MedTech Europe
from diagnosis to cure

Single-use by design: why reusability should not be the regulatory default under MDR Article 17

A supplement to MedTech Europe's position on the MDR/IVDR Revision

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A. Executive summary

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The European Commission's proposal to revise Article 17 of the Medical Devices Regulation 2017/745/EU would significantly change the EU framework for single-use medical devices. It would require manufacturers to justify why a single-use device cannot be reused; in the absence of such justification, the device would become reusable by default and require reprocessing instructions. The proposal also extends the application of the established concept of full refurbishment within Article 17 to certain single-use devices and devices that have reached the end of their reusable life.

The medical technology sector supports the Commission's objectives of creating a more harmonised EU framework, reducing fragmentation between Member States, and ensuring that operators who fully refurbish single-use devices assume manufacturer responsibility. The sector recognises the importance of sustainability and continues to innovate in reusable technologies, material optimisation, recycling initiatives, packaging reduction, and lifecycle-oriented product development.

MedTech Europe does not oppose reprocessing where it is scientifically shown to be safe. Its concern is with reversing the default. Making reusability the default unless manufacturers provide a new justification would create a substantial regulatory burden, while the level of evidence required remains unclear. For the large number of single-use devices that plainly cannot be reused, this is redundant paperwork with no safety benefit, which runs against the simplification aim of the revision as a whole. It would also depart from the MDR's established science- and risk-based framework and could undermine regulatory certainty, innovation, competitiveness, device availability for patients, and the smooth functioning of healthcare systems.

MedTech Europe therefore recommends retaining the Commission's objective of clarifying responsibilities for reprocessing and full refurbishment but removing the proposed requirement for manufacturers to justify why a single-use device cannot be reused. Reprocessing of single-use devices should not become a regulatory default. The intended purpose of a device should remain determined by the manufacturer, in line with existing MDR requirements regarding clinical benefit, safety and performance, and the state of the art in medicine.

Sustainability and circularity objectives should apply irrespective of devices being single-use or reusable. They should be pursued through dedicated environmental policy instruments that are better suited to transforming the healthcare ecosystem. The revised MDR framework should remain grounded in scientific evidence, risk-based decision-making, and clearly allocated responsibilities.

How this paper relates to MedTech Europe's overall position

This paper is a supplement to MedTech Europe's overall position on the revision of the EU medical devices and in vitro diagnostic medical devices regulations (5 May 2026) and should be read alongside it. It develops in full the position's call to rethink the Commission's approach to reprocessing and reuse of single-use devices.

B. Reusable devices, single-use devices and reprocessing

For the purposes of this paper:

- a single-use device refers to a medical device intended by the manufacturer to be used on one individual during a single procedure or single episode of use only, in accordance with MDR Article 2(8) and the manufacturer's validated intended purpose;
- a reusable medical device refers to a device specifically designed, validated, and intended by the manufacturer to undergo appropriate cleaning, disinfection, sterilisation, maintenance, and repeated use while maintaining safety and performance throughout its intended lifecycle;
  reprocessing refers to a process performed on a used medical device to allow its safe reuse, including appropriate cleaning, disinfection, sterilisation, maintenance, functionality, testing, and restoration (if applicable) for technical and functional safety.

Single-use and reusable categories of medical devices both play important and complementary roles within modern healthcare systems. The designation of a device as single-use or reusable is not arbitrary. It forms part of the manufacturer's intended purpose and results from comprehensive lifecycle risk-management processes conducted in accordance with MDR requirements and harmonised standards, including EN ISO 14971 as well as device processing and validation requirements relating to cleaning, disinfection, sterilisation, biocompatibility, packaging integrity, functional durability, shelf-life, and validated lifetime performance.

Whether a device is intended for single or multiple use depends on multiple factors, including intended clinical application, material characteristics, technical feasibility of cleaning and sterilisation, infection prevention considerations, functional performance, usability, traceability, and healthcare system infrastructure. It also depends on the ability to ensure consistent implementation of validated reprocessing procedures in real-world healthcare settings, including the availability of appropriately trained personnel, operational competencies, quality management systems, and adequate regulatory oversight of reprocessing activities.

Single-use devices – are designed to be used once and disposed of. Syringes, catheters, blood bags, surgical blades and implants are typical examples of devices that are designed to be used only once.

Reusable medical devices – examples include surgical instruments such as reusable stapling devices and biopsy forceps; diagnostic & examination devices such as stethoscopes and blood pressure cuffs; and general patient care devices such as hospital beds and suction equipment.

Single-use devices are often developed to respond to public health concerns or the needs of healthcare professionals. These disposable medical devices eliminate cross-contamination risk between patients entirely and ensure optimum performance (where after first use, for example, functionality degrades). They significantly can reduce workload bottlenecks and operational pressure on healthcare workers, translating into more time for patient care. In general, the provision of single-use devices is often preferred to being reused, as the processing that would be required in those cases are seen either as error-prone (leading to infection risk) or resource-intensive for health institutions to manage. These devices are not designed to be reused; they may not be designed physically to be disassembled to allow adequate cleaning/inspection or withstand the necessary repeated sterilisation processes that a reusable device is designed for.

Reusable devices are designed to be processed for reuse. The processing of reusable medical devices is a common practice in many clinical settings such as hospitals or doctor surgeries and consists generally of cleaning, disinfection, packaging and re-sterilisation, according to the manufacturer specifications. Reusable medical devices can also be processed by external third-party organisations which are experts in ensuring that the devices can be processed in accordance with the manufacturer's specifications and returned to the clinical practice for use. Processing methods for reusable devices vary significantly depending on the medical device and the treatment needed to be applied to the particular device to render it fit for reuse. In case of an insufficient level of quality in processing, biological contaminants can remain on the device, therefore increasing the risk of patients being exposed to potentially serious health consequences. A high level of control is needed to ensure optimal hygiene and sterility standards (when applicable) are met.

C. Commission proposal and MedTech Europe recommendations

Under the current Medical Devices Regulation (Article 17), reprocessing of single-use devices is subject to a specific regulatory framework distinguishing between reprocessed single-use devices intended for further use within the Union, where the reprocessor assumes manufacturer obligations, and single-use devices reprocessed for exclusive reuse within health institutions, where Member State conditions and applicable

requirements, including Common Specifications established under Commission Implementing Regulation (EU) 2020/1207, apply. Most European countries do not allow reprocessing of single-use devices today.[1]

In its proposal to revise the Medical Devices Regulation, the European Commission presents fundamental changes to Article 17. These include:

- Requiring the manufacturer of single-use devices to justify that they cannot be reused, otherwise they become reusable by default.
- For single-use devices which become reusable, reprocessing instructions must be added to the instructions for use.
- Single use devices and devices which can no longer be reused, can only be fully refurbished.

These proposed changes are intended to harmonise the EU framework for single-use devices, reduce fragmentation caused by different national approaches, and promote waste reduction.

The European medical technology sector supports the European Commission's objectives to provide a more harmonised framework and ensure that full manufacturer responsibility is assigned to operators who fully refurbish single-use devices and devices which can no longer be reused. MedTech Europe supports reprocessing where it is scientifically demonstrated to be safe for the specific device. What it cannot support is a blanket reversal of the single-use principle. MedTech Europe also appreciates the intention of supporting sustainability goals; manufacturers are already contributing toward more environmentally responsible healthcare systems through innovation in reusable technologies, material optimisation, recycling initiatives, packaging reduction, and lifecycle-oriented product development.

MedTech Europe sees several issues in the European Commission's proposal to amend Article 17:

1. **The justification itself represents a significant new regulatory burden where the level of evidence needed is unclear** – the proposal introduces unclear and disproportionate obligations for manufacturers to justify single-use designation without sufficiently considering technical feasibility limitations, traceability challenges, post-market surveillance obligations, liability allocation, operational healthcare realities, or the impact on innovation and Small and Medium Enterprises (SME) competitiveness. It is also unclear how to prove a negative (that the device cannot be reused) and the level of evidence which will be required for that. This is not a proportionate measure considering that the vast majority of single-use devices, syringes and blood bags among them, are plainly unsuitable for reuse, yet each would still need a justification on file. This would be redundant, costly paperwork that adds nothing to patient safety and cuts against the revision's own simplification goal.
2. **Making any single-use device reusable should not be the regulatory default** – Single-use devices are specifically designed, validated, and clinically assessed for one-time use, with their intended purpose forming an integral part of their safety and performance profile. Reprocessing would introduce multiple variables that cannot be fully standardised across such single-use devices, healthcare settings, or Member States, making a general presumption of reusability neither scientifically nor operationally justified. Here the proposal insufficiently reflects the operational and regulatory complexities

[1] Today, 10 countries allow reprocessing of single-use devices. 20 countries do not allow reprocessing. 1 country (Poland) allows reprocessing to take place, but the products cannot be used in their country. See European Commission webpage, National rules on reprocessing of single-use devices.

associated with oversight of reprocessing activities across different healthcare systems and Member States, including variability in implementation capacity, inspection practices, competency requirements, and enforcement approaches (EU Commission's 2024 study on reprocessing and reuse of single-use devices). The 'reusable by default' approach could make the EU a global outlier in the regulation of single-use medical devices, diluting rather than strengthening innovation, competitiveness, and patient access to medical technologies.

The European Commission proposal will place a significant and unclear regulatory burden on manufacturers, requiring them either to justify single-use or to make devices reusable, with no clear clinical or operational benefit. In fact, it is unclear if sustainability goals will be met at all, as both single use and reuse have different sustainability challenges. By contrast, the regulatory burden of providing justification could affect marketing decisions for some single-use devices available in the EU.

MedTech Europe therefore argues that the European Commission's proposal could be kept, but the justification that the single-use device cannot be reused should be removed. We call for adopting an approach, whereby:

- Reprocessing of single-use devices is not the regulatory default.
- The intended purpose remains determined by the manufacturer based on assessment of clinical risk-benefit and the state of the art in medicine.
- No additional justification is required for a single-use designation beyond existing MDR requirements.
- Any entity reprocessing a single-use device assumes manufacturer-equivalent responsibilities and becomes the full refurbisher (already in the Commission proposal). This supports a regulated market for reprocessed single-use devices and devices which can no longer be reused.

The revised regulatory framework should remain firmly grounded in patient safety, scientific evidence, risk-based decision-making, and clearly allocated responsibilities.

D. Challenges with a 'reusable by default' approach

1. Lifecycle risk management

The single-use design principle is itself a patient-safety safeguard, grounded in hard lessons from past harm, including infection and cross-contamination risks from reusing devices never designed for it. Reversing the default reopens a risk the current framework was built to close. While reprocessing may be technically feasible for certain single-use devices under highly controlled conditions (including manufacturer responsibility for the full reprocessor), such feasibility cannot justify establishing a general regulatory presumption that medical devices should be reusable by default.

Many single-use devices are specifically engineered for a single clinical application, with material selection, sterility assurance, packaging, usability, and performance characteristics optimised for that intended use. The designation of a device as single-use or reusable is therefore not arbitrary but reflects a fundamental lifecycle and safety & performance determination made by the manufacturer under the MDR framework. This designation also defines the allocation of responsibilities necessary to maintain safety & performance throughout the device lifecycle. For single-use devices, responsibility for ensuring compliance with applicable safety & performance requirements remains with the manufacturer within the validated intended use conditions. By contrast, reusable devices rely on a model of responsibility in which:

- manufacturers must provide validated instructions for cleaning, disinfection, sterilisation, maintenance, inspection;
- reuse is well defined, while healthcare institutions and users are responsible for performing reprocessing activities in accordance with those validated instructions and applicable regulatory requirements.

Safe reuse therefore requires devices to be specifically designed and validated for repeated processing and reuse cycles, including consideration of material compatibility, cleanability, disinfection and sterilisation resistance, functional durability, and maintenance of safety & performance over the validated lifetime.

The risks inherent in reprocessing of devices

Reprocessing can alter material integrity, biocompatibility, sterility assurance, functional performance, or packaging reliability in ways that are not externally visible. Such degradation occurs progressively over repeated reprocessing cycles and is often not detectable through routine inspection or functional testing. In practice, the extent and predictability of such degradation may also depend on numerous external and operational variables that cannot be fully standardised across real-world healthcare settings. These may include variations in water quality, cleaning chemistries and concentrations, disinfection and sterilisation parameters, equipment maintenance, environmental conditions, staff training and procedural adherence, as well as device condition following clinical use, including non-visible damage or use outside validated label claims.

It is critical that any consideration of the reuse or reprocessing of single-use devices remains strictly grounded in the manufacturer's initial validated intended use, the established allocation of responsibilities under the MDR, robust evidence demonstrating the maintenance of safety and performance throughout the device lifecycle, and effective control of all factors that may affect reprocessing outcomes.

Potential risks associated with reuse or reprocessing can include – depending on the device – microbial contamination, residual biological material, endotoxins, biofilm formation, loss of barrier integrity, material fatigue, coating deterioration, altered biocompatibility, and progressive degradation of device performance. Certain categories of technologies present particularly elevated risks, including active implantable devices, blood-contacting devices, software-enabled systems, devices with inaccessible internal channels, coated or porous materials, and technologies intended for contact with the central nervous system.

International standards and regulatory guidance increasingly recognise the growing complexity of reprocessing safety. For example, ANSI/AAMI ST98, ISO 17664-1 and ISO/TS 17664-3 highlight that increasing medical device complexity and the continued emergence of new pathogens, including antibiotic-resistant microorganisms, significantly increase the challenges associated with validated cleaning and reprocessing procedures. Similarly, international regulatory guidance, including FDA guidance on Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labelling, identifies specific design characteristics that may present elevated reprocessing risks based on adverse event reporting and real-world experience.

As set out above, single-use designation already results from a full lifecycle risk assessment under the MDR. Manufacturers (including full refurbishers) should be required to assess intended clinical use, infection prevention considerations, usability, transport and storage conditions, cleaning and sterilisation feasibility, functional performance, foreseeable misuse, packaging validation, and shelf-life validation. These assessments are integrated into design validation, clinical evaluation, post-market surveillance, vigilance, and lifecycle monitoring activities.

At the same time, technological progress continues to evolve. Advances in sterilisation technologies, material science, AI-assisted inspection systems, digital traceability, and reprocessing validation methods may enable certain devices to become safely reusable in the future, even where such reuse is not currently feasible. However, such feasibility must remain device-specific, evidence-based, clinically validated, and supported by appropriate risk management. It should not be presumed through a general regulatory principle.

For this reason, the MDR framework was specifically designed to strengthen harmonisation, predictability, and lifecycle accountability across the Union. Introducing an unclear 'reusable by default' presumption risks creating new fragmentation through divergent interpretation among Notified Bodies and national competent authorities.

2. Legal clarity, traceability and liability

The proposal introduces an unclear requirement to 'justify' single-use designation, without defining the level of evidence needed, scope, or scientific standard. This creates legal uncertainty and risks imposing expectations that are not technically or scientifically bounded.

- The proposal would require manufacturers to prove a negative, that a device cannot be safely reused, with no defined standard, methodology or acceptance criteria. There is a validated framework for demonstrating safe reuse (the ISO 17664 series), but no equivalent framework for demonstrating non-reusability. The proposal creates an evidentiary burden that cannot be met on any agreed basis.
- It is unclear whether this justification requires a simple rationale or an extensive validation to prove that safe reuse is impossible. The latter would be scientifically problematic, particularly for devices not designed for reuse and in light of highly variable reprocessing practices.
- It does not clarify how this requirement would align with MDR lifecycle obligations.
  Reprocessing outcomes depend on numerous interacting variables, including methods, cleaning agents, temperatures, soak times, water quality, sterilization technologies, load configurations, user adherence, device geometry, and materials. Expecting manufacturers to exclude all theoretically plausible combinations would therefore amount to an open-ended evidentiary burden.

This ambiguity over evidence requirements and lack of standardisation risk divergent expectations across Notified Bodies and Member States, leading to inconsistent implementation, a lack of level playing field for business and an undermining of MDR harmonization.

The final agreed revision of MDR regarding Article 17 should ensure clarity regarding the allocation of responsibilities between the original manufacturer, full refurbisher, healthcare institution, and other economic operators. In particular, regulatory responsibility should transfer between lifecycle owners, including conformity assessment, technical documentation, traceability, vigilance, corrective actions, and ongoing regulatory compliance throughout subsequent reuse cycles.

The operational and legal complexity associated with traceability, vigilance, post-market surveillance, and liability is also concerning. Reprocessing can affect device integrity, component reliability, software functionality, material performance, or sterility assurance in ways that are not externally visible and may only emerge after multiple reprocessing cycles.

Maintaining effective traceability across repeated reprocessing cycles presents operational challenges, including tracking device history, preserving continuity of the unique device identifier (UDI), documenting transport and storage conditions, ensuring relabelling accuracy, and linking adverse events to the appropriate responsible entity. Additional complexities may arise regarding maintenance of complete lifecycle

documentation, validation of reprocessing cycle limits, retention of servicing and maintenance records, software version control, component replacement traceability, and interoperability between different institutional documentation systems. Further concerns include competent authority oversight, inspection responsibilities, and enforcement coordination across multiple lifecycle actors operating under different regulatory and operational conditions.

Liability allocation also becomes increasingly uncertain once devices undergo repeated reprocessing or refurbishment outside the original manufacturer's labelling. The fragmentation of lifecycle responsibilities across multiple owners may complicate attribution of adverse events, root-cause investigations, post-market surveillance activities, and legal accountability in the event of device-related incidents. This fragmentation may ultimately weaken the clarity of accountability structures that the MDR framework was specifically designed to establish.

3. Innovation, competitiveness and international divergence

The proposed approach risks negatively affecting innovation, investment, and the competitiveness of the European medical technology sector, particularly for SMEs, where the manufacturer is forced to create a reusable device out of a single-use device without being able to fully cover all needed risks.

No major international regulatory jurisdiction currently applies a comparable 'reusable by default' regulatory presumption. The proposal would therefore place the European Union in a unique regulatory position, diverging from the United States, Japan, the United Kingdom, China and other major global markets, while reducing the attractiveness of the EU market for innovation.

A 'reusable-by-default' presumption could also create open-ended liability exposure and regulatory uncertainty where reuse would occur outside of the original validated lifecycle assumptions or intended design parameters. This may lead manufacturers, especially SMEs, to withdraw products from the EU market or delay European launches, reducing patient access and distorting competition in favour of actors willing or able to operate under higher uncertainty and lower evidentiary thresholds.

The proposal may also restrict design freedom, discourage use of advanced materials or coatings, lengthen development timelines, increase regulatory costs, and impose disproportionate burdens on manufacturers. Because medical devices are frequently engineered around specific clinical and performance needs, mandatory consideration of reusability could force manufacturers to prioritise theoretical reuse over optimal performance, usability, or patient safety.

Manufacturers may additionally face uncertainty regarding the exportability and international acceptance of reprocessed or refurbished devices, recognition of EU reuse frameworks by third countries, and compatibility with non-EU systems. This will complicate global product strategies and increase barriers for internationally marketed technologies.

4. Sustainability and circularity

Medical device manufacturers and healthcare systems should collaborate to advance sustainable healthcare solutions while maintaining safety and performance as the primary consideration. This includes promoting reusable devices where clinically and technically appropriate, supporting safe recycling and waste reduction initiatives, improving healthcare system efficiency, optimising procedural pack configurations, reducing unnecessary waste, and enabling innovation in sustainable product design. It is noted that both single-use and reusable devices carry their own sustainability costs, including water, energy, chemical, and packaging use in

reprocessing. Sustainability objectives should therefore be pursued through evidence-based, proportionate, and clinically appropriate measures that preserve patient safety, device performance, usability, and healthcare efficiency rather than through a generalised 'reusable by default' approach.

Annex I – illustrative examples of single-use devices with elevated reprocessing complexity (non-exhaustive)

Active implantable devices

Active implantable technologies present particularly elevated complexity in the context of reprocessing and reuse due to their long-term clinical function, electronic integration, software dependencies, hermetic sealing requirements, and highly specific performance validation pathways. Reprocessing or refurbishment activities can affect battery integrity, calibration, software functionality, sensing performance, communication systems, or long-term reliability in ways that are not externally visible or readily detectable through routine inspection.

In addition, active implantable devices are typically validated as integrated systems under highly controlled lifecycle assumptions. Repeated reprocessing, refurbishment, or component replacement can therefore create uncertainty regarding traceability, software configuration management, post-market surveillance responsibilities, and long-term clinical performance.

Devices with inaccessible internal channels or complex geometries

Certain devices contain narrow lumens, inaccessible internal channels, porous structures, or complex geometries that can complicate cleaning reproducibility and sterilisation validation. In such cases, residual biological material, endotoxins, or biofilm formation may remain difficult to detect or eliminate consistently.

These challenges become more significant following repeated reprocessing cycles, particularly where degradation or material wear progressively alters internal surfaces or cleaning accessibility. Effective validation of reproducible reprocessing outcomes may therefore require device-specific methodologies and highly controlled operational conditions.

Coated, composite, or porous materials

Some technologies rely on specialised coatings, composite materials, adhesives, surface treatments, or porous structures to achieve specific clinical performance characteristics. Reprocessing activities can affect coating adhesion, material compatibility, barrier properties, lubricity, biocompatibility, or mechanical integrity.

Such degradation occurs progressively over repeated reprocessing cycles and may not be externally visible. In some cases, material interactions with sterilisation agents, cleaning chemicals, heat exposure, or mechanical handling can alter device performance in ways that are difficult to predict or validate through routine functional testing.

Software-enabled and electronic systems

Certain medical devices incorporate software-controlled functions, sensors, electronics, firmware, or digital connectivity features that introduces additional complexity in the context of refurbishment or reprocessing.

Software integrity, calibration status, cybersecurity considerations, version control, and electronic component reliability may require highly specific validation processes following refurbishment or repeated use cycles. Maintaining traceability, software configuration control, and post-market surveillance continuity becomes increasingly complex where multiple actors participate in the lifecycle management of reprocessed or refurbished devices.