Digital Health in the Circular Economy

POLICY RECOMMENDATIONS

ON CIRCULAR DIGITAL HEALTH DEVICES

Deliverable 6.2

This deliverable is awaiting formal review by the Project Officers and may be subject to change.

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ACRONYMS

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Term	Description
Art.	Article (of a regulation)
BoM	Bill of Materials
CMUR	Circular Material Use Rate
CRM	Critical Raw Material
DPP	Digital Product Passport
EEE	Electrical and Electronic Equipment
EFPIA	European Federation of Pharmaceutical Industries and Associations
EPR	Extended Producer Responsibility
EU	European Union
EUC	European Consultation
EUDAMED	European Database on Medical Devices
e-waste	Electrical and electronic waste
FDA	Food and Drug Administration (United States)
GSPR	General Safety and Performance Requirement
Int	Interview
ISO	International Organization for Standardization
NB	Notified Body
PW	Policy Workshop
ReSUD	Reprocessed single-use device
SoC	Substance of Concern
SUD	Single-use device
WEEE	Waste from Electrical and Electronic Equipment
WHO	World Health Organisation

REGULATORY ELEMENTS

Table 2: Regulatory elements

Short name	Official reference	Link
Battery Regulation	Battery Regulation (EU) 2023/1542	https://eur-lex.europa.eu/eli/reg/2023/1542/oj/eng
CRM Act	Critical Raw Materials Regulation (EU) 2024/1252	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202401252
CSRD	Corporate Sustainability Reporting Directive (EU) 2022/2464	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022L2464
CSDDD	Corporate Sustainability Due Diligence Directive (EU) 2024/1760	https://eur-lex.europa.eu/eli/dir/2024/1760/oj
ECGT	Empowering Consumers for the Green Transition Directive (EU) 2024/825	https://eur-lex.europa.eu/eli/dir/2024/825/oj/eng
EHDS	European Health Data Space Regulation (EU) 2025/327	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202500327
ESPR	Ecodesign for Sustainable Products Regulation (EU) 2024/1781	https://eur-lex.europa.eu/eli/reg/2024/1781/oj/eng
EUDR	EU Deforestation Regulation (EU) 2023/1115	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02023R1115-20251226
GDPR	General Data Protection Regulation (EU) 2016/679	https://eur-lex.europa.eu/eli/reg/2016/679/oj
LoW	List of Waste Commission Decision 2000/532/EC	https://eur-lex.europa.eu/eli/dec/2000/532/oj
MDR	Medical Device Regulation (EU) 2017/745	https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng
POPs	Persistent Organic Pollutants Regulation (EU) 2019/1021	https://eur-lex.europa.eu/eli/reg/2019/1021/oj/eng
PPWR	Packaging and Packaging Waste Regulation (EU) 2025/40	https://eur-lex.europa.eu/eli/reg/2025/40/oj/eng
REACH	Registration, Evaluation, Authorisation and Restriction of	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20221217

	Chemicals Regulation (EC) 1907/2006	
RoHS	Restriction of Hazardous Substances Directive 2011/65/EU	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02011L0065-20160715
WSR	Waste Shipment Regulation (EU) 2024/1157	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32024R1157
WEEE Directive	Waste Electrical and Electronic Equipment Directive 2012/19/EU	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32012L0019
WFD	Waste Framework Directive 2008/98/EC	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008L0098-20251016

1. EXECUTIVE SUMMARY

This policy brief presents key policy recommendations to support the effective implementation and further development of the EU regulatory framework for digital health devices, with the aim of improving their circularity. It builds on an assessment of the governing landscape, including an analysis of best practices and challenges in selected Member States. The brief seeks to inform policymakers and stakeholders on targeted actions to strengthen regulatory coherence, foster innovation, and maintain high standards of patient safety and environmental sustainability across the EU.

The analysis highlights significant barriers to advancing circularity in digital health devices across the value chain. Under the MDR, fragmented Member State implementation, particularly regarding reprocessing of single-use devices, combined with limited harmonised guidance, regulatory complexity, high conformity assessment costs, and insufficient evidence and validation frameworks, constrains sustainable practices. EUDAMED usability challenges further limit transparency and effective oversight. Across related legislation (ESPR, WEEE, CRM Act, Battery Regulation, European List of Waste (LoW) classification, PPWR, and transboundary shipment frameworks), additional obstacles arise from hazard-based waste rules that overlook circularity objectives, inconsistent interpretations giving rise to a fragmented overview, gaps in design guidance (including for CRMs and biocompatible materials), insufficient traceability and CRM transparency, and administrative burdens linked to cross-border activities. Overlaps and tensions between legal instruments –particularly between safety and sustainability objectives (MDR–ESPR)– further complicate compliance. Collectively, these factors limit economies of scale for circular strategies and undermine recovery and reuse efforts.

The recommendations in this policy brief propose targeted amendments across pieces of EU regulations and policy mixes to enable circularity in digital health devices.

- Key actions under the MDR include revising Article 17 on reprocessing to provide greater clarity, aligning with the ongoing MDR revision by the Commission, and strengthening digitalisation and traceability through EUDAMED and/or the Digital Product Passport.
- To reconcile safety and sustainability objectives under the MDR and ESPR, the brief proposes a joint risk assessment framework, alongside tailored ecodesign and end-of-use processing guidance for digital health devices, and the prioritisation of digital home-care devices under the ESPR, while prioritizing patient safety.
- Further measures call for greater harmonisation of WEEE and waste legislation, expansion of the LoW to include specific codes for digital health devices, as well as improved collection and segregation practices, simplified cross-border shipment rules, clearer decontamination standards, and enhanced transparency and recovery of CRMs.
- And finally, additional recommendations address clearer sustainability communication, expanded circularity metrics beyond CMUR, and harmonised terminology.

Collectively, these measures are likely to reduce governance fragmentation and create the conditions for scalable circular strategies in the sector.

The outcomes of this work are intended for policymakers at EU and Member State levels, and can also inform future consultations on WEEE, Waste, ESPR, or DPP regulations. Manufacturers, civil society stakeholders, including patients' associations and healthcare worker representatives, may likewise benefit from the findings and recommendations. Together, these frameworks offer opportunities to enhance design for circularity, traceability, and responsible

end-of-life management of healthcare devices, without compromising patient safety or market access.

2. INTRODUCTION AND CONTEXT

The accelerated digitalisation of healthcare is transforming the delivery of care, improving diagnoses, monitoring, and patient outcomes through an expanding range of connected medical technologies. From wearable sensors and remote monitoring systems to advanced imaging equipment and digital therapeutics, digital health devices are becoming integral to modern health systems, which, at the same time, are contributing to a growing stream of electrical and electronic waste, raising questions about resource use, end-of-life management, and environmental impact.

Healthcare remains embedded in a predominantly linear "take, use, and dispose" model of resource utilisation. It is therefore essential to transition towards more sustainable and circular approaches that conserve natural resources, optimise material use, and reduce waste. This transition must be achieved while rigorously complying with the sector's stringent regulatory, quality, and safety requirements and minimising risks to public health and the environment.

At EU level, policies push both digitalisation and circularity. The **European Health Data Space Regulation (2025)** supports further embedding digital aspects within healthcare. The **European Action Plan for a Circular Economy (2015),** the **European Green Deal (2019)** and the **Clean Industrial Deal (2025)** have embedded circular economy priorities into the policy agenda. These commitments have produced regulatory frameworks such as the **Ecodesign for Sustainable Products Regulation (2025**) and will inform new and updated regulations such as **Circular Economy Act (expected 2026)**. By contrast, the **Medical Device Regulation (2017)** provides limited guidance on circularity beyond the optional, member-state-level reprocessing allowance in Article 17. A regulatory gap still exists in the interpretation of the exclusion in the **WEEE Directive (2012)** of medical devices when these are expected to be infective prior to end-of-life.

These regulatory gaps, combined with the lack of detailed guidance, including at national level, are limiting the transition towards circularity in the medical devices industry.

The Digital Health in the Circular Economy (DiCE project) seeks to address these challenges by developing comprehensive, environmentally sound solutions to enhance circularity across the lifecycle of digital health devices. Guided by viable circular business models, DiCE aims at improving product design, empowering consumers, optimising collection and reverse logistics systems, fostering circular strategies and improving recycling yields for digital health devices.

This policy brief[1] reviews the current regulatory landscape affecting the circularity of digital health devices and offers recommendations for European decision-makers and stakeholders. Drawing on identified key drivers and barriers, recent legislative developments, official consultations, and national perspectives, it highlights both challenges and opportunities to support coherent, effective implementation across the European Union (EU).

[1] This report represents DiCE project deliverable 6.5 (D6.5) on Policy recommendations and is linked to task 6.5 (T6.5) 'Review of existing EU legislation, standards and policies'.

3. REGULATORY LANDSCAPE

This section presents the EU regulatory developments from a lifecycle perspective, with a specific focus on circular strategies. It also outlines key international initiatives that complement or influence the EU framework.

3.1 KEY REGULATORY INSTRUMENTS

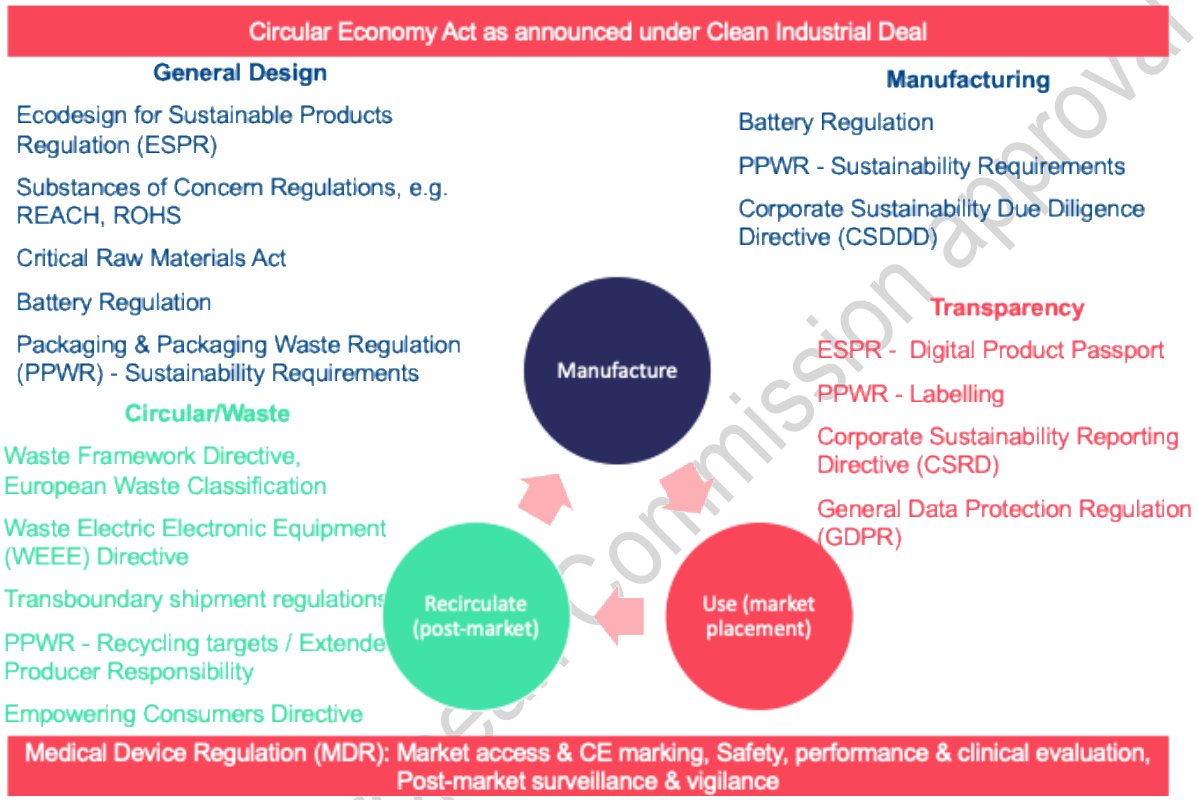


Figure 1: Regulations, Directives and Acts part of the regulatory ecosystem of digital medical devices

Figure 1 shows regulations governing activities across the three interconnected medical devices lifecycle phases of (1) manufacture, (2) use (market placement), and (3) recirculation (post-market)). Together, they form an integrated regulatory architecture that structures how medical devices are designed, manufactured, placed on the market, monitored, and ultimately taken back and recirculated, while aiming to ensure safety, sustainability, transparency, and accountability across the value chain.

At the core of this framework sits the Medical Device Regulation (EU) 2017/745 (MDR), which establishes essential requirements for safety, performance, clinical evaluation, conformity assessment, and CE marking. Its scope spans the entire lifecycle of medical devices, from design and manufacturing controls to post-market surveillance and vigilance. It therefore functions as the central anchor of compliance within the EU for medical devices.

Complementing the MDR is a wider set of sustainability, digital, and transparency instruments that extend governance and regulatory requirements across the lifecycle and may apply in various degrees to medical devices. These regulations, directives, and legislative acts shape product design from an environmental performance perspective, regulate the management of

substances of concern to the environment and health and use and recovery of CRMs, define labelling and disclosure requirements, and structure how data is handled throughout the value chain. They also introduce obligations related to resource efficiency, waste management, circularity, corporate due diligence, and information transparency.

- **Design and manufacturing phase:** the Ecodesign for Sustainable Products Regulation (EU) 2024/1781 (ESPR), the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) 1907/2006 (REACH) and the Restriction of Hazardous Substances Directive 2011/65/EU (RoHS), the Critical Raw Materials Regulation (EU) 2024/1252 (CRM Act), the Battery Regulation (EU) 2023/1542, the Packaging and Packaging Waste Regulation (EU) 2025/40 (PPWR), and the Corporate Sustainability Due Diligence Directive (EU) 2024/1760 (CSDDD) influence product composition, resource efficiency, and responsible sourcing.

- **Market placement stage:** transparency instruments such as the Digital Product Passport (DPP) under ESPR, PPWR labelling requirements, CRM Act labelling and disclosure requirements, Corporate Sustainability Reporting Directive (EU) 2022/2464 (CSRD), and the General Data Protection Regulation (EU) 2016/679 (GDPR) reinforce traceability and accountability.

- **Post-market phase:** the Waste Framework Directive 2008/98/EC (WFD), the Waste Electrical and Electronic Equipment Directive 2012/19/EU (WEEE Directive), the Waste Shipment Regulation (EU) 2024/1157 (WSR), CRM Act, and Extended Producer Responsibility (EPR) principles govern collection, sorting, reuse, recycling, material recovery and final disposal of targeted product categories.

A comprehensive description of these regulatory instruments can be found in Annex A, while Table 2 provides a detailed list of short names and links.

3.2 EU REGULATORY INSTRUMENTS WITH STRONG LINKAGES

Interlinkages between key regulations form several clusters that help explain how the EU regulatory ecosystem addresses design, chemical management, waste management, and sustainable purchasing and transparency.

- **Managing design to prevent waste (ESPR-PPWR-WFD-CSDR-Battery Regulation).** The ESPR provides a horizontal framework in principle aligned with the PPWR, the Battery Regulation, the CRM Act, and the WFD, to ensure repairability and proper end-of-life handling from the design phase. Depending on the double materiality assessment it requires, the CSRD could further strengthen this linkage by requiring companies within its scope to disclose how their design, and waste-management strategies translate into measurable environmental sustainability outcomes.

- **Managing substances of concern (SoCs) (REACH-RoHS-Battery Regulation-PPWR-MDR)**. REACH serves as the foundational EU chemicals regulation, interfacing with RoHS, the Battery Regulation, the PPWR and the MDR, to ensure consistency in hazardous substance restrictions, exemptions, and information requirements.

- **Waste management (WEEE Directive-WFD-Battery Regulation-Waste Shipment Regulation).** The WFD sets the fundamental principles of EU waste law, including definitions, waste hierarchy and EPR, which directly underpin the WEEE Directive and

Battery Regulation. It also governs how waste can be shipped within, into, or outside the EU, imposing strict controls, notification requirements, and prohibitions on illegal exports. This ensures that waste in general and WEEE in particular is properly collected, treated, and transported in a legally compliant and environmentally sound manner.

- **Responsible sourcing and transparency (CSRD-CSDDD and related frameworks).** On the corporate and governance side, CSRD requires companies to report on sustainability risks and impacts, while CSDDD obliges them to identify, prevent, and mitigate those risks across their value chains. These requirements are complemented by other EU instruments pursuing similar objectives, including the Battery Regulation, which introduces due diligence obligations, and the CRM Act, which strengthens transparency and resilience across CRM value chains. In addition, sustainability issue-specific frameworks such as the EU Deforestation Regulation (EUDR) further reinforce traceability and responsible sourcing principles. For the companies in their scope, these instruments establish a chain-of-responsibility model in which design, sourcing, manufacturing, reporting, and market activities are treated as interconnected steps rather than independent obligations.

3.3 KEY INTERNATIONAL INITIATIVES

Three layers beyond the EU are identified as influencing EU value chains:

- **The first layer comprises widely recognised supranational guidance** that functions as de facto requirement for the sector. This is particularly true for recommendations, standards, and frameworks issued by the **World Health Organization (WHO),** which are widely adopted by national authorities and industry. Relevant WHO resources include the Global Atlas of Medical Devices (2022b), the Standardization of Medical Devices Nomenclature (2022c), the Global Model Regulatory Framework (2017), guidance on decontamination and reprocessing (2016, 2022), and healthcare waste management guidance (2014, 2024), all aimed at ensuring safe handling, reprocessing, disposal and environmental protection.

- **The second layer relates to non-EU regulations that have achieved acceptance beyond their jurisdictions**. With the largest medical device producers located in the United States (US) (40%) and Europe (35%), followed by China (10%) and Japan (8%) (Global Growth Insights, 2025), large companies can exert considerable influence over suppliers worldwide, including on regulatory and technical compliance. The **US Food and Drug Administration (FDA)** framework often serves as an international reference point and complements the EU MDR in the global regulatory landscape.

- **The third layer consists of international standards widely adopted by industry and frequently referenced in regulatory documents.** Key examples include ISO 13485 (2016) on quality management systems, ISO 14937 (2020) on sterilisation of medical devices, ISO 11607 (2019) on the use of materials in packaging and the ISO 59000 family of standards on circular economy (2024) (such as ISO 59004 on CE terms and definitions, 59010 on circular business models and 59020 on circularity performance indicators). More details about these international standards are introduced in Annex D.

4. EVIDENCE FROM DICE

This section introduces the methodology used to assess the policy framework shaping circularity in health devices in general, and the digital health devices in particular. Findings are presented across the value chain stages and complemented by an analysis at Member State level.

4.1 APPROACH

The policy brief was developed using a multi-step, evidence-based methodology combining desk research, contributions from policy-related findings from DiCE work packages, stakeholder engagement, cross-project collaboration, and regulatory analysis at both EU and national levels (Figure 2). This approach was complemented by systematic evidence collection and synthesis. The process culminated in an assessment of barriers, drivers, gaps, and opportunities forming the basis for targeted policy recommendations.

A detailed description of relevant regulations and policies is provided in Annex A. Stakeholders and consultation processes considered in developing this policy brief are listed in Annex B. To ensure clarity and consistent terminology, a concise glossary of key terms and agreed definitions was developed (DiCE, 2025a), with a selection presented in Annex C.

Figure 2: Key steps in digital health policy research

4.2 REGULATORY FINDINGS ACROSS VALUE CHAIN STAGES

The following subsections summarise the findings of the EU regulatory framework assessment conducted within DiCE concerning the circularity of digital health devices.

4.2.1 MDR IMPLEMENTATION

Stakeholder consultations and interviews, public responses to the EU Call for Evidence on the Evaluation of the MDR (EC, 2024) (Annex B), and the European Commission's Study on MDR Article 17 (EHDEA, GÖ S&P Areté, 2024) highlight several key challenges in the MDR implementation, particularly concerning the reprocessing of single-use medical devices (SUDs):

- **Lack of evidence:** Decisions on whether reprocessing is permitted are often not based on robust evidence. Additional data is needed on the safety, effectiveness, post-market surveillance, economic and environmental impacts, and ethical considerations of reprocessed single-use devices (ReSUDs). Differences between reprocessing conducted by healthcare institutions versus manufacturers must also be considered.

- **Lack of harmonisation:** While the MDR requires strict control and validation of SUD reprocessing processes, implementation varies widely across Member States. A focused analysis of this issue is provided in in Section 4.3.1.

- **Uncertainty over what can be reprocessed:** Many devices are not designed for multiple uses. Despite MDR Common Specifications (Article 9), ambiguities around "single-use", "single-patient use", "reuse", and "multi-use", lead to overly cautious interpretations.

- **Procedural differences and efficiencies, in particular for international value chains:** The CE marking process (Article 20) for new or reprocessed devices remains lengthy and administratively demanding. Approval timelines of 18–30 months and costs of EUR 700,000–1.4 million (MedTech Europe, 2025) contrast with the US FDA's 9–12-month approval process costing USD 300,000–600,000. Fragmented EU implementation further raises per-device costs.

- **Incentives linked to single-use labelling:** MDR requires manufacturers to demonstrate compliance with all applicable requirements for reusable devices, including validated cleaning and reprocessing instructions which need Notified Body (NB)[2] approval. Labelling as a SUD avoids these obligations.

- **Lack of harmonised validation protocols for disinfection:** Under the MDR, reprocessors must demonstrate general conformity and validation per the General Safety and Performance Requirements (GSPRs). However, there is a lack of harmonised, device-specific standards, leaving practitioners without operational guidance.

- **Labelling differences for reprocessed devices and lack of guidance for reprocessors and users:** The MDR (Articles 10 and 18) requires devices to meet general labelling requirements. However, the regulation does not provide reprocessing-specific standards comparable to FDA guidance. EU reprocessors and users may therefore face gaps in information about reuse limits, safety, and instructions.

[2] A notified body (NB) s an independent organization designated by a competent authority to assess whether a medical device complies with applicable regulatory requirements before it can be placed on the market.

These gaps highlight the need for harmonised, evidence-based guidance on recirculation, alongside simplified regulatory pathways and clearer operational standards to ensure patient safety while enabling the circular practice of reprocessing.

4.2.2 EUDAMED DATA MANAGEMENT AND IMPLEMENTATION UNDER THE MDR

Public consultations, including the EU Call for Evidence on the Evaluation of the MDR (EC, 2024), indicate recurring challenges related to European Database on Medical Devices (EUDAMED) rollout, functionality, and usability. Delays in the phased implementation and uncertainties over mandatory module use have led to inconsistent registration and reporting across Member States. Stakeholders also reported technical and operational issues such as complex data entry processes, limited functionality for bulk uploads, and insufficient user guidance.

These issues are particularly relevant for medical devices reprocessed under Article 17 of the MDR, where clear, accurate, and traceable information is essential.

Linked to sustainability data that could feed the EUDAMED, stakeholders noted that the Circular Material Use Rate (CMUR)[3] being highly recommended within the future Circular Economy Act discussions (CE Act consultation, 2025) may not be fully adequate to capture broader circularity aspects such as product design, repairability, durability, and end-of-life recyclability. In addition, the platform does not include modules for other sustainability information required under separate legal instruments, which limits its usefulness.

4.2.3 ESPR IMPLEMENTATION

The limited clarity on cross-border shipment rules for medical devices considered hazardous at end of life and on how the ESPR interfaces with existing waste and shipment legislation are challenging. Furthermore, since design guidance for medical devices is not yet developed and overlapping exist with MDR guidance for design, the potential of increased circularity strategies in medical devices is limited. In addition, the timeline for the application of the ESPR to medical device components and intermediate products covered by its requirements remains unclear creating uncertainty. Moreover, the lack of differentiation between consumer devices, home-care medical devices, and hospital medical devices, leads to uncertainty regarding applicable reuse, recycling, and waste requirements. Finally, several definitions lack clarity such as i.e., sustainable choices.

4.2.4 WEEE DIRECTIVE IMPLEMENTATION

The WEEE Directive is often narrowly or inconsistently applied to medical devices, particularly with regard to contaminated and/or SUDs. The WEEE Directive excludes medical equipment where it's expected to be infective prior to end of life (Article 2), but this exclusion is usage-expectation base. Consequently, in the absence of risk of infection after use, for instance due to its reusability or validated sterilisation/decontamination, the medical device would fall within the scope of the WEEE Directive. This interpretation is summarised in the EU FAQ (EC, 2014) and the European WEEE Registers Network guidance (EWRN, 2016), but neither is legally binding. Although this possibility is not explicitly foreseen in the WEEE Directive, it is recognised under certain Member State regulatory frameworks (Spain, France, UK, or Germany). Moreover,

[3] It measures the share of a material in a product that comes from recycled sources

the absence of standardized collection and segregation practices within healthcare facilities frequently results in mixed, hence, potentially hazardous waste streams and the default incineration, undermining circular economy objectives. There is also the lack of effective traceability systems, which limits producers' ability to track medical devices once they are collected as WEEE, as well as limited awareness and understanding among healthcare actors of their respective obligations under WEEE legislation.

Finally, there is as well the absence of clear guidance on reverse logistics for home-care medical devices, where contamination risks, dispersed users, and unclear allocation of responsibilities complicate the establishment of effective take-back systems.

4.2.5 CLASSIFICATION OF MEDICAL WASTE

The classification of medical waste under the EU List of Waste (LoW) (Commission Decision 2000/532) presents a key challenge for circular management. While the LoW provides a harmonised EU framework to support consistent waste handling and regulatory compliance across Member States, its approach to medical waste is largely hazard-based and relies on broad categories. This limitation is particularly critical for digital health devices, which combine regulated medical functionality with characteristics of EEE, falling potentially under the WEEE Directive if properly decontaminated. This low level of differentiation, with little distinction by material composition, device type, or reuse and reprocessing potential e.g. of digital health devices, limits the classification and sorting of digital healthcare devices for further implementing circular economy practices, including reprocessing and recycling.

4.2.6 CRM ACT IMPLEMENTATION

The CRM Act establishes that at least 25% of annual EU consumption of CRMs should be met through recycled materials. However, information on CRM content is largely unavailable, as CRM reporting requirements for finished products are conditional on very recent or future rule-making, as it is the case of medical devices. Present-day Bills of Materials (BoMs) do not specify the presence, type, or location of CRMs in a product, but only indicate the use of alloys or components (such as printed circuit boards) that could ultimately contain CRMs. Additionally, it has been proven that identifying CRMs requires costly, highly specialised analysis, which is nowadays impractical given the low concentrations and wide range of CRMs used (DiCE, 2024a). Furthermore, the absence of design guidance under the CRM Act and the ESPR to address issues such as chemical binding of CRMs in alloys, dilution of CRM-rich components in mixed-material streams, and contamination during medical device use, limits recycling yields and reduces the contribution of digital health devices to CRM recovery.

4.2.7 TRANSBOUNDARY MOVEMENTS OF USED MEDICAL DEVICES

The management of transboundary movements of used healthcare and medical devices is affected by a range of regulatory and operational challenges. These include fragmented national responsibilities and approval procedures, which often require consent from multiple competent authorities along shipment routes, leading to delays and increased complexity. Inconsistent terminology and differing interpretations of key concepts such as "waste," "risk," and "contamination status" further contribute to legal uncertainty.

In addition, the international framework established by the Basel Convention4 and its recent amendments on WEEE, duly incorporated in the WSR, adds regulatory requirements for many cross-border shipments of WEEE by subjecting them to prior notification and consent procedures. While these measures are essential to prevent illegal exports and ensure environmentally sound management, they may also create unintended barriers to circularity. Recycling, reprocessing, or recovery facilities with the required technical capabilities are not necessarily located in the Member State where waste is generated, and efficient secondary raw material markets often depend on cross-border movements. Consequently, burdensome shipment procedures and divergent national requirements for the transport of contaminated products can increase administrative costs, reduce predictability for economic operators, and limit the development of specialised circular value chains across Europe.

4.2.8 BATTERY REGULATION IMPLEMENTATION

Compliance with the Battery Regulation may require changes to battery and product design, for example, to meet removability or replaceability requirements. Such design modifications can constitute a significant change to the device, potentially triggering an update of the conformity assessment. As a result, a review by the NB may be required, which could lead to an extension or modification of the scope of the existing MDR certificate. This additional review would therefore result in a more complex and time-consuming process, with associated administrative burden and increased costs for manufacturers.

4.2.9 CONTRADICTIONS AND TENSIONS OF SELECTED REGULATORY INSTRUMENTS

Even though the EU policy mix and associated governing instruments are designed to be complementary, areas where overlapping EU legislation may create practical compliance challenges have been identified (see a consolidation in Table 3).

- **MDR–ESPR | Quality and safety vs Sustainability.** Potential tensions between the MDR and ESPR arise from their scope and objective angle: MDR prioritises patient safety and clinical performance, while ESPR pursues sustainability objectives such as durability and repairability. MDR-compliant design choices (such as single-use or sealed devices justified on safety grounds) may remain environmentally suboptimal without corresponding sustainability obligations. In contrast, ESPR's emphasis on repairability can conflict with MDR requirements on infection control.
  ESPR requirements on product information and transparency may also complicate MDR-mandated labelling and instructions for use in the future, once the corresponding implanting acts are published. While it is acknowledged that the ESPR DPP is still under development, there is also a perceived risk of overlap between the information required for EUDAMED and that envisaged for the DPP.
  The uncertainty created by the phased inclusion of medical devices under ESPR will necessitate gradual implementation of these future sustainability requirements in particular where they would lead to design changes affecting existing MDR conformity assessments.

- **PPWR vs National waste rules | Harmonisation tensions.** The PPWR is a directly applicable EU regulation that establishes harmonised requirements for packaging and

[4] The Basel Convention is an international treaty adopted in 1989 under the United Nations Environment Programme (UNEP) that regulates the transboundary movements of hazardous wastes and other wastes, aiming to protect human health and the environment by ensuring their environmentally sound management. https://www.basel.int/

mandates EPR schemes across all Member States. However, it relies on national legal frameworks for the implementation, enforcement, producer registration, and fee collection of EPR obligations. As a result, while the PPWR introduces greater alignment in objectives, definitions, and certain requirements (e.g. labelling, targets), EPR systems are likely to remain operationally fragmented across Member States. Hence, Member States retain discretion to maintain or introduce stricter, or sector-specific requirements, including those specific to healthcare waste management. National collection systems and producer responsibility arrangements may need restructuring to align with PPWR's standardised labelling, recycling targets, and obligations. Overall, the tension reflects a trade-off between EU-wide legal certainty and national autonomy in waste management.

- **Transparency obligations and trade secret risks | CSRD and CSDDD.** The CSRD reporting and CSDDD due diligence obligations may conflict with trade secret protection and intellectual property concerns, as companies are required to disclose risks, impacts, and mitigation measures without revealing proprietary design or sourcing details. These tensions require careful legal interpretation, governance mechanisms, and technical safeguards to ensure compliance.

- **Substance restrictions | Navigating REACH and RoHS.** REACH and RoHS regulate hazardous substances but through different mechanisms, scopes, and exemption processes. REACH broadly applies to chemicals, mixtures, articles and complex products, requiring registration, authorisation, and communication of substances of very high concern, while RoHS focuses on specific hazardous substances in electrical and electronic equipment. For medical devices, this can result in situations where a substance is restricted under REACH but still temporarily exempted under RoHS (or vice versa), requiring manufacturers to carefully assess which rule prevails under the principle of *lex specialis* and to manage dual compliance strategies.
  When dealing with SoCs, the landscape is much broader, including the Stockholm Convention on Persistent Organic Pollutants (POPs) and other regulatory instruments such as the Battery Regulation, the PPWR and the ESPR. In particular, the Batteries Regulation and the ESPR provide for restrictions on substances that can impede the recyclability of products, components, or materials, while the PPWR introduces equivalent requirements specifically for packaging and packaging components. Together, these instruments compound the complexity of SoCs management from the design stage onwards.

Table 3: Tension dynamics across selected regulatory frameworks

Interaction	Type of tension	Core objectives in tension	Level of tension	Key drivers of tension
MDR – ESPR	Policy objective misalignment	Patient safety & clinical performance vs sustainability (durability, repairability, transparency)	Systemic	Diverging regulatory goals; design constraints (e.g. single-use vs repairable); evolving scope of ESPR.
PPWR vs National Waste Rules	Governance / competence tension	EU harmonisation vs Member State autonomy	Systemic	Differences in national waste management systems; varying implementation and interpretation of EU rules.
CSRD & CSDDD vs Trade Secrets	Transparency vs confidentiality	Disclosure of ESG risks and impacts vs protection of IP and proprietary information	Systemic	Increasing corporate due diligence obligations and stakeholder expectations for

				transparency; legal uncertainty over disclosure boundaries.
REACH, RoHS and related frameworks	Regulatory overlap / rule interaction	Broad chemical safety vs product-specific substance restrictions	Operational / regulatory complexity	Evolving regulatory requirements and compliance complexity.

4.3 FINDINGS AT MEMBER STATE LEVEL

4.3.1 FRAGMENTED MDR IMPLEMENTATION AT MEMBER STATE LEVEL

A dominant issue across regions is the fragmentation of the MDR implementation. The different status of EU countries concerning the adoption of reprocessing option under the MDR has been extensively researched and is illustrated in Figure 3.

Additional expert input through interviews and in the European Commission's Study on the implementation of MDR Article 17 (EHDEA, GÖ S&P Areté, 2024) highlights the opt-in/opt-out clause in MDR Article 17, which allows Member States to individually determine whether to permit reprocessing of SUDs. This undermines market harmonisation and creates legal uncertainty.

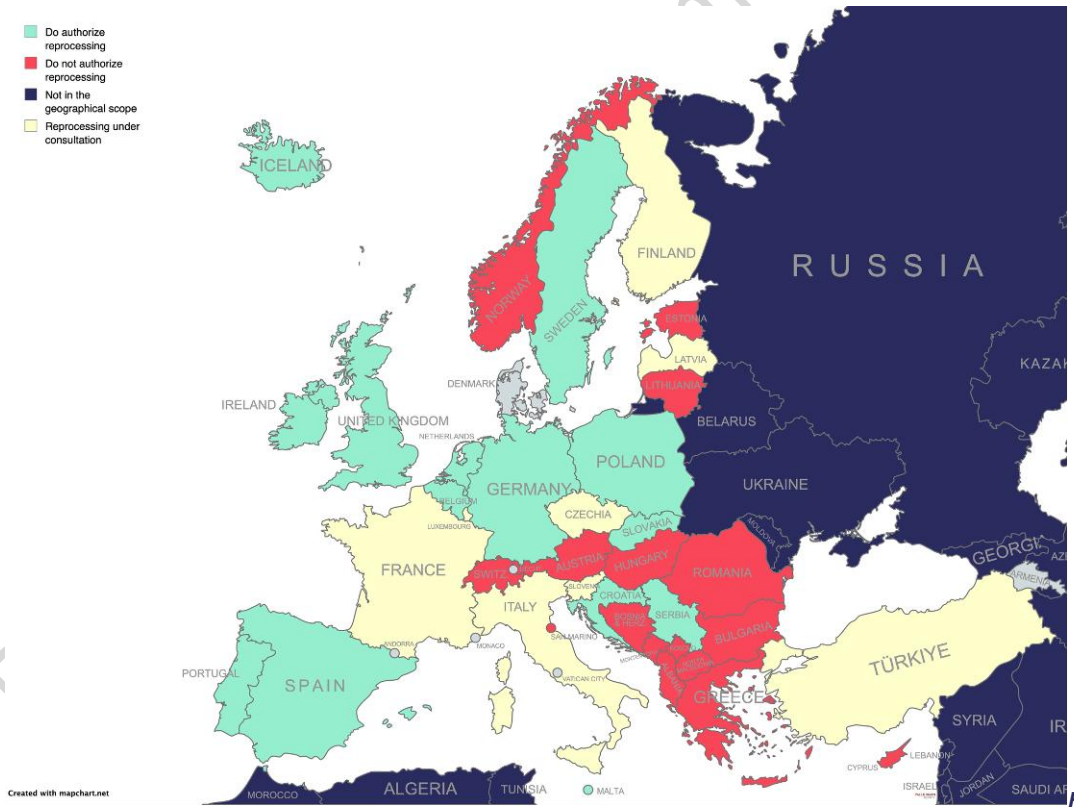


Figure 3: European countries and their regulatory status on the authorization (or not) of reprocessing of single-use medical devices (June 2026) (no updates by May 2026)

4.3.2 FINDINGS FROM SELECTED EUROPEAN COUNTRIES

Key issues identified in Slovenia, Belgium and Spain (where DiCE conducted more in-depth research, pilots and consultations) that are limiting the circularity of digital health devices,

include inconsistent classification, fragmented waste streams management, and regulatory gaps. More specifically, the following issues outstand:

- Classification inconsistencies: Digital health devices face unclear categorization, complicating WEEE compliance and take-back obligations.
- Exclusion from WEEE streams: Contaminated/infectious devices are barred from standard WEEE pathways post-decontamination, alongside unclear recycling routes for sterilized ones prioritizing risk over material recovery.
- Standardized terminology gaps: Lack of harmonised definitions (e.g., "single-use device," "reprocessable device," "recyclable waste").
- Fragmented national implementation: Decentralised systems (e.g., Belgium's regional splits; Spain's varying regional timelines) cause inconsistent practices.
- Cross-border and financial hurdles: Administrative complexity blocks transboundary reprocessing of SUDs; many digital MDR-classified devices are not declared as EEE, skipping PRO fees (“freeriding”) for end-of-life management.
- Procurement and safety oversights: Tenders ignore lifecycle costs, repairability, and take-back opportunities. None of the three countries currently has a mandatory sustainable public procurement framework applicable to healthcare centres and hospitals.
  Note. Lithuania and France are examples of countries with advanced mandatory green procurement regulations to be applied by healthcare centers: French Loi n° 2021-1104 (2021), French MEFSIN (2022), and Lithuanian Ministerial Order (MERL, 2021).

More background information and details about the findings identified in Slovenia, Belgium and Spain are presented in Annex E.

5. BARRIERS

This section summarises the main regulatory, operational, and governance barriers across the value chain that currently constrain the circularity of digital health devices in the EU. Barriers are grouped according to lifecycle stages.

Design stage and manufacturing stages

Barrier 1. *Safety–sustainability tensions (MDR vs ESPR).* Repairability and durability objectives may conflict with infection control and patient safety requirements.

Barrier 2. *Absence of regulatory incentives*. MDR requirements for reusable devices (validation, documentation, NB review) does not create incentives to market devices as reusable.

Barrier 3. *Uncertainty around device reprocessability and terminology.* Ambiguities around "single-use," "single-patient use," and "reuse" can limit circular design choices.

Barrier 4. *Lack of design guidance for CRM recovery (ESPR & CRM Act*). No clear regulatory guidance on designing for recycling or recovery of critical raw materials.

Barrier 5. *Battery regulation triggering MDR reassessment.* Battery removability and replaceability requirements may trigger new conformity assessments under MDR.

Barrier 6. *Limited guidance on biocompatible and non-toxic materials.* This can support increasing the sustainability of devices and packaging materials.

Barrier 7. *Lengthy and costly CE Marking and conformity assessment procedures.* High administrative burden and long timelines for new and reprocessed devices.

Barrier 8. *Overlapping compliance pathways of substances of concern (REACH, RoHS and others).* Compliance requirements create regulatory complexity.

Use stage and data governance

Barrier 9. *Insufficient reprocessing-specific labelling standards.* Lack of tailored labelling guidance for ReSUDs limits clarity for healthcare professionals.

Barrier 10. *Delayed and inconsistent rollout of EUDAMED.* Phased implementation and uncertainty around mandatory modules hinder consistency.

Barrier 11. *Administrative and technical burdens in EUDAMED data management.* Complex data entry, limited bulk upload functions, and insufficient guidance.

Barrier 12. *Trade secret risks under CSRD and CSDDD disclosure obligations.* Sustainability reporting may conflict with IP protection.

Recirculation stage

Barrier 13. *Fragmented and non-harmonised MDR implementation across Member States.* National variations increase compliance costs and limit scale.

Barrier 14. *Insufficient evidence base for reprocessing decisions.* Insufficient data on safety, environmental impact, and economic performance of reprocessed devices.

Barrier 15. *Broad, hazard-based classification of medical waste (LoW).* Limited differentiation by material composition or reuse potential.

Barrier 16. *Lack of standardised collection and segregation practices.* Mixed waste streams in healthcare settings often result in default incineration.

Barrier 17. *Inconsistent application of the WEEE Directive to medical devices.* Divergent national interpretations and narrow scope application.

Barrier 18. *Absence of harmonised validation protocols for decontamination.* No device-specific standards for cleaning, sterilisation, and disinfection of SUDs.

Barrier 19. *Limited traceability for devices entering WEEE streams.* Producers cannot effectively track devices once discarded.

Barrier 20. *Insufficient CRM content transparency.* Lack of BoMs specifying CRM presence hampers recycling.

Barrier 21. *Insufficient economies of scale for viable CRM recycling or reprocessing.* This is due to the low amounts of collected CRM-containing health devices.

Barrier 22. *Fragmented rules for transboundary movements of used devices.* Multiple approvals, inconsistent terminology, and legal uncertainty.

Barrier 23. *Unclear cross-border shipment and reverse logistics rules.* Particularly problematic for contaminated and home-care devices.

Barrier 24. *Tensions between EU-level and national waste rules.* Harmonisation reduces fragmentation but may limit Member States' flexibility to maintain stricter sector-specific practices.

Barrier 25. *Limited scope of circularity metrics in the CE Act.* The proposed CMUR indicator focused narrowly on recycled materials use. Additional indicators are needed to capture broader circularity dimensions such as durability and repairability.

6. POLICY RECOMMENDATIONS

This section presents a concise set of policy recommendations to address the regulatory, operational, and governance barriers identified in Section 5. Each recommendation is linked to the relevant barrier numbers.

By addressing the tensions and gaps in the current regulatory scenario that limit the expansion of circularity in the lifecycles of health devices, opportunities are consolidated to benefit both patient safety and environmental and social sustainability. Overall, these could be reached by:

C improving the regulatory **coherence** and balance and, by doing this, aligning rules so patient's safety and environmental goals may be addressed together without conflicts,

E enhancing implementation **efficiency,** e.g., through procedures' simplification and administrative burdens reduction to enable faster, cost-effective compliance,

D clarifying and implementing **data** management aspects, e.g., through setting clear rules for data collection, sharing, and use to support traceability and evidence-based decisions,

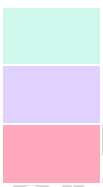
G providing **guidance** and information for users and those designing and managing the devices to support compliant, circular design and use of devices.

T enhancing the clarity of key **terms**

For the regulations outlined in Section 4, specific recommendations are provided, indicating the relevant life cycle stages (design/manufacturing, use, and recirculation. See legend below on life cycle stages concerned) to which they correspond and the improvement areas (represented by the letters **C, E, D, G** and **T** as previously explained). An overview of barriers and corresponding recommendations is also available in Table 4.

Legends:

Life cycle stages



Design/manufacturing

Use

Recirculation

Recommendations to the MDR.

Barrier 1. Safety–sustainability tensions between MDR and ESPR
Barrier 2. Absence of regulatory incentives.
Barrier 7. Lengthy and costly CE marking procedures
Barrier 9. Insufficient reprocessing-specific labelling standards
Barrier 10. Delayed and inconsistent EUDAMED rollout
Barrier 11. Administrative burdens in EUDAMED data management.
Barrier 13. Fragmented MDR implementation across Member States
Barrier 14. Insufficient evidence base for reprocessing decisions

The Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices, contain proposed changes to Article 17 on "Single use devices and their reprocessing". In essence, this revision aims to tackle the lack of regulatory incentives for reusable device design.

Article 56 on '**certificates of conformity'** is amended: *'The maximum period of validity of certificates (currently five years) is removed. Instead of recertifying devices, notified bodies will carry out periodic reviews proportionate to the risk of the device while the certificate is valid.'*

Some **classification rules** (Annex VIII) *'are adapted resulting in lower risk classes for certain devices, such as reusable surgical instruments, accessories to active implantable devices and software.'*

The amending Regulation introduces simplification measures as well as new reporting obligations, hence it has an impact on the modules of **EUDAMED**[5]: *'Alignment with European Data strategy. The proposal aligns with the Data strategy since it promotes the further digitalisation compared to MDR and IVDR of certain processes such as the transmission, by manufacturers to notified bodies, of technical documentation and other relevant documents; it includes, in EUDAMED, new elements such as the certificates of free sales and the devices' instructions for use , thereby further expanding the publicly available data; additionally, it simplifies certain workflows that need to be carried out in EUDAMED, thus facilitating systems' use for the actors involved.'* This revision to the MDR is, thus, essentially addressing the issue of experienced administrative burdens in EUDAMED data management.

As a result, it can be expected that a greater number of reusable devices will be developed and that the time and costs implications of issuing certifications will be reduced, leading to increased reprocessing once these devices enter the market and thereby contributing to more circular flows of digital health devices. It can be also expected that this development will benefit also European micro, small and medium-size enterprises.

The proposed amendments on simplification and burden reduction are consistent with the various consultations (Annex A) which highlighted a need for regulatory changes to achieve a

[5] EUDAMED: this is an interconnected IT system composed of six modules, to store data relating to the entire lifecycle of devices placed on the EU market. Four out of six modules of EUDAMED are complete. https://webgate.ec.europa.eu/eudamed/landing-page#/page-not-found

clearer policy framework balancing circularity with safety and feasibility, as underpinned in our recommendations.

The following recommendations aim to increase efficiency and transparency to be considered in a next revision of the MDR:

C, E,G,D

Establish a negative EU-level list of devices that, due to technical or safety constraints, are not suitable for reprocessing. This would provide a clear foundation for manufacturers to determine where reprocessing may be considered a viable design choice.

Introduce the principle of risk-based assignment of responsibilities, with full manufacturer responsibilities clearly assigned to any entity reprocessing such devices.

Preserve transparency through mandatory reprocessing labels and cycle counts reinforcing accountability under the principle that the reprocessor assumes full manufacturer responsibilities, including quality management, post-market surveillance, vigilance, and traceability obligations.

Consider a streamlined regulatory framework for reprocessing carried out internally by healthcare institutions within a closed-loop model, which represents a distinct operational context warranting proportionate treatment.

Ensure alignment between the EUDAMED and the forthcoming ESPR DPP systems, avoiding unnecessary duplication and reducing the data management burden on users. Rather than operating as parallel mechanisms, the two systems should be conceived as structurally integrated and organically complementary, together constituting a dynamic, trusted, accessible, and traceable data infrastructure.

The overall package of amendments aims to also address the challenges of the fragmented adoption of the MDR at Member State level. However, this aspect is not explicitly addressed in the Parliament document. The following is recommended:

E

Introduce mechanisms to support and monitor the adoption of the MDR at Member State levels.

Recommendations to the MDR & ESPR and other environmental regulations.

Barrier 1. Safety–sustainability tensions (MDR vs ESPR)
Barrier 10. Delayed and inconsistent EUDAMED rollout
Barrier 14. Insufficient evidence base for reprocessing decisions
Barrier 19. Limited traceability for devices entering WEEE streams

To align patient safety objectives with environmental sustainability goals under the relevant regulations, notably the MDR and ESPR, the following actions are recommended to be implemented in an articulated way (DiCE, 2023):

Develop a comprehensive risk assessment framework that addresses

C, G

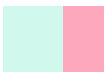
both patient safety and environmental performance considerations, ensuring a careful balance to support coherent and informed decision-making across the MDR and ESPR. Such a framework would help reconcile product safety requirements with the need for design-for-disassembly, recyclability, and compliance. Its implementation requires a multi-level approach as follows:

- European Commission: Lead development via guidance or implementing/delegated acts, ensuring alignment between safety and sustainability requirements.
- EU expert and scientific bodies: Provide technical input on methodologies, indicators, and lifecycle-based assessment criteria. These include the European Commission's Joint Research Centre (JRC), which provides scientific and technical evidence to support EU policy design and implementation, alongside expert groups such as the Medical Device Coordination Group (MDCG), which offer regulatory guidance on medical device safety, and SCHEER, which delivers independent scientific advice on health, environmental, and emerging risk issues.
- Standardisation bodies (e.g. CEN, CENELEC): Develop harmonised standards to operationalise the framework.

G, D

Require in instructions for use and/or product guide explicit instructions on how to handle the device at the end-of-use, including disposal options.

For strengthening risk vigilance systems, the following is recommended.



G, D

Introduce guidance for reprocessed devices, including the specification of the number of permitted reprocessing cycles, in order to strengthen risk vigilance systems. This information should be recorded in and feed into the EUDAMED system.

Recommendation to the ESPR.

Barrier 16. Lack of standardised collection and segregation practices
Barrier 23. Unclear cross-border shipment and reverse logistics rules

To optimise the circular resource pathway of digital health devices[6], including homecare ones

[6] Digital health device: 'Physical device used for health applications that contains electronics and operates on a source of energy other than that generated by the human body. Digital health devices that classify as medical devices according to the definition of the EU MDR (2017) can also be defined as active devices' (DiCE, 2025a)

which are often classified as Class I[7] due to their low safety risks or sometimes not even subject to the MDR, the following is recommended (DiCE Policy Workshop, DiCE (2025b)):

G — Introduce a distinct regulatory category for digital health devices, in particular of homecare, in the ESPR priority list, clearly differentiating them from both consumer electronics and hospital-based medical devices, and reflecting their specific risk profile and use environment.

G — Introduce criteria relating to the feasibility of recycling technologies, reverse logistics, and end-of-life pathways as explicit ecodesign and product (re)design requirements, alongside established ecodesign principles (such as disassembly, of a reduced number of materials, etc.).

Recommendation to the WEEE Directive.

Barrier 16. Lack of standardised collection and segregation practices
Barrier 17. Inconsistent WEEE Directive application to medical devices
Barrier 18. No harmonised decontamination validation protocols

The following points aim to clarify the pathway for those handling used digital health devices from the point of generation, where a decision is made on what type of waste this is (hence, under which framework it should be regulated), to the segregation step in the reprocessing or recycling facility, as well as to improve the ability to track medical devices once they are collected as WEEE (DiCE Policy Workshops, DiCE (2025b) & DiCE (2026a)):

C, G — Greater harmonisation across Member States should be pursued, including consideration of converting the WEEE Directive into a Regulation, alongside the standardisation of collection and segregation practices such as colour-coded bins and integrated decontamination workflows and the introduction of economic incentives to improve collection rates.

G — Guidance on segregating/sorting contaminated and non-contaminated components to increase the recovery of valuable materials that would otherwise be lost to incineration if not properly segregated should be considered.

G — A product classification system linked to defined processing pathways should be developed, including standardised decontamination procedures. The adoption of the WHO guidance (2016, 2022) with decontamination and reprocessing protocols could fill this gap.

G — As for infective wastes (in this context, infective digital health devices), provision or reference in the WEEE Directive to guidance or delegated/implementing acts regarding the decontamination steps for allowing these devices to be qualified as WEEE for further treatment.

[7] Devices in Class I are considered to present low risk and do not fall under any of the higher risk rules defined in Annex VIII." — MDR 2017/745, Annex VIII, Rule 1

C, G	Develop harmonised EU guidance on the interface between healthcare waste and WEEE, clarifying and regulating in which cases validated decontamination allows medical devices in contaminated healthcare waste pathways to enter appropriate circular WEEE management routes.
D	Robust traceability WEEE system linked to DPP in the ESPR.

Recommendations on waste classification (LoW), WEEE, PPWR and transboundary shipment regulatory requirements.

Barrier 15. Hazard-based medical waste classification limits reuse
Barrier 16. Lack of standardised collection and segregation practices
Barrier 19. Limited traceability for devices entering WEEE streams
Barrier 22. Fragmented rules for transboundary device movements
Barrier 23. Unclear cross-border shipment and reverse logistics rules
Barrier 24. Tensions between EU-level and national waste rules

To address the challenges identified such as legal uncertainties and multiple levels of approvals in the implementation of medical waste classification and their transboundary shipment, the following is recommended (DiCE Policy Workshops, DiCE (2025b) & DiCE (2026a)):

C, E	Move towards EU-level responsibility and liability frameworks for the cross-border shipment of WEEE to reduce regulatory fragmentation. Led by the European Commission, revise the WEEE Directive, ESPR, waste legislation, PPWR, and waste shipment rules to ensure coherence between EPR obligations and waste classification. The revision should introduce minimum EU-level requirements for EPR for cross-border WEEE flows, while leaving operational implementation to Member States. It should also include amendments and implementing/delegated acts to align definitions and scope across waste law (including the LoW) and the , clarifying the distinction between waste, used equipment or device, and end-of-waste status.
C, E	Align the latest provisions on WEEE from the Basel Convention with the WSR and national waste regulations to prevent the risk of additional barriers to transboundary movements of used medical devices intended for authorised preparation for reuse, refurbishment, recycling, or CRM recovery within the EU, while maintaining high standards of environmental protection and traceability.
G	Guidance on procedures allowing/disallowing cross-border movements of contaminated products.

E	Member State clusters or single-market hubs with harmonised rules should be established to enable scale and operational efficiency
D	EU-wide labelling linked to the DPP/ESPR data should be introduced to capture contamination and treatment status, alongside the creation of certification schemes for collectors and logistics operators to enable integrated, compliant cross-border transport.
C, G	Expansion of the waste classification within the LoW to introduce specific codes for medical-related devices, including reusable medical devices – subject to the MDR, and digital health devices– not subject to the MDR, to be uniformly applied across all Member States.
C	Member States to review and adapt their packaging and waste legislation, including EPR schemes, eco-modulated EPR fees, and sector-specific rules, to align with the harmonised requirements of the PPWR while avoiding fragmentation of the internal market. Effective national practices should be maintained, and measures that exceed EU minimum standards, particularly those that enhance environmental protection, should be welcomed. Early coordination among national authorities, industry, and EU institutions is recommended to support smooth implementation and an appropriate balance between harmonisation and flexibility.

Recommendations to the CRM Act and Battery Regulation.

Barrier 4. No design guidance for CRM recovery
Barrier 5. Battery rules triggering MDR reassessment
Barrier 20. Insufficient CRM content transparency in devices
Barrier 21. Insufficient economies of scale for CRM recycling

The following actionable guidance points should be made explicit in the CRM Act and Battery Regulation's implementing acts to improve the recovery of CRMs from complex products such as digital health devices (DiCE, 2024a):

D	Require manufacturers of finished products to document the presence and location of CRMs in their products including in their batteries. This should establish standardised and accessible information requirements and systems (such as enhanced BoMs and DPPs) aligned with, or where appropriate connected to, the EUDAMED database. These systems should remain flexible and adaptable to future updates of the EU list of CRMs.
G	Provide guidance for efficient and viable CRM recovery, including in scenarios with low volumes or low CRM concentrations.

Recommendation to the PPWR. *Barrier: 6*

Barrier 6. Limited guidance on biocompatible sustainable materials

To support decision-making towards the selection of environmentally friendly and safe materials, the following is recommended (DiCE, 2023):


G

Provide guidance on the use of biocompatible and non-toxic materials balancing safety and environmentally friendliness aspects.

Recommendation to the Directive on Empowering Consumers for the Green Transition (ECGT).

Barrier 12. Trade secret risks under CSRD and CSDDD disclosure obligations.
Barrier 16. Lack of standardised collection and segregation practices
Barrier 21. Insufficient economies of scale for CRM recycling

To improve the collection, segregation and return of digital health devices and their packaging, while strengthening the economies of scale required for viable circular business models, the following is recommended (DiCE, 2024b):


C, G

Ensure that consumer-facing sustainability information under the ECGT is consistent, verifiable and operational, providing users with clear guidance on the durability, repairability, reuse potential and appropriate EoL management of digital health devices, while avoiding misleading environmental claims and safeguarding confidential business information.

- European Commission, European Parliament, and Council of the European Union: Develop harmonised guidance on sustainability claims, promote standardised communication on repairability, reuse and recycling, and ensure that mandatory consumer information complements existing product information requirements.
- EU expert bodies (e.g. the Joint Research Centre (JRC), the European Financial Reporting Advisory Group (EFRAG) and European Chemicals Agency (ECHA)): Provide technical input on disclosure granularity, methodologies and communication formats, ensuring consumer-understandable information on materials and hazard levels while safeguarding confidential business information.


D, G

Introduce instructions for use to assist consumers on how to use, handle, repair and dispose of the devices.


G

Promote nudging based on simplicity of the communications about sustainability in circular digital health devices.

Recommendation to SoC-related regulatory instruments.

Barrier 8. Overlapping substance compliance pathways

The recommendation proposed calls for coordinated alignment across multiple regulatory frameworks (DiCE Policy Workshop, DiCE (2025b) and (DiCE, 2023)):


G

Develop under the European Commission leadership a guide on multi-compliance strategies for managing SoCs in medical device manufacturing by aligning key frameworks, including the REACH, RoHS and Battery Regulations, and the PPWR. EU expert bodies (notably the ECHA, the JRC, and the MDCG) develop associated technical methodologies (e.g. an Operational Manual with Instructions for Reverse Logistics), while standardisation bodies can translate them into practical tools. The EFPIA form on Substance Regulatory Compliance Declaration for Articles[8] developed by the European Federation of Pharmaceutical Industries and Associations (EFPIA)[9] can serve as basis to support broader uptake.

Recommendations to the upcoming CE Act.

Barrier 25. Narrow circularity metrics in the CE Act

Beyond the Circular Material Use Rate (CMUR)[10] applied in the Battery Regulation and proposed to be also included in the future Circular Economy Act (according to the CE Act document consulted in 2025 (European Commission, 2025)), it is recommended to (DiCE, 2026b):


C, D

Require an additional indicator for application at the meso level (sectoral level): 'end-of-life recycling input rates'. This concept has been already explored in Eurostat[11] and basically indicates the percentage of materials that are recovered and reintegrated into the production process as recycled material.

Recommendations on terms and definitions.

Barrier 3. Ambiguous single-use and reuse terminology

For addressing the needs to improve and harmonised interpretations, a consolidated and coherent terminology framework with terms and definitions should be established. Examples

[8] https://www.efpia.eu/media/636868/efpia-substance-regulatory-compliance-declaration-for-articles-form.xlsx

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe. EFPIA's mission is to create a collaborative environment to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy.

[10] It measures the share of a material in a product that comes from recycled sources

[11] Eurostat is the statistical office of the European Union. https://ec.europa.eu/eurostat

of key terms with harmonized definitions needed include: single-use medical device, reusable medical device, digital health device. The implementation of the needed framework requires a multi-level approach as follows.

C, T

- European Commission: Lead the development of a cross-cutting terminology framework by proposing a legally anchored glossary (e.g. in a horizontal instrument or through alignment of existing legislation), supported by guidance to ensure consistent interpretation across frameworks.
- EU co-legislators (European Parliament and Council of the European Union): Provide the legal basis by adopting or amending legislation to incorporate harmonised definitions and ensure their consistent use.
- EU expert bodies (e.g. ECHA, JRC): Develop and maintain the technical content of the glossary, ensuring scientific robustness and consistency across substances, materials, and waste definitions.

A Glossary consolidated by DiCE (DiCE 2025a) can serve as basis to support broader uptake. This document is publicly available in the project website[12] (Annex C).

[12] https://circulardigitalhealth.eu/

Table 4: Summary of recommendations addressing the main barriers to EU policy mix regarding digital health devices

Barrier \ Recommendations to ✓	MDR	MDR & ESPR and other environmental	ESPR	MDR and WEEE Directive	LoW, PPWR and transboundary shipment	CRM Act and Battery Regulation	PPWR	Empowering Consumers for the Green Transition	SoC-related regulatory instruments	CE act	Terms and definitions
1. Safety-sustainability tensions (MDR vs ESPR)	✓	✓									
2. Regulatory incentives favouring single-use labelling	✓										
3. Uncertainty around device reprocessability and terminology											✓
4. Lack of design guidance for CRM recovery (ESPR & CRM Act)						✓					
5. Battery regulation triggering MDR reassessment						✓					
6. Lack of guidance re on biocompatible and non-toxic materials							✓				
7. Lengthy and costly CE marking and conformity assessment	✓										
8. Overlapping compliance pathways of substances of concern									✓		
9. Insufficient reprocessing-specific labelling standards	✓										
10.Delayed and inconsistent rollout of EUDAMED	✓	✓									
11. Admin. / technical burden in EUDAMED data management	✓										
12. Trade secret risk under CSRD / CSDDD disclosure obligations								✓			
13. Fragmented MDR implementation across Member States	✓										
14. Insufficient evidence base for reprocessing decisions	✓	✓									
15. Broad, hazard-based definition of medical waste (LoW)					✓						
16. Lack of standardised collection and segregation practices			✓	✓	✓			✓			
17. Inconsistent application of WEEE directive to medical devices				✓							
18. Absence of harmonised validation protocols for decontamination				✓							
19. Limited traceability of devices collected as WEEE		✓			✓						
20. Insufficient CRM content transparency						✓					
21. Insufficient economy of scale for viable CRM recycling / reprocessing			✓			✓		✓			
22. Fragmented rules for transboundary movement of used devices					✓						
23. Unclear cross-border shipment and reverse logistics rules					✓						
24. Tensions between EU-level and national waste regulations					✓						
25. Limited scope of circularity metrics in the CE Act										✓	

No correspondence between the barrier and the regulatory requirement concerned

7. OUTLOOK

The regulatory landscape governing digital healthcare devices is set to evolve significantly over the coming years.

The **EU MDR** is undergoing its most significant revision since its adoption. The EC targeted proposal to revise the MDR[13] is currently under the ordinary legislative procedure, and its final content and date of adoption remain subject to the outcome of those negotiations. While the legislative proposal is primarily focused on simplification and access, by clarifying rules applicable to reprocessing and the regulatory framework applicable to a circular design choices, it represents an opportunity to advance on circular strategies such as design for reuse, repairability and reprocessing.

Although medical devices are not among the first priority product groups under the **ESPR Working Plan 2025–2030**, the regulation explicitly foresees that even complex product systems, including medical devices, may be regulated at some stage under its prioritisation approach. More immediately, ICT products are already included through horizontal requirements on repairability and recyclability, establishing design precedents directly relevant to digital medical devices. The DPP architecture, expected to be operational from 2027/2028, will progressively require product-level disclosure of SoCs, material composition, and recyclability parameters. As delegated acts expand to cover additional product groups through 2030, manufacturers of devices containing CRMs or hazardous substances should anticipate increasing alignment pressure between ESPR disclosure requirements and existing SoC obligations under REACH and RoHS.

The **CRM Act** sets 2030 benchmarks of 25% recycling of annual EU consumption of strategic raw materials, with implementing acts specifying products, components, and waste streams with CRM recovery[14]. This will progressively increase pressure on device manufacturers to design for material recovery.

A formal legislative proposal for the **Circular Economy Act** is expected in late 2026, with phased implementation across sectors anticipated from 2028. Once adopted, the Act is likely to introduce harmonised end-of-waste criteria, reformed EPR schemes, and recycled-content targets with a view to establishing a genuine single market for secondary raw materials. For the digital health device sector, the critical question will be whether sector-specific carve-outs or adapted pathways are introduced to better reconcile circularity obligations with patient safety requirements under the MDR.

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[13] Proposal for a regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025PC1023

[14] Commission Implementing Regulation (EU) 2026/1116 of 26 May 2026 listing the products, components and waste streams considered as having a relevant critical raw materials recovery potential under Regulation (EU) 2024/1252. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AL_202601116&mc_cid=ffea2f42b2&mc_eid=2de29716f3

Preparatory work for the revision of the **WEEE Directive** is also expected to advance within the broader Circular Economy Act agenda, with a legislative proposal likely to follow the adoption of the new framework and implementation anticipated towards the end of the decade. The review is expected to strengthen the contribution of WEEE legislation to the development of a genuine European market for secondary raw materials while improving collection, traceability, and preparation for reuse. For the digital health device sector, it may provide an opportunity to clarify the interface between healthcare waste and WEEE, harmonise approaches to decontaminated devices across Member States, strengthen producer responsibility for complex medical electronics, and facilitate cross-border movements of devices destined for authorised reprocessing, refurbishment, reuse, or recycling. The extent to which the revised framework accommodates the specific safety and regulatory requirements of medical devices will be critical for unlocking their circularity potential.

Public procurement policy is also undergoing significant review at EU level. The EC has announced a revision of the EU public procurement framework through a forthcoming Public Procurement Act, aimed at simplifying the current legislative architecture while mainstreaming sustainability, resilience, and circularity considerations into procurement decisions. Although the legislative process is still ongoing, the initiative signals a progressive shift from award criteria based predominantly on lowest price towards lifecycle value and strategic objectives. For the digital health device sector, this could strengthen the use of criteria such as durability, repairability, recycled content, take-back schemes, and lifecycle costing in healthcare procurement, thereby creating stronger market incentives for circular product design and reverse logistics systems.

At the international level, two parallel processes will shape the chemicals and materials governance context for medical devices. The **Global Framework on Chemicals (GFC)**[15], requires that by 2030, stakeholders make available reliable information on chemicals in materials and products throughout the value chain, a transparency obligation directly relevant to SoCs in medical devices and their recyclability. The alignment with the DPP and the ESPR frameworks creates a pathway for harmonised global chemicals disclosure that could progressively tighten SoCs requirements at design stage.

On plastics, the trajectory is less certain; after several failed attempts to finalise a global plastics treaty[16], substantive negotiations are expected to resume later in 2026, with persistent disagreements over whether the treaty should tackle plastic production or focus mainly on waste and recycling remaining unresolved. Should a treaty eventually be adopted, its provisions on product design, hazardous substances, and EPR would carry significant implications for single-use plastic medical devices and packaging.

[15] The Global Framework on Chemicals presents a comprehensive plan to guide countries and stakeholders in jointly addressing the lifecycle of chemicals, including products and waste. The Framework was adopted in September 2023 at the fifth International Conference on Chemicals Management (ICCM5). https://www.unep.org/global-framework-chemicals

[16] https://www.unep.org/inc-plastic-pollution

8. CONCLUSION

This policy brief on circular digital health devices draws on two years of research and consultations with a wide range of stakeholders, including policymakers, businesses, experts, and healthcare professionals. Its findings will inform EU and Member State policy development and support the transition towards more circular digital health devices.

Enhancing the circularity of digital health devices requires a coherent and aligned regulatory framework that balances patient safety and environmental sustainability. A key step in this process is the use of an **integrated risk assessment system** that enables the collaborative evaluation of safety and environmental impacts across the device life cycle. This approach allows for informed decision-making and harmonisation between the Medical Device Regulation (MDR, 2017) and the Ecodesign for Sustainable Products Regulation (ESPR, 2024), which targets sustainability and circularity in product design.

The ongoing MDR revision (2025–2027) is expected to strengthen the regulatory framework for medical devices, including for reprocessing where applicable, by introducing simplifications and efficiency improvements. However, uncertainty persists regarding the revised MDR's impact on its fragmented implementation at Member State levels, particularly reprocessing authorisations, as these remain a national competence. While EU harmonisation and tailored national implementation may appear to be in tension, they should instead be viewed as complementary. Harmonised and common regulatory principles can provide consistency across the EU, while implementation and oversight remain adapted to national systems and administrative contexts.

Broader alignment across legal requirements is also critical. This includes clarifying the classification of end-of-use digital health devices by expanding the European LoW to include specific codes for these devices, ensuring consistent application across Member States. Reporting requirements for CRMs should be introduced and supported by standardised tools such as enhanced Bills of Materials (BoMs) and Digital Product Passports (DPPs), ideally linked to EUDAMED. Moreover, within the WEEE Directive it is crucial to provide clearer guidance on classifying infectious devices as WEEE, along with standardised procedures for separating contaminated and non-contaminated components. Additionally, decontamination protocols and recovery guidance for CRMs linked to the MDR and the CRM Act are essential. Addressing barriers to the cross-border movement of used devices through Member State clusters or single-market hubs, EU-wide labelling or product information, and certification schemes would further enhance traceability, compliance, and operational scale. These measures should be underpinned by consistent terminology across all regulations to support effective implementation.

Implementing these recommendations carries important strategic implications. For industry, they improve efficiency and with this cost reduction and resilience across the value chain, strengthen enabling conditions for European actors, enhance global competitiveness, reduce pressure on CRMs, and increase circularity. For policymakers, the measures provide a coherent regulatory framework, facilitating effective implementation and enforcement across different sectors. For society, the strategic implications include more sustainable and resilient healthcare systems, while maintaining high standards of patient safety, trust, and transparency.

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ANNEXES

A. ANALYSIS OF KEY REGULATIONS

This Annex A offers a structured description of key EU examined through a lifecycle lens and with specific emphasis on circular strategies.

A.1 Design regulations

When designing digital medical devices, several instruments influence material choices, product architecture, and lifecycle considerations, with specific legal hooks.

1. The **MDR (Medical Device Regulation (EU) 2017/745)** regulates the design of medical devices primarily through Annex I (General Safety and Performance Requirements), which requires devices to be designed and manufactured so that they achieve their intended purpose while ensuring safety throughout the lifecycle (Annex I, Chapter I, Sections 1–9). This includes risk management by design (Section 3), reduction of risks related to use error (Section 5), consideration of ergonomic features and the environment of use (Section 5), and, where relevant, requirements on chemical, physical, and biological properties (Sections 10–12). For software and devices incorporating software, Annex I, Section 17 imposes design requirements on lifecycle management, validation, cybersecurity, and data integrity. Together, these provisions embed safety, performance, and usability into the device design phase.
2. The **ESPR (Ecodesign for Sustainable Products Regulation (EU) 2024/1781) establishes** a horizontal framework for durability, reparability, energy and resource efficiency, and recyclability (Articles 5–9), and introduces product information and Digital Product Passport (DPP) obligations (Articles 10–14); while medical devices are specifically regulated by the MDR, ESPR's principles apply to components and overall product lifecycle, requiring a shift in design philosophy.
3. **Substances of Concern (SoCs) regulations** directly constrain design.
    - **REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals regulation (EC) 1907/2006)** restricts substances via registration and authorisation (Articles 5, 56–60) and information duties (Article 33);
    - The **POPs regulation** (**Persistent Organic Pollutants Regulation** (EU) 2019/1021) bans or severely limits POPs (Articles 3–5); and

- **RoHS** (**Restriction of Hazardous Substances Directive 2011/65/EU)** restricts hazardous substances in electrical and electronic equipment as medical devices (Article 2 (1) and Annex II). However, it explicitly excludes active implantable medical devices (Article 2(4)) and limits substance restrictions for certain medical applications as specified in Annex IV;

4. The **CRM Act (Critical Raw Materials Regulation (EU) 2024/1252)** affects design indirectly by promoting substitution, recyclability, and supply security for critical raw materials (Articles 5–8, 25) such as cobalt and lithium, which is relevant for electronics-intensive devices.
5. The **Battery Regulation (EU) 2023/1542** imposes binding requirements for batteries placed on the market or integrated into products, including safety and performance (Articles 6–10), removability and replaceability where applicable (Article 11) which influence device architecture. Batteries incorporated in medical devices will have to satisfy the new upstream and downstream requirements. These requirements apply also during the manufacturing stage.
6. The **PPWR (Packaging and Packaging Waste Regulation (EU) 2025/40**) affects packaging design through requirements on recyclability (Article 6), packaging minimisation (Art. 10), labelling (Article 12), and waste reduction and Extended Producer Responsibility (EPR) obligations (Articles 40-57), which are particularly relevant for sterile or single-use medical devices.

A.2 Manufacturing regulations

Manufacturing operations are shaped by the following requirements:

7. Under the **MDR,** the requirements that govern the manufacturing of medical devices in the EU are set out in the general obligations for manufacturers, particularly Article 10 of the Regulation and the General Safety and Performance Requirements set out in Annex I and in particular Article 10(9). The latter mandates that manufacturers establish, implement, maintain, and continuously improve a quality management system that covers all stages of the device lifecycle, including production, and ensures that series production remains in conformity with the MDR. Complementing these provisions, Annex I specifies safety and performance requirements that directly influence design and manufacturing, ensuring devices fulfil their intended purpose while maintaining a high level of protection for patients and users.
8. The **Battery Regulation** affects manufacturing information and labelling requirements (Articles 13–14), and obligations to ensure compliance of battery components sourced from suppliers (Article 48). The manufacturer becomes a battery producer under this regulation, imposing them EPR obligations.
9. The **PPWR** introduces manufacturing-relevant obligations by requiring packaging to be minimised by design (Article 6), recyclable at scale (Article 6), and manufactured without unnecessary hazardous substances (Article 5, 7), directly influencing packaging material selection, packing line configuration, and quality controls.
10. The **CSDDD (Corporate Sustainability Due Diligence Directive (EU) 2024/1760)** obliges manufacturers to integrate due-diligence processes into their operations and supply chains (Articles 5–7), identify and mitigate environmental and human-rights risks linked to manufacturing activities (Article 8), and establish preventive or corrective action plans (Article 10), influencing site selection, supplier audits, and operational controls.

A.3 Requirements associated with communications for use and market placement

Following EU regulations set key requirements for transparent communication on digital health devices, including safety, performance, traceability, and information disclosure.

11. The **MDR** governs communication and use of medical devices through Annex I, Chapter III, which sets detailed requirements for information supplied with the device, including labelling and instructions for use (Sections 19–23). These clauses require that information be clear, understandable, and appropriate for the intended user, covering safe installation, operation, maintenance, reprocessing, and safe disposal. Articles 7 and 10 (11) further regulate external communication by prohibiting misleading claims and requiring manufacturers to make safety and performance information publicly available, including summaries of safety and clinical performance where applicable. Collectively, these provisions ensure that devices are used correctly and safely, and that users and patients receive reliable and transparent information throughout the device's use.
12. The **DPP (Digital Product Passport)** under the **ESPR** mandates digital access to selected product information across the lifecycle (Articles 11–14), supporting transparency during use, including information on materials, safe use, repair, and end-of-life handling; the precise scope for medical devices will depend on future delegated acts.
13. The **PPWR** regulates information at the point of sale and use through mandatory labelling on material composition, recyclability, and packaging waste sorting (Article 11 and Annexes), enabling correct handling by users and healthcare facilities.
14. The **CSRD (Corporate Sustainability Reporting Directive (EU) 2022/2464)** does not regulate individual devices but requires manufacturers to publicly report on sustainability impacts, risks, and opportunities related to products placed on the market (Articles 19a and 29a of the Accounting Directive as amended), including use-phase environmental impacts and product-level circularity metrics. This increases external scrutiny of real-world device performance.
15. The **GDPR (General Data Protection Regulation (EU) 2016/679)** applies whenever medical devices process personal data, including health data, imposing requirements on lawful processing (Articles 6 and 9), data protection by design and by default (Article 25), transparency (Articles 12–14), and security (Article 32). These obligations directly affect device functionality, user interfaces, data governance, and post-market data handling during routine use.

A.4 Recirculating stage

The following EU regulations provide a legal framework for the recirculation of digital health devices, their materials and components:

16. The **MDR** enables the reprocessing of single-use medical devices by establishing a clear legal framework under which it is allowed, subject to strict conditions (Article 7). Article 17 requires reprocessed devices to meet the same safety, performance, and compliance standards as new devices, and allocates manufacturer obligations to the reprocessor, including quality management, risk management, and traceability. Once a device is no longer eligible for reuse or reprocessing under the MDR, waste law fully applies. Thereby safe reprocessing and circular economy practices in healthcare are supported.
17. The **WFD (Waste Framework Directive 2008/98/EC)** provides the baseline legal framework for when digital medical devices become waste. Article 3 defines waste, while Article 4 establishes the waste hierarchy, prioritising reuse and preparation for reuse over recycling where safe and lawful. Articles 5 and 6 clarify conditions for by-products

and end-of-waste status, which are relevant for controlled reprocessing or recirculation models. Article 13 requires waste handling without risk to human health, a key constraint for infection control.

18. For medical devices containing electrical or electronic components, the **WEEE Directive (Waste Electrical and Electronic Equipment Directive 2012/19/EU)** applies once such devices become waste (Article 2). The Directive prioritises preparation for reuse (Article 4) requiring separate collection (Article 5) and establishes recovery and recycling targets (Article 12), thereby assigning producers responsibility for their products throughout the lifecycle under the EPR policy approach. Medical devices exempted according to Article 2 are medical devices that are expected to be infective prior of end of life, and implantable devices. The exemption applies only to collection and recovery obligations. Where used devices or components are sent across borders for reuse, reprocessing, or recycling, the **WSR (Waste Shipment Regulation (EU) 2024/1157)** applies, with Articles 3–5 setting notification and consent requirements depending on whether the shipment is for recovery or disposal, tightly constraining cross-border recirculation.
19. Obligations related to recycling and EPR for packaging used with medical devices are governed by the **PPWR**. The PPWR establishes EPR obligations requiring producers to finance the collection, sorting, and recycling of packaging waste (Articles 40–45, proposal numbering) and sets material-specific recycling targets (Article 46 and Annex II). While PPWR does not regulate the medical device itself, it directly affects how packaging associated with medical devices is recirculated and recycled.
20. The **Battery Regulation** establishes a lifecycle-based framework that promotes battery reuse, refurbishment and repurposing prior to recycling, clarifying that batteries removed from devices do not automatically constitute waste. Articles 55–59 regulate second-life and repurposed batteries by requiring renewed compliance with safety, performance and information obligations, and by assigning manufacturer responsibility to the actor carrying out repurposing or remanufacturing. Extended Producer Responsibility obligations further limit recirculation of batteries from medical devices to regulated, professional and closed-loop systems consistent with MDR safety requirements. End-of-life responsibilities are covered throughout Articles 56–65.

Together with the MDR, these instruments create a structured boundary: reuse and reprocessing of medical devices are permitted only under MDR's safety framework, while collection, recycling, disposal, and cross-border movements are governed by EU waste and packaging law, ensuring that circularity objectives do not compromise patient or environmental safety.

A.5 Snapshots

This section provides a summary of the key EU legislative instruments applicable to digital health products

B.STAKEHOLDER CONSULTATIONS

The insights gathered for this study stem from multiple sources, including direct interviews, a dedicated consultation event, and publicly available information.

B.1 Interviews

Ten Interviews were conducted in 2024 and early 2025 with the aim of identifying barriers and expectations related to the current policy landscape for the circularity of medical devices. Feedback from the interviewees placed a strong emphasis on the MDR and on issues related to the classification of medical waste. The organisations interviewed are listed in Table 5 (Int1 to Int10). Insights gathered served as input to the DiCE feedback provided to the EC Calls for evidence on the Circular Economy Act (EC, 2025, 01/08/2025-06/11/2025) and on the EU MDR (EC, 2024, 12/12/2024-21/03/2025).

DiCE Response to the EC Call for Evidence on the Circular Economy Act (Submission date: 31 October 2025)[17]	DiCE Response to the EC Call for Feedback on the EU MDR (2017) (Submission date: 21 March 2025)[18]

[17] Call for Evidence for an Impact Assessment on the Circular Economy Act. https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14812-Circular-Economy-Act_en

[18] Call for Evidence for an Evaluation on EU rules on medical devices and in vitro diagnostics – targeted evaluation. https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14155-EU-rules-on-medical-devices-and-in-vitro-diagnostics-targeted-evaluation_en

The Digital Health in a Circular Economy consortium (...) wants to highlight four points that will support the circular transitioning of healthcare. 1. Broadening the CE Act Beyond Recycling: Embedding a Hierarchy of Circular Strategies. The Clean Industrial Deal recognizes that products must stay in circulation for as long as possible, but its proposed measures place most emphasis on recycling. To achieve its objectives, the CE Act should extend its scope to other circular strategies. Hoveling et al. (2024a) mapped best circular practices and identified gaps for medical devices. Additionally, Hoveling et al (2024b) demonstrated that the waste hierarchy (in the Waste Framework Directive) may not yield the maximal environmental impact reduction and that a holistic revision of different strategies must be considered while delivering economic value (Rønn et al., 2023). Guidance on circular priorities must be informed by lifecycle assessments to target the most impactful areas. Without this, the CE Act risks locking in end-of-pipe solutions instead of improving upstream efficiency. Using an evidence-based approach would help the EU strengthen harmonisation and set a global benchmark for comprehensive circularity policy. 2. Harmonised Terminology. The CE Act should establish clear and harmonised terms & definitions to ensure consistent use. DiCE highlighted the value and need of a unified glossary to be able to communicate along the value chain. Hoveling et al (2024a)2 revealed that key actors were unclear of how circularity applies to them, and which strategies may be used. Therefore, DiCE consolidated Terms & Definitions can serve as the basis and be adopted by the CE Act for promoting a common understanding among value chain actors and regulatory bodies, reduce fragmentation, and support coherent application of the legislation. 3. Expanding CE metrics beyond circular material use rate (CMUR). Relying only on the CMUR is too narrow to capture the full circularity. While useful, CMUR misses aspects like product design, repairability, durability, recyclability at end-of-life. To ensure comprehensive monitoring, the Act should add indicators such as recycled content, recyclability	The Digital Health in a Circular Economy consortium (…) wants to highlight four points that will support the circular transitioning of healthcare. Lack of evidence - As outlined in the Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market, commissioned and published by the European Commission, decisions on whether reprocessing is allowed or not allowed are currently not evidence-based. There is a need for further evidence and facts, particularly regarding safety, surveillance, economic and environmental impacts, and ethical considerations related to the ReSUDs, taking into account the differences between reprocessing by healthcare institutions or manufacturers. Lack of harmonisation - EU MDR states that reprocessing should be strictly controlled and allowed only for products where there is scientific evidence that such products can be reprocessed safely, including demonstration of cleaning, sterilization, and relevant functionality. These regulations should be uniformly implemented across Member States. Reprocessing outside of these regulatory boundaries cannot guarantee the same level of patient safety and therefore should not be allowed. Further, significant discussion can be triggered around the direct marking requirements for reprocessed devices. The EU requires direct marking regardless of the level of reprocessing, unlike the FDA, which bases it on the level of reprocessing/sterilization. Lack of clarity on what can and can't be reprocessed - Many products currently on the market, have not been designed with reprocessing in mind and therefore the materials and design may not withstand multiple uses. The Common Specifications of the MDR give some guidance on products which could be unsuitable for reprocessing, but there is still a need for further clarification on which types of devices are deemed suitable or unsuitable for reprocessing. Also, there are difficulties

metrics (e.g. recycling rates, Jager et al., 2024) and repairability index, among others. This broader framework would track progress across product lifecycles more effectively, helping policymakers to target interventions where it matters and positioning the EU as a global leader in circularity monitoring. 4. Advancing circularity and social sustainability through awareness and cooperation. The CE Act should focus on awareness-raising and fostering collaboration among actors and change agents as these are key enablers of circularity and social sustainability. Engaging all stakeholders including the public can boost medical device collection rates and speed up acceptance and adoption of circular practices2. Engagement can lower the (perceived) health & safety risks when circularising medical devices and support social benefits such as skills development and the creation of new jobs, particularly within Europe (Valdivia et al., 2025). Finally, citizen engagement is an essential component to enable closed loops. Integration of behavioural science through e.g. co-creation and motivational strategies is critical (Vermeylen et al. (2024)) to ensure that products designed for closed-loop systems are returned and can be recirculated. The key DiCE deliverables referenced are attached to this submission.	encountered with the different interpretations of "re-processed" and "single-use" vs. "single-patient use."

B.2 DiCE Policy Workshops in 2025 and 2026

Policy Workshop in Eindhoven (The Netherlands) held on 25 November 2025

This consultation at the premises of Philips aimed to explore preliminary policy recommendations in a lively World Café exchange. Discussions covered the WEEE Directive, the Ecodesign for Sustainable Products Regulation, and rules on cross-border shipment of medical devices. A total of 44 participants attended the workshop, including EC officials, manufacturers (Philips, J&J, Medtronic), a manufacturer association (MedTech), a recycling facility (Mirec), and representatives of clustering projects ENKORE[19] and INCREACE[20] The list of participants is provided in Table 5 (PW1 to PW14). The presentations with a summary of the discussions are available here: https://circulardigitalhealth.eu/news/annual-event-presentations-recording/.

[19] https://enkoreecohealthcare.eu/

[20] https://increace-project.eu/synergetic-projects/

Policy Workshop in Brussels (Belgium) held on 21 May 2026

The second Policy Workshop, aimed to introduce the DiCE Policy Recommendations and gather perspectives from relevant actors along the value chain of digital health devices.

Key policy recommendations that would enhance the competitiveness in the European value chain and enhance the up-scalability of circular strategies in digital health devices covered mandatory sustainable procurement by healthcare service providers which support creating demand and stimulate investment in circular solutions. Further, the tailored regional ecosystems approach and pathways was debated for upscaling circular strategies connecting innovators, SMEs, healthcare providers, researchers and industrial actors.

25 representatives attended the workshop including from regulatory affairs offices, European initiatives, EC officials, manufacturers (J&J, Medtronic, AMDR) and clustering projects ENKORE[21] and INCREACE[22] . The list of key participants is in Table 5. See the slide-deck and recoding here: https://circulardigitalhealth.eu/news/policy-dialogue-project-synergies.

B.3 Publicly available feedback to the EU Call for Evidence on the MDR (2017)

Key stakeholders were identified from the publicly available list of respondents to the EU Call for Evidence on the MDR (EC, 2024). These corresponds to EUC1 to EUC27 in Table 5. Contributions came from a broad range of stakeholders representing clinical practice, healthcare delivery, industry, academia, and public authorities across Europe and beyond. Respondents included major university hospitals and healthcare providers from Belgium (University Hospital Antwerp, UZ Gent), Sweden (Karolinska University Hospital, Region Västerbotten, and healthcare services within the Västra Götaland Region), and Denmark (Danske Regioner and Local Government Denmark), reflecting the perspectives of frontline medical device users and public health systems. Professional and scientific expertise was provided by European-level medical and research organisations such as the European Society of Cardiology and BioMed Alliance, while sustainability and public health considerations were represented by Health Care Without Harm Europe. Industry and manufacturer viewpoints were contributed by companies and associations including Cochlear Ltd (Australia), eurocom e. V. (Germany, Austria, Switzerland), Ibec (Ireland), and the Association of Healthcare Sector Organizations (BoZ, the Netherlands). Specific issues related e.g. to EUDAMED and their need for effective implementation and to good practices in the FDA were raised by several organizations.

[21] https://enkoreecohealthcare.eu/

[22] https://increace-project.eu/synergetic-projects/

Table 5: Stakeholder views considered

#	POSITION AND/OR FD NUMBER IN EU CALL*	ORGANIZATION – ROLE IN THE VALUE CHAIN	COUNTRY	INTERVIEW	POLICY WORKSHOPS 1. 25 NOV'25 EINDHOVEN 2. 21 MAY'26 BRUSSELS	2024 EU CALL FOR EVIDENCE ON MDR (2017)	REMARKS (E.G. TOPIC FOCUSED)
Int1	Auditor	TIMIAN – Notification body	Slovenia	☑			Certification
Int2	Safety, Health & Environmental Manager, F3530190	University Hospitals of Leuven (UZ Leuven, KU Leuven hospitals) – Healthcare facilities	Belgium	☑			Reuse /reprocessing/ EUDAMED
Int3	Senior Sustainability Manager	Medtronic - Manufacturer	UK	☑			Health safety
Int4	Member	Conselho Português para a Saúde e Ambiente - Physician	Portugal	☑			Reuse /reprocessing/ classification of medical waste
Int5	F3528898	The Association of Medical Device Reprocessors (AMDR) – Reprocessors' association	Germany	☑	2 ☑		Reuse /reprocessing/ classification f medical waste
Int6	Project manager	Vanguard – Reprocessor	Germany, UK	☑	2 ☑		Reuse /reprocessing

Int7	Marketing and Public Affairs Executive	Innovative Health - Reprocessor	USA	☑		Reuse /reprocessing
Int8	Member	Swiss Nurses' Association (ASIE) – Healthcare worker	Switzerland	☑		Mandate and guidelines
Int9	Deputy chief	Emergency Department of the Réseau hospitalier neuchâtelois (RHNe) – Neuchâtel - Physician	Switzerland	☑		Mandate
Int10	Director	Footstray Hospital, Western Health, Melbourne - Physician	Australia	☑		Reuse /reprocessing/ Classification of medical waste
PW1	Official 1	European Commission	Europe		1,2 ☑	Circularity
PW2	Official 2	European Commission	Europe		1 ☑	Circularity
PW3	Official 3	European Commission	Europe		1 ☑	Circularity
PW4	Employee 1	Mirec	The Netherlands		1 ☑	Circularity
PW5	Employee 1	Philips	The Netherlands		1 ☑	Circularity
PW6	Employee 2	Philips	The Netherlands		1 ☑	Circularity
PW7	Employee 3	Philips	The Netherlands		1 ☑	Circularity

PW8	Employee 1	Medtronic	Belgium	1 ☑		Circularity
PW9	Employee 2	Medtronic	Belgium	1 ☑		Circularity
PW10	Employee 3	Medtronic	Belgium	2 ☑		Circularity
PW11	Employee 1	Medtech Europe	Europe	☑		Circularity
PW12	Employee 2	Medtech Europe	Europe	☑		Circularity
PW13	Consortium member	ENKORE (IHI funded project. Clustering)	Europe	1,2 ☑		Circularity
PW14	Consortium member 1	INCREACE (HEU funded project. Clustering)	Europe	1 ☑		Circularity
PW15	Consortium member 2	INCREACE (HEU funded project. Clustering)	Europe	1 ☑		Circularity
EUC1	F3513956	Dr. Schwab GmbH.	Germany		☑	U.S. FDA
EUC2	F3514037	Welcony Inc.	UK		☑	U.S. FDA
EUC3	F3516635	senetics healthcare group GmbH & Co. KG	Germany		☑	U.S. FDA
EUC4	F3516410	Kimetek GmbH	Germany		☑	U.S. FDA

EUC5	F3524630	Spiorad Medical Ltd	Ireland	☑	U.S. FDA
EUC6	F3526691	University Hospital Antwerp	Belgium	☑	Reuse /reprocessing / certification
EUC7	F3526836	Cochlear LTD	Australia	☑	Sustainability and circularity /EUDAMED
EUC8	F3526980	Netherlands Institute for Neuroscience	The Netherlands	☑	U.S. FDA
EUC9	F3527383	KL (Local Government Denmark)	Denmark	☑	Reuse / reprocessing
EUC10	F3527410	Ayfer Bektas, Regulatory Affairs Manager, PRRC	Germany	☑	Certification/E EUDAMED
EUC11	F3527703	Agoria	Belgium	☑	U.S. FDA
EUC12	F3530006	MexBrain	France	☑	U.S. FDA
EUC13	F3530107	Regional samverkansgrupp medicinsk teknik Sydöstra sjukvårdsregionen	Sweden	☑	Reuse /reprocessing / certification
EUC14	F3530230	Biotech Santé Bretagne (innovation cluster)	France	☑	U.S. FDA
EUC15	F3530456	Danske Regioner	Denmark	☑	Reuse /reprocessing/ EUDAMED

EUC16	F3530612	Health Care Without Harm (HCWH) Europe	Europe	☑	Reuse /reprocessing/ EUDAMED
EUC17	F3530679	Karolinska University Hospital	Sweden	☑	Certification
EUC18	F3530700	Nuova Ompi	Italy	☑	U.S. FDA
EUC19	F3530701	Vereniging Brancheorganisaties Zorg / the Association of Healthcare Sector Organizations (BoZ)	The Netherlands	☑	Sustainability and circularity
EUC20	F3530714	EUROSPINE, the Spine Society of Europe	Switzerland	☑	U.S. FDA
EUC21	F3530860	BioMed Alliance	Europe	☑	Reuse /reprocessing/ EUDAMED
EUC22	F3530903	France Biotech	France	☑	U.S. FDA
EUC23	F3531023	European Society of Cardiology (ESC)	Europe	☑	Reuse /reprocessing/ EUDAMED
EUC24	F3531035	Region Västerbotten	Sweden	☑	Reuse /reprocessing
EUC25	F3531036	Ibec	Ireland	☑	Sustainability and circularity, EUDAMED

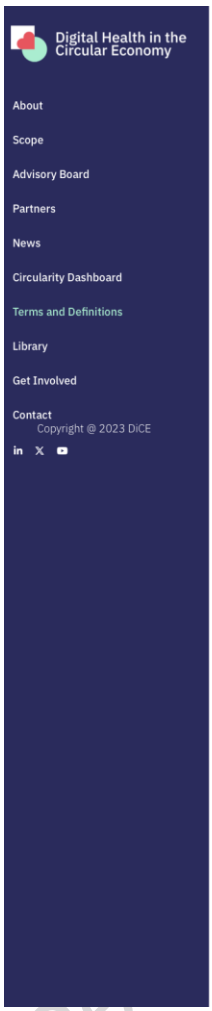
EUC26	F3531054	Hälso- och Sjukvård inom Västra Götalandsregionen (Healthcare and Medical Services within the Västra Götaland Region)	Sweden		☑	Reuse / reprocessing
EUC27	F3513796	UZ Gent	Belgium		☑	Sustainability and circularity
EUC28	F3499125, F3516870, F3499082	eurocom e. V. (European Manufacturers Federation for compression therapy, orthopaedic devices and digital health applications)	Germany, Austria, Switzerland		☑	UDI for reprocessed devices
PW16	Employee 1	UDG Alliance - Research and Development (Swiss organization supporting legal compliance in healthcare value chains)	Switzerland, Europe	2 ☑		Regulations
PW17	Employee 4	Philips - Government Affairs	Belgium	2 ☑		Regulations
PW18	Employee 1	Eindhoven University of Technology – Researcher on circular electronics	The Netherlands	2 ☑		Regulations
PW19	Employee 1	University Campus Biomedico	Italy	2 ☑		Regulations
PW20	Employee 1	National College of Art and Design	Irland	2 ☑		Design
PW21	Employee 1	OSAI Automation System	Italy	2 ☑		Recycling
PW22	Employee 1	Conseillère en Transition énergétique et écologique en Santé	France	2 ☑		Healthcare provider

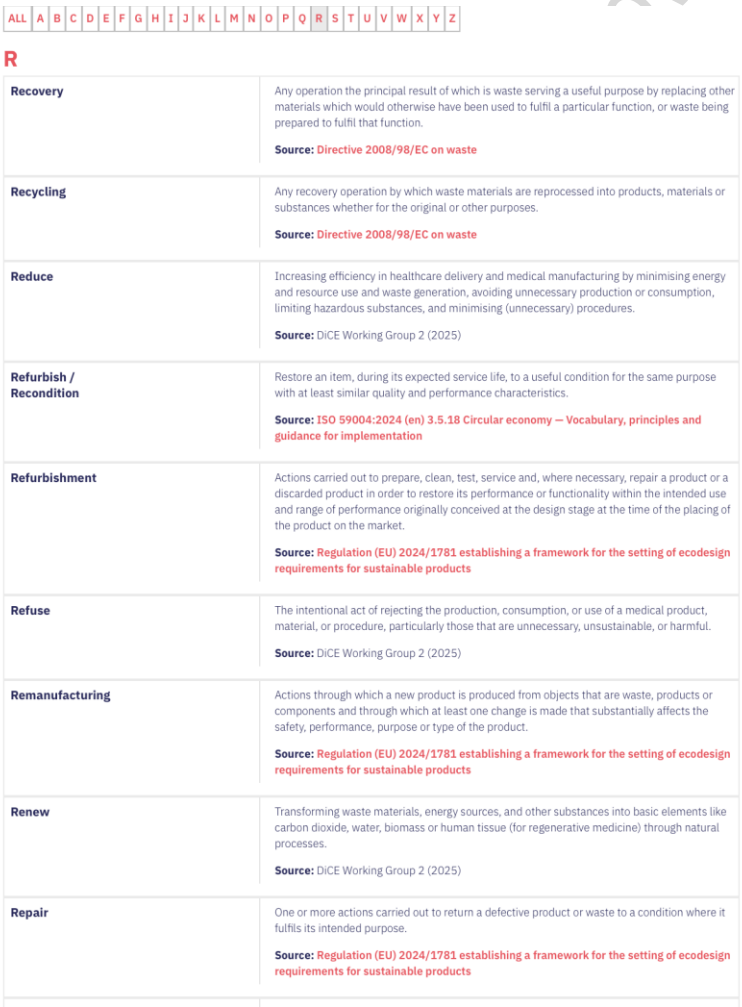
PW23	Employee 1	INCREACE project, Fraunhofer IZM, researcher on circular electronics	Germany	2 ☑	Design
PW24	Employee 2	INCREACE project, Fraunhofer IZM, researcher on circular electronics	Germany	2 ☑	Design
PW25	Employee 1	TAKEDA, medical devices packaging	Switzerland, Europe	2 ☑	Design, regulations

C. DICE GLOSSARY

The terms and definitions listed in the DiCE glossary have been identified as relevant ones for the purpose of DiCE. The main sources include authoritative ones such EU Directives and Medical Device Regulation. In addition, internationally accepted sources such as from UNEP, International Resource Panel, International Atomic Energy Agency and ISO. Finally, when no definitions are found or no appropriate versions for the context of DiCE exist, project definitions are included (such as those developed for DiCE deliverables).

The DiCE glossary is publicly available in the project website: https://circulardigitalhealth.eu/terms-and-definitions/





D. INTERNATIONALLY ACCEPTED ISO STANDARDS

The standards landscape for medical device manufacturing and reprocessing encompasses requirements for quality management and conformity, guidance on material use, and validated sterilization processes.

D.1 ISO 13485 on Quality management system

ISO 13485 provides the foundational framework for the quality management system that underpins medical device design and manufacturing, covering key areas such as design and development controls (Clause 7.3), risk management (Clause 7.1), and design verification and validation (Clauses 7.3.6–7.3.7). By aligning with ISO 13485, manufacturers ensure that sustainability-driven changes and routine production processes remain compliant with safety, performance, and regulatory requirements under the MDR. Specifically, the MDR sets out manufacturing obligations primarily in Article 10, supported by Annexes IX, X, and XI, which require manufacturers to establish, document, and maintain a quality management system encompassing production, process control, verification, and validation (Article 10(9)). Articles 10(4) and 10(7) further oblige manufacturers to ensure that series production conforms to the approved design, maintain comprehensive technical documentation, and implement post-market surveillance and vigilance processes that feed back into manufacturing controls. The conformity assessment annexes detail how manufacturing processes are audited and certified by Notified Bodies, ensuring that devices placed on the market are consistently produced in line with approved designs and regulatory expectations.

D.2 ISO 14937 on Sterilization of healthcare products

ISO 14937:2009 outlines requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices. This framework for safe and effective sterilization of medical devices is widely recognized internationally, particularly by manufacturers and healthcare facilities involved in reprocessing, and is considered a fundamental reference for sterilization validation due to its general, science-based approach applicable across technologies and device types. Regulatory bodies (including the US FDA, EU (MDR/IVDR), and Health Canada) often refer to ISO 14937 when evaluating sterilization processes. By offering a standardized validation methodology, it ensures consistent sterility assurance, supports flexible approaches for diverse device materials, promotes evidence-based decision-making through microbiological validation and process control, and emphasizes risk management and routine monitoring, strengthening patient safety and confidence in reprocessed devices.

D.3 ISO 11607 and the use of recycled materials in packaging

While recycling aligns with circular economy principles, ISO 11607 provides specific guidance for packaging of terminally sterilized medical devices, emphasizing that materials used in sterile barrier systems (primary packaging) must ensure sterility and patient safety. According to this ISO standard, primary packaging (sterile barrier) cannot be made from recycled materials unless equally rigorous validation is performed, which is generally very difficult with current technology. From the technology point of view, ISO 11607 does not prohibit recycled materials for secondary packaging, but it requires full traceability, risk assessment, and validation to ensure the sterile product is not affected.

D.4 ISO 59000 (2024) family of standards

ISO 59004, 59010, and 59020 together create a structured foundation for improving circularity of products in general and can also be applied to medical devices. Whenever authoritative terms in the context of circularity are missing, ISO 59004 helps align stakeholders with consistent terminology, reducing ambiguity across complex healthcare supply chains. ISO 59010 illustrates design cases of circular business models such as product-as-a-service, refurbishment, and take-back systems which can be tailored to regulated medical contexts. ISO 59020 introduces measurable indicators, enabling manufacturers to track material efficiency, product lifespan, and recovery rates. Combined, these standards help manufacturers of medical devices move from

linear production toward lifecycle-focused strategies, improving resource use, regulatory compliance, and sustainability while maintaining patient safety and product reliability.

E. BACKGROUND INFORMATION AND FINDINGS FROM SELECTED EUROPEAN COUNTRIES

Slovenia

The MDR implementation in Slovenia is complemented by the Medical Devices Act (ZMedPri1, 2025). The WEEE Directive is transposed through the Regulation on waste electrical and electronic equipment (2015)), and healthcare waste is governed by the Environmental Protection Act (ZVO2, 2022) and associated implementing acts. Devices are classified by risk (infectious, hazardous, non-hazardous) and managed according to the LoW. Cross-border shipments of medical device waste follow the WSR, though national practices favour contained handling. International standards, such as ISO 14937 (2009), provide general guidance on sterilization and traceability.

The key issues are outlined below:

- **Classification issues**. Devices at the interface of medical and electronic equipment are inconsistently classified, affecting take-back obligations and WEEE compliance.
- **Fragmented waste streams**. Contaminated or infectious devices are excluded from WEEE streams, creating uncertainty after validated decontamination.
- **Limited circular integration**. Waste segregation prioritizes risk management over material recovery; recycling pathways for sterilized devices are unclear.
- **Cross-border challenges**. Administrative complexity and legal uncertainty limit transboundary reprocessing of SUDs.
- **Procurement gaps**. Lifecycle costs, repairability, and take-back requirements are rarely included in healthcare tenders, reducing sustainability uptake, e.g. of more sustainable medical devices.
- **Standards implementation**. ISO sterilization and traceability standards exist, but their role in supporting circularity and integrating device-to-waste monitoring is not fully realized.
- **Terminology gaps**. A lack of harmonised definitions across sectors, for example, “single-use device”, “device suitable for reprocessing”, “sterilized device”, “waste suitable for recycling”, “take-back”, “closed-loop return,” and “extended producer responsibility”, creates legal uncertainty, hinders enforcement, and limits scalable circular models.

Belgium

The MDR implementation in Belgium is regulated through national implementing laws, while the WEEE Directive is transposed through regional and federal producer responsibility schemes due to the regional nature of the environmental policy in the country. Contaminated or infectious devices are treated as healthcare waste and managed according to risk-based classification, aligning with infection control requirements. Public procurement frameworks and international standards, such as ISO 14937, provide guidance on sterilization, traceability, and device safety. Cross-border shipment of medical device waste follows the WSR, although national practices favour contained management.

Notably, the following challenges stand out:

- **Regulatory-financial barrier**. Many MDR devices are not classified as EEE, so PRO contributions for recycling are not collected, limiting financial support for end-of-life management.
- **Contamination risk**. Variability in decontamination and sterilization protocols creates uncertainty about safe reprocessing or recycling of used devices.
- **Fragmented national implementation**. Belgium's WEEE management is regionally fragmented (Flanders, Wallonia, Brussels), leading to inconsistent practices.

Spain

Spain permits the reprocessing of single-use medical devices under strict rules via Royal Decree 192/2023 (implementing MDR), overseen by the Spanish Agency for Medicines and Health Products. It is limited to healthcare facilities or authorised reprocessors, with no outsourcing or cross-border reuse. The WEEE Directive is nationally applied through the Royal Decree 110/2015 on WEEE. Digital traceability is enforced through Order TED/1032/2024, tracking sensitive waste, including data-containing devices. The PEMAR 2025–2035 (State Framework Waste Management Plan) sets the national strategic direction for waste policy, guiding future reforms without replacing current laws.

As for issues, the ones listed below outstand:

- **Decentralised implementation.** Despite a robust national framework, regulation implementation is decentralised in Spain, resulting in varying transition speeds and timelines depending on the region. For example, in Castilla y León region, any medical device used in clinical settings is still categorised by default as infectious, leading to incineration, despite the existence of a different, more updated legislative framework in force.
- **Increased safety risks of digital health devices.** Moreover, the increasing energy density in wearables requires updated safety protocols in the collection points to prevent fire risks. These aspects impact the inefficacity waste collection from private households and increase the safety risks during collection.