# Digital Health in the Circular Economy

## Terms and Definitions

**Version 1.0**

**TABLE 1 VERSION HISTORY**

| VER. NO. | DATE | REASONS FOR RELEASE | RESPONSIBLE |
|---|---|---|---|
| *0* | *19 March 2024* | *First draft of a consolidation of definitions of key terms for DiCE* | *Sonia Valdivia – WRFA*<br>*With inputs from Sonia Valdivia, Tamara Hoveling, Maria Anta and Adrien Specker* |
| *1* | *16 June 2025* | *Update based on emerging definitions and discussions held within WP meetings and on deliverables produced* | *Sonia Valdivia – WRFA*<br>*Maria Anta – WEEE Forum* |
| *2* | *15 August 2025* | *Update based on definitions updated in WP2 and after prioritizing those to be made publicly available* | *Sonia Valdivia – WRFA*<br>*Maria Anta – WEEE Forum* |
| *3* | *13 October 2025* | *Finalization based on feedback received from DiCE Consortium members* | *Sonia Valdivia – WRFA*<br>*Maria Anta – WEEE Forum* |

# NOTICE



# TERMS & DEFINITIONS

***Notes to the reader.*** The terms listed in Table 1 have been identified as relevant ones for the purpose of DiCE. The main sources include authoritative ones such EU Directives and Medical Device Regulation. In addition, internationally accepted sources such as from UNEP, International Resource Panel, International Atomic Energy Agency and ISO. Finally, when no definitions are found or no appropriate versions for the context of DiCE exist, project definitions are included (such as those developed for DiCE deliverables).

***TABLE 1 – Glossary of words used in DiCE project***

| TERM | DEFINITION | SOURCE |
|---|---|---|
| A | | |
| Active (medical) device | Any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices. Software shall also be deemed to be an active device.<br>**Note 1 to entry**: this term is synonym of Digital medical device for the purposes of the DiCE project. | Regulation (EU) 2017/745 on medical devices (MDR) |
| Active implantable medical device | Any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure. | Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) |
| B | | |
| Best circular practices | Selected examples of circular digital health devices in the current market based on criteria of practicality, acceptability and affordability. | Hoveling T. et al. (2024) Barriers and opportunities to circularizing digital health devices and an inventory of best practices |
| C | | |

| | | |
|---|---|---|
| Circular flow of resources | Systematic cycling of the provision and use of resources within multiple technical or biological cycles.<br>**Note 1 to entry**: The biological and technical cycles represent loops into the complex system of resource flows in the economy. | ISO 59004: 2024 (en) 3.1.6 Circular economy — Vocabulary, principles and guidance for implementation |
| Circular health flows strategies (CHFs) | Strategies outlining specific steps for the efficient collection, processing, and safe reintegration of materials, medical products within the healthcare system with the aim of minimizing waste and maximizing resource value.<br>Examples include: refuse, replace, rethink, reduce, maintain, repair, reuse, refurbish, remanufacture, repurpose, recycle, renew, and recover energy — adapted to the specific requirements and safety standards of the healthcare sector. | DiCE – Working Group 2 (2025) |
| Circular recovery hierarchy | Structured sequence of prioritized circular health flows strategies (CHFs) for guiding decision-making while minimizing environmental impacts. | Hoveling T. et al. (2024) Barriers and opportunities to circularizing digital health devices and an inventory of best practices |
| Cleaning | Removal of contaminants to the extent necessary for further processing or for intended use. | ISO 11139:2018(en), 3.46 Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards — Terms and definitions |
| Clinical benefit | The positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health. | Regulation (EU) 2017/745 on medical devices (MDR) |
| Collection | The gathering of waste, including the preliminary sorting and preliminary storage of waste for the purposes of transport to a waste treatment facility. | Directive 2008/98/EC on waste |

## D

| | | |
|---|---|---|
| Decontamination | Process of removing or neutralizing contaminants such as microorganisms from surfaces or devices to prevent infection spread.<br>Examples include (pre-)cleaning, disinfection, and sterilization based on the intended medical application of the device. | Hoveling T. et al. (2024) Barriers and opportunities to circularizing digital health devices and an inventory of best practices |
| Depollution | Selective treatment during which certain substances, mixtures or components that are potentially harmful are safely removed.<br>**Note 1 to entry:** Examples of removed elements include pollutants and declared hazardous substances.<br>**Note 2 to entry:** Depollution does not include the cleaning of food. | ISO 59014:2024 (en) 3.5 Environmental management and circular economy — Sustainability and traceability of the recovery of secondary materials — Principles, requirements and guidance — Terms and definitions |
| Digital health device | Physical device used for health applications that contains electronics and operates on a source of energy other than that generated by the human body. Digital health devices that classify as medical devices according to the definition of the EU MDR (2017) can also be defined as active devices. | DiCE – Working Group 6 (2025) |
| Disassembly | Process whereby a product is taken apart in such a way that it could subsequently be reassembled and made operational. | IEC 62542:2013 Environmental standardization for electrical and electronic products and systems - Glossary of terms |
| Disinfection | Process to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose. | ISO 11139:2018(en) 3.301 Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards — |

| | | Terms and definitions |
|---|---|---|
| Disposal | Any operation which is not recovery even where the operation has as a secondary consequence the reclamation of substances or energy. | Directive 2008/98/EC on Waste |
| **E** | | |
| Ecodesign | The integration of environmental aspects into product design with the aim of improving the environmental performance of the product throughout its whole life cycle. | Regulation (EU) 2024/1781 establishing a framework for the setting of ecodesign requirements for sustainable products |
| Electrical and electronic equipment (EEE) | Equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1 000 volts for alternating current and 1 500 volts for direct current. | Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) |
| End of life (EoL) | The life cycle stage that begins when a product is discarded and ends when the waste material of the product is returned to nature or enters another product's life cycle. | Regulation (EU) 2024/1781 establishing a framework for the setting of ecodesign requirements for sustainable products |
| Energy recovery | Use of combustible waste as a means to generate energy through direct incineration with or without other waste but with recovery of the heat. | Directive 2009/125/EC on ecodesign requirements for energy-related products |
| **F** | | |
| Fancy plastics | Plastic materials that may be challenging to separate and recycle due to their unique composition or combination of different plastic types, additives, or coatings. | Hoveling T. et al. (2024) Barriers and opportunities to circularizing digital health devices and an |

| | | |
|---|---|---|
| | | inventory of best practices |
| **H** | | |
| Hazardous waste | Waste which displays one or more of the hazardous properties listed in Annex III, including 'infectious', which refers to substances and preparations containing viable micro-organisms or their toxins which are known or reliably believed to cause disease in man or other living organisms. | Directive 2008/98/EC on Waste |
| Health device | Product or technology used in and/or within the healthcare sector for health applications with a varying degree of regulation such as medical devices for which the Medical Device Regulation (MDR, 2017) apply. | DiCE – Working Group 2 (2025) |
| **I** | | |
| Infectious waste | Waste that is capable of causing or spreading disease in man or other living organisms as it is containing or suspected to contain viable microorganisms or their toxins, or human pathogenic microbiological agents. | Combined definition from ISO 28901:2011 Soil quality — Guidance for burial of animal carcasses to prevent epidemics, ISO 12891-1:2015 Retrieval and analysis of surgical implants — Part 1: Retrieval and handling, and ISO 24161:2022 Waste collection and transportation management — Vocabulary |
| Invasive device | Any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body. | Regulation (EU) 2017/745 on medical devices (MDR) |
| In vitro diagnostic medical device | Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro | Regulation (EU) 2017/746 on in |

| | | |
|---|---|---|
| | for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:<br>(a) concerning a physiological or pathological process or state;<br>(b) concerning congenital physical or mental impairments;<br>(c) concerning the predisposition to a medical condition or a disease;<br>(d) to determine the safety and compatibility with potential recipients;<br>(e) to predict treatment response or reactions;<br>(f) to define or monitoring therapeutic measures.<br>Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices; | vitro diagnostic medical devices |
| **M** | | |
| Maintain | Preserving the quality, function, and safety of medical products and clinical environments to ensure reliable performance, extend their lifespan, and reduce the risks of malfunctions that could lead to potential treatment failures. | DiCE – Working Group 2 (2025) |
| Manufacturer | A natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark. | Regulation (EU) 2017/745 on medical devices (MDR) |
| MDR criticality classification | A risk-based system that uses a set of criteria to determine classification of medical devices. It involves considering factors such as the intended use of the device, physical characteristics, part of the body affected by the use of the device, duration of contact with the human body, degree of invasiveness, potential toxicity, and if the device depends on a source of energy. Devices are divided into the following four classes I, IIa, IIb and III, with Class III devices having the highest level of risk and regulatory requirements. | Regulation (EU) 2017/745 on medical devices (MDR) |
| Medical device | Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:<br>— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,<br>— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,<br>— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, | Regulation (EU) 2017/745 on medical devices (MDR) |

| | | |
|---|---|---|
| | — providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,<br><br>and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.<br><br>The following products shall also be deemed to be medical devices:<br><br>— devices for the control or support of conception;<br><br>— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point. | |
| Medical incineration | Burning of wastes generated by healthcare facilities, including hospitals, veterinary clinics, and research facilities, for the purpose of disposal. | Emission factor documentation for AP-42 Section 2.6 Medical waste incineration |
| Medical waste | Waste generated by health care activities, ranging from used needles and syringes to soiled dressings, body parts, diagnostic samples, blood, chemicals, pharmaceuticals, medical devices and radioactive materials. | World Health Organization (WHO), Medical waste |
| Medication adherence | The extent to which a person's behaviour, taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a healthcare provider. | World Health Organization (WHO) (2023). Adherence to long-term therapies. Evidence for action |
| Medicinal product | (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or<br><br>(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. | Directive 2001/83/EC on the community code relating to medicinal products for human use |
| **N** | | |
| Nudge | Any aspect of the choice architecture that alters people's behaviour in a predictable way without forbidding any options or significantly changing their economic incentives. | Thaler, R. H., & Sunstein, C. R. (2009). Nudge: Improving decisions about |

| | | |
|---|---|---|
| | | health, wealth, and happiness. Penguin Books. |
| **P** | | |
| Preparing for re-use | Checking, cleaning or repairing recovery operations, by which products or components of products that have become waste are prepared so that they can be re-used without any other pre-processing. | Directive 2008/98/EC on Waste |
| **R** | | |
| Recovery | Any operation the principal result of which is waste serving a useful purpose by replacing other materials which would otherwise have been used to fulfil a particular function, or waste being prepared to fulfil that function. | Directive 2008/98/EC on Waste |
| Recycling | Any recovery operation by which waste materials are reprocessed into products, materials or substances whether for the original or other purposes. | Directive 2008/98/EC on Waste |
| Reduce | Increasing efficiency in healthcare delivery and medical product manufacturing by minimising energy use, resources use and waste generation at the source, avoiding unnecessary production or consumption, limiting hazardous substances, and carefully minimising (unnecessary) procedures to meet healthcare needs. | DiCE – Working Group 2 (2025) |
| Refurbishment | Actions carried out to prepare, clean, test, service and, where necessary, repair a product or a discarded product in order to restore its performance or functionality within the intended use and range of performance originally conceived at the design stage at the time of the placing of the product on the market. | Regulation (EU) 2024/1781 establishing a framework for the setting of ecodesign requirements for sustainable products |
| Refurbish / Recondition | Restore an item, during its expected service life, to a useful condition for the same purpose with at least similar quality and performance characteristics. | ISO 59004:2024(en) 3.5.18 Circular economy — Vocabulary, principles and guidance for implementation |

| | | |
|---|---|---|
| Refuse | The intentional act of rejecting the production, consumption, or use of a medical product, material, or procedure, particularly those that are unnecessary, unsustainable, or harmful. | DiCE – Working Group 2 (2025) |
| Remanufacturing | Actions through which a new product is produced from objects that are waste, products or components and through which at least one change is made that substantially affects the safety, performance, purpose or type of the product. | Regulation (EU) 2024/1781 establishing a framework for the setting of ecodesign requirements for sustainable products |
| Renew | Transforming waste materials, energy sources, and other substances into basic elements like carbon dioxide, water, biomass or human tissue (for regenerative medicine) through natural processes. | DiCE – Working Group 2 (2025) |
| Repair | One or more actions carried out to return a defective product or waste to a condition where it fulfils its intended purpose. | Regulation (EU) 2024/1781 establishing a framework for the setting of ecodesign requirements for sustainable products |
| Replace | Substituting a medical product or procedure with an alternative that serves the same purpose but significantly reduces environmental impact. | DiCE – Working Group 2 (2025) |
| Reprocessing | A process carried out on a used device in order 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. | Regulation (EU) 2017/745 on medical devices (MDR) |
| Reprocessor | (1) 'reprocessor' means the health institution and the external reprocessor reprocessing single-use devices;<br><br>(2) 'external reprocessor' means the entity reprocessing single-use devices at the request of a health institution;<br><br>(3) 'reprocessing cycle' means a cycle that includes all reprocessing steps applied to a single-use device to ensure that the safety and performance of the reprocessed device is equivalent to that of the original device. | Commission Implementing Regulation (EU) 2020/1207 laying down rules for the application of Regulation (EU) 2017/745 on medical devices (MDR) as regards common specifications for the reprocessing of single-use devices |

| | | |
|---|---|---|
| Repurpose | Adapt a product or its component parts for use in a different function than it was originally intended for, without making major modifications to its physical, chemical or mechanical structure. | ISO 59004:2024(en)3.5.22 Circular economy — Vocabulary, principles and guidance for implementation |
| Rethink | Design device use, function and its surrounding systems for intensifying the use of the device, resulting in less devices and materials needed. | Hoveling T. et al. (2024) Barriers and opportunities to circularizing digital health devices and an inventory of best practices |
| Reusable medical device<br><br>(synonym in the context of DiCE: multiple-use medical device) | Medical device designated or intended by the medical device manufacturer as suitable for processing and reuse.<br><br>**Note 1 to entry**: This is not a medical device that is designated or intended by the manufacturer for single use only.<br><br>**Note 2 to entry**: This term is synonym of Multiple-use medical device for the purposes of the DiCE project. | ISO 11139:2018, 3.23 Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards — Terms and definitions<br><br>Note 2 to entry was added by DiCE – Working Group 6 (2025) |
| Reuse | Any operation by which products or components that are not waste are used again for the same purpose for which they were conceived. | Directive 2008/98/EC on Waste |
| Reverse logistics | Activities engaged to recapture the value of products, parts, and materials once they have reached end-of-use or end-of-life. | United Nations Environment Programme & International Resource Panel (2018) Re-defining value: The manufacturing revolution - Remanufacturing, refurbishment, |

| | | |
|---|---|---|
| | | repair and direct reuse in the circular economy |
| **S** | | |
| Separate collection | The collection where a waste stream is kept separately by type and nature so as to facilitate a specific treatment. | Directive 2008/98/EC on Waste |
| Sharps | Objects or instruments necessary for the exercise of specific healthcare activities, which are able to cut, prick, cause injury and/or infection. | Council Directive 2010/32/EU implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector |
| Single-use medical device | Medical device labelled or intended to be used on one individual during a single procedure. | ISO 11139:2018, 3.255 Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards — Terms and definitions |
| Sterilisation | Validated process used to render product free from viable microorganisms.<br>**Note 1 to entry**: In a sterilization process, the nature of microbial inactivation is exponential and thus, the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero. | ISO 11139:2018, 3.39 Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards — Terms and definitions |
| **W** | | |

| | | |
|---|---|---|
| Waste | Resource that is no longer considered to be an asset as it, at the time, provides insufficient value to the holder.<br><br>**Note 1 to entry**: The holder can choose to retain, discard or transfer the waste.<br>**Note 2 to entry**: Value can be assigned to waste as a result of a need from another interested party, at which point the resource is no longer considered waste.<br>**Note 3 to entry**: The assignment of value to waste as a resource is linked, in part, to the available technology (e.g. landfill mining).<br>**Note 4 to entry**: Some regulations require the holder to dispose of certain types of waste, while others assign value to waste.<br>**Note 5 to entry**: Because resources include the energy content or energy potential of materials, such energy, when liberated during a process and not recovered for another use, can be considered a waste. | ISO 59014:2024 (en), 3.3.6 Environmental management and circular economy — Sustainability and traceability of the recovery of secondary materials — Principles, requirements and guidance — Terms and definitions |
| Waste electrical and electronic equipment | Waste electrical and electronic equipment' or 'WEEE' means electrical or electronic equipment which is waste within the meaning of Article 3(1) of Directive 2008/98/EC, including all components, sub-assemblies and consumables which are part of the product at the time of discarding.<br><br>Addition below from Directive 2008/98/EC to complement:<br><br>Electrical or electronic equipment which the holder discards or intends or is required to discard; including all components, subassemblies and consumables which are part of the product at the time of discarding. | Directive 2008/98/EC on waste and Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) |
| Waste hierarchy | Priority order in waste prevention and management legislation and policy: (a) prevention; (b) preparing for re-use; (c) recycling; (d) other recovery, e.g. energy recovery; and (e) disposal. | Directive 2008/98/EC on Waste |