



Digital Health in the Circular Economy

Generation of Roadmap for DiCE Replication across Europe

Deliverable 6.5

This deliverable is awaiting formal review by the European Commission and may be subject to change.



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EXECUTIVE SUMMARY

Digital Health in Circular Economy (DiCE) is a project that spans across industry, interest organizations, and academia with the goal of introducing viable circular business models for medical technologies containing electronic equipment. The healthcare industry represents 4.4% of global CO₂ emissions, and with its increasing adoption of digital health devices, it is expecting to increase levels of electronic waste (e-waste) (HCWH, 2019). This deliverable integrates the evidence generated across 12 preceding DiCE deliverables (D) and the country's Waste Electrical and Electronic Equipment (WEEE) infrastructure data into a roadmap that presents which circular business models can be implemented where, in what sequence, and which conditions to be aware of, providing manufacturers and policy-makers with a structured basis for entry, scaling, and regulatory engagement. Most of the findings are applicable beyond the European Economic Area (EEA), apart from any regulatory-specific insights.

The roadmap is constructed in two stages. The first stage synthesises findings across product and system design (D2.1–D2.4, D5.1, D5.2), material retrieval (D3.1, D3.8), reverse logistics and behaviour (D3.4, D4.2, D4.3), policy (D6.2), and business models (D6.1, D6.3, D6.4). The synthesis is organised at three levels (product, system, and geographical) and translate each finding to business model relevant insights.

The second stage applies these conditions to the EEA and the United Kingdom (UK) through a readiness assessment built on two dimensions: reprocessing legal status under the Medical Device Regulation (MDR) Article 17 and the WEEE infrastructure. The roadmap includes two additional dimensions, one being the behavioural return-driver profile established in D4.3, and the other the national hospital procurement architecture. The readiness assessment categorises EEA and the UK into four tiers.

- **Tier 1** (Denmark, Germany, Netherlands, Sweden, Belgium, UK and Iceland) supports the broadest range of circular configurations.
- **Tier 2** (Croatia, Portugal, Slovenia, and Spain) supports reprocessing but has more limited WEEE arrangements, required Original Equipment Manufacturer (OEM)-sponsored setups.
- **Tier 3** (Austria, Bulgaria, Czech Republic, Finland, France, Ireland, Latvia, Norway, Poland, and Slovakia) supports recycling partnerships with an established WEEE infrastructure but does not allow reprocessing.
- **Tier 4** (Cyprus, Estonia, Greece, Hungary, Italy, Lithuania, Luxembourg, Malta, and Romania) covers the remaining Member States, where circular operations would remain largely manufacturer-owned until regulatory conditions evolve.

The classification is not fixed, and over time it can be expected that countries move towards Tier 1, as regulation becomes more circular friendly. For instance, Denmark moved from Tier 3 to Tier 1 within four years allowing reprocessing, through hospital-led advocacy, and similar trajectories with on-going pilots are visible in France.

The roadmap then proposes three sequential phases.

- **Phase 1** is proof-of-concept through OEM-led in-hospital pilots in Tier 1 and Tier 2 countries, anchored to an economic case in which retrieval rate is treated as the central variable and hospitals are incentivised from the outset.
- **Phase 2** extends the configuration to controlled third parties at regional scale, requiring contractual minimum retrieval guarantees, co-designed scope-of-responsibility agreements, and digital product passport aligned digital traceability.
- **Phase 3** opens cross-regional configurations conditional on EEA-level regulatory alignment on MDR Article 17, WEEE applicability, and medical waste classification.



ABBREVIATION LIST

Abbreviation	Terminology	Description
B2B2C	Business to Business to Consumer	Exchange of products or services first between businesses and then between business and consumers.
BM	Business Model	A conceptual representation of how value is created, delivered, and captured.
CBM	Circular Business Model	How circular value is created, delivered and captured
D	Deliverable	A formal output of the DiCE project, e.g. D6.4.
DDL	Digital Display Label	Electronic display replacing traditional labels in clinical trials.
DiCE	Digital Health in a Circular Economy	European Union funded project focusing on circularity for digital health devices.
DPP	Digital Product Passport	A digital record providing structured information on a product's origin, materials, use, repair history, and end-of-life options.
ECG	Electrocardiogram	A medical test that records the electrical activity of the heart.
EEA	European Union	A political and economic union of European member states that coordinate policies, regulations, and standards across shared institutions.
EEA	European Economic Area	The EEA includes EU countries and also Iceland, Liechtenstein and Norway.
MDR	Medical Device Regulation	EEA regulation governing medical devices (EEA 2017/745).
OEM	Original Equipment Manufacturer	Company that designs and produces the product.
WP	Work Package	A structured project component within DiCE.
WEEE	Waste Electrical and Electronic Equipment	Waste category for electronic products.





Digital Health in the Circular Economy

INTRODUCTION

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INTRODUCTION

Europe has a mission to make the circular economy and environmentally sustainable practices its competitive advantage, including for the healthcare industry and its digital health devices (European Commission, 2026b). The Medical Device Regulation (MDR), the Waste Electrical and Electronic Equipment (WEEE) Directive, the Ecodesign for Sustainable Products Regulation (ESPR) including the digital product passport (DPP), and the Circular Economy Act can together, if aligned in the future, create a framework that expects digital health devices to be reusable¹, refurbishable², and recyclable³ (D2.1; MedTech Europe, 2025). However, whether those frameworks can deliver on those expectations and enable circular business models to emerge depends on conditions that vary significantly across Member States. depends on conditions that vary significantly across Member States.

The Digital Health in Circular Economy (DiCE) project has, across its preceding deliverables, generated the evidence base needed on several important streams. It has created product and system design guidelines (D2.1–D2.4⁴, D5.1⁵, D5.2⁶) documenting the technical and environmental case for circular configurations across five representative devices: the endocutter (hospital use/ follows the MDR), the smart pillbox (home use/ not subject to MDR), the digital display label (DDL) (hospital use/ not subject to MDR), the electrocardiogram (ECG) lead set (hospital use/ follows the MDR). It has also produced evidence on reverse logistics and behavioural research (D3.4⁷, D4.2⁸, D4.3⁹) to map how digital health waste actually moves through European systems and what determines whether patients and clinicians return devices for circular operations (e.g., reusing, refurbishing or recycling). It has furthermore looked into material recovery (D3.1¹⁰, D3.2¹¹), establishing recycling and refurbishment yields and business model research (D6.1¹², D6.3¹³, D6.4¹⁴) by developing and pressure-testing viable configurations across device categories. At last, it has created policy recommendations (D6.2) that identify the regulatory gaps that constrain operational scaling in the European Economic Area (EEA).

The purpose of this deliverable is to reflect on all those learnings and integrate them into a roadmap across Europe and its learnings beyond, explaining which business models can be implemented where, in what sequence, and under what conditions. It does so in five steps. Chapter 2 describes the method used to construct the country readiness assessment and the phased roadmap. Chapter 3 sets out the synthesis of key findings from the preceding DiCE deliverables that establish the structural conditions for circular business case viability. The

¹ Reusable refers to devices that can be used more than once, potentially after having been sterilized or cleaned if necessary.

² Refurbishable refers to when devices are after a process of cleaning, sterilizing sold as good as new. This can for instance be the process of medical reprocessing, where devices are taken apart, cleaned and reassembled for sale.

³ Recycling refers to when devices are through mechanical or chemical technologies being separated to recover valuable material that can be used in the manufacturing of new products.

⁴ Physical prototypes and report for circularising ePaper labels (D2.2), smart pillboxes (D2.3), endo-cutter (D2.4)

⁵ D5.1 Mapping of benchmark and novel scenarios

⁶ D5.2 Circularity and sustainability assessment

⁷ D3.4 Digital application connecting the collection boxes with the reverse logistics chain

⁸ D4.2 Report on small scale pilots in 3 regions

⁹ D4.3 Final nudging strategies

¹⁰ D3.1 Recycling technology & optimised processes developed to improve recycling yields for digital health devices.

¹¹ D3.2 Demonstration of refurbishment process and technologies for refurbishment of the ePaper labels, not subject to EU MDR

¹² D6.1 Circular digital health business model

¹³ D6.3 Pilot Value estimation

¹⁴ D6.4 Global Pressure Test Report

roadmap section presents the readiness assessment itself: a four-dimensional analysis across the EEA and the United Kingdom (UK), structured around reprocessing legal status (and its Article 17 options), WEEE infrastructure, behavioural return-driver profile, and national hospital procurement architecture. The result is a tier classification that identifies where in Europe each phase of the roadmap can plausibly begin. A roadmap with three-phases is then presented and including key findings from the synthesis of DiCE findings conducted in the background section. The intended readers of this deliverable are mostly manufacturers and policymakers. The business modelling was developed for Original Equipment Manufacturers (OEMs), although reproprocessors could find value in the different models presented in the cases where they become medical device manufacturers themselves. Policy-makers at the Member State and EEA level may find the deliverable interesting to support further reform of some of the regulatory frameworks mentioned above.



Digital Health in the Circular Economy

METHOD

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METHOD AND DATA

This deliverable is constructed in two stages. The first stage synthesises evidence from DiCE to identify the structural conditions under which circular business models for digital health devices can operate. The second stage applies these conditions to the European geography, producing a four-dimensional readiness assessment for the EEA and the UK that anchors the regional adaptation framework and the phased implementation roadmap. The two stages serve different purposes, use different methods and are described separately below.

Stage 1: Cross-deliverable synthesis

The synthesis in the background section integrates findings from 15 DiCE deliverables across product and system design (D2.1 to D2.4, D5.1, D5.2), reverse logistics and behaviour (D3.4, D4.2, D4.3), material recovery (D3.1, D3.8), business models (D6.1, D6.3, D6.4), and policy (D6.2). No new primary data were therefore collected for the synthesis. Rather than summarising each deliverable in turn, the synthesis is organised around three levels at which the conditions for operational and economic viability must be met: product, system and business model, and geographical implementation context.

Stage 2. Europe readiness assessment

Chapter 4 introduces the readiness assessment dimensions and roadmap covering the EEA and the UK (Table 1). The assessment supports two functions: it provides the empirical basis for the readiness map (

Figure 1), and it identifies country-specific entry points for the phased roadmap. Table 2 includes influencing factors which are not directly included in the chosen dimensions but are important to consider in the implementation of a roadmap.

Table 1. Readiness Assessment Dimensions

Dimension	Definition
D1: Reprocessing legal status (MDR Article 17)	Reprocessing legal status (MDR Article 17). This dimension reflects on whether national law authorises the reprocessing of single-use medical devices. This dimension is in this analysis treated as binary (permitted / not authorised) although it has a couple of sub-sections in Article 17(2),17(3), and 17(4) that can be opt-in/out.
D2: Reverse-logistics & WEEE infrastructure for medical devices	Reverse-logistics and WEEE infrastructure. This dimension includes operational capacity to move end-of-life digital health devices through the WEEE system or equivalent take-back pathways. It has been divided into two levels: established, or partial. Established refers to when the WEEE infrastructure is well set up and active. Partial refers to when the infrastructure is either set up or mostly set up but the collection rates are low compared to the other EEA countries. The dimension captures formal WEEE compliance based on national collection rates.

Legend: D is short for Dimension

Table 2. Influencing Factors in the Roadmap

Dimension	Definition
D3: Behavioural return-driver profile	Behavioural motivation for return. The dominant psychological and structural drivers of return intention and behaviour, as identified by the analysis in DiCE D4.3. This dimension is reported only for the three DiCE pilot countries (Belgium, Slovenia, Spain). It is not part of the readiness score but is referred to in the roadmap.



D4: Procurement architecture (tender entry point)	Member States hospital procurement architecture. The dominant entry point into the health system procurement chain, classified as National, Regional, Hospital-dominant, Mixed, or Regional/hospital-mixed. This dimension is descriptive of whether there are procurement requirements and of where in the health system a manufacturer or reprocessor must approach the buyer.
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Data Collection

Each dimension has its own data collection stream, which can be found in detail in Appendix A. D1 is taken from the European Commission's official notification page on national rules for reprocessing single-use devices, supplemented by the Commission's November 2024 Report on the Operation of Article 17 (European Commission, 2026a; European Commission, 2017). UK status is drawn from the Medicines and Healthcare products Regulatory Agency (MHRA) guidance on single-use medical devices and the Design for Life Roadmap (Department of Health and Social Care, 2025; MHRA, 2021).

The data for D2 is collected from Eurostat WEEE statistics (collection rate per capita). It considers both medical-device-specific WEEE data and general WEEE collection rates, in order to capture the broader infrastructural conditions on which medical-device circular flows depend (Eurostat, 2025). D3 is taken directly from the country-level models reported in DiCE D4.3, covering 228 co-creation participants and 45 stakeholder interviews across the three pilot countries (i.e., Belgium, Slovenia, and Spain). D4 is based on national health system structure, drawing on the Health Systems in Transition (HiT, 2020) country reviews published by the European Observatory on Health Systems and Policies. The classification simplifies hybrid arrangements (most countries have multiple coexisting entry points) by labelling the most prominent route.

Data Analysis

The 2x2 readiness assessment combines D1 and D2 only. D3 is excluded because it is available for only three countries, and D4 is excluded because it is more of a contextual, not a readiness dimension, but will be included in the discussion. The tiers should not be judged as overall country performance on circularity in general, as several other dimensions would be important to consider, such as general usage of secondary raw material in digital health and medical devices, etc., which is not relevant for this deliverable (Eurostat, 2026). Instead, it should be viewed as a classification of countries that have more favourable conditions for circular economy strategies related specifically to digital health devices. The different tiers are described in Table 3. Medical device reprocessing is rated as having a higher value than recycling, due to its relatively lower environmental and social footprint in most life cycle analyses (D5.2). As explained before, some countries' regulations limit the reprocessing¹⁵ e.g., only allowing the full-manufacturer reprocessing route (Article 17(2)). If they allow two out of three of the reprocessing sub-articles, they will fall in a Tier 1 or 2.

Table 3. Readiness Tier Description

Tier	Description
Tier 1	Medical device reprocessing is permitted and a WEEE infrastructure is established. These countries would be the best suited for several circular activities (reuse, refurbishing and recycling) and related partnerships (ranging from

¹⁵ Article 17(2) a reprocessor is considered and regulated as product manufacturer. Article 17(3) Reprocessing within health institutions, which may not follow all rules equivalent to a product manufacturer. Art.17(4) third-party servicing hospitals with reprocessing of devices.



	transaction-based to service-based)
Tier 2	Medical device reprocessing is permitted but a WEEE infrastructure is only partially implemented. These countries would be suited for certain forms of circular activities and partnerships.
Tier 3	Medical device reprocessing is not permitted or only to a limited extend but WEEE infrastructure is established. These countries would be suited for certain forms of circular activities and partnerships.
Tier 4	Medical device reprocessing not authorised and a WEEE infrastructure only exists partially or limited.

Scope and Limitation

Two limitations of this method should be made explicit, as they shape how the readiness assessment and the roadmap that follows can be used. Because WEEE collection data specific to medical devices is very limited, the general WEEE collection rate serves as the primary indicator of whether a system is partially or fully established. Furthermore, the WEEE Eurostat data has not been updated since 2023, which makes this a relatively outdated baseline for an assessment today, 2026. Second, the D3 dimension is reported only for the three DiCE pilot countries; the behavioural profile findings should not be assumed to generalise beyond Belgium, Spain, and Slovenia, and other countries are explicitly marked as 'not assessed in DiCE'. D4.3 establishes that behavioural drivers differ significantly across the three pilot countries, which is itself the reason for treating D3 as country-specific rather than as a Europe-wide dimension. At last, the assessment made is a snapshot of the regulatory state in June 2026. The findings may need to be updated in the event of a regulatory change, such as the MDR updates in 2026.





Digital Health in the Circular Economy

BACKGROUND

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BACKGROUND SYNTHESIS OF KEY FINDINGS FOR IMPLEMENTATION

To build a roadmap across the EEA, this deliverable integrates findings from the wider DiCE project across three categories: product-level, business and system-level and geographical-level. Together, these categories provide the holistic basis on which implementation conditions can be assessed. The following section synthesises the key findings relevant to implementation. Readers seeking the full empirical and methodological detail behind each finding are referred to the underlying deliverables (Table 4).

Table 4. Key Synthesis of DiCE Deliverables

Deliverable	Contribution	Key Evidence	Implication for CBM Configuration
Product-Level Findings			
D2.1, D2.3, D3.2, D6.1, D6.3	Circular design attributes (durability, modularity, reliability) are prerequisites that constrain or enable the circular economy	Modular devices enable service models (repair agreements, refurbishment); devices with high recyclability enable specialised recycling OEM–recycler partnerships.	Design attributes impact which CBM configuration fits to follow and vice versa. The more modular the design is, the easier it is to pursue a service type of business model, whereas smaller less durable products would be more based on volume focused business models.
D3.1, D3.2, D2.1	Recycling and refurbishment yield and CRM retrieval are design-dependent: material choices and (dis)assembly methods determine end-of-life outcomes	ECG lead sets achieve ~89% recyclability rate via cable recycling routes; OBDS reach ~67.9% due to complex plastics and embedded lithium battery; smart pillbox has a 3% recyclability rate (65% redesigned); Endocutter has a 51% recyclability rate (90% redesigned); DDL has a 91% successful refurbishing rate.	
D3.6, D3.7, D5.1, D5.2, D6.4	Circular product strategies must be matched to device complexity: simple and complex devices require different circular pathways	Recovery pathways are device-specific, not uniform: a reuse-strategy decision tree has been built for the circular strategies the ECG lead set can take, and its routes differ from those for the DDL (D3.7). Whether the device is contaminated also shapes the route (D3.6): 60% of respondents report recyclers refusing certain hospital waste streams, mainly over contamination, and over 50% operate under national rules that default hospital waste to incineration (D3.6).	The environmental argument for circularity varies by device. Strong where reuse displaces repeated manufacturing (ECG); moderate where modular redesign replaces single-use (endocutter); weak where the baseline is already low-impact (DDL). Circularity should be understood from a portfolio question, not a single corporate strategy. Different devices warrant different circular configurations, justified by different combinations of economic and environmental evidence, where clinical outcomes and surgical workflow also play a key role. Circularity should be a means for environmental sustainability.
Business and System-Level Findings			
D3.2, D6.3	Retrieval rates are a crucial economic variable for circular business model viability	Moderate declines in retrieval rates erode the financial viability of refurbishment, recycling and reuse models. D6.3 value estimation demonstrates that circular models require a minimum retrieval threshold to break even.	CBM configurations must include contractual minimum retrieval guarantees, meaning a certain number of devices must be guaranteed to be recovered for it to be financially attractive for the collector. Models sensitive to volume require scale to be viable; low-volume devices may need aggregated collection across several OEMs.



D6.1, D6.3, D6.4,	Value distribution between stakeholders is asymmetric: hospitals bear operational burden while manufacturers capture economic value	D6.1 interviews revealed three misalignment themes: stakeholder interrelations, perceived responsibilities, and expectations. D6.4 workshop and survey findings confirm hospitals bear collection, sorting, and decontamination costs without proportional economic returns.	CBM design must explicitly address value redistribution. Service agreements that internalise reverse logistics costs for manufacturers are preferred over models that externalise burden to hospitals.
D6.1, D6.3	No single business model is viable across all devices and regions; a configurable continuum is needed	D6.1 proposes four BM taxonomies along two dimensions (in-house vs. disintegrated; standalone vs. full-service). Products may fit multiple BMs depending on Intellectual property (IP) rights, volume, technology level, and customer type. Migration between models is expected when the circular model matures e.g., from a sale per unit and recycling model to a modular device, where parts are cleaned for reuse and others recycled or incinerated.	The contribution is the continuum itself: rather than prescribing one model, the framework enables incremental-to-transformative configurations matched to context.
D2.3, D3.4, D5.2, D6.2	Digital traceability (Digital Product Passport, smart collection boxes, measurable circularity indicators) is a prerequisite infrastructure layer for all circular business models	Digital Product Passport mandated under ESPR for product-level sustainability data. D2.3 specifies Digital Product Passport content for pillbox redesign (product ID, material composition, recyclability, end-of-life instructions). D3.4 demonstrates smart collection box with QR/barcode identification, AI-based product validation, and cloud connectivity. D5.2 identifies circularity indicators and notes that no unified measurement approach exists yet.	Traceability is a shared infrastructure requirement. It enables quality assurance for reuse, material tracking for recycling partnerships, regulatory compliance (MDR, ESPR), and data-driven optimisation of retrieval rates.
Geographical-level findings			
D4.2, D4.3, D4.4	E-waste return behaviour is structurally different across regions	Statistical structural model (n=228): 5 predictors explain 48.5% of return intention variance. Spain: attitudes, subjective norms, perceived control, and producer intervention all significant. Slovenia: only attitudes and subjective norms significant. Belgium: only convenience is significant, but Belgium is the only country where intention significantly predicts actual behaviour ($R^2=0.267$). Spain and Slovenia show an intention-behaviour gap.	Collection infrastructure design in circular business models must be regionally differentiated. Belgian models should prioritise convenience (e.g., pharmacy drop-off, smart bins). Spanish and Slovenian models need attitudinal nudging and norm-based interventions alongside infrastructure.
D6.4	Institutional actors drive circular adoption decisions, not the customer.	Patients' influence on circular device decisions: mean 1.83/5 (all responses clustered 1–3). Clinician's trust in reused/refurbished devices: mean 3.00/5 (neutral-to-moderate, largest group at level 4). Strongest value driver: cost savings, environmental sustainability, and regulatory compliance tied at 53% each.	CBM design should target institutional decision-makers (hospital admin, procurement). Patient-facing models are less viable than B2B2C models routed through healthcare providers. Clinician trust-building is a prerequisite. Hospital definitions on how waste is consigned as "contaminated" based on interpretation of legislation is another key point of inconsistency.
D2.1, D6.2, D6.5,	Regulatory fragmentation across EEA creates overlapping and conflicting compliance pathways towards a circular economy	D6.2 identifies 25 distinct barriers across lifecycle stages. Key tensions: MDR vs. ESPR on safety-sustainability trade-offs; MDR Article 17 opt-in/opt-out fragments reprocessing authorisation across member states; Overlapping compliance pathways of substances of concern (REACH, RoHS and others). Compliance requirements create regulatory complexity	CBM scalability is constrained until regulatory alignment improves. Cross-border models face highest regulatory friction. Business models have to comply with national regulation, and pilots can be used as proof of concept to influence regulation.

Legend: CBM stands for Circular Business Model





Digital Health in the Circular Economy

ROADMAP

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MOBILIZING CIRCULAR DIGITAL HEALTH

This section maps the readiness dimensions presented in the method section across the EEA including the UK and connects it to the feasibility of the circular business model continuum. Figure 1 presents two structural conditions to determine whether a circular business case can operate in a given country. 1) whether the law permits reprocessing of single-use medical devices, and 2) whether reverse-logistics infrastructure enables WEEE recycling pathways. The countries in Tier 1 therefore enables most circular activities for digital health, making them the most mature markets to enter and where partnerships with third-party actors becomes relevant. Each tier is described below.

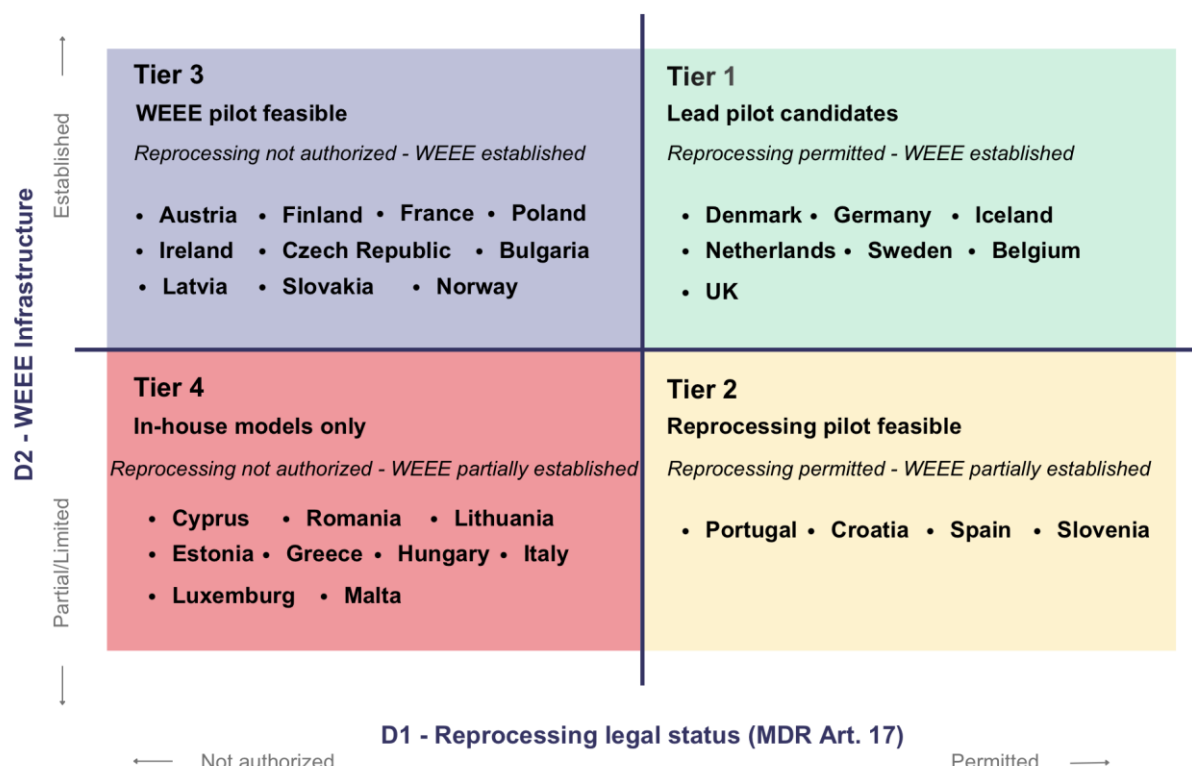


Figure 1. Europe Readiness Categorization

In Tier 1, the countries are both allowing reprocessing of medical devices according to MDR Article 17 and has an established WEEE infrastructure. The countries fitting in this category are Belgium, Denmark, Germany, Iceland, Netherlands, Sweden, UK. In Tier 2, reprocessing is permitted but there is a partial or limited implementation of WEEE infrastructure. This includes the countries Croatia, Portugal, Slovenia, and Spain. Partnerships will therefore more easily be made with reprocessors, whereas WEEE recycling may need to be OEM sponsored for the first pilots to help build the infrastructure. In Tier 3, the countries have established WEEE infrastructure but reprocessing of medical devices are illegal (opt. out of MDR article 17). This category includes the countries Austria, Bulgaria, Czech Republic, Finland, France, Ireland, Latvia, Norway, Poland, and Slovakia. This makes WEEE partnerships with recyclers and Producer Responsibility Organisations (PROs) attractive, whereas reprocessing pilots would need to be applied for. In Tier 4, there is both limited WEEE infrastructure and an opt-out of reprocessing, making it illegal. This includes the member states Cyprus, Estonia, Greece, Hungary, Italy, Lithuania, Luxembourg, Malta, and Romania. In these with countries, circular operations would need to be in-house, manufacturer-owned, and stakeholders must engage with policymakers to create favourable conditions for them to have third-party circular

operations. Although a WEEE infrastructure is established in Tier 1 and Tier 3, an important issue companies still would face is the cross-border movement of waste being prevented that limits access to recycler facilities for medical devices, which is niche equipment at this time.

A general pattern that can be observed is how the tier classification follows a clear north-west to south-east cluster across Europe, with the most mature markets concentrated in the north-central area (e.g., UK, Netherlands, Belgium, Iceland, Germany, Denmark, Sweden and Norway) and the most constrained markets clustering across eastern, and southern Europe. The tier classification is, however, not fixed, and countries can, through regulatory interventions, move placement. Denmark is an example of this, as they moved from Tier 3 to Tier 1 within four years through hospital-led advocacy for legalizing reprocessing (HCWH, 2024). Aarhus University Hospital had operated an in-hospital reprocessing arrangement with a German reprocessor before the MDR. The MDR transition in 2021 cut that arrangement off, because Danish national law did not permit reprocessing (HCWH, 2024). Rather than abandon the activity, the hospital partnered with the Centre for Sustainable Healthcare to convene a working group, generate evidence, and lobby for a national regulatory framework. The resulting executive order took effect on 1 January 2025, moving Denmark into Tier 1 and opening for any Danish hospital wishing to follow the Aarhus pathway (HCWH, 2024). Similarly in France, hospitals have pushed for reprocessing, which now opens for running a four-facility pilot project that may signal similar movement, and the MDR revised version scheduled for 2026 to 2027 may shift further countries across the tiers (Köhler, 2025). The full assessment per country can be read in Table 5. The tiers can also be seen in Figure 2. Some countries could not be mapped because of missing publicly available data.

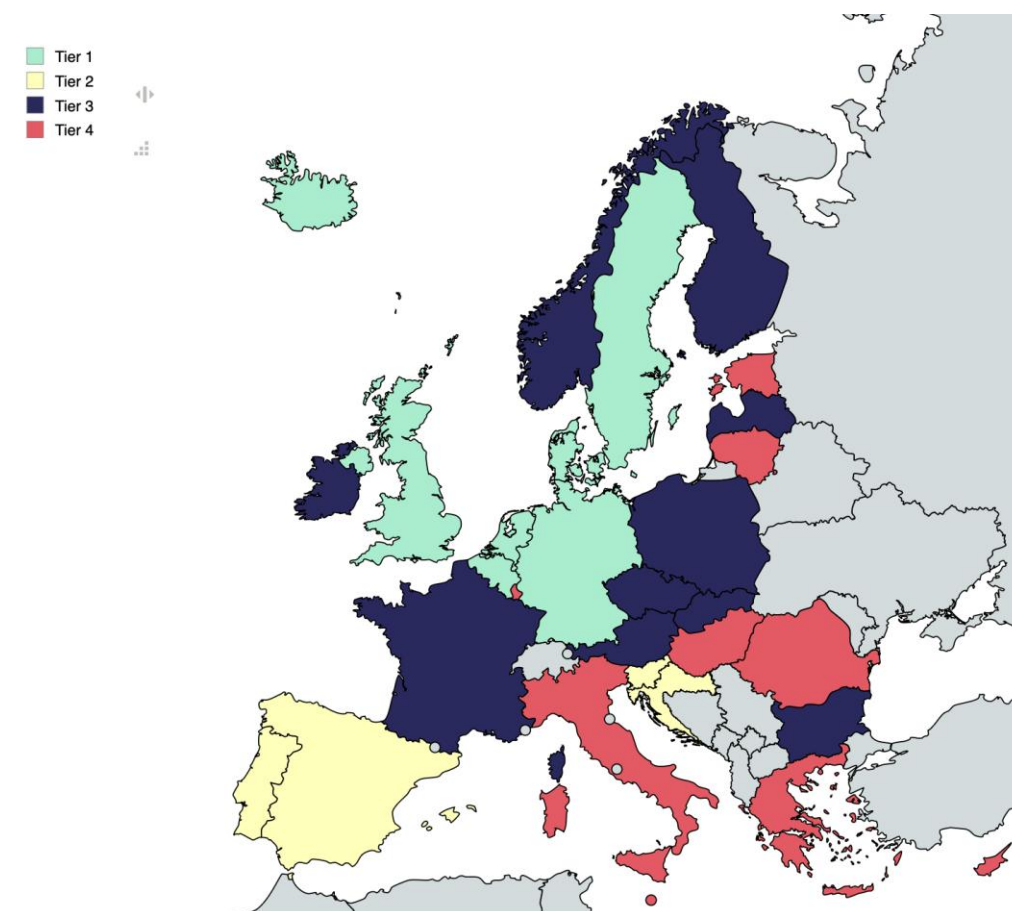


Figure 2. EEA Mapping of Tier Categorization

Legend: The grey countries do not have any data or not part of EEA

Table 5. Readiness Assessment Across European Countries

ISO	D1 status (Article 17)	D1 score	17(2) Manufacturer	17(3) Common Specs	17(4) Outsourcing	D2 WEEE infrastructure	D2 WEEE infrastructure Medical Device filter	D3 Behavioural profile	D4 Procurement	Tier
AT	Not authorised	0 / 3	Not permitted	Not permitted	Not permitted	Established (15.87 kg/cap, 2023)	Active channel (0.030 kg/cap, 2014–2018 avg)	Not assessed in DiCE	Regional	Tier 3
BE	Authorised	3 / 3	Permitted	Permitted	Permitted	Established (14.36 kg/cap, 2023)	None (0.006 kg/cap, 2014–2018 avg)	Convenience driven	Regional/Hospital-mixed	Tier 1
BG	Not authorised	0 / 3	Not permitted	Not permitted	Not permitted	Established (17.94 kg/cap, 2023)	Trace (0.015 kg/cap, 2014–2018 avg)	Not assessed in DiCE	Mixed	Tier 3
HR	Restricted¹⁶	2 / 3	Not permitted	Permitted	Permitted	Partial (8.31 kg/cap, 2023)	None (0.002 kg/cap, 2014–2018 avg)	Not assessed in DiCE	Mixed	Tier 2
CY	Not authorised	0 / 3	Not permitted	Not permitted	Not permitted	Limited (3.79 kg/cap, 2023)	None (0.002 kg/cap, 2014–2018 avg)	Not assessed in DiCE	National	Tier 4
CZ	Not authorised	0 / 3	Not permitted	Not permitted	Not permitted	Established (16.79 kg/cap, 2023)	Trace (0.012 kg/cap, 2014–2018 avg)	Not assessed in DiCE	Mixed	Tier 3
DK	Authorised	3 / 3	Permitted	Permitted	Permitted	Established (15.01 kg/cap, 2023)	None (0.004 kg/cap, 2014–2018 avg)	Not assessed in DiCE	Regional	Tier 1
EE	Not authorised	0 / 3	Not permitted	Not permitted	Not permitted	Partial (9.12 kg/cap, 2023)	None (0.002 kg/cap, 2014–2018 avg)	Not assessed in DiCE	National	Tier 4
FI	Not authorised	0 / 3	Not permitted	Not permitted	Not permitted	Established (13.23 kg/cap, 2023)	Trace (0.008 kg/cap, 2014–2018 avg)	Not assessed in DiCE	Regional	Tier 3
FR	Not authorised	0 / 3	Not permitted	Not permitted	Not permitted	Established (15.22 kg/cap, 2023)	None (0.000 kg/cap, 2014–2018 avg)	Not assessed in DiCE	Mixed	Tier 3
DE	Authorised	3 / 3	Permitted	Permitted	Permitted	Established (10.88 kg/cap, 2023)	Active channel (0.030 kg/cap, 2014–2018 avg)	Not assessed in DiCE	Hospital-dominant	Tier 1

¹⁶ Restricted refers to when not all MDR reprocessing articles are authorized

EL	Not authorised	0 / 3	Not permitted	Not permitted	Not permitted	Partial (8.14 kg/cap, 2023)	Traced (0.012 kg/cap, 2014–2018 avg)	Not assessed in DiCE	Mixed	Tier 4
HU	Not authorised	0 / 3	Not permitted	Not permitted	Not permitted	Partial (8.16 kg/cap, 2023)	None (0.002 kg/cap, 2014–2018 avg)	Not assessed in DiCE	Mixed	Tier 4
IS	Authorised	3 / 3	Permitted	Permitted	Permitted	Established (14.08 kg/cap, 2020)	Active channel (0.116 kg/cap, 2014–2018 avg)	Not assessed in DiCE		Tier 1
IE	Restricted	1 / 3	Permitted	Not permitted	Not permitted	Established (12.04 kg/cap, 2023)	None (0.000 kg/cap, 2014–2018 avg)	Not assessed in DiCE	National	Tier 3
IT	Not authorised	0 / 3	Not permitted	Not permitted	Not permitted	Partial (8.64 kg/cap, 2023)	None (0.000 kg/cap, 2014–2018 avg)	Not assessed in DiCE	Regional	Tier 4
LV	Not authorised	0 / 3	Not permitted	Not permitted	Not permitted	Established (10.37 kg/cap, 2023)	Active channel (0.024 kg/cap, 2014–2018 avg)	Not assessed in DiCE	National	Tier 3
LT	Not authorised	0 / 3	Not permitted	Not permitted	Not permitted	Partial (9.17 kg/cap, 2023)	Active channel (0.020 kg/cap, 2014–2018 avg)	Not assessed in DiCE	National	Tier 4
LU	Not authorised	0 / 3	Not permitted	Not permitted	Not permitted	Partial (8.81 kg/cap, 2023)	Traced (0.010 kg/cap, 2014–2018 avg)	Not assessed in DiCE	National	Tier 4
MT	Not authorised	0 / 3	Not permitted	Not permitted	Not permitted	Limited (5.75 kg/cap, 2023)	None (0.002 kg/cap, 2014–2018 avg)	Not assessed in DiCE	National	Tier 4
NL	Authorised	3 / 3	Permitted	Permitted	Permitted	Established (12.28 kg/cap, 2023)	None (0.000 kg/cap, 2014–2018 avg)	Not assessed in DiCE	Hospital-dominant	Tier 1
PL	Restricted	1 / 3	Permitted	Not permitted	Not permitted	Established (15.21 kg/cap, 2023)	Traced (0.018 kg/cap, 2014–2018 avg)	Not assessed in DiCE	Mixed	Tier 3
PT	Authorised	3 / 3	Permitted	Permitted	Permitted	Limited (5.79 kg/cap, 2023)	Traced (0.010 kg/cap, 2014–2018 avg)	Not assessed in DiCE	National	Tier 2
RO	Not authorised	0 / 3	Not permitted	Not permitted	Not permitted	Partial (7.63 kg/cap, 2021)	None (0.000 kg/cap, 2014–2018 avg)	Not assessed in DiCE	Mixed	Tier 4

SK	Not authorised	0 / 3	Not permitted	Not permitted	Not permitted	Established (10.94 kg/cap, 2023)	None (0.000 kg/cap, 2014–2018 avg)	Not assessed in DiCE	Mixed	Tier 3
SI	Restricted	2 / 3	Not permitted	permitted	permitted	Partial (7.85 kg/cap, 2023)	Active channel (0.026 kg/cap, 2014–2018 avg)	Attitude- & norm-driven	National	Tier 2
ES	Authorised	3 / 3	Permitted	Permitted	Permitted	Partial (9.27 kg/cap, 2023)	Traced (0.006 kg/cap, 2014–2018 avg)	Attitude- & norm-driven	Regional	Tier 2
SE	Restricted	2 / 3	Not permitted	Permitted	Permitted	Established (12.98 kg/cap, 2021)	None (0.004 kg/cap, 2014–2018 avg)	Not assessed in DiCE	Regional	Tier 1
UK	Authorised	2 / 3	Permitted (MHRA equivalent)	Not applicable (non-EEA)	Permitted	Partial (7.05 kg/cap, 2023) ¹⁷	-	Not assessed in DiCE	National (NHS England/Scotland/Wales)	Tier 1
NO	Not authorised	0 / 3	Not permitted	Not permitted	Not permitted	Established (20.08 kg/cap, 2023)	-	Not assessed in DiCE	-	Tier 3

¹⁷ <https://www.gov.uk/government/statistical-data-sets/waste-electrical-and-electronic-equipment-wEEE-in-the-uk>

Three Phases of a Roadmap

This roadmap is organised in three sequential phases: proof of concept, creation and test of partnerships, and scaling. The sequence is mostly driven by the capability of organizations themselves. The phases will refer to the responsible-actor axis of the D6.3 business model continuum (first column of Figure 3). In Phase 1, most of the pilots will naturally stay in row 1 where the OEM owns the circular take-back and proves the economic case in-house (the continuum's Row 1). In Phase 2 the activity can in some cases be extended to controlled, mandated third parties, where partnership, contracting, and shared traceability become the central concern (Row 2). Not all circular business model configurations will move to Row 2, although many would eventually need to collaborate with suppliers and contractors to scale their respective models, even when the OEM is responsible for the sale and take-back of the product. Row 3 refers to when uncontrolled third parties are responsible for take-back of the product, which may or may not always be in agreement with the OEM (such as uncontrolled third-party reproducers, public waste or recycling streams, or hospitals' own circular agendas and/or partnerships independent of the OEM).

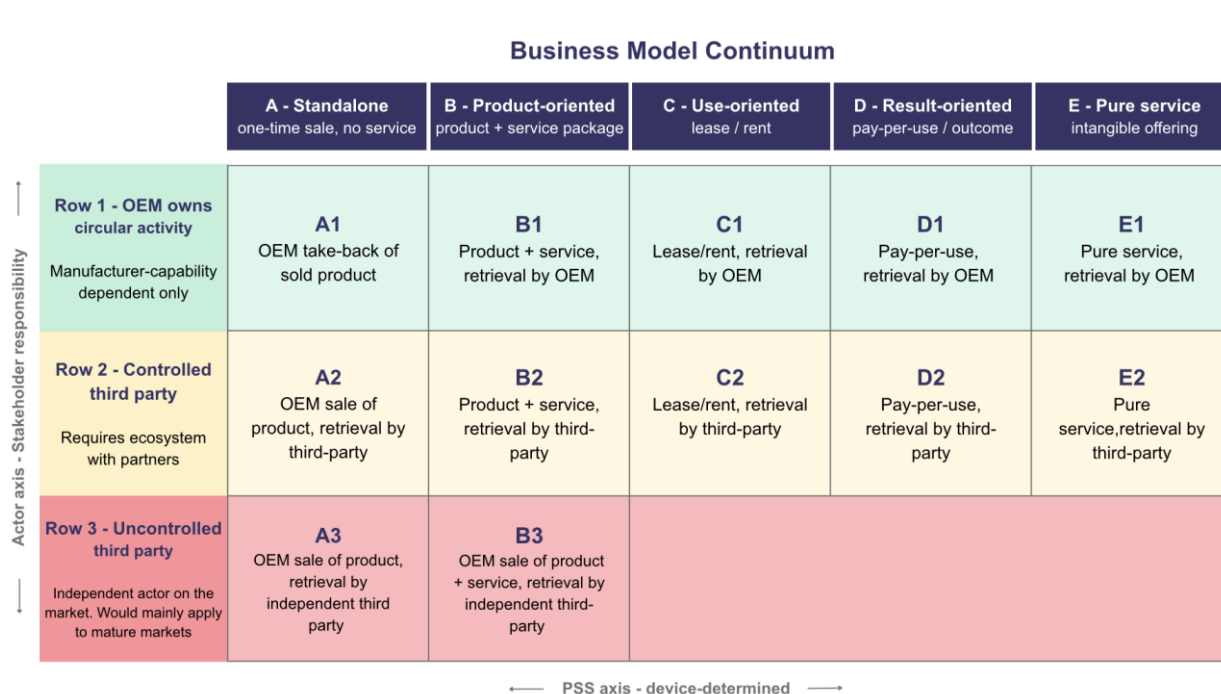


Figure 3. Business Model Continuum

Legend: The alphabet letter refers to the column and the number to the row

Phase 1 Proof-of-Concept: In-hospital/Clinic Pilots in Tier 1 and Tier 2 Countries

In Phase 1, the objective is to demonstrate the economic case for a circular configuration in a controlled setting before exposing the model to ecosystem complexity. Tier 1 and Tier 2 countries are the appropriate entry points based on the assessment that reprocessing is legally permitted under MDR Article 17, and WEEE infrastructure is either partially or well established. Depending on the business model configuration (See business model continuum) and the circular strategy (i.e., reuse, refurbishing, or recycling etc.) pursued, tier 3 countries could also be an option, although countries in Tier 1 would have better conditions for future development into other circular strategies.

Two decisions are therefore important in this phase. The first is country and product selection. The manufacturer should match the intended circular configuration to a country tier where the regulatory and infrastructural preconditions are met, and second is the construction of an economic case in which the retrieval rate is the central variable. The D6.3 financial models for

the DDL demonstrate that retrieval rate is the single most consequential parameter for circular economic performance: total cost savings for the original equipment manufacturer fall from approximately €970,000 at a 91% retrieval rate to approximately €420,000 at 40%, a reduction of 57% (D6.3, Tables 11–12). Deliverable 6.3 Recommendations support this by adding that this implementation should prioritise contexts where return logistics, incentives, and stakeholder participation can realistically deliver high retrieval rates, and pilots should explicitly measure return behaviour to inform future scaling. Retrieval rate should be treated as a ramp-up parameter that improves through learning and incentive refinement, rather than as a fixed assumption (D6.3).

Within this phase, institutional rather than patient-driven configurations could be prioritised. The D6.4 pressure test found that institutional models are preferred across stakeholder groups, meaning models where the OEM, hospital or clinic, instead of the patient, retains ownership of the product. The surveys in D6.4 indicate that adoption decisions are made by institutions, and that pilot designs which depend on patient return behaviour carry significantly higher operational risk than those routed through existing clinical workflows. A condition that runs through the phase, and that determines whether the pilot will translate into a viable business model rather than a stuck at in a pilot, is the interaction and inclusion of hospitals in the circular model. Deliverable 6.3 and 6.4 found that hospitals carry most of the operational burden of circular models without a corresponding share of the economic benefit. Deliverable 6.3 concludes hospitals must be evaluated at the system level of the circular models (e.g., not based on the individual product), and clear economic incentives for them must be designed into the pilot from the outset. In other words, hospitals would be easier to engage if they get some kind of cost reduction from e.g., lower product costs, easier workflows saving them labour cost or a reduction of its waste management costs. Thus, a pilot that achieves a favourable retrieval rate but leaves the hospital uncompensated is not scalable, because the hospitals will on the long term consider cost first, and thereafter the environmental sustainability impact when procuring devices.

Hospital procurement architecture varies significantly across countries, and this variation shapes both the design of a Phase 1 pilot and the strategy for scaling. Three structural patterns are visible in the EEA. In countries with national procurement frameworks (such as Denmark, France and Ireland, where centralised tenders cover large portions of the public hospital network), a successful pilot can translate relatively quickly into a national-scale agreement, but the upfront tender requirements are more demanding, and the procurement cycle is longer. In countries with regional procurement (such as Spain, where the autonomous communities tender independently, or Italy and Sweden where regional health authorities lead), a pilot is anchored to a single region and replication requires repeating the procurement engagement region by region. In countries with hospital-dominant procurement (such as Germany, where individual hospitals or hospital groups make autonomous purchasing decisions), a pilot can move quickly with a willing institution, but national scaling requires hospital-by-hospital engagement. Reimbursement schemes can also impact which devices in the end are procured and is different across member states.

Success criteria for a manufacturer:

- **A positive economic case at the achieved retrieval rate.** The pilot generates real cost data, replacing the assumption-based estimates of D6.3, showing the chosen configuration is financially viable for the OEM, with retrieval rate confirmed as the decisive parameter (D6.3, Tables 11–12).
- **A retrieval rate at, or credibly trending toward, the configurations break-even.** Rather than a fixed sector-wide target, the pilot meets or shows a believable ramp-up toward the break-even rate derived from the device's own financial model, treating retrieval rate as a parameter that improves with incentive refinement (D6.3).
- **A demonstrated hospital benefit.** The hospital realises a measurable gain: lower device cost, a labour or workflow saving, or reduced waste-management cost, rather than carrying the reverse-flow burden uncompensated. A pilot with a strong retrieval rate but an uncompensated hospital would have difficulty scaling (D6.3, Recommendation 2).

- **Circularity routed through institutional workflows.** If possible, depending on the device, explore return and collection run through existing clinical routines rather than depending on patient return behaviour, keeping insufficient retrieval rate risk low (D6.4).
- **A mapped procurement pathway.** The manufacturer has identified the route to scale in the chosen country (national, regional, or hospital-level) and how reimbursement affects device selection there.

Recommendations for policy makers:

- **Give regulatory clarity for pilots.** Issue explicit national guidance that the intended strategy (reuse, refurbishment, or reprocessing where permitted) is allowed and how it is to be governed, removing the ambiguity that deters OEMs and hospitals from starting. Denmark's 2025 executive order and France's pilot project show how national action can open a market (Chapter 3).
- **Correct the hospital incentive through procurement.** Because hospitals procure medical devices primarily on cost, policy should encourage or require tenders to weigh lifecycle cost and circularity rather than unit price alone, so circular configurations are not disadvantaged at the point of purchase/sale (D6.3, Recommendation 2).
- **Align reimbursement so circular devices are not penalised.** Since reimbursement rules vary across member states and shape what is procured, policymakers should ensure a reused, refurbished, or reprocessed device is not reimbursed less favourably than its single-use equivalent.
- **Clarify waste and decontamination classification.** Resolve inconsistent interpretation of when a used device counts as contaminated waste versus a recoverable product, which otherwise blocks in-country circular handling before any cross-border question arises (D6.2).

Phase 2 Circular Partnerships: Regional Scale with Controlled Third Parties

In Phase 2, the manufacturer will, depending on its business model configuration, need to shift into including contracted third parties. For instance, a manufacturer that sells a device with a service package and currently handles take-back in-house in a pilot setting (configuration B1) moves into configuration B2 in the business model continuum once a licensed third party takes over retrieval and refurbishment. This transition therefore introduces the ecosystem complexity that D6.1 identifies through three interrelated misalignment themes between stakeholders: their interrelations (the strength and structure of connections or disagreements between manufacturers, hospitals, recyclers, PROs, reproducers and patients), their perceived responsibilities (who is accountable for which activity in the circular loop), and their expectations of one another. These misalignments are key partnership barriers stakeholders will need to consider. It is important to note that today there is still no coordination between some of the stakeholder groups such as the bigger OEMs and reproducers. The D6.4 workshops on the DDL Reuse-as-a-Service model was an example of the barriers mentioned such as ambiguity over data ownership and IP rights, uncertainty about liability if reused devices fail, and hospital reluctance to assume responsibility for storage and delivery of devices to OEMs. Phase 2 therefore requires contractual mechanisms that explicitly resolve responsibility and expectation gaps before scaling, rather than after operational failures exposing them. These failures could be related to device malfunction or uncertainty on stakeholder responsibility or inadequate tracking systems that do not accurately document ownership and usage history important for potential reuse.

The first contractual suggestion is agreeing on a minimum retrieval guarantee with third parties to account for the retrieval rate sensitivity identified in Phase 1 into enforceable performance metrics. The second is a scope of responsibility agreements which should be co-designed with the third parties and hospitals involved, drawing on D6.1's finding that stakeholder

responsibilities cannot only be assigned top-down and must be negotiated against each actor's operational reality. Digital traceability becomes a prerequisite at this stage. This is because in Phase 1 the single OEM–hospital relationship can be governed through bilateral records. Phase 2 introduces a third actor or at least a wider network, which turns those bilateral records into a multi-party coordination challenge: the involved stakeholders need the device's identity, usage history, and ownership status to perform the circular activity safely. Deliverable 6.3 states how insufficient visibility across product ownership, times of usage and retrieval flows risks create accountability and safety risk. Phase 2 also tests whether the family-of-models approach i.e., group similar products into similar business model configurations (D6.3) holds in practice. Rather than deploying a single business model configuration across countries, the OEM should develop a shared logic with predefined configuration options that can be adapted to local regulatory interpretation, reprocessing capacity, and hospital workflow constraints.

Success criteria for a manufacturer:

- **A functioning controlled-third-party partnership.** A working relationship with a mandated collector, distributor, reprocessor or refurbisher is in place with data access, device approvals, and joint quality oversight closing.
- **An enforceable minimum retrieval guarantee.** The contract converts the Phase 1 retrieval-rate sensitivity into a binding performance metric set at or above the configuration's own break-even, and the partnership is measuring against it (D6.3).
- **Co-designed scope-of-responsibility agreements in force.** Liability for device failure, and responsibility for storage, return logistics, and quality control, are contractually assigned, negotiated with the third parties and hospitals involved (D6.1; D6.4).
- **An operational multi-party traceability system.** A shared chain-of-custody record, device identity, usage history, ownership status, is running and aligned with the Digital Product Passport framework, sufficient to support accountability and to document a recovered device as fit for reuse (D6.3).
- **The model validated beyond a single configuration.** The family-of-models logic holds in practice making sure it supports more than one device or configuration, adapted to local conditions, rather than being rebuilt each time. This is the condition for moving to cross-regional scale in Phase 3 (D6.3).

Recommendations for policy makers:

- **Clarify liability in multi-party circular chains.** Clearer default rules for those who bear liability when a reused or reprocessed device fails across a manufacturer–reprocessor–hospital chain would remove a documented barrier to forming partnerships (D6.4).
- **Accelerate interoperable traceability.** Advancing the Digital Product Passport under the ESPR for medical devices and aligning it with existing UDI/EUDAMED identifiers would make the chain-of-custody infrastructure Phase 2 depends on shared and interoperable, rather than rebuilt by each OEM (D6.3).
- **Create EU level optional guidelines on procurement.** Procurement and reimbursement rules that allow regional tenders to buy a circular service arrangement involving a third party would let proven partnerships scale within a region or nation.

Phase 3 Scale: Independent Markets and Cross-Regional Configurations

By Phase 3, the configuration is assumed to have reached a maturity where it can scale across regions and Member States rather than operate within a single national setting. The precondition is regulatory alignment across the EEA on the three fronts identified in the synthesis (Background section): harmonisation of national authorisation under MDR Article 17 (removing the opt-in/opt-out fragmentation that currently splits reprocessing rights across Member States), the consistent application of the WEEE Directive to medical devices, and a harmonised classification of medical waste (D6.2). Until these align, cross-border circular flows remain



operationally constrained, which in the end impact on the needed volume for economic viability and an environmental benefit. The limitations on volume of materials mean the flows will not see material return to devices, however, the impact benefit of not incinerating waste as a default still contribute significantly to decarbonisation roadmaps for institutions.

If regulation permits cross-border movement, recovered devices can be pooled across regions to reach the volume thresholds that the Phase 1 economic models require. Here the geography of the readiness assessment becomes strategically relevant. The Tier 1 markets are concentrated in north and western Europe, and their continental core (Denmark, Germany, the Netherlands, Belgium, and Sweden) is geographically proximate, which means first viable cross-regional configurations would be likely to form within this area, benefiting from regulatory maturity and shorter transport distances. Both reverse-logistics cost and the transport emissions can erode the environmental case (D5.2), and rise with distance, so pooling between neighbouring markets is more defensible than continent-spanning flows. The island Tier 1 markets (Ireland, Iceland, and the UK) share the regulatory readiness but face higher cross-border logistics friction, which may shape how they integrate into pooled configurations.

Success criteria for a manufacturer:

- **A cross-regional configuration in operation.** The model runs across more than one Member State or region rather than within a single national setting, with the controlled partnership and traceability system proven in Phase 2 replicated across the footprint (D6.3). This may, however, currently be limited by regulation.
- **Volume thresholds met through pooling.** Recovered devices are pooled across neighbouring markets to reach the volumes that the Phase 1 economic models show a single market can struggle to sustain, so the configuration is economically viable at scale (D6.3).
- **The environmental case preserved at distance.** The manufacturer has verified that reverse-logistics transport emissions do not offset the benefit, which at this scale comes mainly from avoided incineration rather than material return to devices, by keeping pooling between proximate markets rather than spanning the continent (D5.2).
- **A footprint aligned to the readiness map.** Scaling forms first within the proximate Tier 1 continental core (Denmark, Germany, Netherlands, Belgium, Sweden), with the island Tier 1 markets (Ireland, Iceland, UK) integrated in a way that accounts for their higher logistics friction (Chapter 3).

Recommendations for policy makers:

- **Harmonise MDR Article 17 authorisation.** Replace the current opt-in/opt-out fragmentation with a common authorisation basis, so single-use reprocessing rights no longer split across Member States and a configuration can operate on the same legal footing throughout its footprint (D6.2; background section).
- **Harmonise medical-waste classification.** A common classification removes the situation where a recovered device is treated as contaminated waste in one country and a recoverable product in another, which today blocks cross-border handling.
- **Simplify procedures for the cross-border movement of recovered devices.** Beyond classification, allow recovered devices and medical-device waste to move across borders for pooling and reprocessing (See D6.2).
- **Provide a mutual recognition route for non-EEA markets.** Because the UK sits outside EEA harmonisation yet is a Tier 1 market, a mutual-recognition mechanism would let it integrate into pooled market.



Digital Health in the Circular Economy

CONCLUSION

Deliverable 6.5



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CONCLUSION AND OUTLOOK

This deliverable set out to convert the evidence generated across 15 preceding DiCE deliverables into a single, useful roadmap. It focuses on which circular business models for digital health devices can be implemented where, and under which conditions. It considers individual European countries and creates a readiness assessment.

The readiness assessment showed that under the two conditions considered, countries in Europe could be divided into four categories based on: whether national law permits reprocessing of single-use devices under MDR Article 17, and whether WEEE infrastructure can move end-of-life devices through retrieval pathways, including transboundary movements. This tiered classification had the most enabling conditions (Tier 1) concentrated in north-western Europe, and the most constrained countries (Tier 4) clustered across southern and eastern Europe. The classification is a snapshot, thus not a fixed ranking: Denmark's move from Tier 3 to Tier 1 in four years, driven by hospital-led advocacy, shows that countries can shift their own position, and comparable trajectories are emerging in France.

On this basis, the deliverable proposed a three-phase roadmap. Phase 1 establishes the business case through OEM-led in-hospital pilots in Tier 1 and Tier 2 countries, with the device retrieval rate treated as the decisive variable and hospitals incentivised from the outset. Phase 2 extends the chosen model to contracted third parties at regional scale, by focusing on resolving the responsibility and expectation gaps identified in D6.1 through minimum retrieval guarantees, co-designed scope-of-responsibility agreements, and Digital Product Passport and aligned traceability. Phase 3 opens up towards cross-regional configurations, but only once EEA-level regulatory cross-border barriers are revised, which currently makes cross-border flows of e.g., contaminated products unviable. Running through all three phases are findings that hold regardless of geography: retrieval rate is one of the most important variable regardless of economic configuration; the value asymmetry that leaves hospitals carrying operational burden without commensurate return must be designed out rather than ignored; no single business model fits all devices and regions, so a configurable continuum is needed; and digital traceability is a shared prerequisite rather than an optional feature.

Article 17's national opt-in (the provision (17(1)) allowing each Member State to decide whether reprocessing is permitted on its territory, together with the national restrictions allowed under 17(9)) is the single largest source of the fragmentation these deliverable maps, and it is at the time of writing the subject of a concrete simplification proposal of the MDR (MDR, 2026). Rather than leaving reprocessing permission to national law, the proposal would require manufacturers to justify any "single-use" designation, with devices not justified as single-use becoming reprocessable in line with manufacturer instructions, which also will end the national opt-in/out to harmonise reprocessing across the single market.

For the framework in this deliverable, harmonising Article 17 would be a major change. It would remove the reprocessing dimension (D1) that the tier classification partly rests on. Tier 3 countries (those that already have WEEE infrastructure but do not currently allow reprocessing) would gain access to the full range of circular configurations, and the European map would resort around WEEE infrastructure and operational readiness rather than legal permission. A single, harmonised market for reprocessed and refurbished devices would bring several benefits. It would let the cross-regional pooling that Phase 3 depends on work in practice. It would keep device materials and components inside EEA retrieval loops, in line with the Critical Raw Materials Act, and it would widen access to lower-cost reprocessed devices for hospitals while supporting circular refurbishing within the EEA, rather than sending that value abroad, potentially strengthening EEA autonomy and regional competitiveness.

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Appendix A

Appendix A. Data Collection for EEA Readiness Assessment

Dimension	Value	Description	Source	URL
D1 Reprocessing status (Art. 17)	Full	17(2) Manufacturer obligations + 17(3) Common Specifications + 17(4) Outsourcing all permitted, no 17(9) restrictions. All business model configurations viable.	European Commission notification page (Jan 2025)	LINK
D1 Reprocessing status (Art. 17)	Outsourcing-permitted	17(2) + 17(4) permitted (17(3) optional). Disintegrated business models (BM3/BM4) legally available — Vanguard-style outsourcing viable.	EC notification page	LINK
D1 Reprocessing status (Art. 17)	OEM-only	17(2) permitted but 17(4) Outsourcing not permitted. Only OEM in-house reprocessing legal — disintegrated BMs blocked.	EC notification page	LINK
D1 Reprocessing status (Art. 17)	Restricted	17(2) permitted but 17(9) restriction in force (Poland: making-available or further reuse of reprocessed SUDs prohibited). Reprocessing legal but commercial market blocked.	EC notification page	LINK
D1 Reprocessing status (Art. 17)	Not authorised	No national notification under Art. 17. Pilots and strategic roadmaps captured separately as Trajectory signals (do not score).	EC notification page	LINK
Art. 17 sub-options	17(2) Manufacturer obligations	Reprocessor takes on full manufacturer obligations under MDR Art. 17(2): technical documentation, clinical evaluation, post-market surveillance, vigilance, product liability. Binding sub-option — without 17(2), no commercial reprocessing.	MDR Art. 17(2)	LINK
Art. 17 sub-options	17(3) Common Specifications	National rules align with EEA Common Specifications for reprocessing. Enabling but not binding.	MDR Art. 17(3)	LINK
Art. 17 sub-options	17(4) Outsourcing	Reprocessing may be outsourced to an external operator under national rules. Critical for BM3/BM4 disintegrated business models — without 17(4), only OEM-owned reprocessing is viable.	MDR Art. 17(4)	LINK
Art. 17 sub-options	17(9) Restriction/prohibition	National restriction (e.g. Poland: making available or further reuse prohibited). Blocks the commercial market even where 17(2) is permitted.	MDR Art. 17(9)	LINK
D1 special cases	UK MHRA re-manufacturing	UK permits commercial re-manufacturing under MHRA — legally equivalent to MDR Art. 17(2) under a different regulator. Vanguard operates UK subsidiary under this pathway. Scored as Full pending finer assessment of outsourcing rules under MHRA framework.	MHRA guidance; Vanguard public communications	LINK
D1 special cases	Denmark (Jan 2025 reform)	Denmark legalised SUD reprocessing via executive order effective 1 Jan 2025; EC notification page (last updated Jan 2025) had not yet reflected this at time of access. Scored as Full pending Danish executive order specifics on sub-options.	Health Care Without Harm Europe; Danish Ministry of Health	LINK



D1 special cases	France (not authorised)	pilot	France runs a 4-facility 2-year pilot project but is on the EC 'do not authorise' list. Pilot is a trajectory signal, not regulatory authorisation. D1 = 0.	Vanguard public communications; French government announcements	LINK
D2 WEEE infrastructure	Established		Mature WEEE collection system	Eurostat WEEE statistics	LINK
D2 WEEE infrastructure	Partial		WEEE in place but regional fragmentation or medical-classification gaps	Eurostat WEEE statistics	LINK
D2 WEEE infrastructure	Limited		Lower baseline collection rates and limited capacity	Eurostat WEEE statistics	LINK
D3 Behavioural profile	Convenience-driven		PBC dominant predictor (Belgium)	DiCE D4.3 PLS-SEM	DiCE D4.3
D3 Behavioural profile	Attitude- & norm-driven		Attitudes and subjective norms drive return (Slovenia, Spain)	DiCE D4.3 PLS-SEM	DiCE D4.3
D4 Procurement	National		Single national authority	Health system structure	LINK
D4 Procurement	Regional		Devolved regional health authorities	Health system structure	LINK
D4 Procurement	Hospital-dominant		Hospital-level procurement primary	Health system structure	LINK
D4 Procurement	Mixed		Hybrid arrangement	Health system structure	LINK
D4 Procurement	Regional/Hospital-mixed		Regional fragmentation + hospital autonomy	Health system structure	LINK