Digital Health in the Circular Economy

Instruction Manual For Operational Workers Handling Digital Health Devices

Funded by
the European Union

VER. NO.	DATE	REASONS FOR RELEASE	RESPONSIBLE
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3	*30/04/2026*	*Draft 3*	*Michelle Wagner*
4	*30/05/2026*	*Draft 4*	*Michelle Wagner*
5	*12/06/2026*	*V1*	*Consortium*

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Terms and Definitions

DiCE project	DIGITAL HEALTH IN THE CIRCULAR ECONOMY
DiCE project	*Digital Health in the Circular Economy*
EEE	*Electrical and Electronic Equipment*
EPR	*Extended Producer Responsibility*
EU	*European Union*
EU GPP	*European Union Green Public Procurement*
EU MDR	*European Union Medical Device Regulation (Regulation (EU) 2017/745)*
EWC	*European Waste Code*
EWRN	*European WEEE Registers Network*
GDPR	*General Data Protection Regulation (Regulation (EU) 2016/679)*
GPP	*Green Public Procurement*
ICT	*Information and Communication Technology*
JRC	*Joint Research Centre (European Commission)*
OEM	*Original Equipment Manufacturer*
PPE	*Personal Protective Equipment*
SUD	*Single-Use Device*
UDI	*Unique Device Identifier*
WEEELABEX	*WEEE Label of Excellence (certification scheme based on EN 5062)*
WHO	*World Health Organisation*
e-waste	*Electronic Waste*

1 EXECUTIVE SUMMARY

The rapid expansion of digital health technologies has brought significant benefits to healthcare systems, patients, and professionals. At the same time, it has led to a growing volume of used digital health devices that must be managed safely, compliantly, and in an environmentally responsible manner. These devices often contain electronic components, batteries, sensitive data, and, in some cases, may be biologically or chemically contaminated after use, making their end-of-life management more complex than that of conventional Electrical and Electronic Equipment (EEE).

Despite progress in environmental legislation and waste electrical and electronic equipment (WEEE) management, the health sector still lacks practical, operational guidance tailored specifically to digital health devices. Existing legislations are often fragmented across waste, medical device, health and safety, and data protection frameworks, leaving operational workers with limited, practice-oriented support.

The Digital Health in the Circular Economy (DiCE) project addresses this gap by developing this Manual for Operational Workers. The manual translates regulatory requirements and circular economy principles into clear, actionable guidance for the prevention, collection, sorting, handling, transport, treatment, and re-processing of digital health devices.

A key objective of this manual is to support waste prevention and life-extension strategies, in line with the waste hierarchy. Wherever safe and feasible, reuse, re-deployment, repair, and refurbishment of digital health devices are prioritised over recycling and disposal. The manual also provides structured guidance for decision-making, including a practical decision tree to support correct routing of devices between reuse, refurbishment, recycling, or medical waste treatment pathways such as incineration.

The manual is designed primarily for operational workers in healthcare facilities, waste collection and logistics organisations, and treatment, refurbishment, and recycling facilities. It also supports managers, supervisors, and trainers by providing a consistent framework for procedures, training, and compliance. Specific guidance is included for both medical facilities and household generated devices, recognising the different risks and collection pathways involved.

In line with Extended Producer Responsibility (EPR) and WEEE legislation, the manual highlights the role of Producer Responsibility Organisations (PROs) in managing non-infectious digital health devices and or components thereof and supporting safe and compliant collection and treatment. It also emphasises the importance of segregation at source, documentation, and traceability to protect human health, safeguard data, and enable high-quality material recovery.

Through its practical focus, visual tools, and annexed operational materials (i.e., decision trees, labels, and leaflets), this manual supports the implementation of circular economy practices in the digital health sector. It contributes to reduced environmental impacts, improved safety for workers and patients, and better recovery of valuable materials, in line with the objectives of the DiCE project and broader EU Circular Economy goals.

2 INTRODUCTION

Despite significant progress in environmental legislation and e-waste management practices, the health sector continues to show potential for improvement in reducing the environmental impacts associated with digital health devices. In many cases, practices aimed at preventing waste generation and reducing the environmental footprint of equipment used in healthcare activities are limited, inconsistent, or not systematically implemented. This is particularly critical given that digital health devices often rely on Critical Raw Materials (CRMs), which are essential for high-tech components used in medical devices but face significant high environmental costs during extraction and high environmental costs during extraction.

Within the framework of the DiCE project, a review of existing protocols, guidelines, and best environmental practices related to digital health devices was carried out. This review revealed that very few high-tech components used in medical devices have guidelines exist that specifically address the collection, sorting, handling, transport, and treatment of digital health devices across healthcare facilities, households, logistics operations, and treatment facilities. The lack of specialised handling often results in the loss of CRMs, as standard end-of-life processes, including recycling, may not be optimised to recover these low-volume but high-value elements.

To address this gap, the present document compiles and consolidates good practices and practical guidance for the management of digital health devices throughout their lifecycle. The instruction manual focuses on the operational level and aims to support safer, more consistent, and more environmentally responsible practices, while facilitating reuse, refurbishment, and high-quality recycling where feasible. By prioritising these circular pathways, we can secure the secondary supply of CRMs, enhancing resource autonomy, supply chain resilience, and long-term competitiveness while reducing reliance on virgin mining.

2.1 Aim of the training material

This training material aims to support operational workers in the health and waste management sectors by providing clear, practical, and easy-to-apply guidance on how to manage digital health devices in a safe, compliant, and environmentally responsible manner.

Specifically, this manual aims to:

- Promote the recovery and preservation of CRMs found within electronic components;
- Support safer handling and treatment practices, including for infected or potentially contaminated or hazardous devices;
- Improve consistency and quality of operations across collection, transport, and treatment stages;
- Promote reuse, refurbishment, and high-quality recycling where feasible;
- Support the transition of the health sector towards more circular economy practices, in line with DiCE and EU objectives.

This document is designed as a hands-on reference tool, not as a regulatory or policy document. It complements existing legislation and standards by focusing on what operators need to do in practice, rather than on legal interpretation. It is recommended to complement this document with applicable legislation in force and state of the art guidelines (if any published after the publication of the current document).

2.2 How and when to use this manual

The manual has been developed to support the practical, day-to-day management of digital health devices within a circular economy framework. It is intended to be used as a hands-on guide, supporting safe, consistent, and environmentally responsible practices across all relevant operational stages.

How to use this manual

The manual follows the logical operational flow of digital health devices, from prevention to end-of-life. Each section corresponds to a specific step in the process and provides:

- Clear descriptions of what needs to be done;
- Practical guidance on how tasks should be carried out;
- Key safety, environmental, and data protection considerations;
- Decision points to support appropriate routing of devices.

This manual is intended to complement existing legislation, standards, and internal procedures; it does not replace them. Where internal procedures or legal requirements exist, they must lways be followed. The added value of this manual lies in translating these requirements into clear, practical actions that support consistent implementation on the ground.

When to use this manual

This manual should be consulted at different moments throughout daily operations, including:

- As part of onboarding new staff and a refresher for existing staff;
- During routine activities, such as collection, handling, storage, transport, and treatment of digital health devices;
- When facing non-standard situations, such as damaged devices, missing information, mixed waste streams, or potentially infected devices;
- When decisions are required regarding reuse, refurbishment, recycling, or disposal.
- When a healthcare facility is determining the most appropriate destination for end-of-life equipment, whether through reuse, refurbishment, recycling, or treatment channels (Section 5).

How this manual is structured

The manual is organised into three parts so that each user can quickly find the sections that apply to their role:

- **Part A — Healthcare center operations** (Sections 6–10). For operational workers and managers in hospitals, clinics, laboratories, and other facilities that generate digital health device waste.
- **Part B — Transport, treatment and recycling** (Sections 11–13). For logistics providers, treatment and recycling facilities, and reprocessing operators.
- **Annexes**. Decision trees, fact sheets, bin labels, leaflets and selection checklists are ready to be printed and adapted by each facility.

READ FIRST: Sections 4 (Roles and Responsibilities) and 5 (Manager's Guide) apply to all parts and should be read first by anyone setting up or supervising the management of digital health devices.

3 SCOPE

This section defines the scope of application of the DiCE instruction manual, including the intended audience and the types of products covered.

3.1 Target audience

The target audience of this document includes operational workers and managers employed by organisations involved in the management of digital health devices at different stages of their lifecycle. This includes, but is not limited to, personnel working in the following main groups of organisations:

3.1.1 Healthcare and Health-Related Organisations

Organisations carrying out medical or health-related activities where digital health devices may be used and where waste digital health devices or similar equipment may be generated. In line with the World Health Organization (WHO) publication *Safe Management of Wastes from Health-Care Activities* (Chartier et al. 2014), digital health device waste may arise in a wide range of healthcare settings, including:

- Hospitals and hospital networks (University hospital, General Hospital, District hospital);
- Other healthcare facilities (e.g. outpatient clinics, dialysis centres, long-term care facilities, hospices, Emergency and medical care services);
- Related laboratories and research centres (medical and biomedical laboratories, Biotechnology laboratories and institutions, medical research centres);
- Nursing homes and elderly care facilities;
- Mortuary and autopsy centres;
- Animal research and testing;
- Blood banks and blood collection services;

A comprehensive list of healthcare institutions and minor sources of healthcare waste is provided in Annex 1 Healthcare Institutions and Activities Potentially Generating Digital Health Device Waste.

3.1.2 Waste Management, Treatment, and Re-processing Organisations

Organisations involved in the collection, sorting, handling, transport, treatment, recycling, refurbishment, or re-processing of digital health devices, including (Chartier et al. 2014):

- Hazardous and non-hazardous waste collection service providers;
- Infectious waste disinfection and sterilisation service providers;
- Hazardous and non-hazardous waste treatment facilities;
- Recycling, refurbishment, and re-processing operators:
- Producer Responsibility Organisations (PROs).

3.1.3 Management, Training, and Planning Roles

Managers and coordinators responsible for developing strategies, operational procedures, working plans, training materials and supplier selection in organisations that generate, collect, or manage digital health devices. Specific manager-oriented guidance is provided in Section 5.

3.2 Products in scope

3.2.1 Digital health devices

In the context of this document, digital health devices and related equipment refer to electrical and electronic equipment (EEE) used in the health sector that is typically of small size (generally less than 50 cm in length) and that is generated by the professional activities listed in Section 3.1 (Target Audience). For terminology and definitions, references are made to the DiCE project Terms and Definitions (*Terms and Definitions - Digital Health in the Circular Economy* 2025).

A digital health device is a physical device used for health-related applications that:

- Contains electronic components, and
- Operates on a source of energy other than that generated by the human body.

Digital health devices that fall under the definition of medical devices according to the EU Medical Device Regulation (EU MDR, Regulation (EU) 2017/745) may also be classified as active devices, in line with the regulatory definition.

Examples of digital health devices include (non-exhaustive):

Table 1 Overview of connected and portable digital health device categories in scope

Icon	Device category
	Patient monitoring devices (vital signs monitors, ECG, pulse oximeters)
	Wearable health sensors (activity trackers, heart rate monitors, sleep monitors)
	Portable diagnostic devices and connected diagnostic devices used at point of care or in home settings
	Connected therapy devices
	Portable patient monitoring devices (blood pressure monitors, glucose meters)
	Remote patient monitoring devices and sensors
	Portable electrocardiogram (ECG) devices
	Digital thermometers and connected temperature monitoring devices
	Smart inhalers and connected respiratory monitoring devices
	Digital insulin delivery and monitoring devices
	Infusion pumps and portable drug delivery devices
	Connected medical implant controllers or external accessories
	Telehealth and telemedicine devices (e.g. connected examination tools)
	Smart pill dispensers and medication adherence devices
	Portable imaging or scanning devices used for diagnostic purposes
	Assistive digital health devices used for rehabilitation or therapy
	Digital health accessories containing electronic components (e.g. external sensors, leads, probes)

3.2.2 Other electrical and electronic equipment in scope

In addition to digital health devices, this manual may also be applied to:

- Electrical and electronic equipment generated within the health sector that has a similar size and material composition to digital health devices;
- Electrical and electronic equipment generated in other sectors that have a similar size, composition, and functional characteristics, where operational handling, treatment, or re-processing practices are comparable.

Examples include (non-exhaustive):

- Small electronic accessories;
- Chargers and docking stations;
- Peripheral devices;
- Tablets, laptops, and terminals used for clinical purposes;
- Communication hubs and connected sensors;
- Cables, leads, probes, sensors;
- External power supplies.

The inclusion of these devices supports consistent operational practices for equipment with comparable handling, safety, and treatment requirements. Where specific regulatory or operational requirements apply, national legislation and internal procedures take precedence.

OUT OF SCOPE: This manual does not cover large medical equipment (e.g. MRI machines, CT scanners). For end-of-life management of large equipment, the original manufacturer or the supplier of the replacement equipment should be consulted (see Chapter 12 TREATMENT).

4 Roles and Responsibilities

Effective management of digital health devices requires clear roles and responsibilities across all actors involved in their lifecycle. This section outlines the key responsibilities of operators, medical facilities, logistics providers, and treatment and recycling facilities, with a focus on safe handling, regulatory compliance, and circular economy outcomes.

The roles below are based on the WHO healthcare waste management guidance, EU WEEE and waste legislation, Extended Producer Responsibility (EPR) frameworks, and relevant provisions of the EU Medical Device Regulation and EU Battery Regulation (Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on Waste and Repealing Certain Directives (Text with EEA Relevance) 2008; WHO 2024b, 2024c).

4.1 Summary of roles

Light green indicates roles inside the healthcare centre. Light purple indicates external roles outside the healthcare centre.

Table 2 Summary of roles

ROLE	CORE RESPONSABILITIES	KEY DECISIONS	MAIN RISKS MANAGED
Operators	*Sort, handle, label, and route devices correctly during daily operations.*	*Correct stream selection (reuse / repair / WEEE / medical waste).*	*Infection risk, battery risk, data risk, and physical injury.*
Medical Facilities, Healthcare facility managers	*Set procedures, train staff, ensure segregation and storage, select and contract PROs and other partners, coordinate collection.*	*Internal classification rules, routing rules, and partner selection.*	*Cross-contamination, non-compliance, data breaches, contract failure.*
Producer Responsibility Organisations (PROs)	*Organise compliant collection, treatment and reporting on behalf of producers under EPR; provide collection logistics and documentation.*	*Authorised treatment partners, collection scheduling and reporting.*	*Non-compliance, incorrect treatment routing, and lost traceability.*
Logistics Providers	*Collect, transport, and document device movements; maintain chain of custody.*	*Safe transport route, packaging, and labelling.*	*Loss, damage, data access, leakage, transport non-compliance.*
Treatment & Recycling Facilities	*Disinfect, treat, refurbish, recycle, or dispose of devices in compliance with permits and EN 50625 / WEEELABEX.*	*Treatment vs recovery vs disposal; depollution; data destruction.*	*Environmental harm, unsafe treatment, insufficient recycling of WEEE, prevention of fires caused by batteries and data exposure.*

4.2 Operators

Operators are individuals directly involved in the daily handling, sorting, storage, collection, transport, treatment, or re-processing of digital health devices. They include staff inside healthcare facilities (cleaning staff, nurses, biomedical technicians, waste handlers) and staff at logistics, treatment and recycling facilities.

Operators are responsible for:

- Correctly identifying and sorting digital health devices according to this manual;
- Applying the precautionary principle when contamination or classification is uncertain;
- Using appropriate personal protective equipment (PPE) as required;
- Handling devices in a way that prevents damage, contamination, or data breaches;

- Placing devices in the correct labelled containers or streams;
- Following site-specific procedures for infected, high-risk, or damaged devices;
- Reporting incidents, uncertainties, or non-compliance to supervisors.

Operators play a critical role in enabling reuse, refurbishment, and high-quality recycling by ensuring early and correct segregation at source.

4.3 Healthcare facility managers

Healthcare facility managers include hospital directors, technical and biomedical service managers, infection-control officers, waste management leads, and procurement officers responsible for purchasing and end-of-life management of digital health devices.

Healthcare facility managers are responsible for:

- Establishing and maintaining internal procedures for the management of digital health devices, in line with this manual and applicable legislation;
- Selecting and contracting authorised partners (PRO, logistics, treatment, refurbishment), see Section 5;
- Ensuring segregation at source, including clear differentiation between infected and non-infected devices;
- Providing labelled containers, signage, and storage areas (see Annex 6, fact sheet, Annex 7, bin labels);
- Ensuring staff receive initial and refresher training on sorting and handling procedures;
- Appointing responsible persons (e.g. waste management lead, infection-control officer) and communicating their contact details to operators;
- Ensuring secure storage of devices containing sensitive or personal data;
- Embedding circularity criteria in procurement (Section 6.1);
- Monitoring performance, addressing segregation errors, and supporting continuous improvement;
- Ensuring compliance with applicable health, safety, data protection, and waste regulations.

4.4 Producer Responsibility Organisations (PROs)

Producer Responsibility Organisations are entities that fulfil EPR obligations on behalf of producers (manufacturers and importers) of EEE, including digital health and medical devices, under Directive 2012/19/EU on WEEE (WEEE Directive 2012/19/EU 2012a). For non-infectious digital health devices, healthcare facilities can transfer much of the operational burden of WEEE management to a PRO (WHO 2024c, 2025).

A PRO is typically responsible for:

- Organising compliant collection, transport, treatment, recycling and reporting of WEEE on behalf of its members;
- Providing collection logistics (containers, scheduling, documentation);
- Selecting authorised treatment partners and verifying their permits and certifications;
- Reporting collection and recycling performance to national authorities;
- Communicating reuse, recycling, and recovery rates to its members.

Guidance on how a healthcare facility selects a PRO is provided in Section 5.1 How to select a Producer Responsibility Organisation (PRO).

4.5 Logistics providers

Logistics providers include organisations responsible for the collection, transport, and interim storage of digital health devices. They may operate directly under contract with a healthcare facility or as subcontractors of a PRO.

Logistics providers are responsible for:

- Holding all required permits and authorisations for transporting WEEE and, where applicable, medical waste;
- Ensuring safe and secure transport, including protection against damage, leakage, or unauthorised data access;
- Using appropriate containers and packaging, clearly labelled and compatible with the waste type;
- Maintaining traceability and documentation throughout transport;
- Following specific procedures for infected or high-risk devices;
- Coordinating with healthcare facilities and PROs to ensure timely and compliant collection;
- Training their own staff for handling health-related equipment and reporting incidents.

4.6 Treatment and Recycling Facilities

Treatment and recycling facilities include authorised operators involved in disinfection, treatment, refurbishment, recycling, or final disposal of digital health devices. They are subject to environmental permits and, where applicable, certification under EN 50625 (WEEELABEX).

Treatment and recycling facilities are responsible for:

- Operating in compliance with environmental permits, EN 50625 / WEEELABEX where applicable, and health and safety regulations (Weelabex 2026b);
- Applying appropriate treatment or disinfection processes for infected or contaminated devices;
- Ensuring secure data destruction or data wiping prior to reuse or material recovery;
- Implementing processes that support reuse, refurbishment, and high-quality recycling, where feasible;
- Safely managing batteries, hazardous components, and residual waste;
- Maintaining records and reporting on treatment and recovery outcomes;
- Cooperating with PROs, healthcare facilities, and authorities as required.

Treatment and recycling facilities contribute directly to resource recovery, pollution prevention, and the achievement of circular economy objectives within the DiCE framework.

5 Manager’s Guide: Setting Up the System

This section is addressed to managers of healthcare facilities and to anyone responsible for setting up the management of digital health devices on site. It explains, step by step, how to select external partners and how to organise internal procedures so that the operational instructions in Parts A and B can be applied effectively.

A healthcare facility cannot carry out treatment/recycling on its own. At least three external partners are usually needed: a PRO (or equivalent take-back scheme), a logistics provider, and an authorised treatment/recycling facility. A refurbishment partner may also be required.

5.1 How to select a Producer Responsibility Organisation (PRO)

Under Directive 2012/19/EU on WEEE and national EPR legislation, producers of EEE (including digital health and medical devices) are responsible for the end-of-life management of their products (WEEE Directive 2012/19/EU 2012a). In practice, healthcare facilities fulfil their obligations by working with an authorised PRO that organises the collection, treatment and reporting of non-infectious WEEE.

5.1.1 Step-by-step PRO selection

Table 3 Guidance for Selecting and Contracting Producer Responsibility Organisations (PROs)

PROCEDURE ROLE	CORE RESPONSABILITIES
	• *Identify authorised PRO/s in your country and verify they cover the relevant device category (medical/electronic devices).* • *In case there is more than one PRO, request from each candidate PRO: list of permits and authorisations; covered EEE categories; reuse, recycling and recovery rates; types of receptacles provided; minimum collection load and frequency; reporting deliverables.* • *Compare offers using the checklist in Annex 12.* • *Verify references with at least two existing healthcare clients of the PRO.* • *Sign a written contract specifying responsibilities, collection conditions (minimum load, frequency, receptacles), documentation, data protection, KPIs and termination clauses.* • *Verify permits and authorisations at least annually and request the annual reuse/recycling/recovery rates report.*
Responsible	• *Healthcare facility manager (procurement/waste management lead).* • *Supported by: legal / compliance officer; technical biomedical service.*
Timing	• *When setting up the system for the first time, when contracts are renewed, or when current performance is unsatisfactory.*

5.1.2 Where to find authorised PROs

PROs in European countries can be identified through the following channels:

Primary official channels

- **National WEEE registers:** maintained by national authorities; they list authorised PROs and compliance schemes operating in each country.
- **National waste or environmental authorities:** ministries or agencies responsible for waste management usually publish or validate lists of approved PROs.
- **National WEEE coordination bodies/clearing houses:** in countries with collective systems, these bodies coordinate producer compliance and publish PRO information.

Sector-wide and cross-country sources

- **European WEEE Registers Network (EWRN)**, facilitates cooperation between national registers and provides pointers to country-specific systems (European WEEE Registers Network 2026).
- **WEEE Directory**: weee-directory.com, industry-maintained directory aggregating PROs by country and equipment category (WEEE Forum 2026).

Project-based and policy mapping sources

- **EU-funded projects and mapping exercises:** LIFE programme (e.g. LIFE4EPR project mapping of existing EPR and PROs across the EU), Horizon Europe, and similar projects often publish up-to-date mappings (LIFE4EPR 2026).

IMPORTANT: Authorisation, scope (medical devices vs. general EEE), and operational coverage of PROs vary by country. Healthcare facilities should always verify that a PRO is authorised nationally, covers the relevant device category, and can manage non-infectious WEEE in compliance with local rules. Depending on national legislation, EPR principles may also apply to other waste streams beyond WEEE.

5.1.3 Information to request from any PRO

When selecting a PRO, request in writing:

- Type of processes followed for the WEEE collected (treatment chain, subcontractors);
- Reuse, recycling and recovery rates for the relevant device category;
- Types of devices covered by the service supplied;
- Conditions for scheduling collections (minimum load, frequency, receptacles);
- Documentation provided (consignment notes, certificates of treatment, annual reports);
- Data protection guarantees for devices that may contain residual data.
- Preventive measures used to handle, store and transport batteries.

The full PRO selection checklist is provided in Annex 12 PRO Selection Checklist.

5.2 How to select a logistics/waste management company

When the PRO does not provide direct logistics, or when the healthcare facility manages part of the chain itself, an authorised waste management or logistics company is needed for emptying receptacles, transporting devices, and delivering them to the treatment facility.

Table 4 Procedure for Selecting and Contracting a Logistics Provider

OPERATIONAL INSTRUCTION: SELECTING A LOGISTICS PROVIDER	
Procedure	• *Define what is needed: types and quantities of devices, locations, frequency, container types, and infectious vs. non-infectious flow.* • *Issue a tender or request for quotation (RFQ) referencing the criteria in Annex 13.* • *Verify that each candidate holds valid permits for collection, transport and storage of WEEE and, where applicable, for medical / hazardous waste, in compliance with Directive 2008/98/EC and national transport legislation.* • *Verify training records for staff handling health-related equipment.* • *Check insurance, traceability systems (consignment notes, weighbridge tickets, GPS) and incident reporting.* • *Sign a written contract specifying scope, frequency, packaging, labelling, documentation, data protection, KPIs, and incident reporting obligations.* • *Re-verify permits at least annually.*
Responsible	• *Healthcare facility manager (waste management lead / procurement).* • *Supported by: legal / compliance officer.*
Timing	• *When setting up the system, when contracts are renewed, or when the PRO does not include logistics in its service.*

5.2.1 Mandatory permits and authorisations

All contracted logistics providers must hold valid and appropriate permits, licences, and authorisations required under applicable transport, waste, health, and safety regulations. These typically include:

- Permit for the collection and transport of WEEE under Directive 2012/19/EU and national WEEE legislation;
- Permit for the transport of hazardous waste, where applicable (Directive 2008/98/EC);
- Permit for the transport of healthcare / infectious waste, where applicable (national legislation);
- ADR certification for road transport of dangerous goods, where applicable;
- Permits for any interim storage facility used between collection and treatment.

Compliance with national and regional legal requirements is mandatory and must be demonstrable upon request. Contractors remain responsible for ensuring their staff are adequately trained for handling health-related equipment.

The full selection checklist for logistics providers is provided in Annex 13 Logistics Provider Selection Checklist.

5.3 How to select a treatment/recycling facility

When the PRO does not impose a specific treatment partner, or when the facility validates the treatment chain itself, the treatment/recycling facility must meet specific environmental, technical and certification requirements.

5.3.1 Key requirements

- **WEEE permits:** Treatment facilities must be permitted for the relevant categories under Directive 2012/19/EU. Categories 4 (large equipment) and 5 (small equipment, < 50 cm) are most relevant for digital health devices (WEEE Directive 2012/19/EU 2012a).
- **EN 50625 / WEEELABEX certification:** The European standard EN 50625 covers general treatment, depollution, collection and logistics, and final treatment of materials. Certified operators are listed at weeelabex.org/operators-list.
- **Disinfection capability:** For (potentially) infectious devices, disinfection must comply with EN 14885 and be allowed under national legislation (European Standards for Chemical Disinfectants and Antiseptics 2022).
- **Data destruction:** Certified logical data wipe for reusable devices, and physical destruction (shredding) of memory storage components for recycled devices, both linked to the UDI.

Table 5 Selecting a treatment facility

OPERATIONAL INSTRUCTION: SELECTING A TREATMENT FACILITY	
Procedure	• *Verify that the facility holds an environmental permit covering the relevant WEEE categories (typically Cat. 4, large equipment or Cat. 5, small equipment of (WEEE Directive 2012/19/EU 2012a).* • *Check WEEELABEX / EN 50625 certification at the WEEELABEX operators list (Weelabex 2026a). The list shows the categories the facility is certified for.* • *For potentially infectious devices, verify that the facility (or a contracted partner) is authorised by national competent authority for disinfection/sterilisation under national rules and that the disinfection process is recognised in your country.* • *For data-bearing devices, request a description of the data-destruction process and a Data Destruction Certificate template linked to the device UDI.* • *Request the latest reuse / recycling / recovery rates per category.* • *Sign a written contract specifying scope, KPIs, documentation, data destruction, traceability and reporting obligations.* • *Re-verify permits and certification annually.*
Responsible	• *Healthcare facility manager or PRO (depending on contractual setup).* • *Supported by: technical biomedical service; data protection officer.*
Timing	• *When setting up the system, when contracts are renewed, or when the PRO updates its treatment chain.*

5.4 How to select a refurbishment/repair partner

Where direct reuse is not possible, refurbishment and repair extend the life of digital health devices. Selecting an authorised partner is essential because medical devices may only be reintroduced to the market by reprocessors holding a registered in EUDAMED, in line with the European Union's Medical Device Regulation Compliance and ISO 13485 certification and (EU MDR) (EU MDR 2020; WEEE Directive 2012/19/EU 2012b; European Commision 2025; TÜV NORD 2016).

Table 6 Selection of refurbishment/repair partner

OPERATIONAL INSTRUCTION: SELECTING A REFURBISHMENT/REPAIR PARTNER	
Procedure	• *Confirm legal status: in the relevant Member State of origin, is the reprocessing of single-use devices (SUDs) permitted? If not, those devices must be diverted to end-of-life treatment options.* • *Verify ISO 13485 certification of the reprocessor and registration of activities in EUDAMED.* • *For non-medical-device equipment, verify authorisation as a refurbisher under national rules and recognised quality management.* • *Request validation evidence for cleaning and disinfection processes under EN 14885 and Regulation (EU) 2020/1207.* • *Request the procedure for battery replacement, calibration and electrical/functional safety testing.* • *Request the data protection procedure (logical wipe certified to recognised standards).* • *Sign a written contract including liability, traceability, KPIs, and reporting.*
Responsible	• *Healthcare facility manager (technical biomedical service / waste management lead).*
Timing	• *When setting up the system; when introducing a new device family; when the original equipment manufacturer (OEM) does not offer refurbishment.*

5.5 Setting up internal procedures

Once external partners are in place, internal procedures translate this manual into something operators can apply on the ground. The healthcare facility manager is responsible for putting them in place (European Standards for Chemical Disinfectants and Antiseptics 2022).

Table 7 Internal procedure set-up

OPERATIONAL INSTRUCTION: SETTING UP INTERNAL PROCEDURES

Procedure	• *Map the points where digital health devices may become waste (wards, outpatient clinics, laboratories, IT department, biomedical service, storage rooms).* • *Define collection points by department and the streams to be used (reuse / repair / WEEE / medical waste / battery).* • *Provide labelled containers using the bin labels in Annex 7.* • *Display the sorting decision tree (Annex 4) at every collection point.* • *Define rules for infected vs. non-infected devices in cooperation with the infection-control officer (Section 8.1).* • *Set up secure storage for devices containing sensitive data.* • *Define documentation and traceability rules (date, location, device type, route, special risks), see Section 8.5.* • *Appoint and communicate the contact details of the waste management lead and infection-control officer.*
Responsible	• *Healthcare facility manager (waste management lead, supported by infection-control officer, biomedical service, data protection officer, IT).*
Timing	• *When setting up the system; when the layout, partner or device portfolio changes; at least annually as part of a management review.*

5.6 Training programme

Operational instructions only work if the people performing them have been trained. The healthcare facility manager is responsible for setting up an initial and refresher training programme.

Table 8 Operational instruction: Setting up internal procedures

OPERATIONAL INSTRUCTION: SETTING UP INTERNAL PROCEDURES	
Procedure	• *Initial training for new staff: minimum 1 hour, covering identification, sorting decision tree, PPE, infection control, data protection, and incident reporting.* • *Refresher training at least once per year for all staff handling digital health devices, and immediately after any procedure change.* • *Targeted training for high-risk activities (handling damaged batteries, contaminated devices, large equipment).* • *Use Annex 6 (Operational fact sheet) and Annex 4 (Sorting decision tree) as training materials.* • *Keep training records (date, attendees, content) for inspection and audit.*
Responsible	• *Healthcare facility manager (waste management lead, supported by infection-control officer and Human Resources (HR)).*

	• *Supported by: external trainers from PRO or logistics provider, where included in the contract.*
Timing	• *Within the first month of hire for new staff; at least annually for existing staff; after any change of procedure, partner, or device portfolio.*

Training is a contractual requirement under several national WEEE and healthcare-waste regulations. Records of training must be kept and made available on inspection.

Digital Health in the Circular Economy

Part A

Healthcare Centre Operations

For operational workers and managers in hospitals, clinics, laboratories, and other facilities that generate or handle digital health device waste.

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6 PREVENTION OF USED DIGITAL HEALTH DEVICES

Prevention is the preferred option in the waste hierarchy and the most effective way to reduce environmental impacts from digital health devices. In operational terms, prevention means (i) reducing the amount of waste generated at source, and (ii) ensuring proper segregation at the point where waste arises, so that devices suitable for reuse, refurbishment, or high-quality recycling are not unnecessarily damaged, contaminated, or mixed with other waste streams.

The first step for proper management of medical waste is source reduction (i.e., minimisation of waste production) and proper segregation at source, as recommended by the World Health Organisation. If segregation is difficult and devices cannot be separated from general waste streams, then they must be treated as medical waste (European Commision 2026; WHO 2024a; WEEE Directive 2012/19/EU 2012a; *Safe Management of Wastes from Health-Care Activities* 2013; EPA 2024; European Commission 2021; 'EU GPP Criteria for Electrical and Electronic Equipment Used in the Health Care Sector (Health Care EEE)' 2021; Delre et al. 2022)

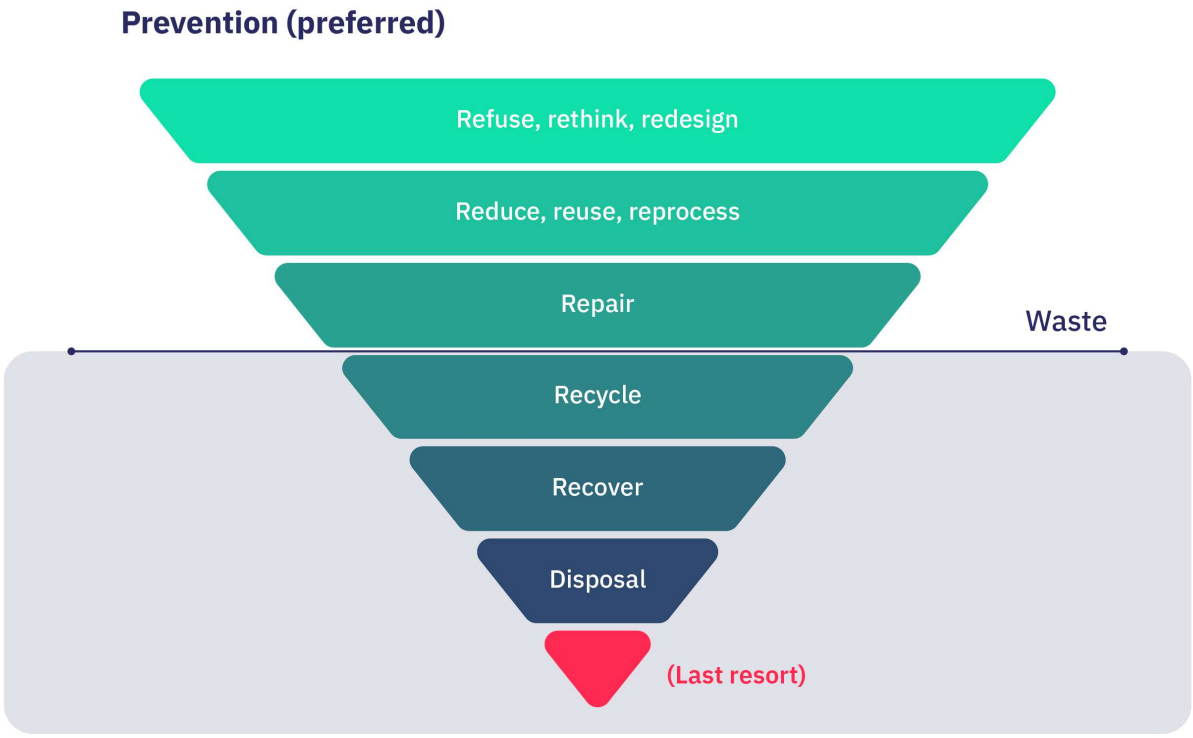

Figure 1: Waste hierarchy guiding the management of products, adapted from the European Commission (WHO 2024a)

Waste prevention practices are aimed at reducing the volume of waste generated by selecting reusable, repairable, and/or more durable devices. This is particularly relevant for equipment that may become infected waste after use, because the collection and management of infected waste is generally more complex and often results in lower recovery potential than non-infected waste (European Commission 2021).

Prevention should therefore start before devices are even purchased, by embedding circularity requirements into procurement, and continue through daily operational practices (segregation, handling, and routing).

6.1 Procurement criteria for prevention

Tenders and purchase conditions for medical and digital equipment should include criteria addressing reusability, repairability, durability, data security, and end-of-life management. These criteria significantly reduce future waste generation — especially for devices likely to become infected waste. Ideally, supplier selection should be based on a final score where circularity has a significant share. The share may increase over time as knowledge in the topic evolves(Delre et al. 2022).

Examples of practices in Green Public Procurement and references to recognised criteria are provided in Annex 14 (References).

Table 9 Embedding circularity in procurement

OPERATIONAL INSTRUCTION: EMBEDDING CIRCULARITY IN PROCUREMENT	
Procedure	• *Before drafting a tender, identify the device family and its expected useful life.* • *Use the questions in Annex 11 (procurement checklist) to build the technical specification.* • *Score offers including a circularity component (typically 15–30% of the total score initially, increasing over time).* • *Require suppliers to provide evidence (test reports, datasheets, take-back agreements).* • *Re-evaluate the supplier at contract renewal based on actual repair turnaround, spare-parts availability, and end-of-life service.*
Responsible	• *Healthcare facility manager (procurement officer).* • *Supported by: technical biomedical service, infection-control officer, data protection officer, waste management lead.*
Timing	• *When preparing a new tender; when renewing a supply contract; when introducing a new device family.*

6.1.1 Reusability and durability

- What is the expected service life under normal clinical use? Provide evidence and test results where available.
- Can the device be used across multiple patients with appropriate cleaning and disinfection procedures?
- What components are most likely to fail, and what is the expected lifetime of those components (battery, sensors, cables)?

6.1.2 Repairability and maintenance

- Is the device designed for non-destructive disassembly (e.g. standard fasteners instead of permanent adhesives)?
- Are spare parts available, and for how long (minimum years after the last unit sold)?
- Are repair manuals, diagnostic tools, or service instructions available to authorised parties?
- What is the typical repair turnaround time and repair cost range?

6.1.3 Battery safety and replaceability

- Is the battery user- or technician-replaceable? If not, what is the replacement process and cost?
- How is battery removal performed safely for end-of-life treatment?
- Provide information on battery type / chemistry and safe handling requirements (in line with the EU Battery Regulation, Regulation (EU) 2023/1542).

6.1.4 Software support and obsolescence prevention

- For connected devices: how long will software and security updates be provided?
- Can the device operate safely if connectivity is limited?
- Are updates delivered in a way that does not make the device prematurely obsolete?

6.1.5 Data security by design

6.1.6 Circular services and take-back

- Does the supplier offer take-back, refurbishment, or trade-in options?
- Are there established routes for reuse / refurbishment through authorised partners?
- Are packaging and logistics optimised for return / redeployment?

6.1.7 Materials and recycling readiness

- Are materials and components labelled or documented to facilitate recycling?
- Are hazardous components identified and removable (batteries, specific sensors)?
- Provide end-of-life instructions for dismantling and treatment.

These tender criteria can be adapted from recognised circular procurement and Green Public Procurement (GPP) approaches, including healthcare EEE and ICT-related criteria used in EU and national guidance (e.g. EU GPP frameworks, JRC technical assessments, and national environmental agency criteria). See Annex 14 for references.

6.2 Daily prevention practices

Once devices are purchased, prevention continues through daily handling. Operators are the first line of defence against unnecessary downgrading of devices to waste.

Table 10 Daily prevention practices

OPERATIONAL INSTRUCTION: DAILY PREVENTION PRACTICES	
Procedure	• *Use devices in line with manufacturer instructions; report defects early to maintenance.*

	• *Keep dedicated, clearly identified containers for "potentially reusable" devices, separate from waste streams.* • *Avoid stacking, crushing, or mixing digital devices with other items.* • *Route devices quickly to assessment to prevent battery leakage, corrosion, or contamination.* • *Apply visual inspection when a device is taken out of service.*
Responsible	• *Operators (clinical staff, biomedical technicians, cleaning staff).* • *Supervised by ward/department manager, biomedical service.*
Timing	• *Continuously, every time a digital health device is taken out of service or moved.*

7 Reuse pathways

Reuse and re-deployment refer to keeping digital health devices in use for their original or a similar purpose, prioritizing the highest-value option before any treatment or disposal. In line with the waste hierarchy, reuse and re-deployment should always be assessed before considering recycling or waste treatment.

The decision on whether a device can be reused, refurbished, or routed to waste treatment must follow the structured logic in Annex 2 (Decision tree: Reuse vs. Waste Treatment) and Annex 3 (Decision tree: Refurbishment and Repair).

7.1 Reuse and redistribution

Reuse and redistribution refer to keeping digital health devices in use for their original or a similar purpose, prioritising the highest-value option before any treatment or disposal. Before a device is considered for reuse or redistribution, appropriate preparation activities should be carried out, including inspection of the device's condition, verification of its integrity and functionality, cleaning and, where applicable, decontamination, as well as data removal or reset procedures. Reuse or redistribution may be considered when:

Reuse or re-deployment may be considered when:

- The device is functionally intact and safe to handle;
- The device is not contaminated (or has been appropriately decontaminated, where allowed (see Sections 8.2.2b–c for contamination assessment and decontamination steps);
- Data can be securely removed or reset;
- Reuse complies with applicable health, safety, and medical device requirements (EU MDR).

Table 11 Guidance for Reuse and re-deployment

OPERATIONAL INSTRUCTION: REUSE / REDISTRIBUTION	
Procedure	• *Identify candidate devices when they are taken out of service (visual inspection, no contamination, intact battery).* • *Establish designated collection points for “potentially reusable” devices;* • *Use separate containers to avoid damage and mixing with waste streams;* • *Place candidate devices in the dedicated "reuse / redistribution" container, never mix with WEEE or medical waste.* • *Apply a visible "REUSE CANDIDATE" label.* • *Route the device to the assessment point (biomedical service or designated reuse coordinator) within 24 hours.* • *Run the data wipe / reset procedure described in Section 7.3.* • *Run the basic functional and safety checks described in Section 7.3.*

	• *Decide the reuse pathway: internal re-deployment, transfer to another healthcare / care institution, or use for training and education.* • *Record the decision and the receiving department / institution for traceability.*
Responsible	• *Operators identify and place; biomedical service / reuse coordinator assesses; ward / department manager validates the routing.*
Timing	• *Every time a digital health device is taken out of service in functional condition.*

Early segregation and protection of devices are essential to maintain their reuse potential and to avoid unnecessary downgrading to waste treatment.

Examples of pathways (depending on local and national rules):

- Internal redistribution within the same healthcare facility;
- Transfer to another healthcare/care institution;
- Use for training/education (where clinical use is not intended).

7.2 Refurbishment and Repair Options

Refurbishment and repair involve restoring a digital health device to a functional and safe condition through technical intervention, such as component replacement (e.g., battery, sensor, cable replacement), repair, or recalibration. These options represent life-extension strategies and should be prioritized when direct reuse or re-deployment is not possible.

A simplified decision tree specific to refurbishment and repair pathways is provided in Annex 3 and should be used in conjunction with Annex 2.

Refurbishment/repair should be considered when:

- The device is not immediately reusable but is technically repairable, and
- Spare parts, tools, and expertise are available (including through original equipment manufacturer (OEM) or service partners), and
- The device can be returned to a safe and compliant condition, and

NOTE: If at any stage the conditions for safe reuse or redistribution cannot be met, devices must be routed according to the decision logic in Annex 2 Decision Tree: Reuse vs. Waste Treatment.

- Data stored on the device can be securely removed or destroyed.

Table 12 Guidance for refurbishment and repair

OPERATIONAL INSTRUCTION: REFURBISHMENT / REPAIR

Procedure	• *Identify and label candidate devices during sorting and collection.* • *Avoid destructive handling (do not cut cables, do not break housings).* • *Route the device to the authorised repair / refurbishment operator selected under Section 5.4.* • *Verify the operator's permits and authorisations are still valid at the time of dispatch.* • *Record the device dispatch (UDI, date, partner, expected return).* • *On return, verify the certificate of refurbishment and the data destruction certificate before re-deployment.*
Responsible	• *Operators identify and label; biomedical service / waste management lead routes; healthcare facility manager verifies contractor status.*
Timing	• *Every time a non-reusable but repairable device is taken out of service; periodically (at least annually) for verification of contractor status.*

For this purpose. it is essential to set contracts with authorised repair/refurbishment operators and verify regularly the status of their permits.

7.3 Data Security and Functional Checks Before Reuse

Digital health devices may contain personal, medical, or sensitive data, as well as configuration settings that must be managed securely. Before any reuse, re-deployment, refurbishment, or repair, data security and basic functional integrity must be ensured. The order of the checks below matters: a device that is visually unsafe (e.g. swollen battery) should not be reused regardless of data status, so visual / safety inspection is performed first.

7.3.1 Order of checks

1. Visual inspection (damage, cracks, corrosion, missing parts).
2. Power and battery condition check (swelling, leakage, overheating).
3. Basic operation test (power on, display, connectivity where relevant).
4. Data wiping / reset / secure deletion (per internal procedure or manufacturer guidance).
5. Confirmation that no user data remains accessible.
6. Label the device with the outcome: REUSE / REPAIR / RECYCLE / MEDICAL WASTE.

Operational workers should follow internal procedures or manufacturer guidance for data removal and functional testing.

Contracts must be in place with authorised repair/refurbishment operators (Section 5.4). Verify the status of their permits at least annually and at every contract renewal.

Table 13 Guidance on data security and functional checks

IMPORTANT: If steps 1–3 reveal a safety risk, stop the procedure: the device cannot be reused. Route to the appropriate stream per Annex 2; do not attempt data wiping on a damaged device.

OPERATIONAL INSTRUCTION: DATA SECURITY AND FUNCTIONAL CHECKS	
Procedure	• *Perform the six checks above, in order.* • *Use certified data-erasure tools (compliant with GDPR, Regulation (EU) 2016/679) that generate an audit trail.* • *Where wiping cannot be verified, do not attempt reuse: route the device to secure data destruction or treatment.* • *Apply the outcome label and update the device record.*
Responsible	• *Biomedical service or designated technical operator.* • *Supervised by: data protection officer for the data wipe procedure.*
Timing	• *Before any reuse, re-deployment, refurbishment, or repair; never on a contaminated or visibly damaged device.*

8 COLLECTION AND SORTING at Healthcare Centres

Correct collection and sorting of digital health devices are essential to ensure safe handling, support reuse and refurbishment, and enable high-quality recycling. Early and correct segregation reduces the risk that devices become contaminated, damaged, or mixed with inappropriate waste streams, and is a prerequisite for compliance with health, safety, and environmental regulations.

In line with the principle of Extended Producer Responsibility (EPR), as defined in national and EU legislation on Waste Electrical and Electronic Equipment regulations (WEEE), producers of electrical and electronic equipment, including manufacturers and importers of digital health and medical devices, are responsible for ensuring that their equipment is properly collected, treated, and recycled at the end of its lifecycle (WEEE Directive 2012/19/EU 2012b; WHO 2024b).

For non-infectious digital health devices, hospitals and medical centres may fulfil these obligations by contracting authorised Producer Responsibility Organisations (PROs). By contracting a PRO, healthcare facilities can transfer much of the operational burden associated with WEEE management, including collection logistics, documentation, treatment, and regulatory compliance, to organisations specialising in environmentally sound and legally compliant waste handling (see Section 5.1) (WHO 2024b).

8.2 Sorting of digital devices

Segregation of waste at source is a key requirement for effective waste management and legislative compliance under Directive 2008/98/EC and Directive 2012/19/EU. Poor segregation leads to increased disposal costs, reduced recycling potential, and higher health and safety risks. Clear internal policies and staff awareness and training are therefore essential (CIWM 2020).

Digital health devices should be sorted as early as possible based on the following criteria:

- **Intended pathway:** reuse / repair / recycling / medical waste
- **Contamination status:** non-infected vs. potentially infected or contaminated
- **Device characteristics:** presence of batteries, sharp edges, fragile components
- **Data sensitivity:** likelihood of containing personal or health-related data

8.2.1 Recommended minimum sorting outputs

- Stream 1 — Reuse / re-deployment candidates: protected from damage; clean, intact, data removable.
- Stream 2 — Repair / refurbishment candidates: faulty but repairable; protected from damage.
- Stream 3 — WEEE recycling (non-contaminated): end-of-life, non-contaminated devices.
- Stream 4 — Medical waste: infected, potentially infected, or unsegregated devices.

- Stream 5 — Damaged battery / high-risk: swollen or leaking batteries, fire and chemical risk.

Bin labels, colour coding, and icons for each stream are provided in Annex 7.

8.2.2 Classification of Digital Health Device Waste

In line with WHO guidance (*Safe Management of Wastes from Health-Care Activities* 2013; WHO 2024b), digital health devices may fall under different waste categories depending on their condition and use context, including:

- Non-hazardous waste
- Hazardous waste
- Sharp waste
- Infectious waste
- Chemical waste

The determination of whether a device should be treated as infectious waste depends on facility-specific procedures. Where clear rules are not available, WHO recommends that classification be based on an understanding of disease transmission risks:

"An item should be considered an infectious waste if there is the likelihood that disease transmission can occur during the handling and disposal of the item in question" (*Safe Management of Wastes from Health-Care Activities* 2013; WHO 2024b).

In larger healthcare facilities, the infection-control officer plays a key role in supporting this classification process. Facilities should apply the precautionary principle: if there is uncertainty and safe segregation cannot be assured, the device should be treated as medical (infectious) waste.

8.2.2.1 Classification Prior to Segregation

Before segregation into the streams described above, devices must be classified in accordance with two overlapping regulatory frameworks. First, under EU MDR Regulation (EU) 2017/745 (EU MDR 2020), digital health devices may fall into different risk classes (Class I–III) depending on their intended purpose, duration of use, and degree of contact with the patient's body. This classification determines which decontamination and reprocessing procedures are legally admissible and who bears responsibility for carrying them out. Second, under applicable medical waste legislation and WHO guidance, devices must be assessed for their infectious risk category (non-hazardous, hazardous, infectious, sharps, or chemical waste) before a pathway is assigned. The infection-control officer and biomedical service should be consulted when classification is uncertain. Where the device class under EU MDR cannot be confirmed, it must be treated as the higher-risk category for the purposes of segregation and downstream management.

8.2.2.2 Assessing Contamination and Determining Responsibility

Determining whether a device is contaminated requires a structured check that goes beyond visual inspection alone. Operators should assess: (i) the patient contact history of the device (did it contact intact skin, mucous membranes, sterile body cavities, or bodily fluids); (ii) any visible soiling, biological residue, or damage to protective housing; and (iii) the patient's known or suspected infection status, where this information is accessible. The decision on whether a

device can be safely decontaminated for reuse or reprocessing, rather than directed to infectious waste, rests with the infection-control officer (for the infectious risk determination) and the biomedical service or reprocessing entity (for the technical feasibility of decontamination). Operators should not make this determination unilaterally. Where decontamination is assessed as feasible, it must be carried out before the device is routed to reuse, refurbishment, or recycling streams. Where decontamination is not feasible or cannot be verified, the device must be directed to Stream 4 (medical waste) in accordance with the facility's infectious waste procedures.

8.2.2.3 Decontamination Steps

Decontamination is a multi-step process designed to ensure the safe reuse or disposal of medical devices, preventing the transmission of infectious agents (WHO 2016). Where decontamination has been assessed as necessary and feasible (see Section 8.2.2.2), the following sequence must be followed:

1. **Segregation and containment:** Devices identified for decontamination must be physically separated from other waste streams and handled in a designated, controlled area. If decontamination is to be performed externally (e.g. at a specialised sterilisation unit), transport must be carried out in closed, leak-proof containers that prevent contamination of the environment or other items during transit (WHO 2016).

2. **Cleaning:** The device is cleaned to remove organic and inorganic residues (blood, tissue, bodily fluids, chemical soiling). Thorough cleaning is a prerequisite for effective disinfection or sterilisation: residual organic matter can shield microorganisms from biocidal agents and compromise the outcome of subsequent steps. Cleaning must follow validated procedures appropriate to the device's material and design (e.g. wipe-down for non-immersible electronics, ultrasonic cleaning where applicable).

3. **Disinfection or sterilisation:** Following cleaning, the device is disinfected or sterilised according to its EU MDR risk classification and intended next use. Disinfection (high-level) is required for semi-critical devices that contact non-intact mucous membranes; sterilisation (e.g. steam autoclave, ethylene oxide) is required for critical devices that contact sterile body areas or the bloodstream. The chosen method must be technically validated under EN 14885 and Regulation (EU) 2020/1207 to ensure complete elimination of all relevant microorganisms, including bacterial spores where sterilisation is required.

4. **Packaging:** Following sterilisation, devices intended for reuse must be packaged in validated sterile barrier systems that maintain sterility until the point of use. Packaging must protect against moisture, microbial ingress, and mechanical damage in accordance with applicable standards. Once packaged, the device should be labelled with the batch reference, date of sterilisation, expiry of sterility, and the name of the reprocessing entity. Devices that have undergone decontamination but are destined for recycling (not reuse) do not require sterile packaging but must still be labelled and tracked to document that decontamination has been completed.

Annex 23 illustrates a decision tree covering the decontamination and classification pathways for devices identified as potentially contaminated.

8.2.3 Batteries and components

Batteries must be removed from WEEE before treatment in accordance with applicable WEEE and battery legislation (Regulation (EU) 2023/1542 2023), to reduce safety risks, facilitate recycling, and enable the proper management of battery-containing equipment. Removal should be carried out using appropriate procedures and by trained personnel.

For digital health devices, battery removal must not be performed on contaminated or potentially infectious devices unless the device has been appropriately decontaminated or a documented risk assessment demonstrates that removal can be carried out safely and in accordance with applicable procedures. Where battery removal is not feasible due to health, safety, contamination, or technical risks, the justification should be documented, and the device should be managed according to best available treatment practices and applicable legal requirements.

Table 14 Operational instruction: Sorting a digital health device

OPERATIONAL INSTRUCTION: SORTING A DIGITAL HEALTH DEVICE	
Procedure	• *Apply* **Annex 4 Decision Tree: Sorting and Routing of Digital Health Devices** *on the device.* • *Place the device in the correct labelled stream (1–5).* • *Apply the corresponding tag or label (REUSE / REPAIR / WEEE / MEDICAL / BATTERY).Visually identify whether the device contains a battery and inspect for signs of damage, swelling, leakage, overheating, or corrosion.* • *Do not remove batteries from contaminated or potentially infected devices.* • *If the battery is swollen, leaking, damaged, or shows signs of thermal stress, route the entire device to Stream 5 without further handling.* • *Record the device in the collection log (Section* **8.5 Documentation and traceability***).*
Responsible	• *Operators in the relevant department; for high-risk items: waste management lead and infection-control officer.*
Timing	• *Every time a device is taken out of service or arrives at a collection point. Battery removal: only when authorised by the internal procedure.*

COMPLIANCE: Only authorised companies with valid permits should be selected for collection and transport (see Section 5.2). Verify permits at least annually and at every contract renewal.

8.3 Collection of digital devices at medical facilities

Collection systems at medical facilities should ensure (BfArM 2026; EU MDR 2020):

- Segregation at source, as early as possible;
- Clearly labelled containers and signage (Annex 7);
- Restricted access for devices containing sensitive data;
- Dedicated procedures for contaminated or high-risk devices

Table 15 Operational instruction: Setting up collection points

OPERATIONAL INSTRUCTION: SETTING UP COLLECTION POINTS	
Procedure	• *Apply Annex 4 (sorting decision tree) on the device.* • *Place the device in the correct labelled stream (1–5).* • *Apply the corresponding tag or label (REUSE / REPAIR / WEEE / MEDICAL / BATTERY).* • *Do not remove batteries from contaminated or potentially infected devices.* • *Where battery removal is allowed and the battery is intact, place the battery in the dedicated battery container.* • *If the battery is swollen or leaking, route the entire device to Stream 5 without further handling.* • *Record the device in the collection log (Section 8.5).*
Responsible	• *Operators in the relevant department; for high-risk items: waste management lead and infection-control officer.*
Timing	• *Every time a device is taken out of service or arrives at a collection point. Battery removal: only when authorised by the internal procedure.*

8.4 Identification of high-risk or sensitive devices

High-risk or sensitive devices include those that are included in these documents ('High-Risk Medical Devices | European Medicines Agency (EMA)' 2018; Regulation (EU) 2023/1542 2023; Fisher et al. 2006):

- Potentially infected or contaminated;
- Physically damaged (cracked housings, exposed components, leakage);
- Presenting battery-related risks (swelling, overheating, leakage);
- Likely to contain personal or health-related data.

Table 16 Operational instruction: Handling high-risk or sensitive devices

OPERATIONAL INSTRUCTION: HANDLING HIGH-RISK OR SENSITIVE DEVICES	
Procedure	• *Apply visible labels or tags: INFECTED, BATTERY RISK, or DATA RISK.* • *Use appropriate PPE (Section 9.2) and handling tools.* • *Route the device immediately to the correct stream (4 or 5).* • *Prevent cross-contamination with reusable or recyclable devices: use separate trolleys, separate containers.* • *Notify the waste management lead and, for infection risk, the infection-control officer.*
Responsible	• *Operators identify and label; ward / department manager and waste management lead validate routing.*
Timing	• *As soon as a high-risk or sensitive device is identified, before further handling.*

8.5 Documentation and traceability

Documentation and traceability are essential for compliance, safety, and circular economy objectives. At a minimum, operational records should allow (EU MDR 2020):

- Tracking of devices from collection to reuse, treatment, or recycling;
- Verification of correct routing (especially infected vs. non-infected);
- Support for reporting, audits, and quality control.

8.5.1 Recommended documentation elements

- Date and location / source of collection (facility, department, household scheme);
- Device category or type (per Section 3.2 and Annex 6);
- Assigned route (reuse / repair / recycling / medical waste);
- Notes on special risks (infection, battery, data);
- Transfer or transport record to the next operator (consignment note, weighbridge ticket).

Table 17 Operational instruction: Documentation and traceability

OPERATIONAL INSTRUCTION: DOCUMENTATION AND TRACEABILITY	
Procedure	• *Record every emptied container in the collection log.* • *Record the dispatch of each container or shipment (date, type, quantity, transporter, destination, EWC code where applicable).* • *Verify that consignment documentation is complete before the transport leaves.* • *Retain records according to legal and contractual retention periods.* • *Make records available for inspection or audit.*
Responsible	• *Operators record at the collection point; waste management lead consolidates and archives.*
Timing	• *Every emptying / dispatch event; periodic review at least quarterly.*

9 Handling at Healthcare Centres

Handling means all physical, non-invasive activities performed on non-infectious WEEE during collection and logistics, such as receiving, moving, sorting, storing, loading, and unloading before treatment begins and without altering the physical structure of the equipment.

Handling begins when the old appliances are placed in a dedicated collection container. When the container is full, or after a given time period, the container needs to be emptied. Usually, the inside layer will be removed and replaced with a new one. The contents of the container must be emptied with due care to avoid damage. The collected materials are then taken to the storage and from there transported to the treatment facility.

9.1 Safe Handling Procedures

According to CENELEC standards (REF) the stakeholders must ensure that all handling of WEEE is safe, traceable and environmentally compliant. Handling must occur only in designated and controlled work zones, which are designed to prevent contamination, cross-mixing of materials, and safety risks. The collection place must be designed, organised and maintained to provide safe access to and egress from it. It must be secured against access by unauthorized persons.

The operator must ensure that the WEEE is handled and stored with due care, to avoid damage to appliances that could be intended for reuse.

Table 18 Operational instruction: Safe handling

OPERATIONAL INSTRUCTION: SAFE HANDLING	
Procedure	• *Handle devices only in designated collection or sorting zones.* • *Restrict access to authorised staff; lock the zone outside working hours.* • *Where access is not controlled through an electronic badge or equivalent system, maintain an access log recording the name, date, time, and purpose of entry of authorised personnel.* • *Do not stack, crush, or drop devices.* • *Replace inner liners without tilting or shaking the container.* • *Use trolleys or carts; never carry containers manually if heavy or unstable.* • *Report any damage, leakage or unauthorised access immediately.*
Responsible	• *Operators in the collection/sorting zone.* • *Supervised by: Waste Management Lead.*
Timing	• *During every handling operation; access control: continuous.*

9.2 Risk management and PPE

Handling of medical WEEE poses chemical, biological, mechanical, and environmental risk. Following EN 50625, a risk assessment of handling operations must be carried out. Because medical WEEE may contain infectious items, operators must ensure that infectious waste is separated from non-infectious waste and that there is no mixing.

When handling WEEE, it is mandatory to use protective equipment that has been determined in the risk assessment according to the level of threat. Protective equipment may include gloves, safety glasses, protective masks (FFP2/FFP3), protective clothing, and protective footwear. Where there is a risk of contact with sharps, broken components, or other piercing hazards, appropriate cut-resistant and/or puncture-resistant gloves should be used in addition to, or instead of, standard protective gloves, as specified by the risk assessment. Management is obliged to provide workers with the necessary protective equipment, which must be maintained and replaced according to established procedures.

Table 19 Operational instruction: Personal Protective Equipment (PPE) use

OPERATIONAL INSTRUCTION: PERSONAL PROTECTIVE EQUIPMENT (PPE) USE	
Procedure	• *Read the risk assessment for the activity before starting.* • *Put on the PPE listed for that activity in the order specified.* • *Replace damaged or contaminated PPE immediately.* • *After the activity, remove PPE in the correct order and dispose of it according to the relevant waste stream.* • *Wash hands thoroughly after PPE removal.*
Responsible	• *Operators in handling zones* • *Supervised by: waste management lead and infection-control officer.*
Timing	• *Before, during, and after every handling activity involving WEEE or medical waste.*

9.3 Data-Bearing Components (Memory, Sensors)

Medical devices often contain sensitive patient data. Before disposal as WEEE, all data carriers must be securely erased or destroyed so that data cannot be recovered. Certified data-erasure tools must be used that ensure compliance with applicable regulations (e.g. GDPR, Regulation (EU) 2016/679) and generate an audit trail proving proper data deletion. If secure erasure is not possible, physical destruction is required.

Batteries and sensors are hazardous components and require special handling. During WEEE collection, all hazardous components, including batteries and sensors, must be removed where this can be done safely. This requirement is defined in the EU Battery Regulation (Regulation (EU) 2023/1542) and national WEEE legislation. Batteries must never be disposed of in mixed municipal waste; they must be collected separately as portable or industrial battery waste.

Table 20 Operational instruction: Data-bearing components

OPERATIONAL INSTRUCTION: DATA-BEARING COMPONENTS	
Procedure	• *For devices going to reuse / refurbishment: apply certified logical data wipe (Section 7.3).* • *For devices going to recycling: route to a treatment facility that performs physical destruction of memory components (Section 5.3).* • *Issue and retain a Data Destruction Certificate linked to the device UDI.* • *For batteries: remove only if safe and authorised; otherwise, let the treatment facility do it.* • *Place removed batteries in the dedicated battery container.*
Responsible	• *Biomedical service / IT for data wipe; operators for battery removal where authorised; waste management lead retains certificates.*
Timing	• *Before any device leaves the facility; battery removal: as soon as the device enters the WEEE stream where allowed.*

9.4 Handling of Damaged or Contaminated Devices

When dealing with electrical or electronic medical devices, two types of risks must be distinguished:

- **Damaged devices** → may release hazardous substances (gases, coolants, chemicals) or pose electrical risks.
- **Contaminated devices** → may contain infectious material (blood, bodily fluids, pathogens) and are therefore handled as infectious healthcare waste.

9.4.1 Damaged devices

Contaminated devices fall under infectious waste if they have been in contact with infected patients, biological specimens, or laboratory cultures. The healthcare waste guidelines classify such items as materials that may contain pathogens in quantities sufficient to cause disease.

Table 21 Operational instruction: Damaged devices

OPERATIONAL INSTRUCTION: DAMAGED DEVICES	
Procedure	• *Do NOT open, break, or dismantle the device yourself.* • *Handle with caution, especially devices with cooling circuits, screens, batteries, or internal medical modules.* • *Place the device in intact, secure transport packaging to prevent further breakage or leakage.* • *Deliver it to an authorised collection centre or WEEE scheme.* • *If the device contains batteries, remove and treat them as hazardous waste only if this can be done safely; otherwise, removal is performed by the treatment facility.*
Responsible	• *Operators and waste management lead.*
Timing	• *As soon as a damaged device is identified.*

9.4.2 Contaminated devices

Contaminated devices fall under infectious waste if they have been in contact with infected patients, biological specimens, or laboratory cultures. Healthcare waste guidelines classify such items as materials that may contain pathogens in quantities sufficient to cause disease.

Table 22 Operational instruction: Contaminated devices

OPERATIONAL INSTRUCTION: CONTAMINATED DEVICES	
Procedure	• *Do NOT clean the device yourself if doing so poses a risk to staff.* • *Label the device clearly: "INFECTIOUS / CONTAMINATED".* • *Use appropriate PPE (gloves, eye protection, mask, protective clothing).* • *Place the device in leak-proof packaging that prevents spills.* • *Where applicable, separate sharp components: they must be treated as sharps waste.* • *Handle the device according to the facility's internal infectious waste protocol.*
Responsible	• *Operators trained in infectious waste handling; supervised by infection-control officer.*
Timing	• *As soon as a contaminated device is identified.*

9.5 Emergency procedures

This section gives the immediate response steps for the four most common emergencies when handling digital health devices. Every operator should know these by heart. They should be displayed at every collection point alongside the sorting decision tree (Annex 4). A wall ready summary is provided in Annex 15.

9.5.1 Lithium battery fire or thermal runaway

Lithium batteries can ignite without warning if damaged, swollen, overheated or short-circuited. Lithium fires release toxic fumes and re-ignite easily (EERA 2025).

Table 23 Operational instruction: Lithium battery fire

IMPORTANT: Contaminated devices are not sent directly for WEEE processing until they are decontaminated. See Annex 5 (Decision tree: Damaged or contaminated devices) and Section 13.3 for the treatment pathway.

OPERATIONAL INSTRUCTION: LITHIUM BATTERY FIRE	
Procedure	• *Do NOT use water or foam, water reacts with lithium and can intensify the fire.* • *Use a dry-powder extinguisher or class-D / lithium-specific extinguisher if available.* • *If the fire cannot be controlled within seconds, evacuate immediately and call the fire brigade.* • *Close doors behind you to contain smoke; do not block the corridor with the burning device.* • *Notify the waste management lead and facility safety officer.* • *Once the fire is out, do NOT touch the device for at least 24 hours (re-ignition risk). Place it in a sand-filled or non-combustible container outdoors if safe to do so.* • *Document the incident (Annex 20).*
Responsible	• *The operator who first identifies the fire.* • *Supported by: waste management lead, facility safety officer, fire brigade.*
Timing	• *Immediately on first sign of smoke, hissing, swelling, or unusual heat.*

9.5.2 Sharps injury or needle-stick exposure

Some digital health devices are accompanied by lancets, needles, or have sharp internal components. A sharps injury is treated as a potential biological exposure (WHO 2014).

Table 24 Operational instruction: Sharps injury

OPERATIONAL INSTRUCTION: SHARPS INJURY	
Procedure	• *Stop the activity immediately. Do not put the device back in the bin.* • *Allow the wound to bleed gently; wash with soap and running water for at least 5 minutes. Do NOT scrub or squeeze.* • *Cover with a waterproof dressing.* • *Report immediately to the occupational health service or emergency department.* • *Identify and isolate the source device for source testing where applicable.* • *Document the incident (Annex 20).* • *Follow the facility's post-exposure protocol (testing, prophylaxis if indicated).*
Responsible	• *Injured operator.* • *Supported by: line manager, occupational health, infection-control officer.*
Timing	• *Immediately, before any further work; report within 1 hour.*

9.5.3 Suspected data breach

A data breach is suspected whenever a device leaves the chain of custody before its data has been destroyed (lost device, theft, misrouted device, broken seal on a secure container) (edpb 2016b, 2016a, 2022).

Table 25 Operational instruction: Suspected data breach

OPERATIONAL INSTRUCTION: SUSPECTED DATA BREACH	
Procedure	• *Do not attempt to restore or investigate alone.* • *Notify the data protection officer (DPO) immediately.* • *Notify the waste management lead and the partner from whose custody the device may have escaped.* • *Document the timeline of events (Annex 20).* • *Under Article 33 GDPR, notifiable breaches must be reported to the national data protection authority within 72 hours.* • *The DPO leads the response, including any communication to data subjects under Article 34 GDPR..*

Responsible	• *First operator who identifies the breach* • *Lead: data protection officer (DPO)* • *Supported by: waste management lead, IT security, legal counsel.*
Timing	• *Notification within 1 hour of discovery; regulatory notification within 72 hours where required by GDPR.*

10 Storage

10.1 Temporary Storage of Collected Items in Smart Collection Machine

Smart collection machines are typically installed in locations where users can return specific types of items. The exact setup depends on the type of items being collected and the operational program implemented by the responsible organisation.

Items are returned through a controlled access process. In the standard setup, the machine opening remains locked by default.

To deposit an item, the user must scan a QR code placed directly on the item. After successful verification, the machine allows the item to be inserted.

Because access to the machine opening is controlled, items are effectively pre-sorted before being deposited. Other return workflows may be implemented depending on the type of collection program and the materials being handled.

Once deposited, items are securely stored inside the Smart Collection Machine until they are collected by the responsible organization.

The storage inside the machine is designed to:

- Prevent unauthorized removal of items
- Ensure items remain stored until scheduled collection or servicing

10.1.1 Monitoring and unauthorized access

The machine includes monitoring functions to maintain the integrity of stored items. If someone attempts unauthorized access to the machine, the system generates an alert to notify the responsible operator or monitoring system. This helps ensure that any attempt to access the stored items without authorization can be identified and addressed.

10.1.2 Collection of Stored Items

Stored items are periodically collected by the responsible organization and transported to the appropriate downstream facility.

Operational procedures for transport and further handling depend on the specific collection program.

Table 26 Operational instruction: Storage of digital health devices

OPERATIONAL INSTRUCTION: STORAGE OF DIGITAL HEALTH DEVICES	
Procedure	• *Designate a dedicated, identified storage area for digital health device waste, separate from general waste storage.* • *Provide separate sub-areas for each stream (1–5) defined in Section 8.2.1.* • *Ensure the area is dry, ventilated, and protected from direct sunlight and heat.* • *Restrict access to authorised staff only; lock the area outside working hours.* • *Provide fire-safety equipment compatible with battery fires (e.g. dry-powder or class-D extinguisher) for stream 5.* • *Avoid stacking unstable or heavy containers; respect manufacturer load limits.* • *Inspect the storage area at least weekly for leaks, damage, and unauthorised access.* • *Empty the area according to the agreed schedule with the PRO or logistics provider, respecting any storage time / volume limits set by national legislation.*
Responsible	• *Healthcare facility manager (waste management lead) sets up; operators maintain.*
Timing	• *Set up at system establishment; weekly inspection; emptying per schedule.*

IMPORTANT: Every incident, even minor, must be documented in the incident log (Annex 20). Trends across incidents are the most reliable signal that a procedure or training gap needs to be fixed.

10.2 Risk Assessment and Regulatory Compliance

Where storage occurs, including inside Smart Collection Machines or at downstream facilities, a risk assessment should be conducted to evaluate operational and health and safety considerations.

Organizations responsible for the collection program should ensure that:

- Necessary permits are obtained where applicable
- Operations comply with health and safety regulations
- Activities follow applicable EU legislation and relevant national regulations

10.2.1 Storage Limits and Operational Requirements

In some jurisdictions, regulations may define limits on storage volume or storage duration. These requirements should be verified as part of the regulatory review for each installation site.

10.3 Signage and Labelling

Where required, appropriate signage and labelling should be used to indicate the purpose of the collection system, the type of items accepted, and any relevant safety or handling information. These should comply with applicable regulatory requirements.

Table 27 Operational instruction: Signage and labelling

OPERATIONAL INSTRUCTION: SIGNAGE AND LABELLING	
Procedure	• *Apply container labels per Annex 7 (colour-coded with icons).* • *Apply room-level signage at the entrance of the storage area: stream identification, hazards, restricted access, contact person.* • *Replace damaged or faded labels within 7 days.* • *Verify labelling during the weekly inspection.*
Responsible	• *Healthcare facility manager (waste management lead).*
Timing	• *Set up at establishment; replacement within 7 days; weekly verification.*

Digital Health in the Circular Economy

Part B

Transport, Treatment and Recycling

For logistics providers, treatment and recycling facilities, and reprocessing operators.

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11 TRANSPORT & SHIPMENT

11.1 Authorisations and permits

The emptying of the recipients, transport and shipment of digital health devices and potentially other collected material is generally subcontracted to external logistics providers.

All the contracted companies must hold valid and appropriate permits, licences, and authorisations required under applicable transport, waste, health, and safety regulations. These include but are not limited to:

- Permits for the collection, transport, and storage of WEEE under Directive 2012/19/EU and national legislation;
- Permits for the transport of hazardous waste under Directive 2008/98/EC, where applicable;
- Permits for the transport of healthcare or infectious waste, where applicable;
- ADR certification for road transport of dangerous goods, where applicable.

Compliance with national and regional legal requirements is mandatory and must be demonstrable upon request. Contractors remain responsible for ensuring their staff are adequately trained for handling health-related equipment.

To optimise compliance and economic efficiency, tenders may be organised to choose appropriate partners.

11.2 Collection, Packaging, and Safety Measures

Digital health devices are collected in plastic bags within specialized recipients (containers or bins). To collect the devices, the recipients must be opened (periodically or on demand) to replace the plastic bags. Handling procedures must ensure:

Table 28 Operational instruction: Collection and packaging by the logistics provider

OPERATIONAL INSTRUCTION: COLLECTION AND PACKAGING BY THE LOGISTICS PROVIDER	
Procedure	• *Verify the receptacle and label before opening.* • *No direct manual contact with loose devices: handle through the bag or with appropriate tools.* • *Close bags before removal; label each bag with collection point and date.* • *Verify that bags and receptacles are intact and suitable for safe containment and handling.* • *Report and replace any damaged or leaking bag or receptacle immediately.* • *Register the collection in the operational system per the agreed procedure.*
Responsible	• *Logistics provider operators*

	• *Supervised by: logistics provider transport supervisor; coordinated with the healthcare facility waste management lead.*
Timing	• *At every collection event.*

Registration of the collection should be done according to specific procedures.

11.3 Transport Documentation

Each shipment must be accompanied by complete and accurate transport documentation, as applicable, including:

- Demand for collection
- Notes or consignment documentation
- Waste transfer documentation (where relevant)
- Identification of origin, destination, and responsible parties
- European Waste Code (EWC) and / or national waste codes, where applicable.

Documentation must be complete and compliant with national legislation and must be retained according to legal and contractual retention periods and be readily available for inspection or audit.

11.4 Traceability, Recording, and Storage

All logistical movements must be properly recorded and traceable, including:

- Date and location of collection
- Type and quantity of devices transported, potentially including national and/or European waste codes
- Identification of the transporter and destination

Where devices are temporarily stored, the material must be registered as waste or equipment in storage, in accordance with applicable regulatory requirements. Storage locations must be secure, clearly identified, and managed to prevent loss, contamination, or unauthorised access.

Table 29 Operational instruction: Traceability of shipments

OPERATIONAL INSTRUCTION: TRACEABILITY OF SHIPMENTS	
Procedure	• *Issue a consignment note for every shipment.* • *Record date, location, type, quantity, EWC code, transporter, and destination.* • *Verify that the receiving facility countersigns the consignment note on delivery.* • *Archive consignment notes per legal and contractual retention periods.* • *For interim storage, register the material on entry and on exit.*

Responsible	•	*Logistics provider transport supervisor; receiving facility staff for countersignature; logistics provider compliance officer for archiving.*
Timing	•	*Every shipment; archiving according to retention periods (typically 3–10 years depending on jurisdiction).*

11.5 Operator Safety and Personal Protective Equipment (PPE)

All operators involved in collection, handling, transport, or storage must:

- Wear appropriate PPE (e.g. gloves, protective clothing, safety footwear, as applicable)
- Be explicitly instructed to beware of sharp objects, including potential needles or lancets
- Receive training and instructions regarding potential infectious risks associated with used digital health devices

Furthermore, operators should be able to assess risks and must follow internal health and safety procedures and report any incidents, injuries, or suspected exposure immediately.

12 TREATMENT

The treatment of medical electronic devices depends, first, on whether the device falls under Directive 2012/19/EU on WEEE. In principle all electronic devices fall under the WEEE directive unless there is an explicit exemption, such as the following exception for medical devices in Article 2(4)(g):

WEEE DIRECTIVE EXEMPTION: "Medical devices and in vitro diagnostic medical devices, where such devices are expected to be infective prior to end of life, and activei mplantable medical devices."

For the electronic devices that fall under the WEEE directive it is important that they are collected separately from hospital waste. Once the devices are in the collection bin for hospital waste it will be classified as hazardous waste. The treatment of hospital waste in many European countries is high temperature incineration (HCWH-Europe, 2020) although alternatives, such as disinfection, enables other possibilities for treating the waste (REMONDIS, 2020).

As for medical electronic devices that are non-infectious and collected separately, disinfected devices can be treated similar to other e-waste of the same size. This means that the material will have to be treated in accordance with the WEEE Directive (Directive 2012/19/EU) and the Waste Framework Directive (Directive 2008/98/EC).

Lastly, whether or not devices or equipment have seen a re-use cycle will usually not impact their recycling pathway. With the possible exception when electronics medical devices fail the check for reprocessing and they have been decontaminated for the reprocessing process in this case the decontaminated can likely go towards regular WEEE recycling.

12.1 Pathway selection (WEEE vs. medical waste)

A visual decision tree for treatment pathway selection is provided in Annex 21. It is intended to be displayed at the treatment / collection interface, where the waste-stream destination is decided.

Table 30 Operational instruction: Pathway selection

OPERATIONAL INSTRUCTION: PATHWAY SELECTION	
Procedure	• *Verify whether the device falls under the WEEE Directive or under the exemption (active implantable medical devices, devices expected to be infective prior to end of life).* • *For non-infectious WEEE: route to a treatment facility certified for the relevant category (Cat. 4 or Cat. 5).* • *For potentially infectious devices: route to disinfection (where allowed) or to high-temperature incineration as hazardous healthcare waste.* • *Verify the receiving facility's permits and certifications before dispatch (Section 5.3).* • *Document the pathway selection (Section 12.3 / Section 12.4).*
Responsible	• *Healthcare facility waste management lead and PRO; receiving treatment facility on entry.*
Timing	• *At every dispatch from the healthcare facility / collection point.*

12.2 Treatment of non-infectious digital health devices

If the medical devices do not fall under the WEEE Directive exemption, described above, and are sorted separately from potentially infectious material, they can be treated as e-waste in specialised treatment facilities.

The treatment facility must hold permits identifying the types of waste it may treat. The WEEE Directive (currently under review) specifies six categories, of which categories 4 (large equipment) and 5 (small equipment) are most relevant. The threshold between large and small equipment is 50 cm of external dimensions.

In addition, the European standard EN 50625 (CENELEC series) covers general treatment, depollution, collection, logistics, and final treatment of materials. The WEEELABEX organisation certifies treatment facilities on compliance with EN 50625. An overview of certified companies is available at:

- **Operators list — WEEELABEX:** the list includes the categories of waste each company is certified for.

Table 31 Operational instruction: Treatment of non-infectious devices

OPERATIONAL INSTRUCTION: TREATMENT OF NON-INFECTIOUS DEVICES	
Procedure	• *On entry, verify consignment documentation and EWC code; reconcile with the agreed shipment.* • *Weigh and record the shipment.* • *Apply depollution per EN 50625: remove batteries, capacitors, mercury components, and other hazardous fractions.* • *Apply data-bearing component destruction (memory shredding) for any device not pre-wiped (Section 9.3).* • *Recover material fractions: PCBA (precious metals), clean plastics (ABS / PP), ferrous and non-ferrous metals.* • *Issue a Certificate of Treatment and a Data Destruction Certificate linked to the device UDI where applicable.* • *Report treatment outcomes to the PRO and / or healthcare facility per the contract.*
Responsible	• *Treatment facility operators; technical manager; quality / compliance officer.*
Timing	• *On every incoming shipment; reporting per the contractual schedule.*

12.3 Treatment of (potentially) infectious digital health devices

The treatment of (potentially) infectious digital devices will be, as described above, most likely be incineration as hospital/hazardous waste. There are developments on disinfecting hospital waste such that the waste stream is no longer infectious and can be treated like non-infectious waste. Countries such as France and the United Kingdom permit validated disinfection treatment routes for infectious healthcare waste, whereas other countries continue to apply stricter controls and rely predominantly on incineration for infectious medical waste streams.

For this type of electronic waste, it is best to inquire with your waste logistics partner if there is the option to send the material to disinfection and further treatment.

Beyond small electronic devices, large equipment such as MRI machines or other imaging equipment can also be potentially infectious at end of life. These can be disinfected prior to going to an e-waste treatment facility. Once they have documentation that they are disinfected, they can go to large-equipment recycling as described in Section 12.2.

When large equipment reaches end of life, generally the original manufacturer or the manufacturer of the replacement equipment will be able to give an insight into the options available.

Table 32 Operational instruction: Treatment of (potentially) infectious devices

COUNTRY-SPECIFIC: Disinfection routes are not allowed in every Member State. Verify the availability of the disinfection route with your waste logistics partner and, where needed, with the WEEE Forum or the national environmental authority.

OPERATIONAL INSTRUCTION: TREATMENT OF (POTENTIALLY) INFECTIOUS DEVICES	
Procedure	• *Verify the consignment documentation and the infectious-waste classification.* • *Apply the appropriate treatment route: high-temperature incineration, or disinfection followed by WEEE treatment where allowed.* • *For disinfection, use processes validated under EN 14885 and Regulation (EU) 2020/1207.* • *After disinfection, document the process and route the device to WEEE treatment per Section 13.2.* • *Issue a Certificate of Treatment.*
Responsible	• *Treatment facility operators; technical manager; biosafety officer.*
Timing	• *On every incoming infectious-waste shipment.*

12.4 Treatment facility requirements (summary)

- Permits: environmental permit covering the relevant WEEE category (Cat. 4 or Cat. 5).
- EN 50625 / WEEELABEX: certification for the relevant category, verifiable on the WEEELABEX operators list.
- Disinfection: where applicable, validated under EN 14885 and Regulation (EU) 2020/1207.
- Data destruction: physical destruction (shredding) of memory storage components for recycling, with a Data Destruction Certificate linked to the UDI.
- Reporting: reuse, recycling and recovery rates per category, per the contract.

Selection of treatment facilities is the responsibility of the PRO or the healthcare facility manager (Section 5.3).

13 REPROCESSING

Reprocessing covers the structured restoration of used digital health devices for safe reuse, in line with the EU Medical Device Regulation (Regulation (EU) 2017/745). Reprocessing of single-use devices (SUDs) is strictly regulated by Article 17 of the MDR and is not permitted in every Member State.

13.1 Definitions and Legal Framework

- **Reprocessing:** According to MDR Art. 2(39), a process carried out on a used device to allow its safe reuse, including cleaning, disinfection, sterilisation, and related procedures, as well as testing and restoring the technical and functional safety of the used device.
- **Single-Use Device (SUD):** A device intended to be used on one individual during a single procedure. Its reprocessing is strictly regulated by Art. 17 of the MDR.
- **Refurbishment:** Actions performed to restore a device to its original aesthetic and functional characteristics without changing its intended use.
- **Reprocessing Entity:** The person or organisation that assumes legal responsibility for the original manufacturer's obligations when processing devices for re-introduction to the market.

13.2 Legal Verification and Reprocessor Requirements

- **National Legal Status:** Before accepting any batch, the person responsible for regulatory compliance within the reprocessing facility must consult the Annex of the DiCE D6.2 Report (Authorisation Map). If the Member State of origin prohibits the reprocessing of SUDs, the batch must be diverted directly to recycling, regardless of its condition.
- **Certifications and Registries:** The processor must hold ISO 13485 certification and register all activities in the EUDAMED database.
- **Validation under Reg. 2020/1207:** All disinfection and cleaning processes must be technically validated to ensure no biological or chemical residues remain that could compromise the safety of the next user.

Table 33 Operational instruction: Legal verification before reprocessing

OPERATIONAL INSTRUCTION: LEGAL VERIFICATION BEFORE REPROCESSING	
Procedure	• *Consult the Annex of the DiCE D6.2 Report (Authorisation Map) to verify the legal status of SUD reprocessing in the Member State of origin. If reprocessing of SUDs is prohibited in that Member State, divert the batch directly to recycling regardless of its condition.* • *Verify ISO 13485 certification of the reprocessor.* • *Verify that all reprocessing activities are registered in EUDAMED.*

	• *Verify validation evidence under Regulation (EU) 2020/1207 for all disinfection and cleaning processes.* • *Verify that no biological or chemical residues remain that could compromise the safety of the next user.*
Responsible	• *Reprocessing entity manager; supported by quality / compliance officer.*
Timing	• *Before accepting any batch; periodically (annual review of certifications and registrations).*

13.3 Preparation for Reuse (Reprocessing Workflow)

A visual decision tree for the reprocessing workflow is provided in Annex 22. It illustrates the sequence of legal verification, condition checks, functional testing, and outcome routing covered in this section

Table 34 Operational instruction: Reprocessing workflow

OPERATIONAL INSTRUCTION: REPROCESSING WORKFLOW	
Procedure	• *Triage and risk assessment: evaluate whether the device can withstand a new cleaning cycle without material degradation.* • *Primary decontamination: deep cleaning following EN 14885 to neutralise pathogens before opening the device.* • *Battery and wear-and-tear replacement: replace the lithium-polymer battery if it shows signs of swelling or has exceeded its rated charging cycles, to guarantee device autonomy.* • *Calibration and safety testing: the device must undergo electrical and functional safety tests (e.g. sensor accuracy) equivalent to those of a new unit.* • *Final inspection and labelling: apply the reprocessor identification and a unique batch reference linked to the UDI.* • *Issue the Certificate of Reprocessing and update EUDAMED.*
Responsible	• *Reprocessing entity operators; technical manager; quality / compliance officer.*
Timing	• *On every batch accepted for reprocessing.*

13.4 Preparation for Recycling and Data Destruction

Devices that fail reprocessing must be routed to recycling. Healthcare-waste-management rules apply: rejected devices are treated as WEEE with potential biohazard risk, requiring protected handling during disassembly.

13.4.1 Fraction recovery

- **PCBA:** manual extraction of boards for the recovery of precious metals.
- **Plastics:** segregation of clean polymers (ABS / PP) for circular economy processes.
- **Batteries:** separate handling per Regulation (EU) 2023/1542.

13.4.2 Privacy (GDPR)

SEE ANNEXES: A sequential operational decision tree for circular management of every received batch is provided in Annex 5 (Decision tree: Damaged or contaminated devices) and Annex 4 (Sorting and routing).

- **Reuse path:** apply a certified logical data wipe of patient information using approved software.
- **Recycling path:** perform physical destruction (shredding) of memory storage components.

13.4.3 Certification

Issue a Data Destruction Certificate linked to the device's Unique Device Identifier (UDI). The certificate is the documentary evidence that data has been securely removed or destroyed and is required for any audit or inspection.

Table 35 Operational instruction: Recycling preparation and data destruction

OPERATIONAL INSTRUCTION: RECYCLING PREPARATION AND DATA DESTRUCTION	
Procedure	• *Segregate rejected devices by material category (PCBA, plastics, batteries).* • *Apply data destruction per the route (logical wipe for reuse, physical destruction for recycling).* • *Issue Certificates of Treatment and Data Destruction linked to the UDI.* • *Report to the PRO and the originating healthcare facility per the contract.*
Responsible	• *Reprocessing or treatment facility operators; technical manager; data protection officer.*
Timing	• *Per batch and per contract reporting cycle.*

13.5 Cross-border movements

Sending digital health devices to a refurbishment, treatment or recycling facility located in another country is regulated under the EU Waste Shipment Regulation (Regulation (EC) 1013/2006) and, for transfers outside the EU, under the Basel Convention. Healthcare facility managers and PROs cannot assume that domestic waste rules apply automatically across borders.

13.5.1 Inside the EU

- Non-hazardous WEEE listed in the "green list" of the Waste Shipment Regulation can normally be shipped between EU Member States without prior consent but is still subject to Annex VII documentation accompanying the shipment.
- Hazardous WEEE (e.g. devices with mercury, certain batteries) requires prior written notification and consent of the competent authorities of dispatch, transit and destination ("notification procedure").
- Healthcare / infectious waste is subject to a stricter notification procedure across all EU Member States.
- Devices intended for reuse (not waste) are normally not covered by the Waste Shipment Regulation, provided functional testing and documentation requirements are met under the WEEE Directive Annex VI.

13.5.2 Outside the EU

- The Basel Convention prohibits exports of hazardous waste from EU Member States to non-OECD countries; this includes most hazardous WEEE.
- Exports for reuse must comply with the WEEE Directive (Annex VI) and the Waste Shipment Regulation. False reuse claims are a frequent source of enforcement action.

Table 36 Operational instruction: Authorising a cross-border shipment

OPERATIONAL INSTRUCTION: AUTHORISING A CROSS-BORDER SHIPMENT	
Procedure	• *Verify whether the shipment is "waste" or "non-waste reuse" under WEEE Directive Annex VI.* • *For waste: classify the shipment per the European Waste Code and identify whether it is on the green list or notification list.* • *For green-list shipments: prepare and accompany Annex VII of Regulation 1013/2006.* • *For notification-list shipments: file a notification with the competent authority and obtain consent before shipping.* • *Confirm that the receiving facility is authorised to receive the relevant category.* • *Retain documentation per the legal retention period (typically minimum 3 years.*
Responsible	• *Healthcare facility waste management lead and / or PRO compliance officer* • *Supported by: legal / compliance officer; logistics provider.*
Timing	• *Before any shipment crossing a national border, periodically (annually) for repeat shipments.*

ANNEXE

For operational workers and managers in hospitals, clinics, laboratories, and other facilities that generarte or handle digital health device waste, logistics providers, treatment and recycling facilities, and reprocessing operators.

List of References

This section is a high-level summary of the EU and international rules governing cross-border waste shipments. It is not a substitute for the legal texts. Authoritative sources:

- Regulation (EC) No 1013/2006 of the European Parliament and of the Council on shipments of waste (consolidated version available on EUR-Lex). The Annex VII document, the green-list / amber-list distinction and the notification procedure are set out in Articles 3, 4, 18 and Annex III–IV.
- Regulation (EU) 2024/1157 of 11 April 2024 on shipments of waste, repealing Regulation (EC) No 1013/2006 (applicable from 21 May 2026). Healthcare facilities and PROs should track the transition to this new Regulation, which tightens controls on exports of waste outside the OECD.
- Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (1989, as amended). The Ban Amendment (in force since 2019) prohibits exports of hazardous waste from EU / OECD countries to non-OECD countries.
- Directive 2012/19/EU on WEEE, Annex VI: Minimum requirements for shipments of used EEE that the holder claims are intended for reuse and not for treatment as waste. False reuse claims are a frequent source of enforcement action.

Healthcare facilities and PROs intending cross-border shipments should consult their national competent authority for waste shipments before the first shipment.

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Annex 1 Healthcare Institutions and Activities Potentially Generating Digital Health Device Waste

This annex provides a non-exhaustive list of healthcare institutions, facilities, and activities that may generate healthcare waste, including digital health devices and related electrical and electronic equipment. The list is based on the World Health Organization (WHO) publication *Safe Management of Wastes from Health-Care Activities* and has been adapted to reflect the context of digital health devices.

Major Healthcare Institutions

- University hospitals
- General hospitals
- District hospitals
- Specialist hospitals
- Military medical services
- Prison hospitals or clinics

Other Healthcare Facilities

- Emergency medical care services
- Health-care centres and dispensaries
- Obstetric and maternity clinics
- Outpatient clinics
- Dialysis centres
- Long-term health-care establishments
- Hospices and palliative care facilities
- Transfusion centres

Residential and Social Care Facilities

- Nursing homes for the elderly
- Convalescent nursing homes
- Psychiatric hospitals
- Disabled persons' institutions
- Rehabilitation centres

Laboratories and Research Facilities

- Medical laboratories
- Biomedical laboratories
- Biotechnology laboratories and institutions
- Medical and health research centres
- Blood banks and blood collection services
- Animal research and testing facilities

Post-Mortem, Forensic, and Funeral Services

- Mortuary services
- Autopsy centres
- Funeral services

Minor Sources of Health-Care Waste (WHO[1] – Box 2.4)

According to the World Health Organization (WHO) publication *Safe Management of Wastes from Health-Care Activities*, the following minor sources of health-care waste may also generate healthcare waste. Digital health devices may be used or discarded in these settings, particularly where monitoring, diagnostic, or treatment-related equipment is involved.

- Small health-care establishments
- First-aid posts and sick bays
- Physicians' offices
- Dental clinics
- Acupuncturists
- Chiropractors

Specialized health-care establishments and institutions with low waste generation

- Convalescent nursing homes
- Psychiatric hospitals
- Disabled persons' institutions

Activities involving intravenous or subcutaneous interventions

- Cosmetic ear-piercing and tattoo parlours
- Illicit drug users and needle exchanges
- Funeral services
- Ambulance services

Funeral services

Ambulance services

Home treatment

- Other health-care facilities
  - Emergency medical care services
  - Health-care centres and dispensaries
  - Obstetric and maternity clinics
  - Outpatient clinics
  - Dialysis centres
  - Long-term health-care establishments and hospices
  - Transfusion centres
  - Military medical services
  - Prison hospitals or clinics

Reference: WHO — Safe Management of Wastes from Health-Care Activities

[1] https://www.who.int/publications/i/item/9789241548564

Annex 2 Decision Tree: Reuse vs. Waste Treatment

A structured decision approach helps avoid unnecessary disposal and ensures safe routing of every digital health device taken out of service. Apply this decision tree to every device taken out of service in a healthcare facility. The five questions are answered in sequence; the first YES answer determines the routing.

1. Is the device contaminated or potentially infected?
   - If yes and cannot be safely segregated/managed → treat as medical waste pathway (per site procedure).
   - If no → proceed.

2. Is the device intact and safe to handle?
   - If no → route to treatment/recycling as appropriate (or medical waste if contaminated).

3. Can the device be reused without repair?
   - If yes → route to reuse/re-deployment stream.

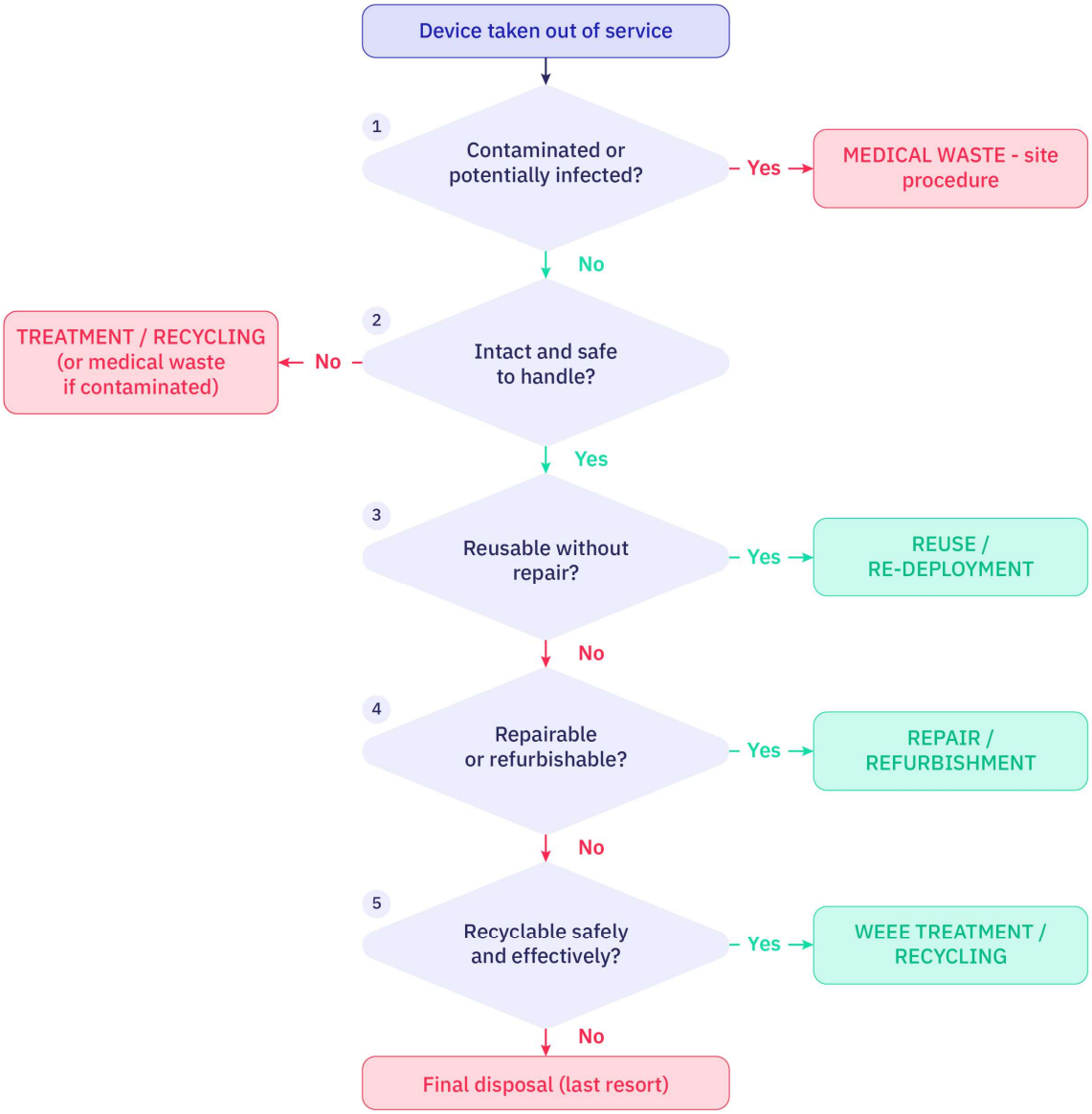
4. If not reusable, is it repairable/refurbishable?
   - If yes → route to repair/refurbishment stream.

5. If not repairable, can it be recycled safely and effectively?
   - If yes → route to WEEE treatment/recycling stream, ensuring battery handling and data security controls.

6. If none of the above apply → route to the appropriate final treatment/disposal pathway.

***Note (WHO segregation principle)*:** If segregation is difficult and devices cannot be separated from general waste streams, they must be treated as **medical waste** (Singh et al., 2020b; WHO, 2020a; UNEP, 2020a).

Decision Tree - Reuse vs Waste Treatment



Precautionary principle:
If segregation is difficult and devices cannot be safety separated from general waste streams, treat as MEDICAL WASTE.
Source: WHO (2014); Singh et al. (2020); UNEP (2020).

Annex 3 Decision Tree: for Refurbishment and Repair

Apply this decision tree only after Annex 2 has identified the device as a candidate for repair or refurbishment. The five sequential checks below verify that refurbishment is technically and legally feasible.

Step 1: Is the device contaminated or potentially infected?

- Yes / Unknown → Do NOT route to refurbishment or repair → Follow medical waste or specialised treatment pathways (see Annex 2)
- No → Proceed to Step 2

Step 2: Is the device intact and safe to handle? (Check for cracks, exposed components, leaking batteries, sharp edges)

- No → Not suitable for refurbishment/repair → Route to appropriate treatment or recycling (see Annex 2)
- Yes → Proceed to Step 3

Step 3: Can the device be repaired or refurbished? (Technical feasibility, availability of spare parts, authorised service options)

- Yes → Proceed to Step 4
- No → Not suitable for refurbishment → Route to WEEE treatment or other appropriate pathway (see Annex 2)

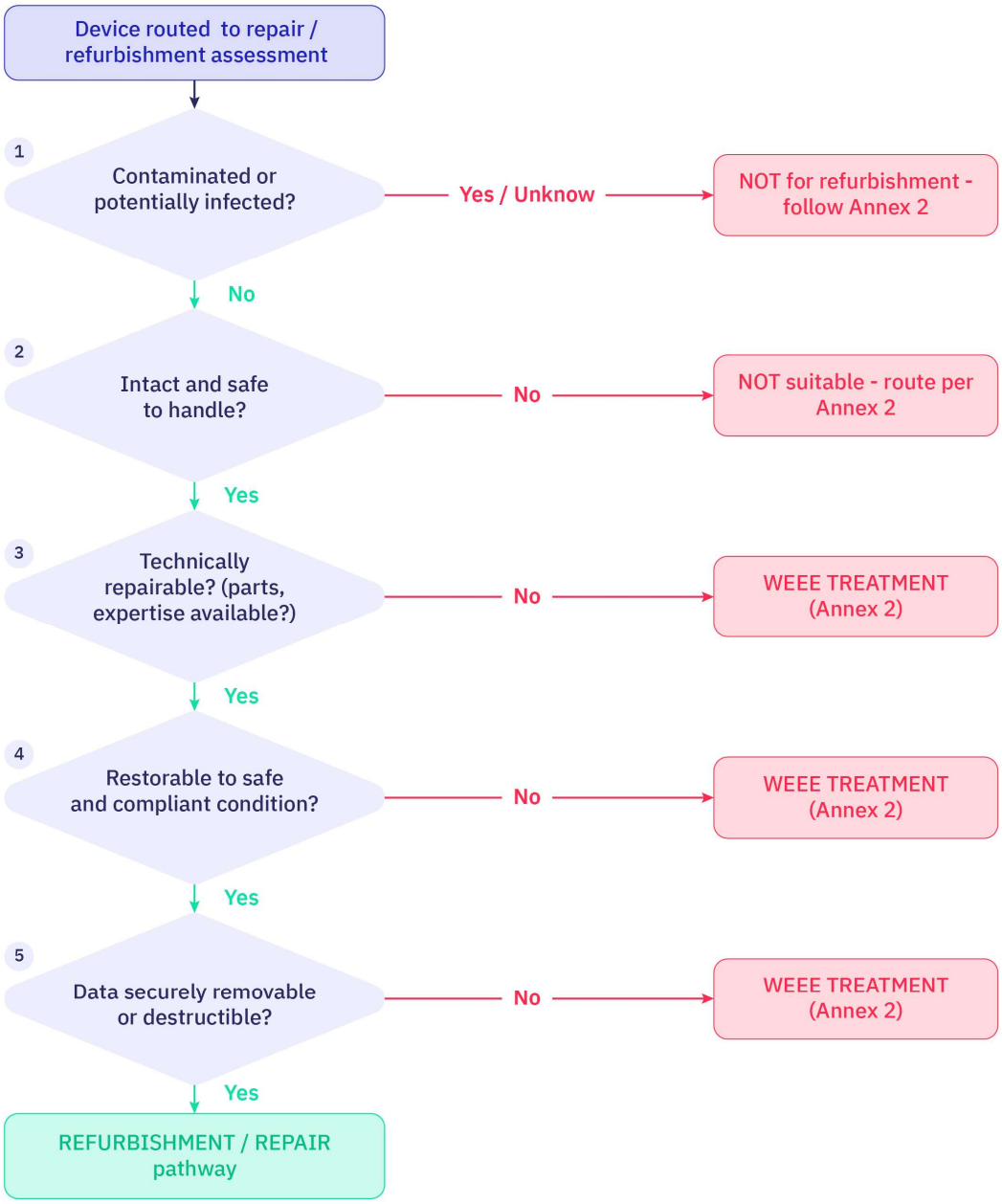
Step 4: Can the device be restored to a safe and compliant condition? (Including performance, electrical safety, and intended use)

- Yes → Proceed to Step 5
- No → Do not refurbish → Route to waste treatment according to Annex 2

Step 5: Can data be securely removed or destroyed? (Personal, medical, or sensitive data)

- Yes → Route to refurbishment or repair pathway
- No → Do not refurbish → Route to waste treatment according to Annex 2

Decision Tree - Refurbishment and Repair



Apply this tree only after Annex 2 (Reuse vs Waste Treatment) has identified the device as a refurbishment / repaur candidate. Compliance with EU MDR (Reg. 2017/745) Art. 17 is mandatory for medical-device reprocessing.

Annex 4 Decision Tree: Sorting and Routing of Digital Health Devices

This is the master sorting decision tree. It must be displayed at every collection point on A3 size, laminated sheet. Five sequential questions route the device to one of five streams. When in doubt, apply the precautionary principle and treat as MEDICAL WASTE.

Target audience: All staff involved in sorting
Use: Posters near sorting areas
Format: A3 or A2 poster, colour-coded

1. Is the device contaminated or potentially infected?

- **YES** → Route to MEDICAL WASTE (per site procedure)
- **NO** → Continue

2. Is the device intact and safe to handle?

- **NO** → Route to TREATMENT / RECYCLING (or medical waste if contaminated)
- **YES** → Continue

3. Can the device be reused without repair?

- **YES** → REUSE / RE-DEPLOYMENT
- **NO** → Continue

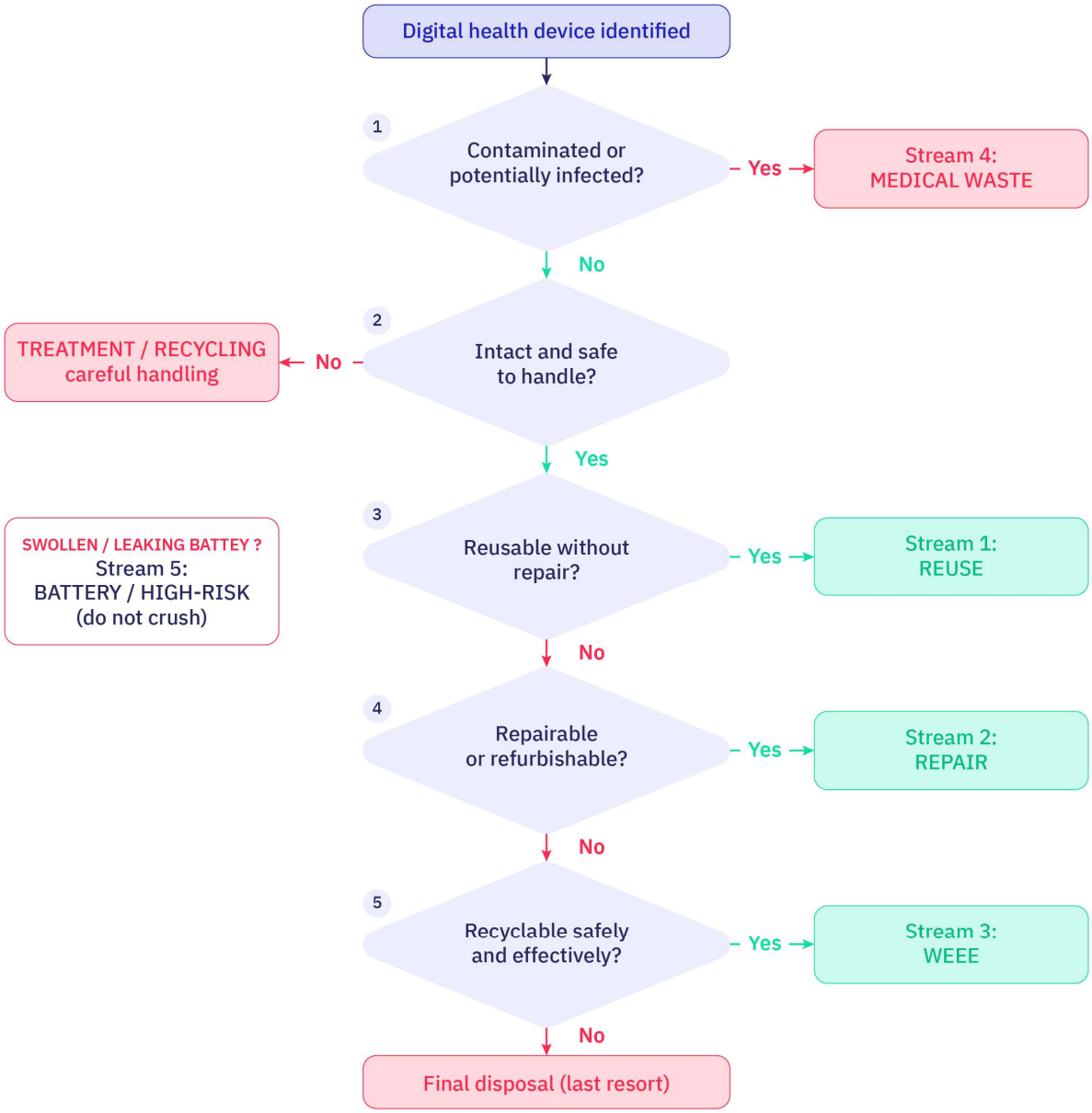
4. Is the device repairable or refurbishable?

- **YES** → REPAIR / REFURBISHMENT
- **NO** → Continue

5. Can the device be recycled safely and effectively?

- **YES** → WEEE TREATMENT / RECYCLING
- **NO** → FINAL DISPOSAL (last resort)

Decision Tree - Sorting and Routing of Digital Health Devices



When in doubt: apply the precautionary principle and treat as MEDICAL WASTE.
Stream colours: 1 GREEN - 2 YELLOW - 3 BLUE - 4 RED - 5 BLACK. See Annex 7 for bin labels.
If unsure, contact the waste management lead or infection-control officer.

Annex 5 Decision Tree: Handling of Damaged or Contaminated Devices

Apply this decision tree at the moment a damaged or contaminated digital health device is identified. Each YES answer triggers a specific protocol; only when all four checks return NO is the device routed via the standard sorting tree (Annex 4).

1. **Assess contamination status**
   - Determine whether the device is contaminated or potentially infected.
   - If contamination is confirmed or cannot be excluded, classify the device as infectious waste and handle according to the applicable infection-control procedures.
   - Place the device in leak-proof packaging, apply the appropriate label, and route it to the infectious waste stream.
   - If the device is confirmed to be non-infectious, proceed to Step 2.

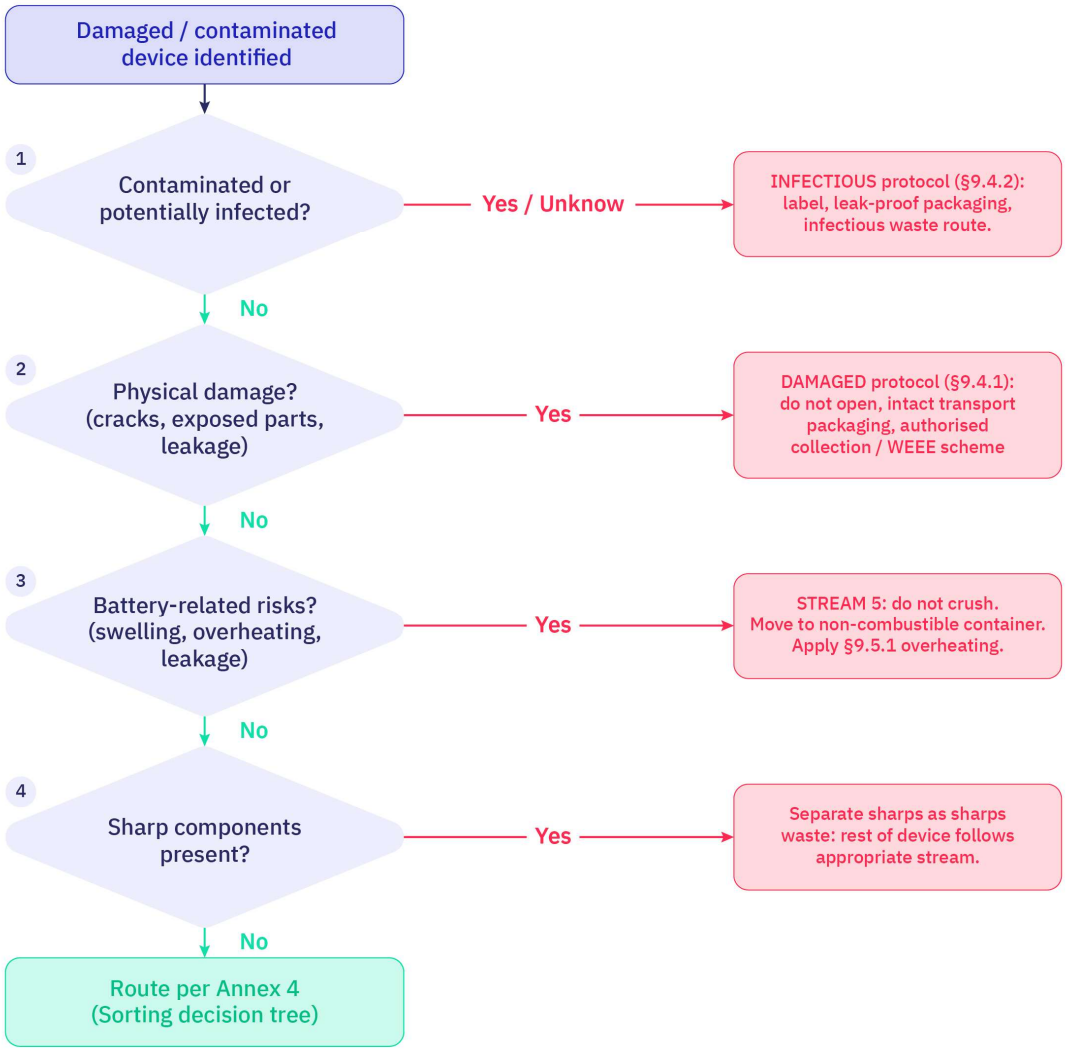
2. **Assess physical damage**
   - Inspect the device for cracks, exposed components, leakage, broken housings, or other signs of physical damage.
   - If significant damage is present, do not attempt repair or disassembly at the collection point.
   - Place the device in suitable transport packaging and route it to the designated WEEE treatment stream.
   - If no significant damage is observed, proceed to Step 3.

3. **Assess battery-related risks**
   - Check for battery swelling, leakage, overheating, burn marks, corrosion, unusual odours, or other signs of battery failure.
   - If a battery-related hazard is identified, do not crush, dismantle, or further handle the device.
   - Route the device to Stream 5 and follow the battery incident procedure.
   - If no battery-related risk is identified, proceed to Step 4.

4. **Assess the presence of sharps**
   - Determine whether the device contains needles, lancets, blades, broken glass, or other sharp components.
   - If sharps are present and can be safely separated, manage them as sharps waste according to local procedures.
   - Route the remaining device to the appropriate stream.
   - If no sharps are present, proceed to Step 5.

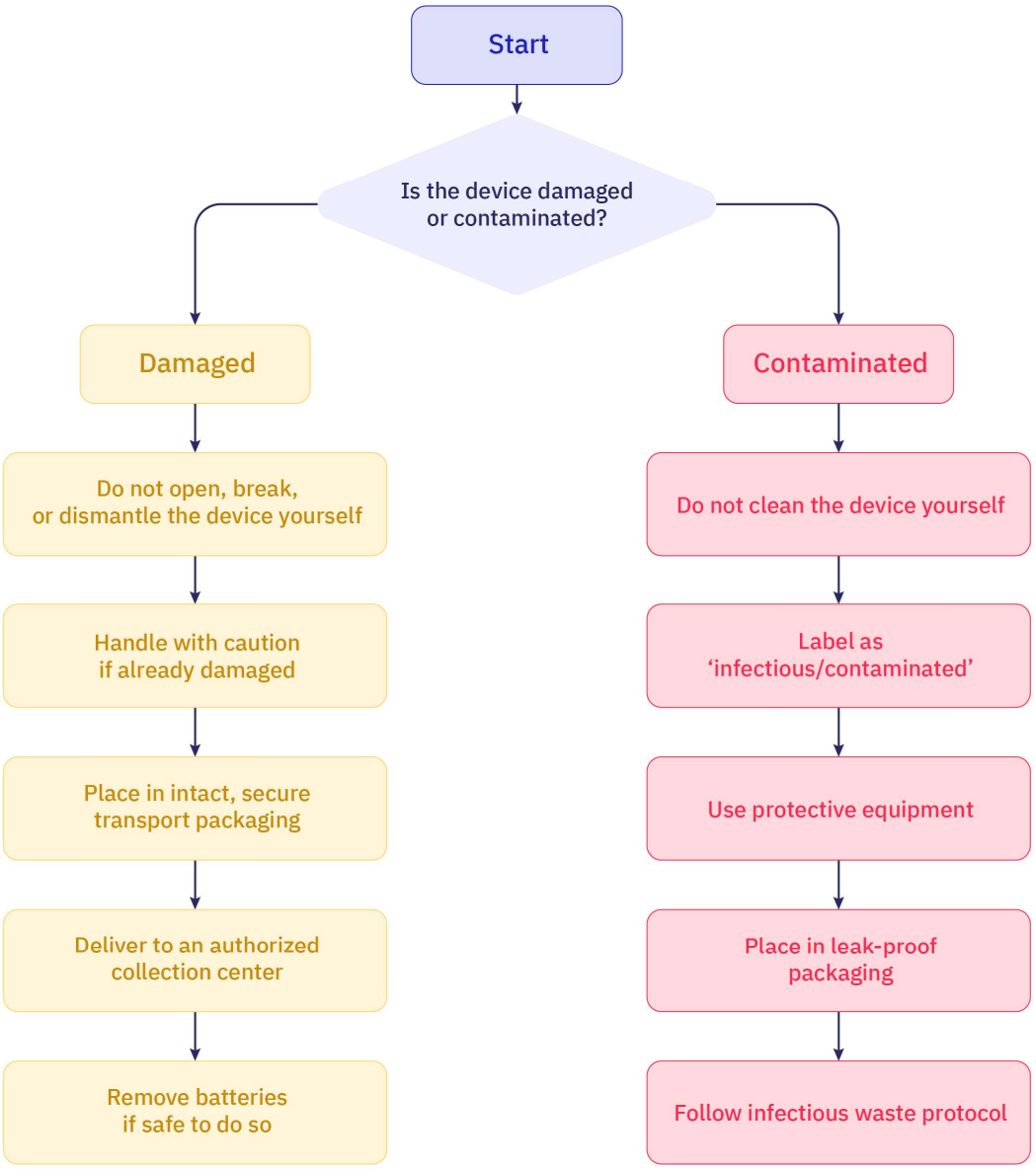
5. **Apply the sorting decision tree**
   - Route the device according to Annex 4 (Sorting Decision Tree) and the applicable reuse, repair, recycling, or disposal pathway.

Decision Tree - Handing of Damaged or Contaminated Devices



Troughout this procedure:
Apply PPE per §9.2 / §12.5 (gloves, eye protection, mask, protective clothing)
Notify the waste management lead.
For infection risk: also notify the infection-control officer.

Handling of Damaged or Contaminated Device Decision Tree



Annex 6 Operational Fact Sheet: How to Sort Digital Health Devices

Target audience: Operational workers, healthcare staff, waste handlers
Use: At collection points, storage rooms, treatment facilities
Format: 1-page, laminated, with photos/icons

STEP 1 – Identify the Device

Ask yourself:

- Is this a digital health device (electronic, powered, used for health purposes)
- Does it contain electronics, batteries, or data?

Photo examples: wearable monitor, blood pressure monitor, ECG device, smart pillbox

STEP 2 – Check Contamination Risk

- Has the device been in direct contact with patients or bodily fluids?
- Is there visible contamination, or is the status unknown?

If yes or unsure → treat as medical (infectious) waste

If no → proceed to next step

⚠ *Precautionary principle applies.*

STEP 3 – Check Physical Condition

Is the device intact and safe to handle?

- Are there signs of damage (cracks, leakage, exposed parts)?

If damaged or unsafe → high-risk stream / treatment
If intact → proceed

STEP 4 – Identify the Correct Sorting Stream

Choose **one** of the following:

1. Reuse / Re-deployment
   - Clean, intact, data removable

2. Repair / Refurbishment
   - Not working, but repairable

3. □ WEEE Recycling (non-infectious)
   - End-of-life, non-contaminated

4. Medical Waste
   - Infected, potentially infected, or not safely segregated

5. Battery / High-Risk Stream
   - Damaged or leaking batteries

STEP 5 – Label and Record

- Apply correct label/tag
- Record device according to site procedure

KEY MESSAGE: Sorting done correctly = safer work + better reuse + better recycling.

Annex 7 Example Bin Labels

Target audience: Operational staff, cleaners, healthcare workers
Use: On bins, containers, cages
Format: Colour-coded labels with icons

Stream	Colour code	Label content
Stream 1 Reuse / Re-deployment	GREEN	Clean, intact digital health devices only. No contamination and data removable.
Stream 2 Repair / Refurbishment	YELLOW	Faulty but repairable devices. Handle with care.
Stream 3 WEEE (non-infectious)	BLUE	End-of-life, non-contaminated devices. Batteries intact or removed (if allowed).
Stream 4 Medical waste	RED	Infected or potentially infected devices. Follow infection-control procedures.
Stream 5 Battery / High-risk	BLACK	Damaged or leaking batteries. Fire and chemical risk.

Annex 8 Information Leaflet for Managers and healthcare staff on sorting

Target audience: Managers, supervisors, infection-control officers
Use: Training, onboarding, awareness
Format: 2-page leaflet or PDF

Why Sorting Matters

Correct sorting of digital health devices:

- Protects staff and patients
- Enables reuse and refurbishment
- Supports compliance with WEEE, EPR, and health regulations
- Preserves valuable materials

Your Role as a Manager or Supervisor

You are responsible for ensuring:

- Clear internal procedures for sorting and collection
- Availability of labelled containers and signage
- Staff training and refresher sessions
- Coordination with Producer Responsibility Organisations (PROs)
- Clear rules for handling infected vs non-infected devices

Key Management Actions

- Define sorting categories and collection routes
- Appoint responsible persons (waste lead, infection-control officer
- Ensure traceability and documentation
- Review incidents and segregation errors
- Communicate procedures clearly to all staff

Support for Staff and Users

- Provide fact sheets and posters at collection points
- Ensure staff know who to contact when unsure
- For household devices, provide simple user instructions

Annex 9 Information Leaflet on How to Sort Digital Health Devices in Hospitals

Where this applies

This guidance applies to wards, outpatient clinics, laboratories, diagnostic units, and storage areas within hospitals.

What staff must do
Identify digital health devices early, check contamination status, and place them in the correct labelled container. When in doubt, apply the precautionary principle and treat as medical waste.

Department-specific notes

- Wards: focus on contamination risk; protect reuse candidates from damage.
- Laboratories: check chemical exposure in addition to biological risk.
- Outpatient clinics: protect reusable devices; identify household-returned devices for the appropriate route.
- IT / biomedical service: ensure data wipe / destruction before any device leaves the facility.

Support
If unsure, contact the infection-control officer or waste management lead. Their contact details should be displayed at every collection point.

Annex 10 Information Leaflet on How to Sort Digital Health Devices at Home

What to Do With Your Used Digital Health Device?

Examples of devices : Blood pressure monitors, glucose meters, wearable health devices, home monitoring equipment.

Before returning the device

- If possible, reset or wipe the device.
- Remove accessories and place everything together (cables, charger, manual).

How to return

- Use official take-back schemes;
- Use designated drop-off points (municipal recycling centre, pharmacy, healthcare provider);
- Use Smart Collection Machines, if available in your area;
- Follow instructions from your healthcare provider or manufacturer.

Important safety note: If the device may be contaminated, damaged, or leaking, do not put it in household waste. Ask your healthcare provider for advice.

Annex 11 Procurement Checklist for Digital Health Devices

A reference checklist for embedding circularity in procurement (Section 6.1). Adapt the weighting to local context. Examples of recognised criteria are listed in Annex 14 (References).

AREA	QUESTIONS / CRITERIA TO INCLUDE IN TENDERS
Reusability and durability	• *What is the expected service life under normal clinical use? Provide evidence / test results.* • *Can the device be used across multiple patients with appropriate cleaning / disinfection?* • *What components are most likely to fail, and what is their expected lifetime (battery, sensors, cables)?*
Repairability and maintenance	• *Is the device designed for non-destructive disassembly?* • *Are spare parts available, and for how long?* • *Are repair manuals, diagnostic tools, or service instructions available to authorised parties?* • *Typical repair turnaround time and cost range?*
Battery safety and replaceability	• *Is the battery user / technician replaceable? If not, what is the replacement process and cost?* • *How is battery removal performed safely for end-of-life treatment?* • *Battery type / chemistry and safe handling requirements (Regulation (EU) 2023/1542).*
Software support and obsolescence prevention	• *How long will software / security updates be provided?* • *Can the device operate safely with limited connectivity?* • *Are updates delivered in a way that avoids premature obsolescence?*
Data security by design	• *Does the device support secure reset / wipe functions?* • *Where is data stored, and how can it be deleted at end-of-use?* • *Is a data-sanitisation procedure provided for operational staff?*
Circular services and take-back	• *Does the supplier offer take-back, refurbishment, or trade-in?* • *Are there established routes for reuse / refurbishment through authorised partners?* • *Are packaging and logistics optimised for return / re-deployment?*
Materials and recycling readiness	• *Are materials / components labelled or documented to facilitate recycling?* • *Are hazardous components identified and removable?* • *Are end-of-life dismantling instructions provided?*

Annex 12 PRO Selection Checklist

Use this checklist when selecting and contracting a Producer Responsibility Organisation (Section 5.1).

AREA	ITEM TO VERIFY	OK?
Authorisation	• *Are end-of-life dismantling instructions provided?Authorised by the national WEEE register / authority.* • *Scope covers medical and / or digital health devices (not only general EEE).* • *Operational coverage in the relevant region(s).*	☐
Service offer	• *Are end-of-life dismantling instructions provided?Types of receptacles provided (size, security, lockable).* • *Minimum collection load and frequency.* • *On-call collection availability.* • *Coverage of household-stream devices, where applicable.*	☐
Performance	• *Are end-of-life dismantling instructions provided?Reuse rate per category (latest year).* • *Recycling rate per category (latest year).* • *Recovery rate per category (latest year).* • *Treatment chain (subcontractors and their certifications).*	☐
Documentation	• *Are end-of-life dismantling instructions provided?Consignment notes provided per shipment.* • *Certificates of treatment provided.* • *Annual report provided.* • *Data Destruction Certificate linked to the UDI provided.*	☐
Compliance	• *Are end-of-life dismantling instructions provided?GDPR compliance for any residual data on devices.* • *Insurance coverage (operations, transport, treatment).* • *Incident-reporting procedure.* • *Audit rights for the healthcare facility.*	☐
Contract	• *Are end-of-life dismantling instructions provided?Scope and KPIs clearly defined.* • *Termination clauses defined.* • *Annual review of permits and authorisations.* • *Reference checks with at least two existing healthcare clients.*	☐

Annex 13 Logistics Provider Selection Checklist

Use this checklist when selecting and contracting a logistics / waste management company (Section 5.2).

AREA	ITEM TO VERIFY	OK?
Permits and authorisations	• *Permit for collection and transport of WEEE (Directive 2012/19/EU).* • *Permit for hazardous waste, where applicable (Directive 2008/98/EC).* • *Permit for healthcare / infectious waste, where applicable.* • *ADR certification for road transport of dangerous goods, where applicable.* • *Permits for any interim storage facility used.*	☐
Operations	• *Receptacle types and labelling compatible with the agreed streams.* • *Collection schedule (frequency, on-call availability).* • *Vehicle types and protective equipment.* • *GPS / chain-of-custody system.*	☐
Staff and training	• *Staff training records for handling health-related equipment.* • *PPE policy and provision.* • *Incident reporting procedure.*	☐
Documentation	• *Consignment notes per shipment.* • *Weighbridge tickets, where applicable.* • *Documentation retention period.* • *Data protection procedures for any residual data.*	☐
Compliance	• *Insurance (operations, transport, treatment).* • *Audit rights for the healthcare facility.* • *Annual review of permits.*	☐

Annex 14 References and Further Reading

EU legislation

- Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE)
- Directive 2008/98/EC on Waste (Waste Framework Directive)
- Regulation (EU) 2017/745 on Medical Devices (EU MDR)
- Regulation (EU) 2016/679 on the Protection of Personal Data (GDPR)
- Regulation (EU) 2023/1542 on Batteries and Waste Batteries
- Implementing Regulation (EU) 2020/1207 on common specifications for the reprocessing of single-use devices

Standards

- CENELEC EN 50625 series — Collection, logistics and treatment requirements for WEEE.
- EN 14885 — Chemical disinfectants and antiseptics: Application of European Standards for chemical disinfectants and antiseptics.
- ISO 13485 — Medical devices: Quality management systems.

WHO and international guidance

- WHO — Safe Management of Wastes from Health-Care Activities

Position papers and sector guidance

- HCWH Europe — Position Paper on Healthcare Waste (2020-11_HCWH-Europe-position-paper-waste).
- REMONDIS Entsorgung — Abfallart medizinische Abfälle (sector guidance on medical waste).
- Healthcare Waste — Circular Online
- WEEE Forum — weee-brochure.pdf (sector overview).

Green public procurement (GPP) and circular procurement

- European Commission — EU GPP Healthcare EEE criteria (CIRCABC)
- JRC — Assessment of GPP criteria for healthcare EEE
- Vergabebrief — GPP criteria for healthcare EEE (DE)
- EPA Ireland — GPP criteria for ICT (2024)

PRO mapping and directories

- LIFE4EPR — Mapping of existing EPR and PROs across the EU
- WEEE Directory
- WEEELABEX — Operators list

Waste hierarchy

- European Commission — Waste prevention and management

Academic and project sources cited

- **Singh, N. et al. (2020). Studies on healthcare waste management.**
- **UNEP (2020). Healthcare waste in the context of COVID-19.**
- **DiCE Deliverable D6.2 Report — Authorisation Map for SUD reprocessing.**

Annex 15 Quick reference card for operators

Target audience: every operator handling digital health devices.
Use: print at A4, laminate, display at every collection point alongside Annex 4 and Annex 7.
Format: one page; "if you see X, do Y".

IF YOU SEE…	DO THIS	WHO TO CALL
A clean, intact device in working order	*Stream 1 (REUSE) — green container. Apply REUSE label.*	*Biomedical service*
A faulty but undamaged device	*Stream 2 (REPAIR) — yellow container. Apply REPAIR label.*	*Biomedical service*
A clean, end-of-life device	*Stream 3 (WEEE) — blue container. Remove battery only if authorised.*	*Waste management lead*
Visible blood, fluids, or contamination	*Stream 4 (MEDICAL WASTE) — red container. PPE on. Leak-proof packaging.*	*Infection-control officer*
Swollen, leaking, hot, or hissing battery	*Stream 5 (BATTERY / HIGH-RISK) — black container. Do not crush. Move to a non-combustible container.*	*Waste management lead + safety officer*
Smoke, flame, or strong smell from a battery	*EVACUATE if not controllable. Dry powder or class-D extinguisher only. NO water.*	*Fire brigade. Then: safety officer*
A sharps injury (needle-stick, cut)	*Wash 5 minutes. Cover. Report within 1 hour.*	*Occupational health*
A biological spill	*Cordon. PPE. Absorbent + disinfectant per protocol.*	*Infection-control officer*
A device with patient identification still attached	*Remove identifier immediately. Document.*	*Data protection officer*
A device that was supposed to be in the system but is missing	*Stop and report. Treat as suspected data breach.*	*Data protection officer*
Damaged container or missing label	*Replace before resuming. Report.*	*Waste management lead*
You are unsure	*Apply the precautionary principle: treat as MEDICAL WASTE.*	*Waste management lead*

ADAPT BEFORE USE: Each facility must add the actual phone numbers / extensions for each "WHO TO CALL" before posting this card.

Sources and basis

The quick reference card consolidates actions described in Sections 8 (sorting), 9 (handling), 9.5 (emergencies) and 12 (transport). The "if you see / do this / who to call" format is general good-practice in operational signage and is not drawn from a single source. Specific items derive from:

- Sorting streams 1–5: derived from WHO, Safe Management of Wastes from Health-Care Activities (2014); Directive 2012/19/EU on WEEE; Section 8.2.1 of this manual.
- Lithium battery emergency response: see references for Section 9.5.1.
- Sharps injury and biological-spill response: see references for Section 9.5.2 and 9.5.3.

Data-protection responses: Regulation (EU) 2016/679 (GDPR), Articles 33 and 34.

Annex 16 Country information template

This manual repeatedly states "verify national legislation". This template gathers all the country-specific information a facility needs in one place. Each healthcare facility should fill in this annex once and review it annually.

TOPIC	INFORMATION FOR OUR COUNTRY / FACILITY
Country	_ _
Competent national authority for waste	_ _
Competent national authority for medical devices	_ _
Competent national authority for data protection (GDPR)	_ _
National WEEE register / clearing house	_ _
Authorised PROs covering medical and digital health devices	_ _
Is reprocessing of single-use devices (SUDs) permitted nationally? (MDR Art. 17)	*YES / NO. Reference:* _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _
Is disinfection of healthcare waste recognised as an alternative to incineration?	*YES / NO. Reference:* _
Maximum on-site storage duration for healthcare WEEE	_ _ _ _ _ _ _ _ *days. Reference:* _ _ _ _ _ _ _ _ _ _ _ _ _ _ _
Maximum on-site storage volume	_ _ _ _ _ _ _ _ *days. Reference:* _ _ _ _ _ _ _ _ _ _ _ _ _ _ _
National waste codes applicable to digital health devices	_ _
Notification procedure for cross-border WEEE shipments	_ _
Local fire brigade emergency number	_ _
Occupational health service contact	_ _
Internal contacts: waste management lead	*Name:* _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ *Tel:* _ _ _ _ _ _ _ _ _ _ _ _ _

Internal contacts: infection-control officer	*Name: _ _ _ _ _ _ _ _ _ _ _ _ _ _ Tel: _ _ _ _ _ _ _ _ _ _ _ _ _ _*
Internal contacts: data protection officer (DPO)	*Name: _ _ _ _ _ _ _ _ _ _ _ _ _ _ Tel: _ _ _ _ _ _ _ _ _ _ _ _ _ _*
Internal contacts: facility safety officer	*Name: _ _ _ _ _ _ _ _ _ _ _ _ _ _ Tel: _ _ _ _ _ _ _ _ _ _ _ _ _ _*
Contracted PRO	*Name: _ _ _ _ _ _ _ _ _ _ _ _ _ _ Tel: _ _ _ _ _ _ _ _ _ _ _ _ _ _*
Contracted logistics provider	*Name: _ _ _ _ _ _ _ _ _ _ _ _ _ _ Tel: _ _ _ _ _ _ _ _ _ _ _ _ _ _*
Contracted treatment / recycling facility	*Name: _ _ _ _ _ _ _ _ _ _ _ _ _ _ Tel: _ _ _ _ _ _ _ _ _ _ _ _ _ _*
Contracted refurbishment partner	*Name: _ _ _ _ _ _ _ _ _ _ _ _ _ _ Tel: _ _ _ _ _ _ _ _ _ _ _ _ _ _*
Last review of this annex	*Date: _ _ _ _ _ _ _ _ _ _ _ _ _ _ By: _ _ _ _ _ _ _ _ _ _ _ _ _ _*

Sources and basis

Items in this template correspond to information requirements arising from EU legislation that is implemented at national level. Authoritative sources:

- National WEEE register / clearing house: Directive 2012/19/EU on WEEE, Article 16 (registration and reporting); European WEEE Registers Network (EWRN) for cross-country information.
- Authorised PROs: Article 12 of Directive 2008/98/EC and national EPR legislation.
- SUD reprocessing authorisation: Regulation (EU) 2017/745 (EU MDR), Article 17. National implementation varies; the DiCE D6.2 deliverable maps the situation across Member States.
- Storage limits: national waste legislation; verify with the national waste authority.
- European Waste Codes: Commission Decision 2014/955/EU establishing the list of waste pursuant to Directive 2008/98/EC.
- Cross-border notification procedure: Regulation (EC) No 1013/2006; from 21 May 2026, Regulation (EU) 2024/1157.

Annex 17 Glossary of commonly confused terms

Operational mistakes often start with a confusion of terms. This glossary clarifies the most frequently confused pairs in the digital health waste context.

TERM	MEANING

Cleaning	*Removal of visible dirt and organic matter, typically with water and detergent. Does NOT kill micro-organisms. Always done before disinfection or sterilisation.*
Disinfection	*Reduction of micro-organisms on a surface or device to a level considered safe for the next user. Performed with chemical agents (per EN 14885) or physical means. Does NOT necessarily eliminate spores.*
Decontamination	*Umbrella term covering cleaning + disinfection (and sometimes sterilisation). Used to make a device safe to handle.*
Sterilisation	*Total elimination of all forms of microbial life, including spores. Required for invasive devices. Not all digital health devices can be sterilised.*
Reuse	*Use of a device again for the same or similar purpose without major intervention.*
Refurbishment	*Restoration of a device to its original aesthetic and functional characteristics, without changing its intended use.*
Reprocessing (MDR)	*Per Regulation (EU) 2017/745 Art. 2(39): a regulated process on a used device for safe reuse, including cleaning, disinfection, sterilisation, and testing. Strict regime applies to single-use devices (Art. 17).*
Recycling	*Recovery of materials from end-of-life devices for use in new products.*
Recovery	*Broader term covering all useful processing of waste, including recycling, energy recovery, and other valorisation.*
WEEE	*Waste Electrical and Electronic Equipment under Directive 2012/19/EU. Most digital health devices fall here UNLESS they are expected to be infective at end of life or are active implantable medical devices (those are exempted by Article 2(4)(g)).*
Medical waste	*Waste arising from healthcare activities. Includes infectious, sharps, chemical, hazardous and non-hazardous fractions per WHO guidance. A digital health device that is contaminated becomes medical waste, NOT WEEE.*
Infectious waste	*Subset of medical waste likely to transmit disease. Treated by incineration or, where allowed, disinfection.*
PRO	*Producer Responsibility Organisation: a legal entity that takes on EPR obligations on behalf of producers under WEEE legislation.*
EPR	*Extended Producer Responsibility: the principle that producers are responsible for the end-of-life management of their products.*
OEM	*Original Equipment Manufacturer.*
UDI	*Unique Device Identifier under the EU MDR. Used to track a medical device throughout its life.*

EUDAMED	*European database on medical devices managed by the European Commission.*
Data wipe (logical)	*Software-based erasure of data, with audit trail. Allows the device to be reused.*
Data destruction (physical)	*Physical destruction of memory components (shredding). Required when reuse is not possible.*

Sources and basis

Definitions are taken from the following authoritative sources:

- **Reprocessing, single-use device, refurbishment:** Regulation (EU) 2017/745 (EU MDR), Article 2 (definitions) and Article 17 (reprocessing of single-use devices).
- **WEEE, recycling, recovery, preparing for re-use:** Directive 2008/98/EC on waste, Article 3 (definitions); Directive 2012/19/EU on WEEE, Article 3.
- **Cleaning, disinfection, sterilisation:** WHO, Safe Management of Wastes from Health-Care Activities (2014); EN 14885 (chemical disinfectants and antiseptics); EN ISO 17665 (sterilisation of healthcare products).
- **Decontamination:** WHO Laboratory Biosafety Manual (4th ed., 2020).
- **Infectious / medical waste:** WHO, Safe Management of Wastes from Health-Care Activities (2014).
- **PRO, EPR:** Directive 2008/98/EC, Article 8 and 8a; Directive 2012/19/EU, Article 12.
- **UDI, EUDAMED:** Regulation (EU) 2017/745 (EU MDR), Articles 27, 28, 29 (UDI) and Articles 33–34 (EUDAMED).
- **Logical data wipe / physical data destruction:** NIST Special Publication 800-88 Rev. 1 (Guidelines for Media Sanitization); ISO/IEC 27040 (Storage Security).

Annex 18 Self-audit checklist for healthcare centres

Use this checklist annually, ideally before the management review. Each item is rated YES / PARTIAL / NO with a short comment. Items rated PARTIAL or NO must trigger a corrective action plan.

Governance and procedures

ITEM	YES / PARTIAL / NO	COMMENT / CORRECTIVE ACTION

A waste management lead is appointed and known to all relevant staff.	_____	_____
An infection-control officer is appointed and consulted on classification rules.	_____	_____
A data protection officer is consulted on data destruction rules.	_____	_____
Internal procedures for digital health devices are documented and accessible.	_____	_____
Annex 16 (country information template) is completed and up to date.	_____	_____

External partners

ITEM	YES / PARTIAL / NO	COMMENT / CORRECTIVE ACTION
A PRO is contracted; permits verified within the last 12 months.	_____	_____
A logistics provider is contracted; permits verified within the last 12 months.	_____	_____
A treatment / recycling facility is contracted or covered by the PRO; permits and EN 50625 verified within the last 12 months.	_____	_____
A refurbishment partner is identified where applicable.	_____	_____
KPIs and reporting deliverables are defined in each contract.	_____	_____

Collection and sorting

ITEM	YES / PARTIAL / NO	COMMENT / CORRECTIVE ACTION
Every department generating digital health devices has at least one collection point.	_____	_____
Every collection point has the five labelled containers (Streams 1–5) where applicable.	_____	_____
The sorting decision tree (Annex 4) is displayed at every collection point.	_____	_____
The quick reference card (Annex 15) is displayed at every collection point.	_____	_____
Containers are emptied on schedule.	_____	_____

Handling and storage

ITEM	YES / PARTIAL / NO	COMMENT / CORRECTIVE ACTION
PPE is available and replaced per the maintenance plan.	_____	_____
A risk assessment is in place for handling and storage activities.	_____	_____
A storage area dedicated to digital health devices is in use.	_____	_____
Fire-safety equipment is available, including for battery fires.	_____	_____
Storage volume and duration limits are respected.	_____	_____

Data and traceability

ITEM	YES / PARTIAL / NO	COMMENT / CORRECTIVE ACTION

A Data Destruction Certificate is issued for every device leaving the facility.	_____	_____
A collection log is kept (Annex 19).	_____	_____
An incident log is kept (Annex 20).	_____	_____
Consignment notes are countersigned and archived.	_____	_____

Training

ITEM	YES / PARTIAL / NO	COMMENT / CORRECTIVE ACTION
Initial training is delivered to new staff within one month of hire.	_____	_____
Refresher training is delivered annually.	_____	_____
Training records are maintained.	_____	_____
Targeted training is delivered after every notable incident.	_____	_____

Sources and basis

The self-audit checklist is structured around the obligations set out in the main body of this manual. The structure follows recognised audit-checklist principles aligned with:

- ISO 19011:2018 — Guidelines for auditing management systems.
- ISO 14001:2015 — Environmental management systems (clause 9, performance evaluation).
- ISO 45001:2018 — Occupational health and safety management systems (clause 9, performance evaluation).

Each item is tied to a specific section of this manual; no single external citation applies.

Annex 19 Landscape report template

Every incident (sharps injury, biological exposure, battery event, data event, near-miss) is documented within 24 hours. The incident report supports the data protection officer in any GDPR notification, the safety officer in occupational health, and the waste management lead in trend analysis.

FIELD	INFORMATION
Incident reference number	_ _
Date and time of incident	_ _
Location (department / room)	_ _
Reported by (name and role)	_ _
Type of incident (tick one or more)	☐ *Sharps injury* ☐ *Biological spill* ☐ *Battery event* ☐ *Data breach* ☐ *Near-miss* ☐ *Other*
Persons involved	_ _
Devices involved (UDI if available)	_ _
Description of what happened (what / when / how)	_ _
Immediate action taken	_ _
PPE used	_ _
External notifications made	☐ *Occupation health* ☐ *Infection-control officer* ☐ *DPO event* ☐ *Fire brigade* ☐ *National authority*
Root cause (where known)	_ _

Corrective and preventive actions	_ _
Status	☐ *Open* ☐ *Pending review* ☐ *Closed*
Closed by (name, date, signature)	_ _

Sources and basis

The data fields in this template reflect the information requirements arising from:

- **Sharps and biological exposures:** Council Directive 2010/32/EU on the prevention of sharps injuries; WHO, Safe Management of Wastes from Health-Care Activities (2014), chapter 7.
- **Personal data breach reporting:** Regulation (EU) 2016/679 (GDPR), Article 33(3) — minimum content of a breach notification.
- **Occupational health and safety incident reporting:** Council Directive 89/391/EEC (Framework Directive on occupational safety and health); ISO 45001:2018, clause 10.2 (incident, nonconformity and corrective action).
- **Battery incidents:** Regulation (EU) 2023/1542 on batteries; EERA Lithium Guidance.

Annex 20 Frequently asked questions for operators

Practical answers to questions operators ask most often during training and the first months of operation.

QUESTION	ANSWER
I am not sure if a device is contaminated. What do I do?	*Apply the precautionary principle: treat it as medical waste (Stream 4). It is always safer to over-classify than to under-classify.*
A patient gave me their personal device to throw away. Can I just put it in the WEEE bin?	*Not directly. Personal devices may contain personal health data and the patient is normally responsible for disposing of their own devices. Politely explain the household route (Annex 10). If the device is contaminated, follow Section 13.3.*
Can I take a device home for personal use?	*No. Even devices that are functional must follow the documented reuse pathway (Section 7.1) so that data is wiped, safety is verified, and the device is traceable.*
I dropped a device. Should I still send it to reuse?	*No. After a drop, the device is no longer eligible for the reuse stream. Inspect it: if undamaged, route to repair (Stream 2); if damaged or with a battery issue, route per Section 9.4.*
A battery is slightly warm. Is that an emergency?	*Slight warmth from recent use is normal. Hot to the touch, hissing, swelling, deformation or smell are NOT normal — apply Section 9.5.1.*
A device is locked with a password. Should I just smash it?	*No. Apply the certified data wipe / destruction procedure (Section 9.3). Never improvise — improvised destruction does not satisfy GDPR.*
The container is full and the logistics pickup is in three days. What do I do?	*Inform the waste management lead immediately. Do not overfill the container. Do not store devices on the floor. An on-call pickup may be required (Section 5.9 cost note).*
I forgot to put the label on a device. Can I label it later?	*Label as soon as you remember, before the device leaves the collection point. Without a label, the device cannot be tracked through the chain.*
What if the receiving facility refuses a shipment?	*Stop the shipment from leaving. Notify the waste management lead. The most common reasons are missing documentation or wrong classification — both are correctable.*
I see a colleague putting devices in the wrong stream. What do I do?	*Politely correct in the moment if you can; otherwise, report to the waste management lead. Mistakes are training opportunities, not blame events.*

Sources and basis

The FAQ consolidates questions commonly raised by operators in training settings. The answers point back to specific sections of this manual; no single external citation applies. The underlying authoritative basis for each answer is:

- **Precautionary classification when contamination is uncertain:** WHO, Safe Management of Wastes from Health-Care Activities (2014); Section 8.1 of this manual.
- **Personal devices and patient responsibility:** Regulation (EU) 2016/679 (GDPR); Section 11 of this manual.
- **Reuse traceability and data wipe:** Regulation (EU) 2017/745 (EU MDR), Article 27 (UDI); GDPR; Section 7.3 of this manual.
- **Battery thermal-runaway warning signs:** EERA Lithium Guidance; Section 9.5.1 of this manual.
- **Improvised data destruction does not satisfy GDPR:** Regulation (EU) 2016/679 (GDPR); NIST SP 800-88 Rev. 1.
- **Container handling and labelling:** Section 8 and 12 of this manual; Directive 2008/98/EC, Article 35.

Further references

The following sources support the operational guidance, emergency procedures, cross-border movements, and selected annexes throughout this manual.

EU legislation (additional)

- Regulation (EC) No 1013/2006 on shipments of waste, consolidated version: https://eur-lex.europa.eu/eli/reg/2006/1013/oj
- Regulation (EU) 2024/1157 on shipments of waste (replacing Regulation (EC) 1013/2006 from 21 May 2026): https://eur-lex.europa.eu/eli/reg/2024/1157/oj
- Council Directive 2010/32/EU on the prevention of sharps injuries in the hospital and healthcare sector: https://eur-lex.europa.eu/eli/dir/2010/32/oj
- Council Directive 89/391/EEC (Framework Directive on occupational safety and health): https://eur-lex.europa.eu/eli/dir/1989/391/oj
- Commission Decision 2014/955/EU on the list of waste (European Waste Codes): https://eur-lex.europa.eu/eli/dec/2014/955/oj

International conventions

- Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (1989, as amended): https://www.basel.int/

GDPR breach-notification guidance

- EDPB, Guidelines 9/2022 on personal data breach notification under GDPR (Version 2.0, 2023): https://www.edpb.europa.eu/system/files/2023-04/edpb_guidelines_202209_personal_data_breach_notification_v2.0_en.pdf

WHO healthcare waste guidance (in addition to the document already referenced in the main list)

- HO Guidelines on Post-Exposure Prophylaxis (PEP) to Prevent HIV Infection (2014).
- WHO Laboratory Biosafety Manual, 4th edition (2020): https://www.who.int/publications/i/item/9789240011311

Lithium battery safety

- European Electronics Recyclers Association (EERA): Lithium Guidance / Industry Guide on safe handling of WEEE containing lithium batteries: https://www.eera-recyclers.com/industry-guide
- Battery University, BU-304a: Safety Concerns with Li-ion: https://batteryuniversity.com/article/bu-304a-safety-concerns-with-li-ion
- NFPA 484 — Standard for Combustible Metals (National Fire Protection Association).

Management-system standards

- ISO 14001:2015 — Environmental management systems.
- ISO 45001:2018 — Occupational health and safety management systems.
- ISO 19011:2018 — Guidelines for auditing management systems.
- ISO/IEC 27040 — Storage security (data destruction).
- EN ISO 17665 — Sterilisation of healthcare products (moist heat).

Data sanitisation

- NIST Special Publication 800-88 Revision 1: Guidelines for Media Sanitization (December 2014): https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-88r1.pdf

Extended Producer Responsibility (cost-structure context)

- OECD (2016), Extended Producer Responsibility: Updated Guidance for Efficient Waste Management: https://www.oecd.org/en/publications/extended-producer-responsibility_9789264256385-en.html

Note on operational good practice

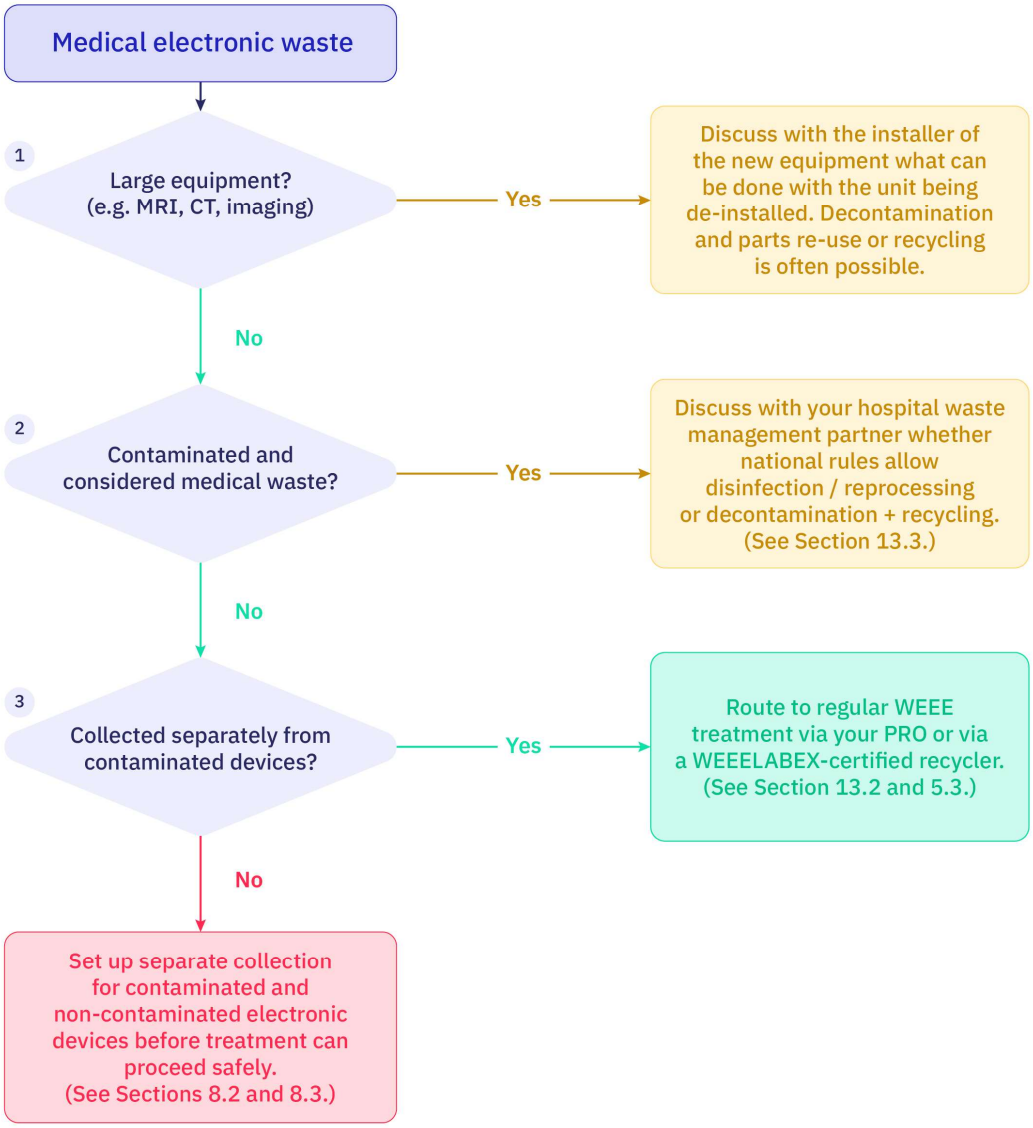
Some content in this manual, Annexes 15, 18, 21 and 22 reflects general operational good practice rather than a single canonical source. Each of those sections includes an explicit "Sources and basis" note explaining the underlying obligations and the documents on which the practice rests.

NOTE: The WEEE Directive is currently under review. Verify the version in force at the time of use. The categories referenced (Cat. 4 —large equipment; Cat. 5 — small equipment) and the 50 cm threshold reflect the directive in force at the time of writing.

Annex 21 Decision Tree: Treatment Pathway Selection

Apply this decision tree at the moment medical electronic waste arrives at the treatment-pathway selection point. It complements Annex 4 (sorting at the source) by guiding the next step: which treatment chain the waste should enter. The first YES answer determines the routing. This tree is referenced from Section 13.1 (Pathway selection: WEEE vs. medical waste).

Decision Tree - Treatment Pathway Selection



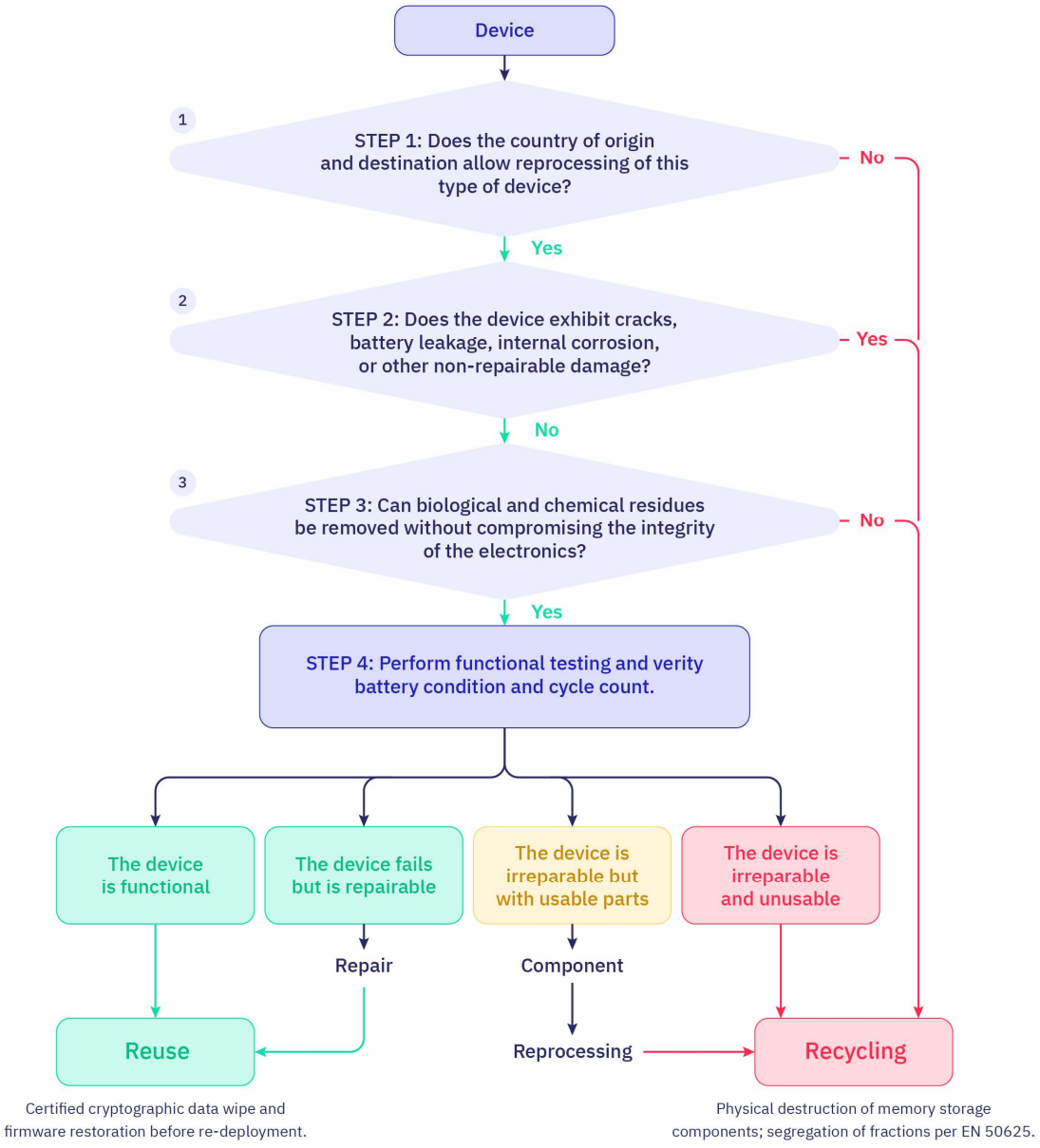
How to use this tree:
Apply at the point where a digital health device or large medical equipment item is identified for end-of-life treatment. The first YES answer determines the routing.

Country-specific:
Disinfection / reprocessing of medical waste is not allowed in every Member State. Verify with your national waste authority.

Annex 22 Decision Tree: Reprocessing Workflow

Steps 1–3 verify that reprocessing is legally permitted and physically feasible; Step 4 sorts devices into four condition categories that route to REUSE, REPAIR, COMPONENT RECOVERY (then REPROCESSING), or RECYCLING. Reprocessing of single-use devices (SUDs) is regulated by Article 17 of Regulation (EU) 2017/745 (EU MDR) and is not permitted in every Member State (see Section 14.2). This tree is referenced from Section 14.3 (Reprocessing workflow).

Decision Tree - Reprocessing Workflow



How to use this three:
Apply only after Annex 2 has identified the device as a candidate for reprocessing. Each step must be passed before the next is reached. A NO at Step 1 or 3, or a YES at Step 2, sends the device directly to recycling.

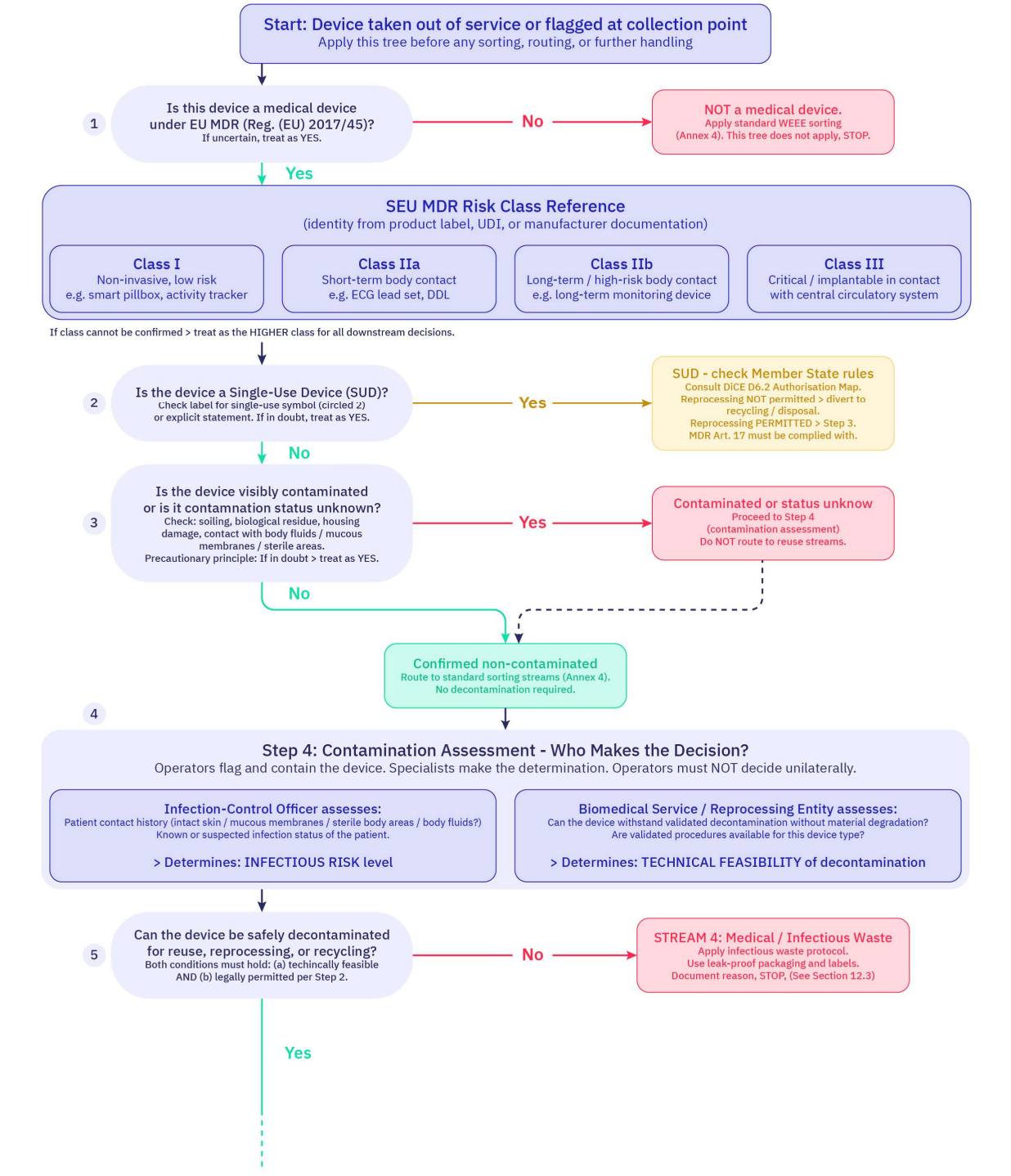
Compliance:
Reprocessing of single-use devices (SUDs) is regulated by Regulation (EU) 2017/745 (EU MDR) Article 17 and is not permitted in every Member State.

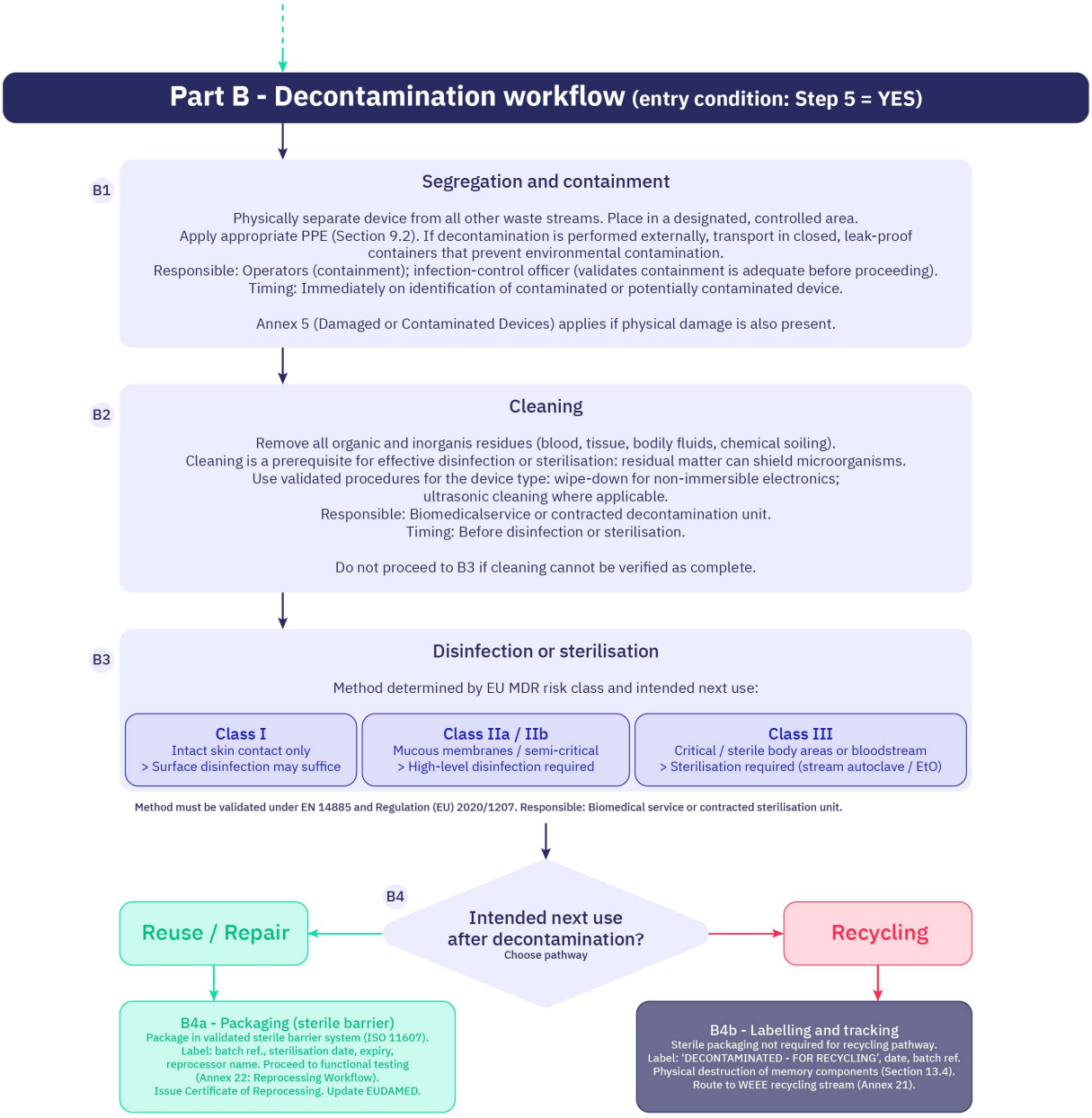
Annex 23 Decision Tree: Contamination Assessment and Decontamination Pathway

Apply this decision tree whenever a digital health device is identified as potentially contaminated, infected, or of unknown contamination status, and before any sorting, routing, or decontamination begins. Part A (Steps 1–5) covers EU MDR classification, SUD legal verification, contamination assessment, and the determination of whether decontamination is feasible, the decision that rests with the infection-control officer and the biomedical service, not with the operator alone. Part B covers the four-step decontamination sequence (segregation, cleaning, disinfection/sterilisation, and packaging or labelling) and routes the device to reuse/reprocessing or recycling. This tree is referenced from Sections 7.1 and 8.2.2 of the manual.

Decision Tree - Contamination Assessment and Decontamination Pathway

Part A - Classification and contamination assessment





How to use this three:

Apply this tree whenever a digital health device is identified as potentially contaminated, infected, or of unknown contamination status. Part A (Steps 1-5) must be completed before any decontamination begins. Part B is entered only when Step 5 = YES.

Use alongside: Annex 4 (Sorting and Routing), Annex 5 (Damaged or Contaminated Devices), Annex 22 (Reprocessing Workflow). Referenced from: Sections 7.1 and 8.2.2 of the manual. Regulatory basis: EU MDR (EU) 2017/745; EN 14885; Reg. (EU) 2020/1207; WHO (2016).

References: EU MDR Regulation (EU) 2017/745; EN 14885; Regulation (EU) 2020/1207; WHO (2016) Decontamination and reprocessing of medical devices for health-care facilities (https://www.who.int/publications/i/item/9789241549851); Safe Management of Wastes from Health-Care Activities (WHO, 2013). See also: Annex 4 (Sorting and Routing), Annex 5 (Damaged or Contaminated Devices), Annex 22 (Reprocessing Workflow).