MedTech Europe
from diagnosis to cure

EU Sustainable Prosperity and Competitiveness: Priorities for the EU Circular Economy Act

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EXECUTIVE SUMMARY

MedTech Europe envisions a future where healthcare systems are environmentally and financially sustainable, equitable and resilient to future crises. Building such resilient and sustainable healthcare systems requires a robust, competitive, and innovation-driven medical technology industry.

The **Circular Economy Act** has been announced as a key component of the EU's efforts to decarbonise the economy and support industrial competitiveness. The strong focus in Europe to maintain robust social security systems and equitable healthcare access can be further enhanced by **improving resource efficiency and circularity in the sourcing, production, distribution, management and disposal of medical technologies**, which can reduce negative impacts on emissions, resource scarcity and biodiversity. This can be realised by leveraging a structured approach to "the five Rs" of "Reduce, Refuse, Reuse, Renew and Recycle" while maintaining sterility and patient safety.

Considering that the medical technology sector[1] represents over 2,000,000 products, services and solutions available on the Union market, and that individual devices differ greatly in terms of complexity; **there is no one-size-fits-all to more circularity in the sector**. It can take many different forms, ranging from maximising the lifetime value of products, minimising the use of materials and resources, to design optimisation, material substitution, recycling, refurbishing, reprocessing or exploring chemical recycling and modular medical technologies, depending on the concrete application in question. Circularity potential varies by material, sterility level, and patient safety risk.
The **exact opportunities for circularity depend on the type of product, business models, and criteria,** such as the value of the material used. Circular practices can only be implemented successfully when they meet patient safety and quality requirements, the needs of customers, users (patients and healthcare professionals), and healthcare systems and are supported by regulations on waste management (with a specific focus on hazardous waste).
The **existing barriers** (i.e., regulatory barriers, policy barriers, fragmented definitions and standards, a lack of harmonised tools and methodologies (such as a harmonised sector specific LCA method), a lack of infrastructure, limited access to product (material) data, financial barriers and fragmented, not science based tender requirements in the healthcare system or technological and clinical barriers) would have to be removed to leverage circular economy potentials in the sector.
MedTech Europe calls for a Circular Economy Act that supports the following ambitions:

- Ensuring **regulatory coherence** between Green Deal legislation, circularity requirements and initiatives and the sector specific regulatory system of the Medical Devices Regulation (EU) 2017/745 and In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746.
- Securing the free circulation of goods in the EU internal market and boosting **an EU internal market for waste** in support of the circular economy: Reinforcing the **Single Market** and the global harmonisation of standards for waste, circularity and secondary raw materials with respect of the quality and safety for patients and healthcare practitioners
- Promoting a **more sustainable pattern of production by making secondary materials more attractive**.
- Establishing **a framework for financing and rewarding circularity** efforts.
- Leverage the **transformation synergies of the Green and Digital agendas** to increase overall system efficiencies and sustainability performance, such as dematerialisation.
- **Seeking international alignment on circularity approaches** for the medical technology sector with respect to the quality and security for patients and healthcare practitioners.

[1] For the purpose of this document, medical technologies include medical devices, *in vitro* diagnostic medical devices (IVDs), Research-use Only (RUO), and the device part of a drug-device combination product.

For a successful design of the Circular Economy Act for the medical technology field, we recommend the following:

- **Circular design including sustainable and recycled materials:** support the development of aligned definitions and standards, for example, on circular design and the ability of materials to enter the technical and biological loops in a circular economy; definitions under the sector specific Medical Device Regulation and circular economy-related definitions (reprocessing, refurbishment) are not aligned either. Researchers and government regulators to begin focused work with industry partners to develop a clear guidance framework on expectations/ patient safety/ biocompatibility considerations. This would enable the creation of market demand for secondary materials, while safeguarding patient safety.
- **Legislative & regulatory review**: review the New Legislative Framework as well as applicable sectorial legislation, such as the Medical Device Regulation, applicable safety standards (e.g., Biocompatibility ISO 10993-1) and chemicals legislation to support circularity and, specifically, reuse, refurbishment and reprocessing of medical equipment.
- **Policy review:** review national purchasing and procurement policies to incentivise manufacturers' circular practices, including reuse, remanufacturing/refurbishment, recycling and leasing as well as take back programmes where suitable and remove barriers to collecting systems from public and private institutions. In particular, the EU Taxonomy Delegated Act on Circular Economy shall be reviewed with a view on specific characteristics of the medical technology sector.
- **Measuring circularity:** support the development of aligned metrics and methodologies to determine the footprint of different medical technologies, including collaborative projects between manufacturers and users, where appropriate, to look at the impact per patient outcome.
- **Invest in R&D:** evaluate suitability and use of certain resources. For example, the application of renewable or biodegradable materials may not be suitable for the healthcare industry, depending on the use case.; earmark funding and unlock financing for the green transition of the medical technology sector under the announced Competitiveness Fund as well as new initiatives on decarbonisation and clean technology, such as the envisaged proposal for an Industrial Decarbonisation Accelerator Act or the new EU Life Sciences Strategy
- **Organisation and financing of health systems:** review financing, budgeting and organization of health systems to support the introduction of value-based and circular business models and sustainable purchasing practices; move to value-based procurement.
- **Implementation of waste collection processes**: support and incentivise (e.g. via appropriate funding mechanisms) the introduction of waste collection processes in hospitals and the waste management sector to suitably treat and, if possible, recycle bio-hazardous medical waste. Quality standards for secondary raw materials should be developed.

Please also see:

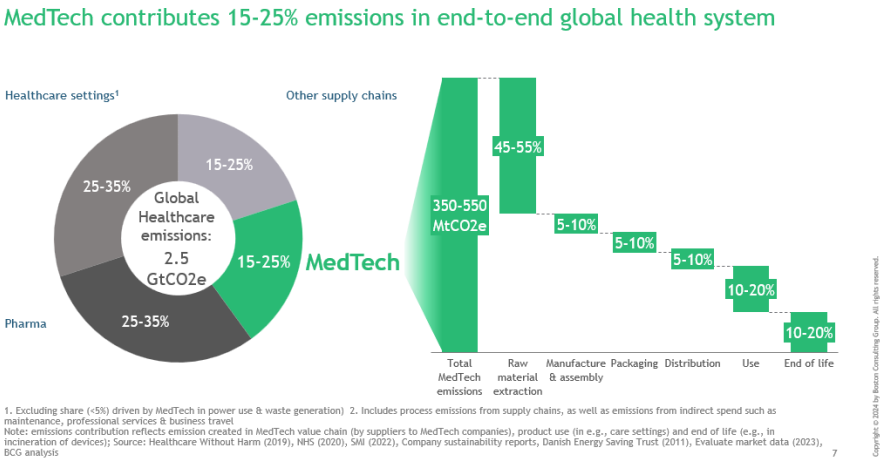
- EU Prosperity and Competitiveness: MedTech Europe Recommendations for Implementing the EU Green Deal in Healthcare
- MedTech Europe Recommendations regarding Simplification of Administrative Burden in EU Environment Legislation
- MedTech Europe response EC consultation on Waste Shipment Regulation
- MedTech Europe recommendations on the revision of the Waste Electrical and Electronic Equipment Directive 2012/19/EU

CHAPTER 1: CIRCULARITY IN THE MEDICAL TECHNOLOGY SECTOR

1. Circularity as a decarbonisation and competitiveness lever in MedTech

In June 2025, MedTech Europe published its flagship report commissioned to Boston Consulting Group (BCG) on "Decarbonising Healthcare: How A Competitive MedTech Industry Can Contribute"[2]. This report identifies how a competitive MedTech industry can support healthcare ecosystems to decarbonise. It showcases the potential of innovative technologies and describes the barriers, opportunities and decarbonisation levers for MedTech companies. It lays out the key pillars of a roadmap and enabling framework for the sector to reach net zero emissions by 2050, in line with a 1.5 °C emissions reduction pathway.

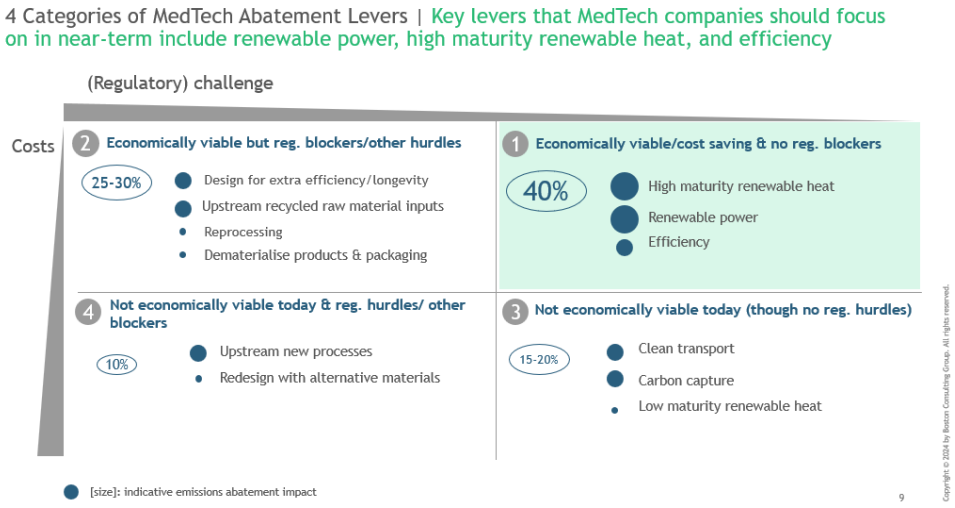
While MedTech contributes to 15-25% emissions in end-to end global health systems, only 5-10% fall within MedTech manufacturers direct control. Reducing scope 3 emissions are the key challenge. This confirms the importance of collaboration among all healthcare system actors and supply chain actors to successfully decarbonise healthcare and drive system change as well as climate resilience and economic security. We **call for a structured, high level (Clean Industrial Deal) dialogue** with the MedTech sector. **Health is an investment**, not a cost.



The study report also found that **four categories of MedTech abatement levers**. Key levers that MedTech should focus on in the near-term are renewable power, high maturity renewable heat and efficiency. They offer a 40% carbon emission reduction potential short term and face no regulatory hurdles. Circularity parameters follow suit with a reduction potential in between 25-30%, however, face important regulatory and other barriers, including fragmentation in the internal market, a lack of harmonised definition, standards and methodologies, slow uptake of value-based procurement. These barriers would have to be removed to unlock this decarbonisation lever for MedTech and scale ongoing pilots and best practice examples.

The upcoming Circular Economy Act is an opportunity to align on a common way forward to removing these existing barriers.

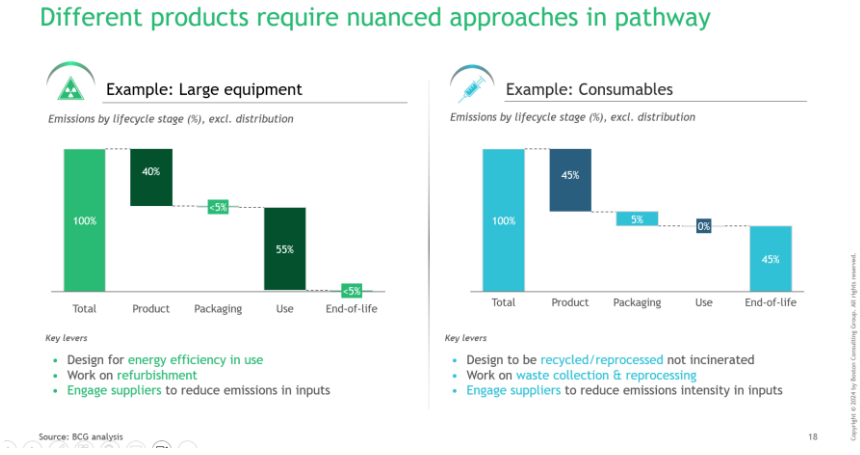
[2] Decarbonising healthcare: how a competitive medical technology industry can contribute - MedTech Europe



In a study of 1400 active-medical devices[3], about 25% implemented at least one circular strategy.
The most common strategies implemented were:

- Introducing devices that eliminate the use of other less environmentally sustainable devices (refuse).
- Enabling sharing among users or offering multiple functions in one device (rethink).
- Minimising the use of material and energy consumption (reduce).
- Reusing devices (after decontamination) for multiple use cycles (reuse).
- Designing devices to be remanufactured at the end of life (remanufacturing).

Circularity and overall decarbonisation solutions in the sector has many different facettes.
There is no one size fits all as also the case studies in above cited MedTech Europe decarbonisation study showcases:



[3] Circular economy for medical devices: Barriers, opportunities and best practices from a design perspective - ScienceDirect; this research focuses on mitigating the environmental impact linked to *active medical devices*, which are defined by the European medical device regulations (EU-MDR) (Regulation, 2024) as "any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy". In this paper the term is used to describe any electronics-based device that is intended by the manufacturer for specific medical purposes for human use.

2. The regulatory landscape of circularity in MedTech

In the light of the current political momentum, with leaders like Mario Draghi and Enrico Letta calling for deeper economic integration and industrial resilience through initiatives such as the Competitiveness Compass and the Clean Industrial Deal – seeking to align EU competitiveness with strategic sustainability - **regulatory coherence** has become a geopolitical necessity as well as an economic one.

While circular economy principles are largely tackled in dedicated legislations, they are no longer confined to waste management related rules. **Circularity has become a cross-cutting theme with fragmented and insufficiently aligned requirements spread out over various policy areas,** including product regulations (such as EU Ecodesign of Sustainable Products), Green Deal measures (Right to Repair, new Packaging or Batteries Regulations), chemicals legislation (i.e., Classification, Labelling and Packaging of substances and mixtures regulation (CLP), the REACH Regulation, RoHS Directive), the Multiannual Financial Framework (MFF), trade and customs law, or the Electromagnetic Compatibility (EMC) and Radio Equipment Directives. Public procurement rules, too, are increasingly being explored as levers for sustainability, however, in a heavily fragmented manner.

The multiplication of circular economy provisions across these various legislative frameworks, often developed in an uncoordinated manner, has revealed important limitations. For instance, chemicals legislation (*RoHS* and *REACH*) does not consistently allow the use of recovered spare parts in repairs, upgrades, or in the manufacturing of new devices, creating a barrier to extending product lifespans. Similarly, public procurement regulations in certain Member States still contain provisions requiring the purchase of new medical equipment by default, undermining reuse and remanufacturing initiatives. Addressing such inconsistencies is essential. **It is only by looking at circularity in a comprehensive and integrated manner that the EU will achieve creating a truly workable framework**.

For the medical technology sector more specifically it entails **coherence of circularity requirements with the strict sector specific regulatory system of Regulations (EU) 2017/475 on Medical Devices and (EU) 2017/746 on in vitro diagnostic medical devices**. Circular solutions in MedTech need to qualify against this stringent framework regarding the safety of patients and healthcare practitioners. Besides, CE approval timelines for product/packaging changes that require CE-resubmission under MDR/IVDR are complex and time-consuming processes today that impact time to market.

On a **global scale** as well, international conventions, such as the Basel Convention and OECD frameworks impose further requirements for materials flows, with potential impacts on secondary raw materials markets and cross-border circular supply chains.

Overall, conflicting policy requirements often arise when safety rules, product regulations, and other related legislation interact without harmonisation. This phenomenon clearly limits the ability of medical technology manufacturers to design and scale circular products. Evidence from the *DiCE project* confirms that **regulatory barriers are one of the most pressing obstacles to circular transition in medical devices ranking as the third biggest barrier after safety and systemic issues, and just before financial and technological barriers**. The *Technopolis study* further highlights how fragmented legislation complicates innovation in remanufacturing and reuse, creating a **compliance burden that discourages circular business models.**

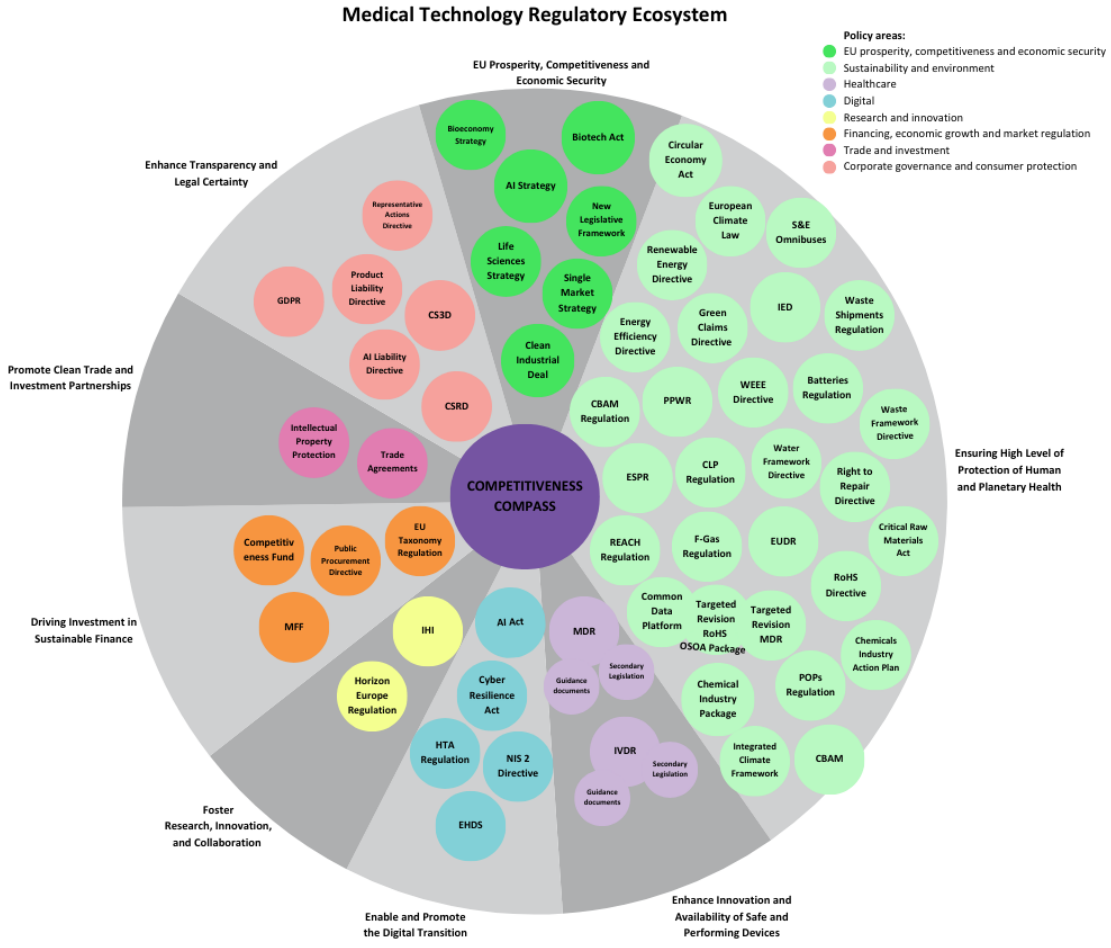
As such, **a lack of strategic alignment between national, European, and international instruments** risks generating friction, regulatory overlap, and even trade barriers that could derail the transition toward circularity, besides hamper Europe's sustainable prosperity, resilience and industrial competitiveness.

A 2016 study prepared for the European Commission identified several regulatory barriers for circularity of medical equipment[4], including in EU chemicals legislation, e.g. to employ used components as spare parts in repair of the installed base as well as for manufacturing of new equipment.

[4] 2288_160713_regulary_barriers_for_the_circular_economy_accepted_hires_1.compressed.pdf

The ambiguity in "end-of-waste" status prevents used medical components from being legally reclassified as products, blocking their reuse or remanufacturing. National differences in interpretation of waste status and recovery operations (e.g., R14 for remanufacturing) further complicate cross-border circularity efforts.
The upcoming Circular Economy Act should remove such barriers as a priority as well as reinforce the acknowledgement of the new Ecodesign Regulation that the Commission should take into account the need to not negatively affect the health and safety of patients and users.

The following flowchart summarises the dense EU regulatory landscape that MedTech is subject to (neither secondary EU legislation nor parallel national implementing legislation being reflected):



3. Practical realities

Healthcare systems use a wide variety of materials, including construction materials, metals, textiles, plastics, and chemicals for transport, pharmaceuticals, medical and digital health technologies and other applications. While EU-level data is not available, the overall healthcare sector was found to be responsible for 13% of the national material

extraction footprint for the Netherlands[5] and 5% for Germany[6]. The 1,893 German hospitals generate 4.8 million tonnes of waste every year, 901 tonnes of which are recyclable materials[7]. Pharmaceuticals and medical devices make up 56.3% of the Dutch healthcare system's non-organic material footprint and 41.4% of healthcare's waste production[8]. The primary material constituent of medical waste includes polymers, metals, and textiles[9]. In the US only 49–60 % of medical waste is incinerated, while 20–37 % is autoclaved and 4–5 % is treated using other technologies.

According to the 2022 Circularity Gap Report[10], circular healthcare systems could reduce global material use by 0.27 Gt. However, while medical technology manufacturers are increasingly aware of the benefits of circularity and starting to invest in more circular solutions, research[11] consistently shows barriers for circular medical device design, (e.g. (perceived) safety and infection risks, (perceived) regulatory difficulties, financial constraints, and difficulties in collection and separation. Barriers to implementing circular practices in the medical technology sector can be categorised in the following chapters. Here, it is important to note that in some cases pilots or small tests may be possible, but commercial implementation at scale is unfeasible, meaning that companies shy away from larger investment in new business models.

Here is an **overview of the most commonly cited practical barriers**, differing and dependent on product type and business model:

- **Logistical and Administrative Hurdles:** The medical technology industry relies on highly complex, cross-border value chains to deliver innovative medical devices and diagnostics efficiently. The current processes for recyclables but also refurbishment are hindered by complex logistics. Trans-European transport of materials may involve crossing EU Member State borders more than once. This process involves significant administrative burdens and financial expenditures, making it viable only for large volumes. Labour costs add another hurdle, especially for reuse models (refurbishment, remanufacturing) that require collection, disassembly and re-assembly of used devices.
- **Lack of collection and treatment infrastructure**: The development and implementation of advanced recycling technologies, such as chemical recycling, are not sufficiently advanced to deliver consistent quality and scalable availability of recycled material compared to primary resources. Currently, only a few countries within the European Union possess the technology and infrastructure to perform this type of recycling. This technological limitation restricts the ability to process a wider range of materials and recover them efficiently. Collection and sorting infrastructure at the level of hospital and care facilities remain a key bottleneck, due to a lack of available space, awareness or mixing of hazardous and non-hazardous medical wastes at healthcare facilities. Medical-grade polymers are high-purity feedstocks. Their key limitation lies in segregation and collection infrastructure.

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[5] Steenmeijer MA, Rodrigues JFD, Zijp MC, Waaijers-van der Loop SL. The environmental impact of the Dutch health-care sector beyond climate change: an input-output analysis. Lancet Planet Health. 2022;6:e949–e957. doi: 10.1016/S2542-5196(22)00244-3.

[6] Ostertag K, Bratan T, Gandenberger C, Hüsing B, Pfaff M. Sustainable resource use in the health care sector–exploiting synergies between the policy fields of resource conservation and health care. 2021. https://www.umweltbundesamt.de/sites/default/files/medien/1410/publikationen/2021-08-04_texte_15-2021_health-sector-resources_summary.pdf

[7] The White Dot: Enabling Circular Economy in MedTech Through Collaborative Innovation White Paper

[8] https://www.rivm.nl/bibliotheek/rapporten/2022-0127.pdf

[9] https://www.sciencedirect.com/science/article/pii/S0921344924006311

[10] https://www.circularity-gap.world/2022#Download-the-report

[11] Circular economy for medical devices: Barriers, opportunities and best practices from a design perspective - ScienceDirect

- **Contamination as a major obstacle:** recycling medical technology components contaminated with chemical and/or biological residues, particularly consumables and primary packaging, can be complicated. End-users often make the final decision on what to recycle, and they tend to favour non-contaminated items. This selective approach, combined with the need to collect a sufficient volume of specific materials to meet recycling quotas, creates storage challenges and limits the overall effectiveness of waste management and recycling efforts, often rendering incineration a more practical and the safer disposal method than recycling.
- **Economic and technical viability**: Misguided or unavailable financial incentives in reimbursement, procurement, as well as unavailable OPEX financing for as-a-service models mean that many circular practices are not commercially viable at scale. In addition, the economic model for recycling is currently unfavourable. The cost of recovering and processing materials is often higher than the cost of using new, virgin materials. This makes recycled materials less competitive in the market and creates a disincentive for companies to invest in recycling programs, as the value of the final recycled product does not justify the high recovery expenses. In addition, the characteristics and quality performances of the recycled material are often not in line with the virgin materials (i.e., plastics).
- **Technological innovation**: Medical technologies in the EU are subject to robust and comprehensive regulatory frameworks to ensure the highest standards of safety, quality, and performance, thereby protecting patients and end-users. In some areas further innovation is needed, for example to maintain quality of performance over many reuses while remaining cost-effective. In certain cases, a lack of safe and performing alternative technologies and materials and long product development cycles (depending on the type of technology more than a decade), mandatory testing, and clinical studies impact timelines of redesign.
- **Fragmentation**: expectations on medical technologies are currently not sufficiently aligned between users, purchasers, policymakers and regulators. That includes a lack of harmonized metrics to measure circularity (especially at product level) and diverging definitions, even at EU level (e.g. between the ESPR and taxonomy).

Recommendations:

- **Allocate structural investments** in waste collection and management infrastructure in healthcare delivery organisations (hospitals, clinical centres) as well as specialized recycling infrastructure to allow recycling of contaminated used devices at scale
- **Shift in in hospital and healthcare budgets from CAPEX to OPEX financing** to allow more circular business models, including repair, upgrades and x-as-a-service models
- **Fund Research & Development for circular design**, including safe and performing use of recycled and bio-based materials in medical devices. These efforts should be accompanied by harmonised EU-wide quality standards for recycled materials in sensitive applications.
- **Develop harmonised metrics for circularity** (building on the Global Circularity Protocol to be released in 2026) as well as harmonised criteria in public procurement to incentivize circularity.
- To make circularity targets meaningful, the industry need **a solid evidence base supporting data-driven procurement criteria** and enable consistent reporting under CSRD and ESRS E5. **A harmonised EU-level material-flow baseline for healthcare**, with MedTech-specific granularity and a split between hazardous and non-hazardous streams, would be helpful.
- The Circular Economy Act should push for allowing **cross-border movement of hospital waste for recycling under traceable and safe conditions**. Smaller member states often lack sufficient volumes to justify national recycling infrastructure; **enabling regional feedstock pooling** is essential to make polymer recovery economically viable.

CHAPTER 2: AN ENABLING FRAMEWORK FOR MORE CIRCULARITY IN HEALTHCARE

1. Ensuring regulatory coherence between Green Deal legislation, circularity requirements and initiatives and the sector specific regulatory system of the Medical Devices Regulation (EU) 2017/745 and In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746

As outlined in the previous chapter, the medical technology sector is a densely regulated sector.
In general, MedTech Europe observes **five recurring key triggers of administrative burden and barriers for more circularity in the MedTech sector**. Below table identifies these triggers and lists **additional recommendations for administrative burden reduction measures** across these legislations while preserving environmental and human health and the EU's safety ambitions for medical technologies. Addressing these will also elevate and support the economic case of circularity:

Triggers of administrative burden	Horizontal recommendations for administrative burden reduction
1. **Incoherence of EU legislation** (such as diverging definitions, terminologies, methodologies, or misaligned compliance deadlines of environmental requirements and MDR/IVDR requirements)	• Take MedTech specificities and the sector's regulatory system set by MDR/IVDR into account from the outset in the design of EU environment legislation • Grant upfront Medtech specific transitional arrangements in EU environment legislation to align environment compliance deadlines with the sector's regulatory system and practical realities, such as supply chain complexity or patient safety requirements; in particular, enact sufficient time in EU environment legislation to transition to safe and better performing alternatives that aligns with MDR/IVDR timelines for regulatory re-approval • Allocate strategic investments into building sustainable, climate resilient healthcare systems in the Multiannual Financial Framework (MFF)
2. **Fragmentation of requirements across Member States and across different policy domains**	• Revive the EU Single Market and secure the functioning of the internal market (i.e., through better harmonised environmental regulations across EU Member States and a consistent implementation of the New Legislative Framework across different policy domains) • Seek alignment with policy makers on a MedTech Green Public Procurement Framework
3. **Untapped synergies between the sustainability and digital transitions**	• Replace outdated paper-based processes by digital compliance tools • When deploying digital tools for compliance, ensure coherence with the sector specific tools, notably EUDAMED • Allow manufacturers to provide information digitally (e.g., in the new Packaging and Packaging Waste Regulation and secondary legislation derived from it); physical labelling requirements should only apply if necessary to avoid serious risks

		• Remove the duplication of reporting *tools*, e.g. Digital Product Passport under the Batteries Regulation and ESPR, Article 33 notifications via REACH and SCIP database).
4.	**Complexity and fragmentation of reporting requirements**	• Apply the "one environmental parameter - one reporting" principle to better harmonise reporting requirements and keeping administrative to the minimum necessary (e.g., removal of reporting overlaps stemming from the above-mentioned parallel application of the EUDR, CSRD, CS3D, Batteries, Packaging and Sustainable Products Regulations) • Introduce a "one stop shop digital EPR gateway at EU level" for EPR registration and reporting; these obligations under Extended Producer Responsibility (EPR) schemes should be streamlined and harmonized across Member States.
5.	**Better international alignment**	• Reinforce the global harmonisation of standards for waste, circularity and secondary raw materials with respect of the quality and safety for patients and healthcare practitioners • Pursue a proactive green diplomacy agenda to promote global carbon pricing and international commitments for tripling renewable energies and energy efficiency

2. Securing the free circulation of goods in the EU internal market and boosting an EU internal market for waste in support of the circular economy: Reinforcing the Single Market and the global harmonisation of standards for waste, circularity and secondary raw materials with respect of the quality and safety for patients and healthcare practitioners

MedTech Europe envisions a reinforced fully functioning EU internal market as the EU's strongest asset and catalyst of both, a high level of environmental protection and a competitive medical technology industry in the EU. Sustainable products circulate freely from one Member State to the other and thereby access to medical technologies for patients and health practitioners is improved. Supply inputs, such as raw materials, for the manufacturing of medical technologies can be sourced across national borders thereby reducing costs. A fully functional internal market is a powerful crisis management tool supporting security of supply, as the COVID-19 pandemic has also evidenced.

With respect to the circular economy, a harmonised EU framework is essential to enable decontamination processes, scale up, cross-border circulation, reduce complexity, and ensure safety while transitioning to more circularity in healthcare. Current divergent practices for medical waste management across EU Member States, and even within regions, create barriers to recycling and the use of secondary raw materials in healthcare. This fragmentation limits cross-border circulation of waste and prevents materials from being effectively recovered and reused.

MedTech Europe also observes an increasing trend of fragmentation, especially regarding Green Deal product related requirements due to an increasing number of often conflicting national measures in parallel to EU regulation ("gold plating").[12]

Fragmentation of the EU Single Market, driven by divergent national measures and "gold-plating," undermines circularity and efficiency in the medical technology sector. At the same time, Europe's accelerating climate risks are straining healthcare systems and supply chains, highlighting the need for resilient, circular approaches that reduce material use, extend product life cycles, and close supply loops. A strengthened Single Market is essential to scale these solutions, aligning the Green and Digital Agendas. With a 60% drop in material extraction between 2017 and 2022, the health sector is, as the Annual Single Market Report highlights, already leading Europe's shift towards a circular economy in healthcare.

MedTech Europe welcomes the new EU Single Market Strategy presented by the European Commission on 21 May 2025 and supports its goal of simplifying and strengthening the single market for a more competitive, sustainable a circular European economy. The strategy addresses various sustainability and circularity aspects needed to achieve a fully functioning single market.

Recommendations:

- **Complete the EU internal energy market**: accelerate the roll out of renewable energies and smart clean energy infrastructures
- **Further leverage the transformational synergies of the Green and Digital agendas** to increase overall system efficiencies and sustainability performance
- **Strengthen monitoring, implementation and enforcement of Single Market principles** to put an end to market barriers resulting from divergent national measures:
    - effective enforcement must be guaranteed, and infringements sanctioned.
    - Addressing barriers derived by diverging national measures: The TRIS Directive (EU)2015/1535[13] should be properly enforced and its notification process strengthened (see also Commission Report on the Operation of the Single Market Transparency Directive from 2016 to 2020 (COM(2022) 481 final).
    - Act as a guardian of the EU Treaty when national action runs counter the functioning of the EU internal market, in particular address the fragmentation of rules on packaging, labelling and waste to reduce market barriers and burden for industry
- **Boost an EU internal market for waste** in support of the circular economy
- Introduce a "**one stop shop digital EPR gateway at EU level**" for EPR registration and reporting; these obligations under Extended Producer Responsibility (EPR) schemes should be streamlined and harmonized across Member States.
- **Future proof the Waste Shipment Regulation for circularity**: uphold the green-list status for non-hazardous intra-EU e-waste shipments beyond 1 January 2027, including the exemption for shipments under 20kg; clarify and harmonise the end of waste status and relevant definitions; ensure a unified waste classification across the EU; opt for EU approval of cross-border shipment in case of registered take-back schemes; simplify the renewal process for approved notifications; harmonise templates and guidelines across the EU and a European Single Waste Market; mandate approval of documents in

[12] The 2025 Annual Single Market and Competitiveness Report - European Commission, 29 January 2025

[13] Commission Report on the Operation of the Single Market Transparency Directive from 2016 to 2020 (COM(2022) 481 final) stresses the untapped potential of Directive (EU) 2015/1535 with respect to addressing persisting bottlenecks in relation to the Single Market and the Green Transition.

English; enact special regulation for own products/waste that has not been used by consumers and waste from clinical trials; Aligning the WSR with other frameworks, i.e. on sustainability reporting.

- **Complementary investment in hospitals and healthcare delivery organisations**—through mechanisms such as the Cohesion Fund and the European Regional Development Fund—will also be vital in ensuring that healthcare infrastructure can adapt to and advance the goals of the circular economy.

Besides, MedTech is also subject to extended producer responsibility schemes, notably on waste electric and electronic equipment, batteries and packaging. **For EPR to work in healthcare, the following principles are of vital importance:**

- EPR schemes have to be 100% European schemes. There should be no national (parallel) schemes.
- Any fees generated from the scheme need to be directed to build the relevant infrastructure, especially hospital collection infrastructure (for collection, sorting, transportation and decontamination)
- To support recycling, a viable legal pathway needs to exist in all Member States to decontaminate all products .
- The mandatory nature of any EPR scheme is essential and preferred over voluntary to manage freeriding
- There should be no extension of existing EPR obligations to medical technologies outside of scope today without parallel Member States funding through e.g., regional development funds.
- A proper definition of where EPR financing obligations start is key to avoid disproportionate financial burden on manufacturers.
- Important data gaps still exist that would have to be closed before drawing further conclusions

3. Promoting a more sustainable pattern of production by making secondary materials more attractive

In order to achieve circularity in sectors with stringent product requirements, such as those for healthcare and hygiene-related products, the recognition of mass balance approaches for bio-based, bio-attributed and chemically recycled feedstocks within EU legislation and sustainability frameworks is crucial. Especially, healthcare materials must meet stringent requirements for biocompatibility, safety, toxicology, and long-term stability. At the same time, healthcare providers and procurement agencies across Europe are increasingly prioritising solutions that align with sustainability and circularity principles.

To bridge these objectives, mass balance offers a practical, credible, cost-effective and scalable approach for increasing the use of circular materials in healthcare applications. This method enables the use of sustainable materials without compromising regulatory compliance or patient safety and without requiring extensive recertification processes, while supporting the co-processing of biomass-derived and virgin fossil feedstocks and outputs from chemical recycling. Its application supports the broader adoption and scaling of sustainable feedstocks, reducing primary resource consumption in chemical production processes and driving circularity in the value chain.

To unlock the full potential of these innovations, the CEA should formally embed mass balance methodologies for bio-based, bio-attributed, and chemically recycled feedstock within EU legislation and sustainability frameworks. This would provide regulatory certainty, encourage investment, and reduce the risk of Europe falling behind other regions in developing advanced recycling and bio-based technologies. Furthermore, the CEA should ensure that product-level (e.g. PEF) and corporate carbon accounting standards allow for appropriate crediting of bio-based carbon sequestration. Recognising this contribution is vital for achieving decarbonisation targets within the

healthcare sector. Transparent third-party certification systems (e.g. ISCC) for mass balance ensure accurate attribution of sustainable materials throughout complex supply chains.

Failing to act would not only hinder the development of sustainable material solutions in the EU but also increase costs and delay innovation, ultimately widening the competitiveness gap with other global regions.

Besides, considering the high level of safety required for medical technologies, secondary raw materials not only need to be available in sufficient quantity but respective quality.

Recommendations:

- Establish **third party certification** for biobased materials and recycled materials
- Develop **quality standards** for secondary raw materials to define the requirements for the materials and the processes
- Provide clarity from regulators as to **what bio-based/recycled materials will be accepted for use in medical devices and under what conditions** (i.e., types/class of devices, % material that is recycled, approval process)

4. Establishing a framework for financing and rewarding circularity efforts

While the current EU budget funds activities to advance the circular economy with many worthwhile projects on-going, efforts are fragmented and not yet contributing to systemic change at national and local level.

We overall welcome the recent proposals for the next EU long term budget, the 2028-31 Multiannual Financial Framework, and the introduction of the circular economy as a specific objective in several of the funding programmes. We believe it is an opportunity to boost up-take of circular practices in the MedTech sector and health systems overall.

Recommendations:

- **Research and Innovation**: in line with the EU Strategic Research and Innovation Agenda on Health and Climate Change[14], the Horizon Europe Programme should support co-creation of innovations for a sustainable healthcare sector, including by integrating circular practices in medical technologies, operations, and care delivery. Digital and data-driven solutions also play a role here to support dematerialisation and optimise care pathways in a circular approach
- Infrastructure: : the new national and regional partnership plans should include a dedicated target to invest in health systems for a more sustainable, and circular, approach to healthcare. That includes investment in effective waste management infrastructure to support healthcare facilities in collecting, separating, and managing waste as well as recycling technologies at scale.
- **Financial incentives**:
    - Infrastructure development should be accompanied by reforms of budget and financing structures in health systems. Innovative access, such as as-a-service models, built on OPEX budgets, should be introduced to create markets for circular business models. A broader investment in sustainability also requires a review of reimbursement and procurement practices, supported by EU funding to increase capacity of under-resourced healthcare actors.
    - Earmark funding and unlock financing for the green transition of the medical technology sector under the announced Competitiveness Fund as well as new initiatives on

[14] https://op.europa.eu/en/publication-detail/-/publication/616cce9c-39e5-11f0-8a44-01aa75ed71a1

decarbonisation and clean technology, such as the envisaged proposal for an Industrial Decarbonisation Accelerator Act or the new EU Life Sciences Strategy
- Introduce a European scheme to boost and integrate national tax incentives for investment in sustainable innovation
- Invest in hospitals and other healthcare delivery organisations – for example, via the Cohesion or European Regional Development Funds
- Seek alignment on a Green Public Procurement Framework for MedTech: it should be clarified hop to quantify the value of circularity for the purpose of a value-based procurement system and how to quantify indirect savings (for example, lower rates of product failure) for the purpose of a value-based system. Different models for different categories of products may be required.
- Ensure capacity building for purchasers of medical equipment, including training to support the application of Green Public Procurement criteria

5. Leverage the transformation synergies of the Green and Digital agendas to increase overall system efficiencies and sustainability performance, such as dematerialisation

As healthcare workforce shortages continue to compound the strain on hospital capacity across the EU, many healthcare leaders are rethinking how and where they deliver care – from hospital to home. European healthcare systems no longer only deliver care in traditional hospital facilities alone but will increasingly leverage resources when and where they are most needed. This will increasingly require open and safe eco-systems for data. Financial pressures also require healthcare organisations to find effective solutions to maximise existing resources, while lowering costs and on-site maintenance personnel. Instead of a traditional model where a hospital may purchase and own technology outright, an increasing number are considering cloud-based technologies and the Software-as-a-Service (SaaS) model for their healthcare IT solutions.
Digitalisation enables remote monitoring, enhance diagnosis and (minimal invasive) treatment while reducing the need of physical resources. Thus, it can support the shift from resource-intensive clinical facilities to networked lower-cost settings and the home, thereby also expanding access to care.

With respect to circularity, digitalisation can be a powerful enabler for tapping into such healthcare system savings potentials, for **making hidden material flows visible**, **enabling smarter design choices upfront** or for **optimising waste management downstream**. It provides data, visibility, and tools to optimise materials, processes, and systems, such as in the following examples:

Exploiting system-level benefits through digitalisation	• **Transparency & Reporting**: Digitalisation supports ESG reporting by making sustainability metrics measurable and verifiable. • **Healthcare user and patient empowerment**: Apps and QR codes on products can educate healthcare professionals and patients and optimise use efficiencies while provide information on end-of-life management • **Artificial Intelligence in products and hospital process improvements:** AI can support hospital process improvements and resource efficiency in healthcare

	systems, for example by improving workflow management or decreasing energy consumption • Telemedicine and remote monitoring reduce CO2 emissions through a reduction in patient travel to surgeries and medical clinics as a result of the possibility of attending digital appointments and get digital access to test results and medical reports. This can reduce the need to travel to a clinic for a face-to-face visit or to pick up printed results or reports[15]. It can also reduce the need for travel by field service engineers and the need of in-hospital or in-office visits for tests etc. and its corresponding travel emissions. Telemedicine can also bring in virtual expertise to hospitals, providing support to staff and patients.
Digitalisation can support Sustainable Product Design	• **Digital Twins & Simulation**: Virtual models allow designers to test products for durability, energy use, recyclability, and environmental impact before physical production. This reduces waste in prototyping and helps optimise material use. • **Lifecycle Assessment (LCA) Tools**: Digital platforms integrate LCA data into the design phase, helping designers evaluate material-specific carbon impacts/design decisions (e.g., which material has lower emissions compared to another). However, simply summarizing a product's emissions based on materials could still be problematic without a standardized methodology for LCAs/PCFs. • **Generative Design & AI**: Algorithms can suggest product geometries that minimise material use while maximising performance, leading to lighter, resource-efficient products. • **Material Traceability & Databases**: Digital product passports (DPPs) and blockchain can track material sources, ensuring sustainable sourcing and enabling future reuse or recycling. • **Additive Manufacturing (3D Printing)**: Digital manufacturing techniques reduce offcuts and enable customised, repairable, and modular designs that extend product life.
Digitalisation can support better waste management practices	• **Smart Waste Tracking**: IoT sensors and RFID tags can track materials across their lifecycle, enabling effective collection, sorting, and recycling. • **Data-Driven Recycling Systems**: AI-powered vision systems in recycling facilities can improve sorting accuracy, ensuring higher-quality recycled materials.

[15] Holmner A, Ebi KL, Lazuardi L, Nilsson M. Carbon footprint of telemedicine solutions--unexplored opportunity for reducing carbon emissions in the health sector. PLoS One. 2014 Sep 4;9(9):e105040. doi: 10.1371/journal.pone.0105040. PMID: 25188322; PMCID: PMC4154849; Cravo Oliveira, Tiago & Barlow, James & Gonçalves, Luis & Bayer, Steffen. (2013). Teleconsultations reduce greenhouse gas emissions. Journal of health services research & policy. 18. 10.1177/1355819613492717.

	• **Circular Economy Platforms**: Digital marketplaces connect companies to reuse, refurbish, or exchange secondary raw materials, reducing landfill waste. • **Predictive Analytics**: Digital tools can forecast waste generation trends, helping cities and companies optimize logistics and design efficient waste collection routes. • **Digital Product Passports**: By embedding material and recycling information into products, waste processors know exactly how to disassemble and recycle items at end-of-life.

In practice, however, important barriers exits and need to be addressed:

- Software development and use also generate emissions. The next years will see a significant jump in the global carbon footprint of the overall ICT sector[16], with 14% of greenhouse gas emissions attributable to ICT by 2040. Training a state-of-the-art medical AI model on a large database of medical images may correspond to the typical carbon footprint of a European citizen[17]. Embracing digital sustainability principles, such as shifting to the cloud and adopting Green Software practices, plays an important role in reducing the energy use of digital health solutions. This includes the development of sustainable artificial intelligence (AI) solutions with more resource-efficient programming languages, helping to reduce energy consumption and needed hardware. Efforts to develop standards, tools and best practices for the development of green software are on-going in the broader software industry.
- The last years have seen the adoption of a high number of new EU legislations impacting digital health, including the Data Act, the Artificial Intelligence Act, the European Health Data Space Regulation as well as cybersecurity requirements. It is important that this legislative framework is implemented in a coherent and consistent manner, as part of an open digital ecosystem based open standards and interoperability.

Recommendations:

- **Gather more evidence and robust data at European level** on the net environmental impact of digital solutions on healthcare systems, and develop standardised metrics, for example building on the work of the European Green Digital Coalition.[18]
- **Support digital innovation enabling environmental impact reduction**, including in data analytics applications, Artificial Intelligence, telemedicine, remote monitoring and up-take of green cloud in healthcare; use digital tools to increase efficiencies in logistics and workflows in healthcare settings.
- Back up upcoming requirements on the digital product passports by **clear and thorough methods and standards** on how to obtain data in the very complex supply chain and avoid disproportionate requirements.
- **Further expand the** use of Electronic Instructions For Use (eIFU) for all medical devices
- Support **dissemination of best practices** on green software and AI model development and implementation in the medical technology industry.
- Ensure **coherence of digital tools**, i.e., DPP with EUDAMED, OSOA, EPREL.
- **Remove or improve impact toward administrative reporting burdens** that currently do not result in meaningful progress toward circularity (for example SCIP database)

[16] The real climate and transformative impact of ICT: A critique of estimates, trends, and regulations. The real climate and transformative impact of ICT: A critique of estimates, trends, and regulations - ScienceDirect

[17] Truhn, D., Muller-Frances, G., Kather, J.K. (2023) The ecological footprint of medical AI. European Radiology https://doi.org/10.1007/s00330-023-10123-2

[18] Home - European Green Digital Coalition

6. Seeking international alignment on circularity approaches for the medical technology sector with the respect of the quality and security for patients and healthcare practitioners.

Health is a human right. It does not stop at national or regional borders.
Besides, supply chains of the medical technology industries are internationally twined while bearing the highest potential of carbon emission reduction for the sector.
Seeking international alignment on circularity approaches in the medical technology sector is without alternative, particularly given the need to uphold the highest standards of quality and safety for patients and healthcare practitioners. Though the importance of facilitating the global circulation of refurbished medical equipment is recognised, significant barriers remain at both the national and international level, limiting the development of truly circular supply chains today.
At the European level, certain Member States' national legislations do currently not allow the purchase of refurbished medical equipment through public procurement procedures—while others fail to provide incentives for take-back schemes. Traditional procurement processes also tend to prioritise outright ownership of medical equipment. This approach leads to higher use of virgin materials and higher costs over the lifetime of the equipment, while simultaneously discouraging innovative models such as remanufacturing.
Today's green public procurement criteria in healthcare are heavily fragmented, complex while relevant standards, methodologies and definitions remain missing. Creating a level playing field based on science, internationally harmonised standards and agreed methodologies would be a game changer. Harmonising green public procurement criteria across the EU to implement the EU Green Deal in Healthcare is key. The pending revision of the EU Public Procurement Directive and New Legislative Framework offer the possibility to move to value based procurement and a consistent promotion of sustainability and resilience across sectors, including healthcare. We urge regulators to take a decisive step to create a predictable market for refurbished devices and to incentivise medtech manufacturers to invest in circular business models.
Waste shipment rules also need to better embrace circularity principles. They play a critical role in operationalising more circularity. According to the *status quo*, the export of used medical devices or components for repair or remanufacturing is often treated as a waste shipment, subjecting equipment to lengthy and costly procedures that undermine viable circular supply chains.
The ongoing European Commission consultation on the *Waste Shipment Regulation* offers a crucial opportunity to adapt the framework, facilitating cross-border movement of equipment while maintaining environmental and safety safeguards. More importantly, establishing a level playing field and dedicated infrastructure for the shipment of used equipment would significantly enhance the EU's ability to scale up circularity in the medtech sector.
At the global level, alignment with *OECD guidelines* is necessary to ensure that medical devices destined for reuse, repair, or refurbishment are not unjustly treated as waste.

References

- Health Council of the Netherlands, Towards sustainable devices in healthcare
- Circular economy of the materials in the healthcare industry: Opportunities and challenges - ScienceDirect
- Recycling technology & optimised processes developed to improve recycling yields for digital health devices- Digital Health in the Circular Economy

ANNEX: CIRCULAR ECONOMY CASE STUDIES

Case study 1: Refurbishment of medical imaging equipment

Description of the circular activity

Refurbishment has been an established practice in the medical imaging equipment industry for close to three decades. It is applied to many imaging modalities, including Magnetic Resonance, Computed Tomography, Molecular Imaging, X-Ray and Ultrasound. IEC 63077 describes and defines the process of refurbishment of used medical imaging equipment and applies to the restoring of used medical imaging equipment to a condition of safety and performance comparable to that of new medical imaging equipment without significantly changing the equipment's performance, safety specification and/or intended use as in its original registration.

Potential opportunities

Reduction of greenhouse gas emissions: the carbon footprint of a refurbished MR system is up to 45% lower than a new one[19].

Less material use: refurbishment saves scarce resources and keeps their value in the loop, including critical raw materials such as rare earths and metals.

Access to care: refurbished equipment is marketed at a lower price than new equipment, while providing the same safety and performance as well as warranty. Refurbishment thus helps hospitals and medical centers with budget restrictions to purchase high-quality equipment.

Commercial: Refurbished imaging equipment accounted for a global revenue of approximately 580 million US Dollar in 2021. Approximately 70% of all refurbished medical imaging equipment are sold in the U.S. (46%) and the European Union (24%).

Barriers

Procurement: several EU member states still require purchase of new equipment by default in their national procurement law. Even if allowed by law, cultural biases by hospital purchasers and healthcare professionals may prevent use of refurbished equipment.

Market access in third countries: many countries outside the EU do not allow refurbishment or import of refurbished equipment. That limits the market size at global level and reduces the commercial opportunity for export-focused European manufacturers.

New Legislative Framework: missing "repair as produced" principle means that changes in legislation lead to a situation where equipment sold outside the EU and refurbished here cannot be placed on the market again in the European Union.

References

DITTA. Good Refurbishment Practice. Good refurbishment practice : DITTA

[19] Figure based on LCA data for one product by one manufacturer. Figures differ based on product configuration, use and refurbishment location and energy mix.

Case study 2: Medical Device as a Service

Description of the circular activity

Instead of selling a medical device, manufacturers give access to devices (e.g. hospital monitors, ultrasound devices, wearable sensors or diagnostic software) under a subscription model, e.g. a fee per use, per patient or per outcome.

Potential opportunities

Environmental impact: performance- and access-based models, where the manufacturer retains ownership of the device, incentivize circular design, including for a long lifetime, durability, and repairability, availability of spare parts and upgrades, maintenance and take-back of the device. In addition, waste is reduced as supply is more efficiently matched to the needs of the users.

Healthcare outcomes: as-a-service models make more flexible adaptation to the real needs of healthcare organisations possible. When implemented with jointly developed KPIs for outcomes and quality of care, they can also contribute to the move towards value-based healthcare overall.

Access: users have access to state-of-the-art medical devices without potentially high upfront costs

Barriers

Budget allocation: strict differentiation between CapEx (that usually finances equipment purchases) and OpEx in hospital and national healthcare budgets may mean that as-a-service models (part of OpEx) are not yet foreseen

Procurement: tenders often still focus on technical device specifications instead of desired capabilities, and thus may exclude service-based offerings

Further case studies can be found here:
MedTech Europe report commissioned to BCG on "Decarbonising healthcare: how a competitive medical technology industry can contribute"

About MedTech Europe

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

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