MedTech Europe
from diagnosis to cure

MDR/IVDR Revision:

A regulatory system at a crossroads

Position & Proposed Amendments

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TABLE OF CONTENTS

Summary Position

A summary of MedTech Europe's position is found [here].

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from diagnosis to cure

MDR/IVDR revision: a regulatory system at a crossroads

Europe's regulatory framework for medical technologies is at a decisive moment. MedTech Europe fully supports the European Commission's objective to streamline the EU regulatory system for medical devices and in vitro diagnostics and urges Parliament and Council to bring these much-needed improvements swiftly.

The Medical Device (MDR) and In Vitro Diagnostics Regulations (IVDR) were designed to raise the bar for patient protection and strengthen trust in medical technologies. Yet, nearly a decade into implementation, the very goals these regulations were meant to achieve are being undermined by structural shortcomings: slow and unpredictable conformity assessment timelines, disproportionate and costly administrative burdens, and inconsistent interpretation across Member States.

The cost of delay in addressing the system's shortcomings is concrete and cumulative. Companies are already redirecting investment away from Europe, patients face avoidable disruptions to the technologies they depend on, and the EU falls further behind competing jurisdictions. The window to act is now.

In vitro diagnostics (IVDs) deserve equal attention in this process. IVDs play a critical role in health systems: they inform diagnosis, guide treatment decisions and underpin public health surveillance. Given that the rules for in vitro diagnostics are being proposed for revision in the same proposal as for medical devices, it is imperative that the co-legislators do not lose focus on the amendments to the In Vitro Diagnostics Regulation which will determine how Europe will ensure access to key diagnostic technologies for decades to come.

MedTech Europe's assessment is structured around three tiers:

WELCOME the core direction on simplification and international cooperation: measures that, if preserved and reinforced, will make a tangible difference for patients and industry alike.

STRENGTHEN several provisions where the proposal's ambition risks being undermined by implementation gaps: including making innovation pathways more fit-for-purpose, ensuring timely inclusion of AI requirements, and avoiding unintended red tape for IVD performance studies.

RETHINK the approach to reprocessing of single-use devices, where the proposed "reusable by default" presumption adds unclear administrative burden and departs from established safety principles.

WELCOME:
what the proposal gets right

Simplification

Nearly nine years of MDR and IVDR implementation have exposed structural shortcomings, but have also given regulators the practical experience to understand how the system can work more efficiently without compromising safety. Key measures MedTech Europe strongly supports:

- **Open-validity certificates with periodic risk-based reviews**: removing fixed five-year recertification cycles eliminates an artificial bottleneck while maintaining ongoing oversight proportionate to the device's risk profile.
- **Streamlined change control**: clearer distinction between product changes manufacturers can implement without prior notification and those requiring approval.
- **Risk-based sampling in conformity assessment**: proportionate scrutiny for lower and medium-risk devices removes duplicative procedural steps.
- **Broader recognition of clinical evidence**: explicit recognition of well-established technologies, and acceptance of non-clinical evidence including modelling and simulation.
- **Proportionate treatment of near-patient IVD tests**: aligning the regulatory pathway for near-patient tests with other professional-use diagnostics.
- **Digitalisation**: electronic submission of technical files, digital EU declarations of conformity, digital labelling and digital provision of information to healthcare professionals and patients.

Simplified and more targeted rules allow all actors in the system to focus attention where it matters most: where there is risk. Reducing administrative 'noise' makes it easier to identify genuine safety signals sooner. Oversight is ensured through ongoing surveillance, annual audits and pre-approval of substantial changes by notified bodies, and strengthened coordination of market surveillance authorities.

A modernised, streamlined regulatory system is the condition for safety and ensuring that safe and effective products reach patients in a timely way.

International cooperation

The proposed International Cooperation chapter is a *critical and timely addition* to the EU's regulatory framework for medical devices, advancing EU regulatory, strategic, and competitiveness interests. Medical technologies are developed, manufactured and used on a global scale. Stronger regulatory cooperation reinforces the international reliance on the CE mark, helping EU-based companies, particularly SMEs, access new markets. It also reduces duplication, lowers costs and accelerates patient access without compromising safety. The Medical Devices Single Audit Programme (MDSAP) allows a single quality management system audit to satisfy the requirements of multiple jurisdictions. Full EU membership in MDSAP, and the use of MDSAP certificates for CE marking purposes, is essential to capture the full benefits of reliance and increase the attractiveness of the EU market.

STRENGTHEN:
targeted improvements needed

The Commission's proposal rightly addresses many structural challenges. In several areas, however, the legislative text does not yet fully deliver on the proposal's own stated ambition. MedTech Europe proposes targeted improvements to ensure it delivers in practice what it promises on paper.

Innovation: breakthrough and orphan pathways

The proposed breakthrough and orphan device pathways need refinement in two areas to realise their full potential:

- **Paediatric inclusion**: paediatric devices should be explicitly included in the scope of Article 52a MDR, ensuring that all children benefit from adapted assessment pathways.
- **Align IVD Orphan devices with rare diseases**: the proposed IVDR threshold of 1 in 12,000 individuals per year risks excluding diagnostics for rare conditions. Aligning the definition with the established European threshold for rare diseases (5 in 10,000) also would bring needed coherence with the orphan medicinal products framework.

Cybersecurity reporting

Two distinct cybersecurity scenarios require different regulatory responses: patient safety incidents should follow established vigilance reporting channels, while vulnerability disclosures must allow manufacturers time to develop patches before disclosure.

AI inclusion

Inclusion of AI requirements into a single MDR/IVDR conformity assessment process is the right approach. To bring legal clarity, a time-bound process to reflect AI Act requirements should be included in the legislation.

Blood draws in performance studies

Routine blood draws and finger-pricks are safe, well-established procedures. Yet under the current framework, they are treated as having the same risk as biopsies or spinal taps. MedTech Europe proposes amending Article 58(1) IVDR to clarify that full authorisation requirements are triggered only where the invasive procedure poses a major clinical risk to subjects.

Health institutions

Where a CE-marked device is available for the same purpose as a lab-developed test or other device, the CE-marked device should be used as the standard.

RETHINK:
reprocessing of single-use devices

The Commission's proposal shifts the regulatory default: devices will be presumed reusable unless manufacturers justify a single-use designation. This is a departure from the current MDR framework and from every other major jurisdiction.

MedTech Europe's position:

- Single-use devices are specifically engineered for single use, and that design choice is integral to their safety profile.
- The proposal should be rebalanced to remove the burden on manufacturers to justify that devices which are single-use only cannot be reused. Instead, indication should be based on risk management and risks from re-using the device.
- Where single-use devices are refurbished, MedTech Europe supports clear assignment of full manufacturer responsibilities to the refurbisher.

Conclusion

The Commission's proposal provides a solid basis for reform. With targeted refinements on predictability, proportionality and support for innovation, the EU can build a regulatory framework that gets safe technologies to patients faster, strengthens health systems and restores Europe's position as the destination of choice for medical technology development.

A simpler, more predictable system is not a shortcut on safety. It is the condition for safety, for patient access, and for Europe's long-term competitiveness.

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 that research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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What is medical technology?

Medical technologies are products, services or solutions used to save and improve people's lives.
In their many forms, they are with you from prevention to diagnosis and cure. There are three main categories of medical technologies:

Medical devices (MDs)
are products, services or solutions that prevent, diagnose, monitor, treat and care for people.

In vitro diagnostics (IVDs)
are non-invasive tests used on biological samples (for example, blood, urine or tissues) to determine the status of a person's health.

Digital health
are tools and services that use information and communication technologies (ICTs) to improve prevention, diagnosis, treatment, monitoring and management of a person's health and lifestyle.

A Introduction: A system at a crossroads

Europe's regulatory framework for medical technologies is at a decisive moment. **MedTech Europe fully supports the European Commission's objective to streamline the EU regulatory system for medical devices and *in vitro* diagnostics — and urges Parliament and Council to deliver on an improved system swiftly.**

The MDR and IVDR were designed to raise the bar for patient protection and strengthen trust in medical technologies. Yet nearly a decade into implementation, the very goals these regulations were meant to achieve are being undermined by structural shortcomings: slow and unpredictable conformity assessment timelines, disproportionate and costly administrative burdens, and inconsistent interpretation across Member States.

The Commission's proposal addresses many of these challenges head-on. MedTech Europe's assessment is clear:

- We strongly WELCOME the core direction on simplification and international cooperation - measures that, if preserved and reinforced, will make a tangible difference for patients and industry alike.
- We call for targeted STRENGTHENING of several provisions where the proposal's ambition risks being undermined by implementation gaps — including making the innovation pathways more fit-for-purpose, ensuring AI Act requirements are reflected in a time-bound manner, and avoiding unintended red tape for IVD performance studies.
- We urge a fundamental RETHINK of the approach to reprocessing of single-use devices, where the proposed "reusable by default" presumption adds unclear administrative burden for most single-use devices and departs from established safety principles.

The cost of delay is concrete and cumulative. Every month without simplification is a month in which manufacturers continue to redirect investment away from Europe, patients face avoidable disruptions to the technologies they depend on, and the EU falls further behind competing jurisdictions as a destination for regulatory approvals. These are not hypothetical risks - they are already happening, and they accelerate the longer the process takes. The window to act is now – and this process should not take years.

In vitro diagnostics deserve equal attention in this process. IVDs play a critical role in health systems: they inform diagnosis, guide treatment decisions and underpin public health surveillance. Because the Commission's proposal revises MDR and IVDR in a single legislative package, there is a real risk that IVD-specific amendments receive less scrutiny. Parliament and Council must ensure that the rules shaping Europe's access to diagnostic technologies for decades to come are given the focus they require.

Parliament and Council now have both the opportunity, and the obligation, to steer the system swiftly back on track. The Commission's proposal provides a solid basis. Much of it deserves strong support; some elements need targeted safeguards.

A.1 Why the revision is important for patient access and safety

A.1.1 A simplified regulatory system to deliver medtech for patients

Today's regulatory system is not delivering for patients as it should. A truly effective MDR/IVDR framework protects availability of safe, high-quality medical technologies, which range from essential consumables and laboratory-based tests used daily in hospitals to complex and innovative devices enabling breakthrough treatments in areas of unmet medical needs.

The system's current shortcomings have real consequences:

- 1 in 2 clinicians has experienced issues with the availability of medical devices since the introduction of the MDR (BioMedical Alliance Survey, Jan 2023; EC data)
- 1 in 2 hospital pharmacists reports that medical device shortages constitute a problem in delivering the best care to patients (EAHP 2025 Shortages Report)
- Companies are relocating performance studies to the US to avoid EU delays, directly limiting European patient access to innovative diagnostics (MTE Admin Burden Report, p.9)

When medical technology innovations that are available in other regions are not available in Europe, patients will pay the highest price. Delayed access to the latest state-of-the-art prevention, screening, treatment, and care undermines the EU's ability to respond to emerging health challenges, from antimicrobial resistance to non-communicable diseases.

For the regulatory system to deliver products swiftly to the patients it serves, that system needs to be efficient, lean, predictable – and equally suitable to regulate products in regular clinical use as well as the most innovative breakthrough technologies. That is why a revision proposal which delivers regulatory simplification is needed urgently.

A.1.2 A simplified regulatory system which delivers on patient safety

MedTech Europe supports a high bar for patient safety. Under the European Commission's simplification proposal, the requirements for safety and performance remain unchanged. What changes is the removal of duplicative and redundant procedures and the adoption of a more risk-based approach. Ongoing surveillance, annual audits and pre-approval of substantial changes are maintained. Open-validity certificates with periodic checks replace burdensome five-year re-certification cycles. Sampling and unannounced audits become more risk-proportionate.

The proposal also reinforces the tools available to regulators, with proposed checks and balances:

- Notified Bodies remain empowered to carry out surveillance assessment, including annual surveillance, periodic checks and unannounced audits, whilst gaining additional flexibility to apply some measures proportionately to risk. When needed, they retain the authority to withdraw certificates or require a new conformity assessment.

- New strategic and operational coordination processes, allowing for a strengthened and more coherent EU and national oversight by market surveillance authorities.
- The European Commission gains the ability to adapt oversight requirements for Notified Bodies through delegated and implementing acts, ensuring the system can respond to emerging risks and implementation experience.

Simplified and more targeted rules allow all actors in the system to focus attention where it matters most: where there is risk. Reducing administrative 'noise' makes it easier to identify genuine safety signals sooner. Devices are scrutinized more closely when there is a real concern, not when a calendar deadline triggers a redundant review.

A modernised, streamlined regulatory system is not a shortcut on patient safety. It is the condition for safety and ensuring that safe and effective products reach patients in a timely way. Proportionate, science-based requirements protect patients better than administrative duplication.

A.2 Why is it important for EU competitiveness

The EU is the world's second-largest medtech market, home to over 37,000 medical technology companies — 90% of them SMEs. Yet Europe's competitiveness is under growing strain. Approximately 60% of manufacturers cite administrative burden and costs of regulatory approval as the most important barrier to bringing innovative devices to the EU market. More than 70% have had to allocate additional resources to regulatory compliance under MDR/IVDR. One in three manufacturers is now deprioritising the EU for first regulatory approvals.

For SMEs, the impact is existential: many cannot commercialise outside the EU and are instead discontinuing individual products, entire product lines, or closing entirely. Many of the discontinued products are orphan devices serving patients with no alternative.

Regulatory efficiency and innovation-friendly pathways are what attract investment, retain talent and keep Europe competitive for first launches globally.

B WELCOME – what we strongly support

MedTech Europe welcomes and supports parts of the European Commission's proposal as a solid basis for meaningful reform of the EU regulatory framework for medical devices and *in vitro* diagnostics.

Several core measures directly address the structural shortcomings that have undermined patient access, innovation capacity and Europe's competitive position as a destination for medtech investment and first launches.

The following elements represent significant and welcome advances. MedTech Europe calls on Parliament and Council to preserve and, in some cases, reinforce them during the legislative process.

We particularly welcome:

B.1 Simplification

B.1.1 Overview

Nearly nine years of implementation of the MDR and IVDR have exposed structural shortcomings, but have also given regulators the practical experience to understand how the system can work more efficiently without compromising safety. The Commission's proposal translates that experience into concrete measures that MedTech Europe strongly supports. It is important to note that even once all the simplification measures are in place, Europe will still have a stringent pre- and post-market regulatory system which is comparable with other major world jurisdictions.

Key simplification measures that will make a real difference include:

- **Open validity certificates with periodic risk-based reviews:** Replacing the fixed five-year recertification cycles with ongoing oversight through periodic checks proportionate to the device's risk profile eliminates an artificial bottleneck for well-controlled, stable products;
- **Streamlined change control**: clearer distinction between changes that manufacturers can implement without prior notification and those requiring approval makes it faster and simpler to act;
- **Risk-based sampling in conformity assessment:** proportionate scrutiny for lower and medium-risk devices removes duplicative procedural steps without reducing oversight where it matters;
- **Broader recognition of clinical evidence**: explicit recognition of well-established technologies, and acceptance of non-clinical evidence including modelling and simulation reflect the growing body of data sources on devices with long, safe track records;

- **Proportionate treatment of near-patient IVD tests**: aligning the regulatory pathway for near-patient tests with other professional-use diagnostics is appropriate, and simplifies access to these IVDs in Europe[1];
- **Digitalisation of the regulatory process***:* electronic submission of technical files, digital EU declarations of conformity, and digital provision of information to healthcare professionals will reduce administrative burden and improve system efficiency. Digital labelling will strengthen supply chain resilience and improve patient access to product information.

Taken together, these measures are critical toward a regulatory system that is leaner, more predictable, and better equipped to deliver timely patient access to safe, high-quality medical technologies.

Some targeted amendments are proposed to "help deliver the proposal's own ambition", below.

MTE proposed amendments

The following amendments refine these simplification measures and should be read as reinforcing the Commission's approach.

MedTech Europe has identified a limited number of provisions in the proposed revision where the current drafting would create significant, avoidable burden for manufacturers without any corresponding benefit for patient safety or regulatory oversight. We are calling for targeted changes in these areas as essential to delivering on the simplification objectives of this revision:

Clarification for 'Well-established technologies' in MDR: these products are defined by not having been associated with safety issues in the past. Clarification that safety issues as per Art.87 MDR are meant will be helpful.

Amendments to Regulation (EU) 2017/745 (MDR) **Article 2 - Paragraph 72**	
Text proposed by the Commission	*Amendment*
well-established technology device' means a device that belongs to a generic device group, which fulfils the following criteria: (…) it has not been associated with safety issues in the past	well-established technology device' means a device that belongs to a generic device group, which fulfils the following criteria: (…)

[1] ***Near-patient testing as professional devices***

- Near patient tests are carried out by medical professionals at the bedside or the proximity of a patient (e.g. in a doctor's office) to deliver diagnostic results in minutes for rapid and effective clinical decision making and patient monitoring.
- These tests have a risk profile which is in every way equivalent to that of other diagnostic tests used by medical professionals.
- As such the Commission's proposal that near patient tests undergo the same regulatory process and pathways as other professional diagnostic tests is appropriate and simplifies access to these IVDs in the EU.

	it has not been associated with safety issues in the past ***as defined by article 87***
Justification	
'Safety issue' needs to be clearly defined now that it is part of the legislation, otherwise it could be interpreted very broadly, leading to ambiguity and discussions.	

New mandatory data validation role for notified bodies: MedTech Europe proposes that the original text is kept. The manufacturer is the data owner for UDI and device registration data and therefore best placed to confirm correctness, accuracy and completeness of this data. Introducing a mandatory data validation role for notified bodies goes beyond the scope of conformity assessment, is not foreseen in MDR/IVDR, shifts legal accountability and imposes a disproportionate administrative burden on notified bodies. Such shift in operational activities would create delays in device registration and market access, would lead to additional notified body fees.

Amendments to Regulation (EU) 2017/745
Art 29 Paragraph 3

Text proposed by the Commission	*Amendment*
3. For devices that are the subject of a conformity assessment as referred to in Article 52(3) and in Article 52(4), second and third subparagraphs, the notified body shall confirm in Eudamed that the information referred to in Part B of Annex VI is correct.	3. For devices that are the subject of a conformity assessment as referred to in Article 52(3) and in Article 52(4), second and third subparagraphs, the notified body shall confirm in Eudamed that the information referred to in Part B ***point 2*** of Annex VI is correct.

Justification

The manufacturer is the data owner for UDI and device registration data and therefore best placed to confirm correctness, accuracy and completeness. Introducing a mandatory data validation role for notified bodies beyond the scope of conformity assessment which is not foreseen in MDR/IVDR, shifts legal accountability and imposes a disproportionate administrative burden on notified bodies. Such shift in operational activities would create delays in device registration and market access, would lead to additional notified body fees.

Propose reverting it back to current MDR and IVDR approach where the notified body confirms only the certificate reference as is part of device registration information submitted by manufacturers.

Amendments to Regulation (EU) 2017/746
Article 26 Paragraph 2

Text proposed by the Commission	*Amendment*
2. For devices that are the subject of a conformity assessment as referred to in Article 48(3) and (4), Article 48(7), second subparagraph, Article 48(8), and Article 48(9), second subparagraph, the notified body shall confirm in Eudamed that the information referred to in Part B of Annex VI is correct.	2. For devices that are the subject of a conformity assessment as referred to in Article 48(3) and (4), Article 48(7), second subparagraph, Article 48(8), and Article 48(9), second subparagraph, the notified body shall confirm in Eudamed that the information referred to in Part B ***point 2*** of Annex VI is correct.

Justification

The manufacturer is the data owner for UDI and device registration data and therefore best placed to confirm correctness, accuracy and completeness. Introducing a mandatory data validation role for notified bodies beyond the scope of conformity assessment which is not foreseen in MDR/IVDR, shifts legal accountability and imposes a disproportionate administrative burden on notified bodies. Such shift in operational activities would create delays in device registration and market access, would lead to additional notified body fees.

Propose reverting it back to current MDR and IVDR approach where the notified body confirms only the certificate reference as is part of device registration information submitted by manufacturers.

The European Commission proposes that **clinical or performance evaluation** and other relevant documents, be updated with certain post-market findings when these are 'relevant for confirmation of safety & performance'. MedTech Europe considers that such wording could be highly subject to interpretation and proposes alternative wording already used in the regulations, referring to 'significant change in the benefit-risk determination'. [MDR Art 61(11); IVDR Art 56(6)]

Amendments to Regulation (EU) 2017/745 (MDR) **Article 61 - Paragraph 11**	
Text proposed by the Commission	*Amendment*
The clinical evaluation, its documentation and, where applicable and needed, the summary of safety and performance referred to in Article 32 shall be updated throughout the life cycle of the device concerned with data and findings obtained from the implementation of the manufacturer's PMCF plan in accordance with Part B of Annex XIV and the post-market surveillance plan referred to in Article 84,'whenever those data and findings obtained from PMCF ***provide information relevant for the confirmation of safety and performance of the device.***	The clinical evaluation, its documentation and, where applicable and needed, the summary of safety and performance referred to in Article 32 shall be updated throughout the life cycle of the device concerned with data and findings obtained from the implementation of the manufacturer's PMCF plan in accordance with Part B of Annex XIV and the post-market surveillance plan referred to in Article 84**,**'whenever those data and findings obtained from PMCF ***demonstrate that there is a significant change in the benefit-risk determination.***
Justification	
The current text 'relevant information' creates ambiguity and would be subject to interpretation and discussion with Notified Bodies. The change is proposed to make the text clearer and more consistent by aligning with wording from article Art 86 (ii) regarding 'significant change in benefit-risk determination'.	

Amendments to Regulation (EU) 2017/746 (IVDR) **Article 56 Paragraph 6**	
Text proposed by the Commission	*Amendment*
6. The performance evaluation, its documentation and, where applicable and needed, the summary of safety and performance referred to in Article 29 shall be updated throughout the life cycle of the device concerned with data and findings obtained from implementation of the manufacturer's PMPF plan in	6. The performance evaluation, its documentation and, where applicable and needed, the summary of safety and performance referred to in Article 29 shall be updated throughout the life cycle of the device concerned with data and findings obtained from implementation of the manufacturer's PMPF plan in

accordance with Part B of Annex XIII and the post-market surveillance plan referred to in Article 79, whenever those data and findings ***provide information relevant for the confirmation of safety and performance of the device.***	accordance with Part B of Annex XIII and the post-market surveillance plan referred to in Article 79, whenever those data and findings ***demonstrate that there is a significant change in the benefit-risk determination.***
Justification	
The current text 'relevant information' creates ambiguity and would be subject to interpretation and discussion with Notified Bodies. The change is proposed to make the text clearer and more consistent by aligning with wording from article Art 86 (ii) regarding 'significant change in benefit-risk determination'.	

No Investigator Brochure for post-market studies on CE-marked devices. The device is already on the market, its safety profile is established. Requiring PMCF sponsors to compile an IB duplicates existing documentation and deters the very studies regulators want to see. MedTech Europe suggests removing the redundant Annex XV cross-reference in Article 74(1) to make this unambiguous. [MDR Art 74(1)]

Amendments to Regulation (EU) 2017/745 (MDR) **Article 74 - Paragraph 1**	
Text proposed by the Commission	*Amendment*
1. Where a clinical investigation is to be conducted to further assess, within the scope of its intended purpose and in accordance with its PMCF plan, a device which already bears the CE marking in accordance with Article 20(1), ('PMCF investigation'), and where the investigation would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome, the sponsor shall notify the Member States concerned at least 30 days prior to its commencement by means of the electronic system referred to in Article 73.The sponsor shall include the documentation referred to in Chapter II, Sections 1, 3 and 4, of Annex XV as part of the notification. Points (b) to (k) ***and (m)*** of Article 62(4), Articles 75 (1), 76 and 77, and Article 80(5) and (6), and the relevant provisions of Annex XV shall apply to PMCF investigations involving additional invasive or burdensome procedures.	1. Where a clinical investigation is to be conducted to further assess, within the scope of its intended purpose and in accordance with its PMCF plan, a device which already bears the CE marking in accordance with Article 20(1), ('PMCF investigation'), and where the investigation would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome, the sponsor shall notify the Member States concerned at least 30 days prior to its commencement by means of the electronic system referred to in Article 73.The sponsor shall include the documentation referred to in Chapter II**,** Sections 1, 3 and 4, of Annex XV as part of the notification. Points (b) to (k) of Article 62(4), Articles 75 (1), 76 and 77, and Article 80(5) and (6), and the relevant provisions of Annex XV shall apply to PMCF investigations involving additional invasive or burdensome procedures.
Justification	
Referring to the same clauses in different ways leads to confusion and possible diverging interpretations at the level of implementation. Article 62(4) point (m) refers to Annex XV. However, the proposed Article 74 paragraph 1 already refers to the relevant provisions of Annex XV. It is a practical simplification to only refer to Annex XV once, clearly and concisely as proposed.	

Combined device-drug trials: The European Commission's proposal improves coherence between the IVDR or MDR and the Medicinal Products legislation. To further improve coherence, the concept of 'urgent safety measures' should be included in the case of trials which combine devices (either medical devices or IVDs) and drugs. This concept already exists in the Clinical Trials Regulation but not yet in the MDR and IVDR which creates problems for combined studies. A new article in each regulation therefore is proposed to close this gap. [MDR Art. 75(5); IVDR Art 71]

Amendments to Regulation (EU) 2017/745 (MDR) **Article 75 paragraph 5 (new)**	
Text proposed by the Commission	*Amendment*
	5. Where an urgent modification of a combined study is necessary, the sponsor and the investigator shall take urgent safety measures to protect subjects as defined in Regulation EU no.536/2014 without awaiting prior authorisation. ***The sponsor shall notify the Member States concerned, through the electronic system referred to in Article 73, of the event and the measures taken, without undue delay but no later than seven days from the date the measures have been taken. If such measures constitute a temporary halt of the combined study, the sponsor should apply for a substantial modification before restarting the study.***
Justification	
The concept of Urgent safety measures currently exists in the Clinical Trials Regulation but not in the MDR which creates problems for combined studies. This addition to Article 75 aims at giving the sponsor (and investigator) of a combined study the tool to rapidly protect subjects (patients enrolled in the study). This will also align practice with CTR provisions which state that "Where unexpected events require an urgent modification of a clinical trial, it should be possible for the sponsor and the investigator to take urgent safety measures without awaiting prior authorisation''. Further, the sponsor shall notify the Member States concerned, through the EU portal, of the event and the measures taken. That notification shall be made without undue delay but no later than seven days from the date the measures have been taken.	

Amendments to Regulation (EU) 2017/746 (IVDR) **Article 71**	
Text proposed by the Commission	*Amendment*
	5. Where an urgent modification of a combined study is necessary, the sponsor and the investigator shall take urgent safety measures to protect subjects as defined in Regulation EU no.536/2014 without awaiting prior authorisation. ***The sponsor shall notify the Member States concerned, through the electronic system referred to in Article 69, of the event and the measures taken, without undue delay but no later than seven days from the date the measures***

	have been taken. If such measures constitute a temporary halt of the combined study, the sponsor should apply for a substantial modification before restarting the study.
Justification	
The concept of Urgent safety measures currently exists in the Clinical Trials Regulation but not in the IVDR which creates problems for combined studies. This addition to Article 71 aims at giving the sponsor (and investigator) of a combined study the tool to rapidly protect subjects (patients enrolled in the study). This will also align practice with CTR provisions which state that "Where unexpected events require an urgent modification of a clinical trial, it should be possible for the sponsor and the investigator to take urgent safety measures without awaiting prior authorisation''. Further, the sponsor shall notify the Member States concerned, through the EU portal, of the event and the measures taken. That notification shall be made without undue delay but no later than seven days from the date the measures have been taken.	

Labelling for active ingredients in IVDR: The European Commission's proposal changes 'active ingredient(s)' to 'critical ingredient(s)'. This change should be reversed, to keep the original text. While the change might aim to improve clarity for users, it raises questions for the industry around what this change means in practice and the clear benefit for users is in making this change. The term 'active ingredient' is already well understood and consistently applied in existing technical documentation, including risk assessments. [IVDR Annex I Ch.III 20.4.1]

Amendments to Regulation (EU) 2017/746 (IVDR) **Annex I Chapter III**	
Text proposed by the Commission	*Amendment*
20.4.1. The instructions for use shall contain all of the following particulars: <…> (h) a description of the reagents and any limitation upon their use (e.g. suitable for a dedicated instrument only) and the composition of the reagent product by nature and amount or concentration of the ***critical*** ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;	20.4.1. The instructions for use shall contain all of the following particulars: <…> (h) a description of the reagents and any limitation upon their use (e.g. suitable for a dedicated instrument only) and the composition of the reagent product by nature and amount or concentration of the ***active*** ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;
Justification	
The European Commission's proposal changes 'active ingredient(s)' to 'critical ingredient(s)'. While the change might aim to improve clarity for users, it raises questions for the industry around what this change means in practice and the clear benefit for users is in making this change. There currently is no clear definition of 'critical ingredient' in the IVDR. New terminology may create potential misalignment with existing IVDR terminology, such as "critical reagents" referenced in Annex II, leading to confusion regarding scope and intent. Users may misinterpret the term "critical", assuming a specific safety or risk significance, even where the ingredient is simply an active component necessary for device performance. The term *active ingredient* is already well understood and consistently applied in existing technical documentation, including risk assessments. From an	

implementation perspective, the proposed change will require significant updates to manufacturer procedures, labelling, and instructions for use, without a clear demonstration of added value for users or patient safety.

Software classification: The proposed revision of MDR Rule 11 is a necessary step toward a more proportionate, risk-based framework, aimed at avoiding unnecessary up-classification of low-risk software The current rule has led to frequent up-classification without sufficient differentiation in clinical impact. In its revision proposal, the European Commission has amended the classification rule for medical devices software to provide wider possibility for software to be regulated in different risk classes – including Class I when the actual patient risk is low. The language used in the European Commission's proposal remains unclear and open to interpretation. Therefore, MedTech Europe proposes an amendment which aligns with international classification rules and should ensure a coherent risk-based approach to classification, including expanding Class I for low-risk software. [MDR Annex VIII – Section 6.3].

Amendments to Regulation (EU) 2017/745

Annex VIII – Section 6.3

Text proposed by the Commission	*Amendment*
'6.3 Rule 11	'6.3 Rule 11
(g) Software which is intended ***to generate an output that confers a clinical benefit*** and ***is used*** for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation or alleviation of a disease or condition is classified as class I, unless ***the*** output is intended ***for a disease or condition***:	(g) Software which is intended ***for a medical purpose*** and ***generates an output that is used*** for diagnosis, treatment, prevention, monitoring, prediction, prognosis, compensation or alleviation of a disease or condition is classified as class I, unless *its* output is intended ***to address a disease or condition in one of the following situations***:
– ***in a critical situation with a risk of causing death or an irreversible deterioration of a person's state of health, in which case it is classified as*** class III;	***- to treat or diagnose in a critical situation, in which case it is*** class III;
– ***in a serious situation with a risk of causing a serious deterioration of a person's state of health or a surgical intervention, or to drive clinical management in a critical situation in which cases it is classified as*** class IIb;	***- to treat or diagnose in a serious situation, or to drive clinical management in a critical situation, in which cases it is*** class IIb;
– ***in a non-serious situation, or to drive clinical management in a serious situation or to inform clinical management in a critical or serious situation in which cases it is classified*** as class IIa.';	***- to treat or diagnose in a non-serious situation, to drive clinical management in a serious situation or to inform clinical management in a critical situation in which cases it is classified*** as class IIa.';

Justification

In its revision proposal, the European Commission has amended the classification rule for medical devices software to provide wider possibility for software to be regulated in different risk classes – including Class I when the actual patient risk is low. MedTech Europe strongly supports legislative correction allowing for more proportionate risk classification. The language used in the European Commission's proposal remains unclear and open to interpretation.The amendment aligns the proposal with international classification rules

(International Medical Devices Regulators Forum), ensuring a coherent risk-based approach to classification, including expanding Class I for low-risk software. Software accessories are clarified as falling outside the scope of this rule (classification of all accessories is based on their intended purpose). It is understood that EU guidelines will be needed to interpret or define what are critical, serious and non-serious situations in the context of this rule.

Limit pre-approval to changes with potential adverse impact: Change control could be further improved by clarifying that changes with an adverse impact on safety and performance require pre-approval by Notified Bodies. Changes with positive impact on safety and performance (i.e. which do not negatively affect the benefit-risk ratio of the device) could be implemented, with review by the Notified Body during annual surveillance assessment. The principle that pre-approval only is needed where there is adverse impact, already is embedded since years in EU guidance on changes being made to products which are transitioning to either the Medical Devices or IVD Regulations. Examples of changes with positive impact include e.g. increase in self-life of reagent or consumable following collection of post-market data which confirms shelf life, extension of temperature or humidity range limitations for operation or storage, change/modification of a connector to reduce misconnection and thereby improve safety of use, etc. Changes which could have a negative impact on safety & performance must be pre-approved before they can be implemented. This provides for faster implementation of changes which takes a risk-based approach.[MDR Annex IX 4.10; IVDR Annex IX 4.11]

Amendments to Regulation (EU) 2017/745 (MDR) **Annex IX section 4.10**	
Text proposed by the Commission	*Amendment*
Changes to the approved device shall require approval from the notified body which issued the EU technical documentation assessment certificate where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device. Where the manufacturer plans to introduce any of the abovementioned changes it shall inform the notified body which issued the EU technical documentation assessment certificate thereof. The notified body shall assess the ***planned*** changes and decide whether the ***planned*** changes require a new conformity assessment in accordance with Article 52 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall ***assess*** the changes, notify the manufacturer of its decision and, where the changes are approved, provide it with a supplement to the EU technical documentation assessment certificate.	Changes to the approved device shall require approval from the notified body which issued the EU technical documentation assessment certificate where such changes could ***adversely*** affect the safety and performance of the device or the conditions prescribed for use of the device. Where the manufacturer plans to introduce ***or has introduced*** any of the abovementioned ***substantial*** changes it shall inform the notified body which issued the EU technical documentation assessment certificate thereof. The notified body shall assess the ***substantial*** changes and decide whether the changes require a new conformity assessment in accordance with Article 52 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall ***determine if*** the changes ***shall be assessed prior to or after implementation***, notify the manufacturer of its decision and, where the changes are approved, provide it with a supplement to the EU technical documentation assessment certificate.

Justification
The proposed amendment clarifies that notified body approval should be required only for substantial changes that may adversely affect the safety and performance of the device or the conditions of use. This reflects the fundamental risk-based regulatory logic of the MDR and IVDR, ensuring that notified body scrutiny focuses on changes that could introduce new or increased risks. The approach is fully consistent with the interpretation already applied in guidance issued by the Medical Device Coordination Group, notably MDCG 2020-3 and MDCG 2022-6, which direct oversight towards changes that negatively affect safety, performance, or intended use. This provides greater legal certainty and harmonised interpretation across Member States while maintaining a high level of patient protection. In addition, limiting mandatory pre-approval to changes that may adversely affect safety or performance ensures that notified body expertise is concentrated on safety-critical issues, without delaying improvements that maintain or enhance safety, quality or cybersecurity. All changes remain fully controlled within the manufacturer's QMS and technical documentation, and manufacturers remain legally responsible for ensuring continued compliance and safety throughout the device lifecycle. The clarification therefore maintains oversight while making the system more proportionate, predictable, and operationally effective. The addition of the wording "or has introduced" further ensures that urgent safety-relevant updates, such as critical cybersecurity patches, can be implemented without delay while remaining subject to notified body review.

Amendments to Regulation (EU) 2017/746 (IVDR) **Annex IX section 4.11**	
Text proposed by the Commission	*Amendment*
Changes to the approved device shall require approval from the notified body which issued the EU technical documentation assessment certificate where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device. Where the manufacturer plans to introduce any of the abovementioned changes it shall inform the notified body which issued the EU technical documentation assessment certificate thereof.	Changes to the approved device shall require approval from the notified body which issued the EU technical documentation assessment certificate where such changes could ***adversely*** affect the safety and performance of the device or the conditions prescribed for use of the device. Where the manufacturer plans to introduce ***or has introduced*** any of the abovementioned ***substantial*** changes it shall inform the notified body which issued the EU technical documentation assessment certificate thereof.
The notified body shall assess the ***planned*** changes and decide whether the ***planned*** changes require a new conformity assessment in accordance with Article 48 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall ***assess*** the changes, notify the manufacturer of its decision and, where the changes are approved, provide it with a supplement to the EU technical documentation assessment certificate.	The notified body shall assess the ***substantial*** changes and decide whether the changes require a new conformity assessment in accordance with Article 48 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall ***determine if*** the changes ***shall be assessed prior to or after implementation***, notify the manufacturer of its decision and, where the changes are approved, provide it with a supplement to the EU technical documentation assessment certificate
Justification	

The proposed amendment clarifies that notified body approval should be required only for substantial changes that may adversely affect the safety and performance of the device or the conditions of use. This reflects the fundamental risk-based regulatory logic of the MDR and IVDR, ensuring that notified body scrutiny focuses on changes that could introduce new or increased risks. The approach is fully consistent with the interpretation already applied in guidance issued by the Medical Device Coordination Group, notably MDCG 2020-3 and MDCG 2022-6, which direct oversight towards changes that negatively affect safety, performance, or intended use. This provides greater legal certainty and harmonised interpretation across Member States while maintaining a high level of patient protection. In addition, limiting mandatory pre-approval to changes that may adversely affect safety or performance ensures that notified body expertise is concentrated on safety-critical issues, without delaying improvements that maintain or enhance safety, quality or cybersecurity. All changes remain fully controlled within the manufacturer's QMS and technical documentation, and manufacturers remain legally responsible for ensuring continued compliance and safety throughout the device lifecycle. The clarification therefore does not reduce oversight or safety requirements, but rather makes the system more proportionate, predictable, and operationally effective. The addition of the wording "or has introduced" further ensures that urgent safety-relevant updates, such as critical cybersecurity patches, can be implemented without delay while remaining subject to notified body review.

Listing of manufacturing sites on certificates: A new requirement to add information on manufacturing sites offers limited added value, introduces complexity and conflicts with the principle of protecting commercially sensitive information. It therefore should be removed. Information on manufacturing sites already is available through other existing documentation (e.g., ISO 13485). When needed, Notified Bodies and regulators also can request the information from manufacturers. [MDR Annex XII Ch I 4(b); IVDR Annex XII Ch I 4(b)]

Amendments to Regulation (EU) 2017/745 (MDR) **Annex XII, Chapter I, point 4(b)**	
Text proposed by the Commission	*Amendment*
EU quality management system certificates and EU quality assurance certificates shall include the identification of the devices or groups of devices, the risk classification ***and the manufacturing site(s) covered.***	EU quality management system certificates and EU quality assurance certificates shall include the identification of the devices or groups of devices, ***and*** the risk classification~~.~~
Justification	
The introduction of a new requirement to add information on manufacturing sites to Notified Body certificates offers limited added value, introduces complexity and conflicts with the principle of protecting commercially sensitive information. The list of manufacturing sites can change and when this happens it is a laborious process to update the Notified Body certificate and can lead to significant paperwork for international registrations based on that certificate – making it more difficult for European companies to export worldwide. Listing manufacturing sites also can expose commercially sensitive information, in particular arrangements related to virtual manufacturing. Information on manufacturing sites already is available through other existing documentation (e.g., ISO 13485). When needed, Notified Bodies and regulators also can request the information from manufacturers. It is recommended to remove this requirement, as the information is already available for regulators and auditors in an appropriate way.	

Amendments to Regulation (EU) 2017/746 (IVDR) **Annex XII, Chapter I, point 4(b)**	
Text proposed by the Commission	*Amendment*
EU quality management system certificates and EU production quality assurance certificates shall include the identification of the devices or groups of devices, the risk classification***, and the manufacturing site(s) covered.***	EU quality management system certificates and EU production quality assurance certificates shall include the identification of the devices or groups of devices, ***and*** the risk classification.
Justification	
The introduction of a new requirement to add information on manufacturing sites to Notified Body certificates offers limited added value, introduces complexity and conflicts with the principle of protecting commercially sensitive information. The list of manufacturing sites can change and when this happens it is a laborious process to update the Notified Body certificate and can lead to significant paperwork for international registrations based on that certificate – making it more difficult for European companies to export worldwide. Listing manufacturing sites also can expose commercially sensitive information, in particular arrangements related to virtual manufacturing. Information on manufacturing sites already is available through other existing documentation (e.g., ISO 13485). When needed, Notified Bodies and regulators also can request the information from manufacturers. It is recommended to remove this requirement, as the information is already available for regulators and auditors in an appropriate way.	

B.2 International cooperation

The proposed International Cooperation chapter is a critical and timely addition to the EU's regulatory framework for medical devices serving important EU regulatory, strategic, and competitiveness interests.

Medical technologies are developed, manufactured and used on a global scale. Effective cooperation between regulatory systems of comparable stringency reduces duplication, lowers costs and accelerates patient access, without compromising safety standards.

Proven models already exist. The Medical Devices Single Audit Programme (MDSAP) allows a single quality management system audit to satisfy the requirements of multiple jurisdictions (US, Canada, Australia, Brazil, and Japan). By engaging with such frameworks and building on the collaborative approach advocated by the World Health Organisation and International Medical Devices Regulators Forum, the EU can increase the efficiency of its own system while reinforcing its role as a global regulatory reference.

The current MDR and IVDR lack mechanisms for structured international regulatory cooperation, **limiting the EU's ability to maintain its position as a preferred launch market** and **weakening availability of new medical technologies for its patients.**

Over the past decade, Europe's historic advantage has weakened: most manufacturers once launched new technologies here first, and **CE marking served as a 'passport' to access other markets**. This erosion stems from the scale and complexity of MDR/IVDR implementation. The

associated uncertainty has weakened confidence among non-EU regulators. As a result, several third countries have reduced (e.g. **Australia**) or removed (**Brazil**) their recognition of CE marking. Even the EU's most important trading partners in medical technology such as the **UK and Switzerland** are reconsidering their reliance pathways and the extent to which they will continue to rely on CE marking, while markets like the **US and Japan** are increasingly viewed as more stable and attractive regulatory partners.

Strengthening cooperation also enhances the international recognition of the CE mark, making it easier for EU-based companies, particularly SMEs, to access new markets. At the same time, it ensures that European patients benefit more rapidly from high-quality medical technologies developed outside the EU.

C STRENGTHEN — targeted improvements to deliver the proposal's ambition

The Commission's proposal rightly addresses many of the system's structural challenges. In several areas, however, the legislative text as drafted does not yet fully deliver on the proposal's own stated ambition. Without targeted safeguards, there is a risk that positive reforms are diluted through inconsistent implementation, regulatory overlap or insufficient operational detail.

MedTech Europe proposes a focused set of targeted improvements, amendments designed not to challenge the proposal's direction, but to ensure it delivers in practice what it promises on paper.

C.1 Innovation – Breakthrough and Orphan pathways

MedTech Europe welcomes the introduction of dedicated breakthrough and orphan device pathways in the proposed revision of the MDR and IVDR. Europe is the last major regulatory jurisdiction without such pathways. Without tailored pathways, such transformative innovations risk being delayed or denied to those in greatest need.

These regulatory tools address a long-standing challenge: technologies targeting small patient populations or representing significant advances often struggle to meet standard clinical evidence requirements due to low patient numbers.

By proposing the creation of **tailored regulatory pathways and sandboxes**, the Commission aligns the EU framework with approaches that have already proven their value in jurisdictions such as the US, Japan and others.

To realise the full potential of these pathways, MedTech Europe proposes targeted refinements:

- **Paediatric inclusion (MDR)**: not all paediatric devices will qualify as orphan or breakthrough. Paediatric devices should be explicitly included in the scope of Article 52a MDR, ensuring that all children, not only those with rare conditions, benefit from adapted assessment pathways.
- **Align orphan device threshold with rare diseases (IVDR):** the proposed threshold of 1 in 12,000 individuals per year risks excluding critical diagnostics such as tests for rare blood groups and rare tissue typing. Aligning the definition with the established European threshold for rare diseases (5 in 10,000) would ensure coherence with the orphan medicinal product framework which are accompanied by companion diagnostics, therapeutic drug monitoring tests and tests for rare genetic conditions.

MTE proposed amendments

Amendments to Regulation (EU) 2017/745 (MDR) **Article 52 a – Paragraph 1**	
Text proposed by the Commission	*Amendment*
1. For the conformity assessment of breakthrough devices and orphan devices, for which a notified body is involved in the conformity assessment, the procedures laid down in Article 52 shall apply subject to the specific arrangements set out in this Article.	1. For the conformity assessment of breakthrough devices**, paediatric** and orphan devices, for which a notified body is involved in the conformity assessment, the procedures laid down in Article 52 shall apply subject to the specific arrangements set out in this Article.
Justification	
Not all paediatric devices will fall into the category of orphan or breakthrough, therefore we suggest including also paediatric considerations here in paragraph 1 and all throughout the article 52a, to make sure all paediatric devices both are covered and their specificities can be supported.	

Amendments to Regulation (EU) 2017/746 (IVDR) **Article 48a – Paragraph 3**	
Text proposed by the Commission	*Amendment*
3. A device shall be considered an orphan device if it meets the following criteria: (a) the device is intended to provide information on a disease or condition that presents in not more than ***12 000*** individuals in the Union per year; (b) at least one of the following criteria is met: (i) there are insufficient available alternatives; (ii) the device is expected to provide a clinical benefit compared to available alternatives or the state of the art.	3. A device shall be considered an orphan device if it meets the following criteria: (a) the device is intended to provide information on a disease or condition that presents in not more than ***5 in 10 000*** individuals in the Union per year; (b) at least one of the following criteria is met: (i) there are insufficient ***CE marked*** available alternatives; (ii) the device is expected to provide a clinical benefit compared to available alternatives or the state of the art
Justification	
The current prevalence 1 in 12 000 risks that certain IVDR requirements (e.g. generation of sufficient performance data) cannot be met, which would exclude many necessary tests, like IVD tests for rare blood groups and rare tissue typing (which is key for successful transplantation and transfusion). Proposed prevalence of 5 in 10 000 is based on the definition of "rare diseases" and would align with the European definition of rare diseases and orphan medicinal products, bringing into scope rare blood groups, rare tissue typing and rare genetic conditions. Furthermore, the proposed definition of 'orphan device' lacks alignment with definition of 'orphan medicinal product' and disconnect for companion diagnostics, therapeutic drug monitoring tests or other complementary or combination diagnostics.	

C.2 Cybersecurity reporting

In the context of the continued development and increased deployment of connected and digital medical technologies, cybersecurity is increasingly critical for patient safety, public health, and system resilience. Software security has always been part of the regulatory scope, but inconsistent interpretation across language versions of the regulations left room for divergent application. It should be addressed in a coordinated and proportionate manner by all relevant stakeholders with clear allocation of responsibilities and legal consequences. The EC proposal usefully addresses this ambiguity. However, the way cybersecurity provisions are integrated into the regulatory framework requires careful differentiation.

A cybersecurity event affecting a medical device, may result in one or both of the following:

(a) a direct or indirect impact on patient safety, within the meaning of the MDR/IVDR vigilance framework, or

(b) the identification of a cybersecurity vulnerability that requires remediation, without necessarily resulting in patient harm.

These situations are fundamentally different in legal nature and in regulatory objective. Therefore, they demand distinct, clearly defined, regulatory responses.

MedTech Europe calls for clear, differentiated mechanisms to address each scenario:

- **Patient safety incidents** involving cybersecurity should follow established MDR/IVDR vigilance reporting channels, ensuring that safety events are captured and acted upon without delay. These remain governed by the MDR/IVDR vigilance framework and are reported to the competent authorities responsible for medical devices and in-vitro medical devices.
- **Cybersecurity vulnerabilities or incidents** that do not themselves give rise to patient harm should be addressed through dedicated cybersecurity risk management and remediation processes, without triggering medical-device vigilance obligations.

To achieve this, MedTech Europe proposes creating a structurally separate section on cybersecurity within Chapter VII of the MDR and IVDR.

In this context, the security risk assessment of medical devices should duly and explicitly account for cybersecurity threats and vulnerabilities and their potential impact on patients. Such assessments should remain within the remit of the competent authorities responsible for medical devices, acting within the MDR/IVDR framework and without prejudice to horizontal Union cybersecurity legislation.

Vigilance and cybersecurity reporting pursue different primary objectives, are governed by different legal frameworks, and are reported to different competent authorities. Terms such as “incident”, “severity” and “impact” under the MDR/IVDR carry legal meanings that differ from how they are used in the cybersecurity legislation. Embedding cybersecurity provisions within the vigilance structure risks generating legal uncertainty for manufacturers, competent authorities, and ultimately patients. MedTech Europe calls for these two domains to be structurally separated within the MDR/IVDR legal framework, e.g. by creating a distinct section on “Cybersecurity” within Chapter VII. Such a structural differentiation would enhance legal certainty for manufacturers and authorities, support timely vulnerability mitigation, and avoid

duplicative or misaligned reporting obligations across MDR/IVDR and horizontal cybersecurity legislation.

Examples for amendments on cybersecurity provisions

Actively exploited vulnerabilities that are not a vigilance incident within the context of the MDR or IVDR

Example 1:
A vulnerability identified within a device's logging functionality that does not impact its clinical performance.

Example 2:
An incident involving a cybersecurity breach where data is accessed, but no patient data is lost and clinical decision-making remains unaffected.

Example 3:
A temporary cybersecurity event causing loss of connectivity between an IVD device and the hospital network, without compromising device performance or clinical outcomes (e.g., the device continues to function correctly offline and the connectivity issue poses no risk to patients).

More examples are available upon request

MTE proposed amendments

Amendments to Regulation (EU) 2017/745 (MDR) Chapter VII Title	
Text proposed by the Commission	*Amendment*
POST-MARKET SURVEILLANCE, VIGILANCE AND MARKET SURVEILLANCE	*POST-MARKET SURVEILLANCE, VIGILANCE*, **CYBERSECURITY** *AND MARKET SURVEILLANCE*
Justification	
Vigilance and cybersecurity are distinct domains with different primary objectives. The proposed amendment structurally separates cybersecurity from vigilance within the legal framework by creating a distinct section within Chapter VII (e.g. adding a dedicated "Cybersecurity" section). Terms such as "incident" and "severity" have different meanings under the MDR and cybersecurity legislation, therefore a separate chapter would enhance clarity and preserve the integrity and focus of the different systems for vigilance and cybersecurity.	

Amendments to Regulation (EU) 2017/745 (MDR) Article 87a	
Text proposed by the Commission	*Amendment*

Article 87a ***Reporting of actively exploited vulnerabilities and severe incidents related to devices*** ***1. Without prejudice to the reporting obligations regarding serious incidents and field safety corrective actions set out in Article 87, the manufacturer of a device shall report to the computer security incident response teams ('CSIRTs'), designated as coordinators of the Member States where a device has been made available, and to the European Union Agency for Cybersecurity (ENISA), any of the following:*** ***(a) any actively exploited vulnerability as defined in Article 3, point (42), of Regulation (EU) 2024/2847 contained in the device;*** ***(b) any severe incident as referred in Article 14(5) of Regulation (EU) 2024/2847 having an impact on the security of the device.*** ***2. The manufacturer shall submit the report referred to in paragraph 1 through the electronic system referred to in Article 92 not later than 30 days after it becomes aware of the actively exploited vulnerability or the severe incident.*** ***3. The report referred to in paragraph 1, as well as any report submitted by a manufacturer in accordance with Article 87 that also qualifies as actively exploited vulnerability or severe incident, shall be made available simultaneously to the CSIRTs designated as coordinators of the Member States in which the device has been made available and to ENISA*** ***4. For the purposes of this Article, the CSIRTs designated as coordinators and the ENISA shall have access to Eudamed.***	***deleted***
Justification	
Vigilance and cybersecurity are distinct domains with different primary objectives. This amendment deletes the proposed article 87a from its location – it is moved to the new section on cybersecurity. The proposed amendment structurally separates cybersecurity from vigilance within the legal framework by creating a distinct section within Chapter VII (e.g. adding a dedicated "Cybersecurity" section). Terms such as "incident" and "severity" have different meanings under the MDR and cybersecurity legislation, therefore a separate chapter would enhance clarity and preserve the integrity and focus of the different systems for vigilance and cybersecurity.	

Amendments to Regulation (EU) 2017/745 (MDR) **Chapter VII Section 2a (new)** **Article 92a (new)**	
Text proposed by the Commission	*Amendment*
	SECTION 2a ***CYBERSECURITY*** ***Article 92a*** ***Reporting of actively exploited vulnerabilities and severe incidents related to devices*** ***1. Without prejudice to the reporting obligations regarding serious incidents and field safety corrective actions set out in Article 87, the manufacturer of a device shall report to the computer security incident response teams ('CSIRTs'), designated as coordinators of the Member States where a device has been made available, and to the European Union Agency for Cybersecurity (ENISA), any of the following:*** ***(a) any actively exploited vulnerability as defined in Article 3, point (42), of Regulation (EU) 2024/2847 contained in the device;*** ***(b) any severe incident as referred in Article 14(5) of Regulation (EU) 2024/2847 having an impact on the security of the device.*** ***2. The manufacturer shall submit the report referred to in paragraph 1 through the electronic system referred to in Article 92 not later than 30 days after it becomes aware of the actively exploited vulnerability or the severe incident.*** ***3. The report referred to in paragraph 1, as well as any report submitted by a manufacturer in accordance with Article 87 that also qualifies as actively exploited vulnerability or severe incident, shall be made available simultaneously to the CSIRTs designated as coordinators of the Member States in which the device has been made available and to ENISA*** ***4. For the purposes of this Article, the CSIRTs designated as coordinators and the ENISA shall have access to Eudamed.***
Justification	
Vigilance and cybersecurity are distinct domains with different primary objectives. This amendment reintroduces the text of article 87a in the new section of cybersecurity as article 92a unchanged.	

The proposed amendment structurally separates cybersecurity from vigilance within the legal framework by creating a distinct section within Chapter VII (e.g. adding a dedicated "Cybersecurity" section). Terms such as "incident" and "severity" have different meanings under the MDR and cybersecurity legislation, therefore a separate chapter would enhance clarity and preserve the integrity and focus of the different systems for vigilance and cybersecurity.

Amendments to Regulation (EU) 2017/746 (IVDR) **Chapter VII Title**	
Text proposed by the Commission	*Amendment*
POST-MARKET SURVEILLANCE, VIGILANCE AND MARKET SURVEILLANCE	*POST-MARKET SURVEILLANCE, VIGILANCE*, **CYBERSECURITY** *AND MARKET SURVEILLANCE*
Justification	
Vigilance and cybersecurity are distinct domains with different primary objectives. The proposed amendment structurally separates cybersecurity from vigilance within the legal framework by creating a distinct section within Chapter VII (e.g. adding a dedicated "Cybersecurity" section). Terms such as "incident" and "severity" have different meanings under the MDR and cybersecurity legislation, therefore a separate chapter would enhance clarity and preserve the integrity and focus of the different systems for vigilance and cybersecurity.	

Amendments to Regulation (EU) 2017/746 (IVDR) **Article 82a**	
Text proposed by the Commission	*Amendment*
Article 82a ***Reporting of actively exploited vulnerabilities and severe incidents related to devices*** ***1. Without prejudice to the reporting obligations regarding serious incidents and field safety corrective actions set out in Article 82, the manufacturer of a device shall report to the computer security incident response teams ('CSIRTs'), designated as coordinators of the Member States where a device has been made available, and to the European Union Agency for Cybersecurity (ENISA), any of the following:*** ***(a) any actively exploited vulnerability as defined in Article 3, point (42), of Regulation (EU) 2024/2847 contained in the device;*** ***(b) any severe incident as referred in Article 14(5) of Regulation (EU) 2024/2847 having an impact on the security of the device.*** ***2. The manufacturer shall submit the report referred to in paragraph 1 through the***	***deleted***

electronic system referred to in Article 92 not later than 30 days after it becomes aware of the actively exploited vulnerability or the severe incident. ***3. The report referred to in paragraph 1, as well as any report submitted by a manufacturer in accordance with Article 82 that also qualifies as actively exploited vulnerability or severe incident, shall be made available simultaneously to the CSIRTs designated as coordinators of the Member States in which the device has been made available and to ENISA*** ***4. For the purposes of this Article, the CSIRTs designated as coordinators and the ENISA shall have access to Eudamed.***	
Justification	
Vigilance and cybersecurity are distinct domains with different primary objectives. This amendment deletes the proposed article 82a from its location – it is moved to the new section on cybersecurity. The proposed amendment structurally separates cybersecurity from vigilance within the legal framework by creating a distinct section within Chapter VII (e.g. adding a dedicated "Cybersecurity" section). Terms such as "incident" and "severity" have different meanings under the MDR and cybersecurity legislation, therefore a separate chapter would enhance clarity and preserve the integrity and focus of the different systems for vigilance and cybersecurity.	

Amendments to Regulation (EU) 2017/746 (IVDR) **Chapter VII Section 2a (new)** **Article 87a (new)**	
Text proposed by the Commission	*Amendment*
	SECTION 2a ***CYBERSECURITY*** ***Article 87a*** ***Reporting of actively exploited vulnerabilities and severe incidents related to devices*** ***1. Without prejudice to the reporting obligations regarding serious incidents and field safety corrective actions set out in Article 82, the manufacturer of a device shall report to the computer security incident response teams ('CSIRTs'), designated as coordinators of the Member States where a device has been made available, and to the European Union Agency for Cybersecurity (ENISA), any of the following:***

	(a) any actively exploited vulnerability as defined in Article 3, point (42), of Regulation (EU) 2024/2847 contained in the device; ***(b) any severe incident as referred in Article 14(5) of Regulation (EU) 2024/2847 having an impact on the security of the device.*** ***2. The manufacturer shall submit the report referred to in paragraph 1 through the electronic system referred to in Article 92 not later than 30 days after it becomes aware of the actively exploited vulnerability or the severe incident.*** ***3. The report referred to in paragraph 1, as well as any report submitted by a manufacturer in accordance with Article 82 that also qualifies as actively exploited vulnerability or severe incident, shall be made available simultaneously to the CSIRTs designated as coordinators of the Member States in which the device has been made available and to ENISA*** ***4. For the purposes of this Article, the CSIRTs designated as coordinators and the ENISA shall have access to Eudamed.***
Justification	
Vigilance and cybersecurity are distinct domains with different primary objectives. This amendment reintroduces the text of article 87a in the new section of cybersecurity as article 92a unchanged. The proposed amendment structurally separates cybersecurity from vigilance within the legal framework by creating a distinct section within Chapter VII (e.g. adding a dedicated "Cybersecurity" section). Terms such as "incident" and "severity" have different meanings under the MDR and cybersecurity legislation, therefore a separate chapter would enhance clarity and preserve the integrity and focus of the different systems for vigilance and cybersecurity.	

C.3 AI inclusion: a welcome direction that requires timely follow-through

Artificial Intelligence (AI)-enabled medical technologies are a fast-evolving area of innovation, enabling new solutions that improve diagnosis, treatment and delivery of care. MedTech Europe supports a regulatory approach that fosters this innovation while maintaining the highest levels of patient safety.

For decades, medical technology software – including AI – has been regulated under the medical devices or IVD framework. The AI Act introduced additional product requirements covering risk and quality management, data governance, transparency and human oversight, among others. In doing so, these requirements have created overlaps and points of friction with the MDR and IVDR.

MedTech Europe welcomes the proposal to regulate AI product requirements under the IVDR and MDR. This avoids inconsistencies between the IVDR or MDR and the AI Act, increases

patient safety and access to essential health technologies, as well as ensures a single, robust conformity assessment process. Importantly, this does not amount to deregulation: AI requirements from the AI Act are to be reflected in the MDR and IVDR, maintaining the same level of safeguards while eliminating duplication and resolving inconsistencies between overlapping frameworks.

AI-enabled medical technologies already comply with a wide range of safeguards embedded in the MDR and IVDR. The remaining horizontal high-risk AI requirements should therefore be reflected within the MDR and IVDR framework rather than applied in parallel. This should enable faster patient access to innovation through a single conformity assessment and strengthen the competitiveness of the EU medtech sector.

This compliance approach, which is already embedded in the AI Act through the sectors listed in Section B of Annex I, has already proven successful in other safety-critical sectors. The EU Aviation Safety Agency (EASA) integrates AI-specific requirements into its existing airworthiness and safety management framework, rather than applying a separate, overlapping AI regime on top of sectoral product rules. The same principle should apply to medical devices and diagnostics.

The proposal should further strengthen patient safety through unified oversight. By applying the market surveillance and vigilance systems of the IVDR and MDR, events or incidents with AI-enabled medical technologies can be reported to the same market surveillance authorities that oversee all medical technologies. This is important, given that AI-enabled devices frequently operate as part of a system with other medical devices or IVDs. A coherent and rapid response to safety signals is essential.

MedTech Europe calls on the Commission to develop delegated acts in a timely manner, reflecting the relevant AI Act high-risk requirements in the General Safety and Performance Requirements of the MDR and IVDR.

Amendments to Regulation (EU) 2017/745 Recital 23a (new)	
Text proposed by the Commission	*Amendment*
	(23a) In order to ensure a coherent regulatory framework for medical devices which use artificial intelligence, relevant requirements of Regulation (EU) 2024/1689 set out in Chapter III, Section 2, of that Regulation should be reflected in the general safety and performance requirements set out in Annex I of this Regulation in a manner that ensures consistency with the requirements of Annex I. That process should avoid duplication and inconsistency of obligations for manufacturers and ensure that the integrity of

	conformity assessment procedures provided for in this Regulation is maintained.

Justification

This recital is helpful to ensure that when AI Act requirements are laid out in the MDR, that this process is carried out in a coherent, sector-specific manner. It clarifies that relevant AI related obligations must be reflected in Annex I in a manner which both ensures the smooth functioning of a single conformity assessment procedure and prevents duplication or conflict with existing requirements. By providing for alignment with Chapter III, Section 2 of the AI Act, where appropriate, the recital preserves legal certainty for manufacturers, maintains consistency across sectors, and ensures predictable implementation through future delegated or implementing acts.

Amendments to Regulation (EU) 2017/746 Recital 23a (new)	
Text proposed by the Commission	*Amendment*
	(23a) In order to ensure a coherent regulatory framework for** in vitro **diagnostic medical devices which use artificial intelligence, relevant requirements of Regulation (EU) 2024/1689 set out in Chapter III, Section 2, of that Regulation should be reflected in the general safety and performance requirements set out in Annex I of this Regulation in a manner that ensures consistency with the requirements of Annex I. That process should avoid duplication and inconsistency of obligations for manufacturers and ensure that the integrity of conformity assessment procedures provided for in this Regulation is maintained.

Justification

This recital is helpful to ensure that when AI Act requirements are laid out in the IVDR, that this process is carried out in a coherent, sector-specific manner. It clarifies that relevant AI related obligations must be reflected in Annex I in a manner which both ensures the smooth functioning of a single conformity assessment procedure and prevents duplication or conflict with existing requirements. By providing for alignment with Chapter III, Section 2 of the AI Act, where appropriate, the recital preserves legal certainty for manufacturers, maintains consistency across sectors, and ensures predictable implementation through future delegated or implementing acts.

Amendments to Regulation (EU) 2017/745 Article 5 paragraph 8a (new)	
Text proposed by the Commission	*Amendment*
	8a. The Commission shall, within 12 months of [the date of entry into force of this Regulation], adopt a delegated act to lay down specific requirements amending the general safety and performance requirements set out in Annex I to this Regulation to reflect the relevant requirements concerning devices deemed high-risk AI systems under Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that use high-risk AI systems as safety components, set out in Chapter III, Section 2, of that Regulation. ***Where the Commission adopts such delegated act specifying such requirements, those measures should reflect the requirements set out in Chapter III, Section 2, of Regulation (EU) 2024/1689 in a manner that ensures consistency with the requirements of Annex I of this Regulation.***
Justification	
This amendment provides for a timebound process for the European Commission to take into account the relevant requirements from the AI Act when amending the MDR General Safety & Performance Requirements for devices deemed high-risk AI systems under the AI Act. It creates a coherent approach for the use of AI in medical technologies, giving manufacturers, notified bodies, and authorities a stable and consistent basis for compliance. It aims to ensure that delegated acts adopted by the Commission reflect the requirements set out in Chapter III, Section 2 of the AI Act. Overall, it offers the clarity and stability needed to reflect AI specific rules in the MDR in a way that is appropriate for medical technologies, supports innovation, safeguards patient safety, and strengthens Europe's competitiveness.	

Amendments to Regulation (EU) 2017/746 **Article 5 paragraph 8a (new)**	
Text proposed by the Commission	*Amendment*
	Paragraph 8a is added ***The Commission shall, within 12 months of [the date of entry into force of this Regulation], adopt a delegated act to lay down specific requirements amending the general safety and performance requirements set out in Annex I to this Regulation to reflect the relevant requirements concerning devices deemed high-risk AI systems under Article 6(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council, or that***

	use high-risk AI systems as safety components, set out in Chapter III, Section 2, of that Regulation. ***Where the Commission adopts such delegated act specifying such requirements, those measures should reflect the requirements set out in Chapter III, Section 2, of Regulation (EU) 2024/1689 in a manner that ensures consistency with the requirements of Annex I of this Regulation.***
Justification	
This amendment provides for a timebound process for the European Commission to take into account the relevant requirements from the AI Act when amending the IVDR General Safety & Performance Requirements for devices deemed high-risk AI systems under the AI Act. It creates a coherent approach for the use of AI in medical technologies, giving manufacturers, notified bodies, and authorities a stable and consistent basis for compliance. It aims to ensure that delegated acts adopted by the Commission reflect the requirements set out in Chapter III, Section 2 of the AI Act. Overall, it offers the clarity and stability needed to reflect AI specific rules in the IVDR in a way that is appropriate for medical technologies, supports innovation, safeguards patient safety, and strengthens Europe's competitiveness.	

C.4 Blood draws in performance studies

Blood is an essential source of diagnostic information for the prevention, diagnosis and management of disease, and hundreds of millions of blood tests are performed every year across the EU. Routine blood draws and finger pinpricks are well-established procedures that have not been shown to pose a significant risk to patients.

Yet under the current framework, routine blood draws are treated as having the same risk as high-risk procedures such as biopsies or spinal taps. This has created a significant barrier to conducting performance studies on these samples in the EU. This approach is unique to the EU and not mirrored in other major jurisdictions, which apply a more proportionate, risk-based classification.

MedTech Europe welcomes the European Commission's stated objective of narrowing the scope of performance study authorisation requirements for low-risk specimen collection, consistent with Recital 50 of their proposal. However, the current drafting of Article 58(1) does not fully deliver on this objective: the term "additional invasive procedures" still might capture routine blood draws and finger-pricks under the general specimen collection authorisation requirement.

MedTech Europe proposes amending Article 58(1) IVDR to clarify that the full set of authorisation requirements (Articles 59–77 and Annex XIV) is triggered only where the invasive procedure poses a major clinical risk to subjects.

MTE proposed amendments

Amendments to Regulation (EU) 2017/746 (IVDR) **Article 58 - Paragraph 1**

Text proposed by the Commission	*Amendment*
Any performance study: that is an interventional clinical performance study as defined in point (46) of Article 2; or where the conduct of the study involves additional invasive procedures, *including high-risk procedures for collection of specimens,* or other risks for the subjects of the studies, shall, in addition to meeting the requirements set out in Article 57 and Annex XIII, be designed, authorised, conducted, recorded and reported in accordance with this Article and Articles 59 to 77 and Annex XIV.	Any performance study: that is an interventional clinical performance study as defined in point (46) of Article 2; or where the conduct of the study involves additional invasive procedures **that might pose a major clinical risk to subjects**, or other risks for the subjects of the studies, shall, in addition to meeting the requirements set out in Article 57 and Annex XIII, be designed, authorised, conducted, recorded and reported in accordance with this Article and Articles 59 to 77 and Annex XIV.
Justification Wording "invasive procedures" in point c, still captures low-risk procedures, like routine blood draws and finger pricks, which still end up classified under the general "specimen collection" authorization requirement. This contradicts the Commission's summary, which suggested a narrowing of scope. Furthermore, it also contradicts preamble 50, which describes simplified treatment for low-risk procedures, including routine blood draws in non-vulnerable individuals.	

C.5 Simplify rules for health institutions – while safeguarding CE-marking

Under the European Commission's proposal, rules are simplified for health institutions, whether laboratories (under IVDR) or hospitals or other organisations (under MDR). This simplification is broadly beneficial and supportive of the work of health institutions and the care they provide to patients. It reduces administrative requirements and allows health institutions to manufacture and use their own devices, and transfer them to other health institutions.

Today, devices manufactured by health institutions range from molecular diagnostic tests for rare diseases to clinical decision-support tools and institution specific instruments. Such devices manufactured by health institutions are not CE-marked, cannot be marketed and must not be manufactured at an industrial scale.

The European Commission's proposal would allow significantly wider use of devices manufactured by health institutions, even where a CE-marked device is available for the same purpose. This represents a significant shift from the current framework.

CE-marking must be upheld as the standard

MedTech Europe broadly supports simplification for health institutions, while asking for the principle that where the CE-marked device is available, it should be used.

- **CE-marked devices should be used to ensure device quality and safety**: When a CE-marked device is available, it should be the default choice. CE-marked devices undergo full conformity assessment under the MDR or IVDR, providing a level of regulatory assurance that health institution devices, by design, do not replicate.

- **The value of investment in CE-marking and marketing of devices in the EU should be protected**. Manufacturers invest heavily in developing and validating CE-marked IVDs and medical devices. Weakening the requirement to use them where available could undermine the incentive to develop regulated devices and risk creating a 'two-tier' system with lower regulatory standards.
- **Equitable competitive conditions across market participants should be maintained**: The exemption for health institution devices exists to serve areas of genuine unmet need, including niche areas of medicine and patient-specific conditions. It should not operate as a lower-cost alternative to regulated products, which would create unequal obligations between market participants.

MedTech Europe proposal

Reinstate Article 5.5(d) IVDR, which requires health institutions which manufacture and use their own tests, to provide justification that there is no equivalent CE-marked device. This preserves the ability of laboratories to use their own tests where justified, while ensuring that CE-marked devices remain the default when an equivalent is available. If there is no justification (e.g. no equivalent device on the market that serves the unmet need), then the laboratory should use the CE-marked test.

These changes would maintain the principle that health institutions should use CE-marked devices where an equivalent device is available, ensuring consistent standards for patient safety across the EU market.

MTE proposed amendment

Amendments to Regulation (EU) 2017/746 (IVDR) **Article 5.5 (d) (new)**	
Text proposed by the Commission	*Amendment*
	(d) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market;
Justification	
The proposed amendment is to bring back the deleted clause which requires health institutions which manufacturer their own tests, to provide justification that there is no equivalent CE-marked device. There are several reasons for this amendment: • **CE-marked devices should be the standard**. The CE-marked IVDs should remain the benchmark as they undergo full conformity assessment and validation. Keeping Article 5.5(d) maintains the **principle that laboratories should use CE-marked tests where an equivalent device is available**, ensuring device quality, patient safety, and adequate regulatory oversight. Patients deserve to have diagnostic information from tests, when available which are compliant with the most stringent standard which is the European regulation. • Maintaining **equitable competitive conditions** across market participants. Without Article 5.5(d), laboratories, especially **commercial** ones, **could potentially outsource manufacturing**	

or distribute tests in ways that bypass IVDR requirements applied to manufacturers who undergo full conformity assessment and lengthy validations. This could create unequal regulatory obligations and distort competition, as manufacturers must comply with IVDR conformity assessment while homegrown tests might avoid similar scrutiny.

- Protecting the **value of investment in CE-marking** and marketing devices in EU. Manufacturers invest heavily in developing and validating CE-marked IVDs. Weakening the requirement to use them where available could undermine the incentive to develop regulated tests and risk creating a "two-tier" system with lower regulatory standards.

D RETHINK — course correction needed

MedTech Europe supports many parts of the Commission's proposal. On the reprocessing of single-use devices, however, a course correction is needed. The proposed shift to a "reusable by default" regulatory presumption represents a departure from established patient safety principles, is not supported by the Commission's own 2024 study on reprocessing, in particular it fails to ensure a dialogue with stakeholders, to develop recommendations on the suitability of different single-use devices for reprocessing and fails to support the risk management approach in this field. The Commission proposal stands alone among global regulatory jurisdictions in their approach.

D.1 Reprocessing and single use devices

The Commission's proposal fundamentally shifts the regulatory default: devices will be presumed reusable unless manufacturers justify a single-use designation. This is a departure from the current MDR framework and from that of every other major jurisdiction.

Under the current MDR (Article 17), reprocessing of single-use devices is permitted only where national law allows and in compliance with common specifications (Implementing Regulation 2020/1207). The proposal reverses this logic: manufacturers must now justify why a single-use device cannot be reused – or it becomes a reusable device and the manufacturer must add reprocessing instructions.

The evidence does not support this shift. The Commission's 2024 study on reprocessing and reuse of single-use devices highlights evidence gaps regarding safety and effectiveness of reprocessing, and recommends developing guidance on which single-use devices are suitable for reprocessing, recognising that not all are appropriate. The single-use design principle is grounded in patient safety – a lesson learned from serious historic incidents, such as the and HIV transmission risks in the 1990s. Most single-use devices cannot be reused, and the proposal places a heavier burden of proof on manufacturers without addressing this reality.

MedTech Europe's position:

- Reprocessing of single use devices should not be the regulatory default. These devices are specifically engineered for single use, and that design choice is integral to their safety and performance profile.
- The European Commission's proposal should be rebalanced to ensure that there is no burden on manufacturers to justify that devices which are single-use only cannot be reused. This otherwise places an unfair and unrealistic burden on the vast majority of single-use devices which could not be reused. Devices designated as single-use only will have clinical data supporting that status; such data would not be expected to address, for example, the risk of infection from reuse.
- The Commission's proposal does not take into account patient safety risks from reuse (since their proposal focuses on physical characteristics of the device). Risk management should be taken into account in determining the indication for single-use only.

- The changes proposed by MedTech Europe clarify that devices should be 'single-use only' where the manufacturer has performed a risk management analysis including the risks from re-using the device. The burdensome and unclear requirement for a justification is removed and manufacturer obligations are clarified.
- Where single-use devices are fully refurbished, MedTech Europe supports clear assignment of manufacturer responsibilities to the full refurbisher. Labelling and traceability of the fully refurbished device should be ensured. Clear responsibility supports patient safety and ensures that risks from off-label use of the fully refurbished device are taken into account.

MTE proposed amendments

Amendments to Regulation (EU) 2017/745 (MDR) **Article 17**	
Text proposed by the Commission	*Amendment*
Article 17 Single-use devices and reprocessing ***of devices that are not for single use***	*Article 17* Single-use devices and reprocessing of devices
1. A device shall only be intended for single-use where the manufacturer, in light of the design, construction, material, chemical, physical and biological properties of the device, cannot ensure that the device continues to meet the relevant safety and performance requirements when reused in accordance with its intended purpose after appropriate reprocessing. The manufacturer's justification of an indication of single use shall be part of the technical documentation referred to in Annex II.	***1. An indication that a device is for single use shall be based on the manufacturer's risk management documentation, where characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used shall be identified.***
2. If the device is not intended for single-use, the manufacturer shall provide information about the appropriate reprocessing process for allowing reuse in the instructions for use in accordance with Annex I, Section 23.4, point (n).	2. If the device is not intended for single-use, the manufacturer shall provide information about the appropriate reprocessing process for allowing reuse in the instructions for use in accordance with Annex I, Section 23.4, point (n).
3. Single-use devices and devices that cannot be further reprocessed may be subject to full refurbishing within the meaning of Article 2(31). The natural or legal person that carries out the full refurbishing shall be considered as the manufacturer of the fully refurbished device.	3. Single-use devices and devices that cannot be further reprocessed may be subject to full refurbishing within the meaning of Article 2(31). The natural or legal person that carries out the full refurbishing shall be considered as the manufacturer of the fully refurbished device ***and must fulfil the obligations incumbent on manufacturers laid down in this Regulation, which also include obligations relating to the labelling and traceability of the fully refurbished device in accordance with Chapter III of this Regulation.*** ***Indication of the fully refurbished state of a device and its traceability in relation to safe use shall be added to the product and delivered to the end user.***
4. The Commission may adopt, in accordance with Article 9(1), CS on general requirements regarding reprocessing of devices or fully refurbishing of single use devices.	

	4. The Commission may adopt, in accordance with Article 9(1), CS on general requirements regarding reprocessing of devices or fully refurbishing of single use devices.
Justification	
The Commission's proposal fundamentally shifts the regulatory default: devices will be presumed reusable unless manufacturers justify a single-use designation. Given that most single-use devices are not reusable, this places a new administrative burden on those devices. It also is unclear how detailed the justification would need to be, what level of evidence would be required and how the manufacturer should prove a negative: that the device cannot be re-used. Finally, the Commission's does not take into account patient safety risks from reuse (since their proposal focuses on physical characteristics of the device). The proposed changes clarify that devices should be 'single-use only' where the manufacturer has performed a risk management analysis including the risks from re-using the device. The burdensome and unclear requirement for a justification is removed and manufacturer obligations are clarified.	

E Closing statement

The Commission's proposal provides a solid basis for reform. With targeted refinements on predictability, proportionality and support for innovation, the EU can build a regulatory model that delivers for patients, strengthens health systems and restores Europe's position as the destination of choice for medical technology development.

A simpler, more predictable system is not a shortcut on safety. It is the condition for safety and the condition for Europe's long-term competitiveness.