

Harmonizing Article 17 of the EU MDR: a Perspective on Overcoming Regulatory Fragmentation for Sustainable Perioperative Care

Federica Pirro^{1*}, Viola Vahle² and Daniel Vukelich³

¹RN Ospedale Santa Croce ASLTO5; Founder of the Italian Centre for Sustainable Healthcare APS, Moncalieri, Italy.

²International Business Development and Sales Manager Vanguard, AG, Berlin, Germany.

³President of the Association of Medical Device Reprocessors (AMDR), Berlin, Germany and Washington, D.C, USA.

*Corresponding author

Federica Pirro, RN Ospedale Santa Croce ASLTO5, Founder of the Italian Centre for Sustainable Healthcare APS, Moncalieri, Italy.

Received: September 08, 2026; **Accepted:** September 23, 2026; **Published:** October 05, 2026

ABSTRACT

Background: Healthcare systems across Europe face a dual challenge: reducing their environmental footprint while managing increasing patient care complexity and rising financial pressure. Third-party remanufacturing of single-use medical devices (SUDs) offers a circular economy solution to mitigate healthcare emissions, divert waste, and lower procurement costs. However, its implementation across the European Union remains constrained. Article 17 of the European Union Medical Device Regulation (MDR 2017/745) delegates regulatory oversight of remanufacturing to individual Member States, creating a fragmented landscape of conflicting national rules that impedes scalability of remanufacturing as sustainable clinical practice.

Methods: This Perspective article synthesizes current regulatory challenges and reflects upon two illustrative, contrasting perioperative experiences -in Ireland and Italy- to examine how national regulatory environments influence the feasibility of clinical sustainability initiatives.

Results: The contrast between the implemented initiative in Ireland and the aborted proposal in Italy suggests that national regulatory fragmentation creates substantial administrative and legal barriers for hospital systems attempting to implement sustainable and circular procurement practices.

Conclusion: Harmonizing remanufacturing regulations across Europe is essential to reduce greenhouse gas emissions from the health sector while managing the cost of care. An urgent revision of Article 17 is required to establish EU-wide harmonization and standardization, unlocking potential environmental and economic benefits for perioperative care across Europe.

Keywords: Single-use medical devices, Remanufacturing, Circular economy, Healthcare sustainability, Medical Device Regulation, Perioperative care

Introduction

The Clinical Imperative for Circularity

Perioperative departments represent one of the most resource-intensive clinical areas within modern acute hospitals and face growing pressure to reduce their environmental impact without compromising clinical care [1,2]. Operating rooms generate substantial volumes of both hazardous and non-hazardous medical waste and contribute significantly to overall healthcare carbon emissions [3-6]. Up to 60% of these emissions originate from Scope 3 supply chain activities, driven primarily by production, distribution, and procurement of medical and surgical devices [3,7]. It is estimated that a single surgical procedure produces,

on average, about the same volume of waste as a family of four in one week [8].

To address these impacts, healthcare systems are increasingly turning to circular economy principles and the waste hierarchy framework [9,10]. Unlike the traditional linear “produce–use–dispose” model, circular approaches prevent waste by rethinking and redesigning the need for products in the first place, prioritizing reuse and repurposing to conserve resources, maximizing both value and shelf life of devices [11,12]. Within this framework, the remanufacturing of medical devices stands out as a key circular strategy for high-value surgical instrumentation [13-15].

Years of peer-reviewed life-cycle assessments (LCAs) and economic research demonstrate that third-party remanufacturing of single-use medical devices (SUDs) — a process where used

Citation: Federica Pirro, Viola Vahle, Daniel Vukelich. Harmonizing Article 17 of the EU MDR: a Perspective on Overcoming Regulatory Fragmentation for Sustainable Perioperative Care. J Med Clin Nurs Stud. 2026. 4(5): 1-5. DOI: doi.org/10.61440/JMCNS.2026.v4.127

surgical instruments are collected, cleaned, re-engineered, tested, and repackaged under strict regulatory standards — can achieve environmental and economic benefits [12,16-18].

Remanufacturing reduces greenhouse gas emissions, lowers hospital procurement costs, diverts valuable raw materials from disposal and incineration, strengthens medical supply chain resilience, without risks to patient safety or lowering standards of care [13,14,19]. Importantly, legal product liability for the remanufactured SUD shifts entirely from the original manufacturer (OEM) to the commercial reprocessor [20]. However, perioperative care teams across Europe face systematic institutional barriers when trying to implement remanufacturing practices.

Regulatory Fragmentation Under Article 17 EU MDR

The root cause of this implementation deficit lies in the structural design of Article 17 of the EU Medical Device Regulation (MDR 2017/745) [20]. In its current form, Article 17 establishes that regulatory responsibility for remanufacturing rests with individual Member States [21]. Consequently, the EU scenario is divided into a patchwork of conflicting national regulations: some countries permit remanufacturing, each under different rules, while others prohibit it altogether [10,21,22]. This fragmentation actively discourages the development of a unified remanufacturing infrastructure in Europe, impeding the adoption and scalability of reprocessing and other circular practices in healthcare [13,23].

This Perspective paper examines how current regulatory structures influence clinical sustainability and advocates for an urgent revision of Article 17 to establish a harmonized, centralized framework across all Member States.

Case Illustrations & Observational Data

To illustrate how macro-level regulatory frameworks influence local clinical practice, this Perspective reflects upon two distinct perioperative experiences in Ireland and Italy between 2021 and 2024. Both initiatives evaluated the feasibility, workflow integration, and operational aspects of third-party collection and remanufacturing, focusing specifically on high-value laparoscopic instrumentation (ultrasonic shears used in general and gynaecological surgical procedures). These two experiences serve as illustrative cases rather than an experimental or comparative clinical trial.

• Permissive Regulatory Model: Ireland

In Ireland, national regulations have permitted third-party SUD remanufacturing under Article 17 of the EU Medical Device Regulation (MDR 2017/745) since 2021. In 2022, a collaborative initiative was established between an acute hospital perioperative team and a certified commercial remanufacturer to collect and redeploy laparoscopic ultrasonic shears. Following surgical use, trained perioperative staff segregated and prepared used devices for collection at the point of care. The remanufacturing company collected the devices according to hospital operational schedule and transported them to a commercial facility for decontamination, remanufacturing and repackaging. At this point, the remanufactured devices were sold for another use as a CE-marked product. Over a 12-month period, 68 devices were successfully collected and remanufactured.

Supported by an active permissive regulatory framework for remanufacturing, the initiative integrated smoothly into the perioperative workflow, with minimal operational burden on the staff involved. During this observational pilot period, zero adverse patient safety events or clinical complications related to the devices were reported.

• Prohibitive Regulatory Model: Italy

A different scenario occurred in Italy, where third-party SUDs remanufacturing is prohibited. Recognizing these restrictions, in 2024, a perioperative team in a public acute hospital attempted to implement a collection and recovery arrangement for used ultrasonic shears in partnership with a certified commercial remanufacturer. To comply strictly with national prohibitions, the initiative was limited strictly to the point-of-care segregation, safe recovery, and external transfer of used devices to authorized facilities outside the national territory, without purchasing or reusing reprocessed devices on-site.

Despite enthusiastic support from both clinical and administrative staff, the initiative stalled prior to launch. In the absence of a supportive national regulatory framework, hospital administrative leadership encountered legal and operational uncertainties concerning accounting, procurement protocols, waste handling logistics and liability. These administrative hurdles led to project discontinuation prior to implementation, resulting in zero devices collected.

Environmental and Financial Data

In the Irish permissive model, the initiative successfully collected and reprocessed a total of 68 single-use laparoscopic shears over a 12-month pilot period. By avoiding immediate post-use disposal, an estimated 8.84 kg of specialized medical waste (based on an average device weight of 0.13 kg) was diverted from high-temperature incineration streams.

Based on published LCA models for ultrasonic device remanufacturing which adopt a comprehensive “cradle-to-grave” system boundary, a net reduction of approximately 0.1825 kg CO₂-equivalent per processed device was estimated, yielding a cumulative avoidance of 12.41 kg CO₂-equivalent across the pilot cohort.

From an economic perspective, theoretical cost savings were achieved both through reduced procurement expenditures, as remanufactured devices typically cost less relative to original equipment list prices, alongside avoided high-cost incineration (estimated at approximately €1.23 per kilogram). However, because site-specific financial transaction data for the Irish hospital were unavailable, precise local procurement savings could not be calculated, and waste disposal savings remain proportional to the small cohort size (68 devices).

Conversely, in the Italian prohibitive model evaluated in 2024, the initiative was aborted prior to launch, resulting in zero devices collected, no waste diverted and no financial or carbon savings.

The Environmental and Financial impacts estimated for the two initiatives are summarized in Table 1.

Table 1: Graphical Summary of Comparative Study Parameters and Implementation Frameworks for Single-Use Medical Device (sud) Remanufacturing (ireland vs. Italy)

Metric Indicator	Domain	Ireland (Permissive Model)	Italy (Prohibitive Model)
Policy Status	Policy & Operations	● Permissive (EU MDR Art. 17 Enacted)	○ Prohibitive (Third-party banned)
Target Device & Cohort	Policy & Operations	● Laparoscopic Shears (n = 68)	○ Laparoscopic Shears (n = 0)
Implementation Scope	Policy & Operations	● Point-of-care collection, reprocessing & CE re-procurement	○ External transfer only (Aborted pre-launch)
Carbon Emissions Avoided	Environmental & Financial	● -12.41 kg CO2-eq	○ 0.00 kg CO2-eq
Specialized Waste Diverted	Environmental & Financial	● 8.84 kg diverted from incineration	○ 0.00 kg diverted
Financial Impact	Environmental & Financial	● Data unavailable	○ N/A (Not applicable)
Patient Safety Impact	Policy & Operations	● Zero adverse events	○ N/A (Not applicable)

Discussion

The Path Forward: Reform and Harmonization

The environmental benefits of SUDs remanufacturing derive primarily from avoiding the resource-intensive raw materials extraction and manufacturing stages required for virgin device production. Multiple Life-Cycle Assessments (LCAs) indicate that the carbon footprint of remanufactured medical devices can be reduced up to 50-70% compared to new equivalent devices [3,13,22,24,25]. Furthermore, diverting medical waste from incineration and hazardous waste streams yields ecological benefits, as surgical waste incineration requires extremely high temperatures that generate significant Scope 3 emissions and residual toxic ash [22].

From an economic perspective, remanufacturing offers procurement cost savings and supply chain stabilization, providing resilience against global supply disruptions inherent to linear supply chains [19,26,27]. However, despite these documented potential benefits, SUD remanufacturing remains a source of uncertainty across European healthcare, with operational protocols-where they exist -varying significantly by Member State [22,26].

The contrasting experiences described in Ireland and Italy suggest that individual clinical commitment alone is often insufficient to overcome structural regulatory barriers. Even where clinical and perioperative staff are eager to implement carbon- and cost-reducing programs, regulatory coherence remains a decisive factor in their viability. In the absence of statutory clarity, hospital leadership and legal departments may adopt a defensive posture, stalling circular initiatives over unresolved questions surrounding accounting, logistics, and legal liability.

This structural challenge is also recognized at the highest policy levels. Under Article 17 of the current EU MDR (2017/745), medical device remanufacturing is permitted in principle, but individual Member States must proactively opt-in for it to be allowed in their jurisdictions [20].

Recent European Commission evaluations on MDR implementation have noted that national fragmentation under Article 17 causes confusion, market distortion and dissatisfaction among healthcare stakeholders, directly limiting the development and scalability of the circular economy initiatives across Europe [21]. The European Commission acknowledges that EU-wide harmonization and standardization of device regulations would unlock remanufacturing and, by extension, deliver environmental and economic benefits in the perioperative care settings.

Consequently, the EU Commission recently proposed a legislative reform to the MDR, specifically targeting Article 17, in order to replace national regulatory fragmentation with a single, harmonized EU-wide framework for SUD remanufacturing, following the example of other regulatory models such as US or Canada: SUDs remanufacturing would be permitted across the continent, provided the remanufactured device meets full CE-marking requirements and safety standards.

Limitations

This study has several limitations that should be acknowledged. First, this work relies on qualitative case illustrations from a single institutional setting within each country (one hospital in Ireland and one in Italy), involving a small cohort of 68 laparoscopic shears in the Irish pilot. Consequently, these

¹Environmental savings for the Irish cohort were calculated using the Association of Medical Device Reprocessors (AMDR) Greenhouse Gas Emissions Calculation Methodology for Reprocessed SUDs, based on ISO 14040-compliant peer-reviewed Life Cycle Assessments (LCAs). Adopting a comprehensive “cradle-to-grave” system boundary, this model accounts for raw material extraction, primary manufacturing, reverse logistics and transportation, industrial decontamination, performance testing, repackaging, sterilization, final redistribution, and avoided waste incineration. The net figure of 0.1825 kg CO₂-eq per device applied in this pilot represents a conservative, modelled estimate based on established international LCA inventories rather than direct site-specific carbon accounting. Available at: <https://amdr.org/wp-content/uploads/2025/04/Rationale-and-Methodology-on-Emissions-Reduction-Calculations.pdf>

²Savings calculations from the first area are calculated based on the difference between the reprocessed sales price and the Average Sales Price (ASP) OR actual costs paid by the facility. Available at: https://amdr.org/wp-content/uploads/2025/04/2024_Data-Methodology-Memo_External_01.25.2025.pdf The data for the Ireland based account are not available, so the actual savings are unknown.

For the second area, savings related to avoided incineration are calculated using the Practice Greenhealth Sustainability Benchmark data. Available at: <https://practicegreenhealth.org/resources/2025-sustainability-benchmark-data>

observations cannot be generalized across different health systems, clinical departments or surgical specialties.

Second, because the Italian initiative was discontinued prior to launch, the study lacks an operational comparator. The two cases represent illustrative contrasts in regulatory and administrative environments rather than a direct comparative analysis of two executed clinical interventions. They also represent specific institutional contexts, where organizational, accounting, and institutional factors beyond national regulations may have contributed to the implementation barriers observed in Italy.

Third, the quantitative environmental savings reported for the Irish cohort represent estimations derived from published LCA models rather than direct site-specific life-cycle measurements, and financial savings reflect estimated unit-price discounts rather than full institutional financial audits.

Finally, while observing zero adverse events across 68 devices indicates positive short-term operational integration in the Irish setting, this small observational cohort cannot establish long-term clinical safety profiles or comparative clinical equivalence. Nevertheless, these observations remain consistent with published international evidence indicating that validated commercial remanufacturing maintains patient safety and device performances.

Conclusion

Sustainability in European healthcare should not depend on geographical location or national jurisdiction. The contrasting experiences in Ireland and Italy illustrate how permissive national regulations facilitate the practical integration of device remanufacturing into perioperative workflows, whereas prohibitive or ambiguous regulatory environments can create administrative uncertainties that halt initiatives before operational launch.

While local observations provide practical context, broader policy literature and European Commission evaluations indicate that national regulatory fragmentation under Article 17 continues to impede the scalability of circular economy practices across Europe. As the European Parliament and Council evaluate regulatory frameworks for medical devices, revising Article 17 to establish a harmonized, centralized EU framework would provide legal clarity, enabling healthcare institutions across all Member States to systematically adopt sustainable procurement practices.

To learn more about the proposed reforms and why they matter, please visit this informational webpage at [AMDR.org/eu-mdr-reforms](https://amdr.org/eu-mdr-reforms), or consult the Health Care Without Harm (HCWH) Europe template for submitting feedback <https://europe.noharm.org/sites/default/files/2026-07/HCWH-Europe-Template-Public-Consultation-MDR-Revision.pdf>

Funding

The authors declare that no external funding, grants, or financial support were received from any public, commercial, or non-profit sector agencies for the conduct of this study or the preparation of this manuscript.

Conflicts of Interest

The authors declare that they have no competing financial interests, commercial affiliations, or personal relationships that could have appeared to influence the work reported in this paper. No author received financial compensation of any kind related to this study. For full transparency, Daniel Vukelich is President of the Association of Medical Device Reprocessors (AMDR). This affiliation did not involve financial compensation and is disclosed here for full transparency.

Acknowledgments

The authors express their sincere gratitude to the Association of Medical Device Reprocessors (AMDR) for their technical support, expert insights, and invaluable assistance in providing regulatory and operational context regarding medical device remanufacturing frameworks across Europe.

References

1. Health Care Without Harm. Health care's climate footprint: how the health sector contributes to the global climate crisis and opportunities for action. Reston (VA): Health Care Without Harm. 2019. <https://noharm-global.org/documents/health-cares-climate-footprint>
2. Romanello M, McGushin A, Di Napoli C, Drummond P, Hughes N, et al. The 2021 report of the Lancet Countdown on health and climate change: code red for a healthy future. *Lancet*. 2021. 398: 1619-1662.
3. Rizan C, Steinbach I, Nicholson R, Lillywhite R, Reed M, Bhutta MF. The Carbon Footprint of Surgical Operations: A Systematic Review. *Ann Surg*. 2020. 272: 986-995.
4. Pirro F, Mezzalana E. Sustainable operating theatres PART I - LEARN. Europe: Nurses Climate Challenge / Health Care Without Harm Europe. 2024. <https://nursesclimatechallenge.org/>
5. Batino M, Mezzalana E, Pirro F, Gigola F, Morabito A, Ciofi D. Sustainability assessment in operating rooms: content and face validity of the Green Theatre Checklist. *Dissertation Nurs*. 2024. 3: 107-118.
6. ElMitainy E, El-Haggag SM. Formulation of a Net Zero Assessment System for Healthcare Facilities. *Journal of Geoscience and Environment Protection*. 2023. 11: 118-135.
7. Thiel CL, Eckelman M, Guido R, Huddleston M, Landis AE, et al. Environmental Impacts of Surgical Procedures: Life Cycle Assessment of Hysterectomy in the United States. *Environ Sci Technol*. 2015. 49: 1779-1786.
8. Kagoma Y, Stall N, Rubinstein E, Naudie D. People, planet and profits: the case for greening operating rooms. *CMAJ*. 2012. 184: 1905-1911.
9. MacNeill AJ, Hopf H, Khanuja A, Alizamir S, Bilec M, et al. Transforming the Medical Device Industry: Road Map to A Circular Economy. *Health Affairs*. 2020. 39: 2088-2097.
10. Rizan C, Mortimer F, Stancliffe R, Bhutta MF. Plastics in healthcare: time for a re-evaluation. *J R Soc Med*. 2020. 113: 49-53.
11. Huijben J, Van Raaij E, Wagelmans A, Piscicelli L, Shen WS, et al. Accelerating the transition from a linear to a circular healthcare sector: ESCH-R: study design and methodology. *Front Public Health*. 2025. 13: 1542187.
12. Health Care Without Harm Europe. Sustainable theatres - Part II ACT. Europe: Nurses Climate Challenge / HCWH Europe. 2024. <https://nursesclimatechallenge.org/>

13. Schulte A, Maga D, Thonemann N. Combining Life Cycle Assessment and Circularity Assessment to Analyze Environmental Impacts of the Medical Remanufacturing of Electrophysiology Catheters. *Sustainability*. 2021. 13: 898.
14. Unger S, Landis A. Assessing the environmental, human health, and economic impacts of reprocessed medical devices in a Phoenix hospital's supply chain. *J Clean Prod*. 2016. 112: 1995-2003.
15. Eussen MMM, Brandwijk RM, Reising RC, Kimman ML, Nakhate P, et al. Surgical tray optimization: a prospective and survey-based evaluation of environmental and economic outcomes. *Surg Endosc*. 2026. 40: 3080-3089.
16. Sousa Martins B, Queiroz e Melo J, Logarinho Monteiro J, Rente G, Teixeira Bastos P. Reprocessing of Single-Use Medical Devices: Clinical and Financial Results. *Port J Public Health*. 2018. 36: 150-156.
17. Sanabria A, Kowalski LP, Nixon IJ, Shaha A, De Bree R, et al. Considerations for environmentally sustainable head and neck surgical oncology practice. *Am J Otolaryngol*. 2020. 41: 102719.
18. Thiel C, Duncan P, Woods N. Attitude of US obstetricians and gynaecologists to global warming and medical waste. *J Health Serv Res Policy*. 2017. 22: 162-167.
19. Trevisan AH, Lobo A, Guzzo D, Gomes LAV, Mascarenhas J. Barriers to employing digital technologies for a circular economy: A multi-level perspective. *J Environ Manage*. 2023. 332: 117437.
20. European Parliament, Council of the European Union. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. *Off J Eur Union*. 2017. L 117:1-175.
21. European Health and Digital Executive Agency, Gesundheit Österreich GmbH, S&P Global, Areté. Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market: final report [Internet]. Luxembourg: Publications Office of the European Union; 2024. <https://data.europa.eu/doi/10.2925/210943>
22. Cunha MF, Pellino G. Environmental effects of surgical procedures and strategies for sustainable surgery. *Nat Rev Gastroenterol Hepatol*. 2023. 20: 399-410.
23. Hoveling T, Svindland Nijdam A, Monincx M, Faludi J, Bakker C. Circular economy for medical devices: Barriers, opportunities and best practices from a design perspective. *Resour Conserv Recycl*. 2024. 208: 107719.
24. Weiss A, Hollandsworth HM, Alseidi A, Scovel L, French C, et al. Environmentalism in surgical practice. *Curr Probl Surg*. 2016. 53: 165-205.
25. Stewart R, Niero M. Circular economy in corporate sustainability strategies: A review of corporate sustainability reports in the fast-moving consumer goods sector. *Bus Strategy Environ*. 2018. 27: 1005-1022.
26. Grantcharov P, Ahmed S, Wac K, Rivas H. Reprocessing and reuse of single-use medical devices: perceptions and concerns of relevant stakeholders toward current practices. *Int J Evid Based Healthc*. 2019. 17: 53-57.
27. Andersen AW, Sørensen SF. A case study of the environmental and economic sustainability of using remanufactured ultrasound catheters. *ResearchGate*. 2022.