicative or conflicting requirements would likely increase compliance complexity, which is particularly burdensome for SMEs, and may lead to fragmented audits or delays in approvals due to inconsistencies between AI and medical technology standards.

### MedTech Europe's proposed solution

The Commission must ensure harmonised AI risk management standards are developed in coordination with existing IVDR/MDR standards and explicitly confirm that compliance with vertical (sectoral) risk standards can fulfil AI Act obligations. CEN-CENELEC should systematically engage sectoral bodies in standard-setting processes.

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## Prefer international standards over EU-only standards to support global convergence

### Issue

The current trajectory of AI and data standardisation in the EU (e.g., CEN-CENELEC standards) may lead to EU-specific frameworks that diverge from widely accepted and co-created international standards (e.g., ISO/IEC), increasing compliance burdens for global medical technology providers, and encouraging global divergence in technology standards.

### Impact on the medical technology sector

Divergence from international norms complicates product development and market access, requiring multiple versions of compliance documentation, risk assessments, and product testing. It undermines the EU's attractiveness as a launch market for globally deployed digital health solutions.

## MedTech Europe's proposed solution

The European Commission should prioritise alignment of harmonised AI and data standards with international frameworks (e.g., ISO 14971 for risk management, ISO 13485 for quality systems). This approach reduces duplication, supports international regulatory convergence, and strengthens the EU's role in global digital health innovation.

# Cybersecurity

## Cybersecurity Act: Reground voluntary aspects within EU cybersecurity certification

### Issue

The 2019 EU Cybersecurity Act aimed at addressing a clear gap in cybersecurity at EU level, both by the formalisation of ENISA as the EU cybersecurity agency, and by establishing the European Cybersecurity Certification Framework. A fundamental pillar of the Cybersecurity Certification Framework is its voluntary nature. This ensures that cybersecurity certification schemes would in no way replace binding EU or national cybersecurity legislation, or international cybersecurity standards. Increasingly we have witnessed a push for the mandatory application of cybersecurity certification schemes, as well as their use as a means of demonstrating legal compliance with mandatory EU cybersecurity legal obligations. In addition, the development of specific cybersecurity certification schemes has been stalled as a result of political discussions over the access of specific economic operators rather than being grounded in cybersecurity best practice.

### Impact on the medical technology sector

Ambiguity between EU-only cybersecurity certification schemes for Information and Communications Technology (ICT) products and services, international cybersecurity standards for products and processes, and EU legal requirements on product cybersecurity and organisational cybersecurity risk management will result in significant unclarity for medical technology manufacturers. Currently, manufacturers are already subject to multiple layers of EU and national cybersecurity legislation, with unclear alignment between those requirements and uncertainty for manufacturers as to which requirements they must comply with.

### MedTech Europe's proposed solution

MedTech Europe encourages the European Commission and national cybersecurity officials to reground voluntary aspects within EU cybersecurity certification. Efforts should be refocused on state-of-the-art cybersecurity and innovative practices within the European digital ecosystem. In doing so, the European healthcare system will continue to benefit from cutting-edge cybersecurity in medical technologies, ICT processes and services.

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## Network and Information Security Directive II (NIS2): Support harmonised transposition, implementation and application across EU Member States

### Issue

Legislation plays an important role in creating a level playing field along the value chain, but fragmentation in legal requirements has increased the burden on manufacturers of health technology. Given that the Network and Information Security Directive II (NIS2) is implemented through national legislation, its

application varies widely among EU Member States and its impact on different sectors contrasts substantially, ultimately fostering a patchwork of cybersecurity laws across the EU and distorting the EU Single Market.

## Impact on the medical technology sector

Medical technology manufacturers are set to be faced with significant legal uncertainty, specifically on how the national NIS2 transposition laws apply, and to whom they apply. The current assortment of cybersecurity rules in the health sector is already inconsistent, and NIS2 risks making this even more complex. Moreover, NIS2 does not clearly define a unified oversight or reporting structure, which clashes with standard cybersecurity practices that focus on managing risks through information security systems rather than legal entities. As a result, the lack of a coherent oversight and reporting framework creates additional administrative and compliance burdens for medical technology manufacturers.

The administrative burden is exacerbated by the complexity of the regulatory system (e.g., the need to conduct a dedicated detailed analysis, even with external support, of the different applicable reporting requirements) and it takes more time and effort to monitor, analyse and implement transposed requirements in different EU Member States (e.g., for registration of legal manufacturers). In conjunction with other EU and national laws on incident reporting, these obligations often differ by authority (e.g., data protection, national cybersecurity agency, etc.) and vary across languages and jurisdictions. This could lead to duplicated reporting of the same incident, which consumes valuable cybersecurity resources without improving data protection and overall cybersecurity outcomes.

## MedTech Europe proposal

MedTech Europe encourages the European Commission to support EU Member States in harmonising their application of transposition laws, implementing the intended objectives of NIS2.

Moreover, the scope of the NIS2 Directive and the Critical Entities Resilience (CER) Directive should be harmonised across EU Member States by using the catalogue of critical medical devices (currently under development) as the basis for designation of important/critical entities in all EU Member States.

Furthermore, MedTech Europe supports greater simplification of NIS2 definitions and processes for **reporting of security incidents**. We recommend greater harmonisation of interpretation among EU Member States under the NIS2, given that we currently see that some EU Member States have introduced new concepts in their national laws (e.g., “near incident”) or have introduced varied reporting timelines. In addition, divergent definitions and processes between the NIS2 and the Cyber Resilience Act (CRA) should also be addressed, to avoid further legal uncertainty for manufacturers.

Finally, the single reporting platform, to be introduced under the CRA, should also be used for the NIS2 Directive, allowing entities in scope to only report an incident once (rather than multiple reports to different national authorities for the same incident).

# Data Act

MedTech Europe stresses the need for the simplification and alignment objectives of the European Data Union Strategy, including within the Data Act. We propose that the Digital simplification package (Digital Omnibus) considers the complexities of the healthcare and medical technology sector. MedTech Europe calls for a proportionate approach that not only simplifies the rules for data sharing in healthcare, but also ensures legal clarity, supports innovation, and safeguards both patient interests and industry's ability to contribute meaningfully to Europe's health and digital objectives.

## Establish a coherent framework for health data sharing

### Issue

MedTech Europe consistently highlighted its concerns that the Data Act could have unintended and potentially detrimental consequences on patient safety. We are concerned that the impact assessment of the Data Act on user-generated data sharing does not sufficiently consider the unique sensitivity of data generated in healthcare settings. An obligation to provide raw, pre-processed and uninterpreted data access, as mandated by the Data Act, may expose patients to unforeseen risks, including patient harm, misinterpretation, loss of clinical context, or potential security breaches.

### Impact on the medical technology sector

The concerns regarding patient safety risk compromising the effective deployment and safe operation of medical technologies in clinical settings and home care. Applying the Data Act's general-purpose data-sharing requirements to regulated medical technologies would result in overlapping, and in some cases conflicting, obligations, with the IVDR/MDR and the EHDS. This creates legal uncertainty, complicates compliance, and undermines investment incentives in medical innovation. Additionally, there is significant uncertainty with regards to how the Data Act will interact with existing regulations like the GDPR, creating legal ambiguity and complicating compliance for manufacturers.

While the Data Act incorporates a so-called "security handbrake" designed to address serious adverse effects on the health, safety, or security of individuals, this provision may not be well-suited for the healthcare context. Proving such potential effects can be challenging in the absence of specialised sectoral authorities, as defining a clear threshold for triggering such a safeguard would be inherently complex and context dependent.

### MedTech Europe's proposed solution

Regulated medical technologies – covered under MDR and IVDR – should be explicitly excluded from the data-sharing obligations of the Data Act. The EHDS already establishes comprehensive, sector-appropriate rules for the access and use of health data and must remain the sole legislative framework governing data flows in the healthcare domain. Horizontal obligations under the Data Act are ill-fitted for the highly regulated clinical, safety-critical, and privacy-sensitive context of medical technologies. Legal clarity is urgently needed to preserve regulatory coherence with IVDR/MDR and avoid undermining the secure, patient-centred data governance model established by the EHDS.

We recommend amending the Data Act's data accessibility obligations (Chapter II) to make them voluntary for medical devices, IVDs, EHR systems, and related services. For products and related services that remain

within the scope of the Data Act, we recommend reviewing the so-called "security handbrake" and implementing a safeguard that limits data sharing when the access of raw and unprocessed data could potentially compromise safety or security, also considering the product performance as a critical factor. Finally, MedTech Europe proposes that whenever health data is involved, rules should be consolidated with sectoral legislation taking precedence.

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## Reduce administrative burden and clarify interplay with GDPR

### Issue

The Data Act imposes a disproportionate administrative burden on medical technology companies through extensive documentation, reporting, and contractual requirements, especially in combination with requirements stemming from other legislation such as General Data Protection Regulation (GDPR). These burdens are exacerbated by a lack of clarity regarding the interplay between the Data Act and the GDPR, especially in scenarios involving mixed personal and non-personal health data.

### Impact on the medical technology sector

There is a lack of clarity regarding the interaction between the Data Act and the GDPR, creating redundant or conflicting requirements, especially in cases where devices generate both personal and non-personal data, requiring companies to navigate compliance with both regulations. Difficulties arise from the complex value chains in healthcare settings. For example, the 'user' of a connected product or related service could potentially be a patient, a healthcare professional, a hospital or an insurance company. This complexity makes a delineation of roles and responsibilities extremely challenging, creating confusion and additional administrative burden. This dual compliance challenge (GDPR and the Data Act) risks diverting resources away from innovation, while the ambiguous benefits of mandatory sharing of raw or pre-processed data may not justify the compliance costs.

### MedTech Europe's proposed solution

For products and related services that remain in scope of the Data Act, MedTech Europe recommends clarifying the interplay between the GDPR and the Data Act, including the attribution of roles along the value chain. We also call for greater clarity on the application of the GDPR principles-based approach, for example related to personal data, minimisation, anonymisation, proportionality, and consent.

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## Extend timeline for the Data Act's application

### Issue

The current application timelines of the Data Act present challenges given the significant legal and practical uncertainties that still need to be addressed. In particular, key interpretative questions on the Data Act's interplay with the GDPR, sectoral legislation and the EHDS are still unresolved. Additionally, ongoing updates

to the European Commission's Frequently Asked Questions (FAQ) document highlight that essential guidance is still in development. While some Member States have yet to achieve operational readiness, several are still without designated competent authorities and are unlikely to meet the Data Act's application date.

## Impact on the medical technology sector

The Data Act's application from 12 September 2025 leaves the medical technology sector with a tight timeline to ensure compliance, especially given the complexity of required changes to connected medical technology and related services. This is particularly challenging if the Data Act remains fully mandatory for medical devices, as products may need substantial design changes to comply with new obligations, potentially triggering new conformity assessments under IVDR/MDR.

## MedTech Europe's proposed solution

Owing to the abovementioned constraints, MedTech Europe recommends that the European Commission extend the application timeline of the Data Act to September 2029 to provide stakeholders with sufficient time to prepare, thereby ensuring legal certainty, harmonised implementation, and practical feasibility.

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### Exclude legacy devices and avoid ad-hoc changes to products

## Issue

The current definition of "placing on the market" in Article 2(22) of the Data Act does not explicitly exclude legacy products and software, and those developed prior to the date of application or those that, although developed and certified years in advance, are placed on the market over extended delivery timelines.

## Impact on the medical technology sector

In the medical technology sector, product development lifecycle from early design to final deployment routinely spans several years due to the complexity of development, regulatory requirements, and lengthy approval processes. Without a clear exclusion for legacy products and related services, the Data Act risks retroactively applying new design obligations regarding data access to devices that were developed under previous regulatory regimes or that have been in the pipeline for years. This could create significant legal uncertainty, increase compliance costs, and potentially delay or disrupt the market entry of essential medical technologies.

## MedTech Europe's proposed solution

MedTech Europe recommends that the European Commission amends the Data Act's definition of "placing on the market" to exclude legacy products developed prior to the Data Act's date of application to ensure these legacy devices can continue to be updated without having to comply, as long as their core functionalities/intended use are not changed.

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## Reduce high burden to protect trade secrets

### Issue

MedTech Europe consistently highlighted its concerns that the Data Act could have unintended and potentially detrimental consequences on a company's ability to protect critical trade secrets and know-how. This could lead to a situation where trade secrets' legal protection becomes the subject of a gradual erosion. Despite the safeguards included, the scope of data sharing obligations under the Data Act is still very broad, which could put sensitive business information at risk, given the nature of data and trade secrets. This is also due to the high burden of proof for the data holder to demonstrate that it is highly likely to suffer serious damage to withhold the data sharing. At the same time, the nuanced reality where IP/trade secret holders are not necessarily the health data holders under the EHDS has to be considered.

While the Data Act aims to foster innovation, it introduces provisions – particularly in Articles 4(8) and 5(11) – that set an unreasonably high threshold for companies to withhold data in order to protect trade secrets. The requirement to demonstrate a risk of 'serious economic damage' places an excessive burden on companies seeking to safeguard sensitive information.

### Impact on the medical technology sector

Possible consequences include, for example, exploiting the innovations of manufacturers and data holders for malicious purposes, lowering of the international level playing field (e.g., by lowering the protection of confidential information granted by Article 39 of the Agreement on Trade-Related Aspects of Intellectual Property Rights – TRIPS), multiple disputes overloading national judicial systems, or the heavy burden of proof for 'serious economic damage' on the data or trade secret holders.

For the medical technology industry, where proprietary algorithms, diagnostic processes, and product performance data are central to competitive advantage, this could lead to the erosion of trade secret protection. Companies may face increased legal exposure, potential IP leakage, and a surge in disputes, which could overburden national courts and undermine incentives to invest in R&D for the European market.

### MedTech Europe's proposed solution

MedTech Europe recommends levelling the protection and the conditions for invoking the trade secrets and security 'hand brake' with international standards. In particular, Article 4(8) and Article 5(11) of the Data Act should not require the risk of suffering serious economic damage as a pre-condition for withholding data sharing.

MedTech Europe also proposes the recognition of trade secrets and cybersecurity as fully legitimate grounds to withhold data under the Data Act, without triggering mandatory notifications. We also recommend the shifting of the burden of contesting refusals to the requester, rather than the data holder.

# European Health Data Space

MedTech Europe welcomes the significant efforts and the political will to establish the EHDS as a building block of a strong European Health Union, aiming to harness the advantages of health data sharing. However, for the EHDS to transition from concept to reality, it is imperative that key concepts are clearly clarified and adequately addressed in the implementation process.

## Limit the overly broad "EHR systems" definition

### Issue

The EHDS Regulation defines an EHR system in Article 2(2)(k) as *"any system whereby the software, or a combination of the hardware and the software of that system, allows personal electronic health data that belong to the priority categories of personal electronic health data established under this Regulation to be stored, intermediated, exported, imported, converted, edited or viewed, and intended by the manufacturer to be used by healthcare providers when providing patient care or by patients when accessing their electronic health data"*. It should be clarified that not "any" system that "allows" the storage of electronic health data should be an EHR system, but only those that primarily serve a storage for health records. Given the current broadness of this definition, many medical devices and IVDs will qualify as EHR systems and will need to comply with the respective EHDS provisions, in addition to IVDR/MDR and the AI Act, as well as numerous other legislation applicable to medical technologies.

### Impact on the medical technology sector

The broad definition of EHR systems in the EHDS Regulation adds significant complexity for medical technology manufacturers, who face long development cycles and strict safety/security requirements laid out in sectoral legislation (IVDR and MDR). This risks bringing many devices or systems into scope, with additional requirements and short timelines to adapt (common specifications for interoperability and logging/security component will be laid down in Implementing Acts, which are expected in 2027, while the law will be applicable in 2029).

To the extent that medical devices claim interoperability with EHR systems, they will already be subject to additional requirements. According to Article 27(1) of the EHDS Regulation, manufacturers of medical devices or *in vitro* diagnostic medical devices that claim interoperability of those medical devices or *in vitro* diagnostic medical devices with the harmonised software components of EHR systems, shall prove compliance with the essential requirements on the European interoperability software component for EHR systems and the European logging software component for EHR systems, laid down in Section 2 of Annex II to this Regulation.

Moreover, manufacturers may be subject to additional requirements laid down by EU Member States as they can ultimately impose further conditions on other aspects than the harmonised components, possibly requiring additional or third-party assessments. Although the EHDS Regulation recital refers to a single assessment process, there is a real risk that divergent national demands will create undue burden, increase costs, and slow down innovation.

## MedTech Europe's proposed solution

MedTech Europe recommends that the definition of EHR systems is clarified and includes a clear delineation between EHR systems intended to serve as a longitudinal repository of structured electronic health information, supporting clinical workflows, care coordination, and patient engagement across multiple settings and IVDR/MDR-regulated products. This can be done by focusing on the "primary intended purpose" of the system. For EHR systems, the primary intended purpose is to make aggregated data available to patients and healthcare professionals at the point of care. The definition should be adapted by, at least as a starting point, adding the wording 'primarily intended by the manufacturer' to prevent that a secondary aspect of a given device's functionality (namely processing of electronic health data) inadvertently classifies it as an EHR system. The primary intended use of a device should be understood as defined in Article 2(12) of the MDR.

Furthermore, in the event that a component of a medical device falls under the definition of an EHR system, it is essential that the EHDS allows for a modular approach to self-certification, to avoid extending EHR system requirements beyond what is necessary.

At the same time, clear guidance should be issued to EU Member States to ensure coherent application of the definition and the resulting requirements. The approach to EHR Systems should feature as a standing agenda point for discussion at both the EHDS Board level and at the Stakeholder Forum, with regular check ins between the two bodies.

## Conclusion

MedTech Europe welcomes the European Commission's commitment to reviewing and simplifying digital legislation where appropriate, with a view to removing unnecessary barriers, ensuring coherence with existing sectoral legislation, and avoiding duplicative or disproportionate requirements for digital medical technologies. We strongly support this effort and encourage EU policymakers to consider the sector-specific needs of digital medical technologies when designing horizontal rules.

We stand ready to work in partnership with EU institutions to ensure that the digital legislative landscape remains fit for purpose, enabling timely access to innovative, safe, and effective digital health solutions that benefit patients, healthcare professionals, and society at large.

### 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.
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