Glossary of single-use devices and Reprocessing terms

Working definitions of terms for the "Study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market"

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In the context of the implementation of Regulation (EU) 2017/745 on medical devices, the European Commission (EC) via European Health and Digital Executive Agency (HaDEA) commissioned a **study on the implementation of Article 17 of Regulation (EU) 2017/745 on medical devices on the EU market** to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG), in collaboration with Areté, Agra CEAS Consulting (S&P Global) and Civic Consulting.

This glossary provides **working definitions for the study** and includes terms from Regulation (EU) 2017/745 on medical devices, Commission Implementing Regulation (EU) 2020/1207 of 19 August 2020 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards common specifications for the reprocessing of single-use devices and further sources.

It is important to mention that there is still a lack of understanding among some stakeholders in the EU of what the term "reprocessing" means. "Refurbishing" or "remanufacturing" are often used as synonyms, despite the fact that these terms have a different meaning than reprocessing (EC 2020a). Thus, this glossary aims to clarify the meaning of these terms and to enable a common understanding in the context of this study.

Terms are **listed alphabetically** in the glossary. Please note that **definitions may be subject to change during the study**. We appreciate any comments and suggestions for change, deletion, or addition. Please contact: medical.devices@goeg.at

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Glossary of terms related to single-use devices and reprocessing

Term	Definition	Source
Actor	Umbrella term for persons and entities which comprises authorities, market players and stakeholders.	WHO CC 2023
AIMDD	Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws relating to active implantable medical devices. This EU Directive was valid until 25 May 2021 and was replaced by the MDR.	AIMDD 1990
Authorised representative (AR)	Any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation [MDR].	MDR (EU) 2017/745
Authority responsible for notified bodies	Entity or separate constituent entities that, under national law, are responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including subcontractors and subsidiaries of those bodies.	MDR (EU) 2017/745
Authority/ Competent Authority	Government entity responsible for designing the regulatory framework and implementing policies (e.g., ministries, public agencies). In the European context, the term "competent authority" is frequently used.	WHO CC 2023
CE marking of conformity/ CE marking (CE)	A marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in the Regulation (EU) 2017/745 and other applicable Union harmonisation legislation providing for its affixing. *Note: The addition of a four-digit number indicates that a Notified Body was involved in the conformity assessment process.*	MDR (EU) 2017/745 Medical Devices Glossary 2022
Cleaning	Physical removal of soil and contaminants from an item to the extent necessary for further processing or for the intended use.	FDA 2015
Common Specifications (CS)	A set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system.	MDR (EU) 2017/745
Conformity assessment	The process demonstrating whether the requirements according to Regulation (EU) 2017/745 relating to a device have been fulfilled.	MDR (EU) 2017/745
Conformity assessment body	A body that performs third-party conformity assessment activities including calibration, testing, certification and inspection.	MDR (EU) 2017/745
Cross-infection	Cross infection refers to the transmission of a pathogenic organism from one person to another.	Gale 2020
Declaration of conformity (DoC)	A mandatory document that a manufacturer or an authorised representative need to sign to declare that the products comply with the EU requirements. By signing the DoC, the manufacturer or the authorised representative takes full responsibility for their product's compliance with the applicable EU law.	EC2022a
Decommissioning	Removal of medical devices from their originally intended uses in a health care facility to an alternative use or disposal.	WHO 2019
Decontamination	Removal of soil and pathogenic microorganisms from objects so they are safe to handle, subject to further processing, use or discard.	WHO & PAHO 2016
Device deficiency	Any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, use errors or inadequacy in information supplied by the manufacturer.	MDR (EU) 2017/745

Term	Definition	Source
Disinfection	A process that destroys pathogens and other microorganisms by physical or chemical means. Disinfection processes do not ensure the same margin of safety associated with sterilisation processes. The lethality of the disinfection process may vary, depending on the nature of the disinfectant.	FDA 2015
Economic operator (EO)	A manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3) MDR.	MDR (EU) 2017/745
End user	End users can be patients, consumers, or professional who directly use the medical device on patients/consumers.	WHO CC 2023
Endotoxin	Endotoxins form part (the lipopolysaccharide complex) of the outer membrane of the cell wall of Gram-negative bacteria. The toxin is released when the cell wall of the bacteria is destroyed.	Pharmaceutical Technology 2023
European Database on Medical Devices (EUDAMED)	EUDAMED is the electronic system established by Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnosis medical devices. With reference to the Articles of Regulation (EU) 2017/745, it includes: the electronic system for registration of devices referred to in Article 29(4); the UDI database referred to in Article 28; the electronic system on registration of economic operators referred to in Article 30; the electronic system on notified bodies and on certificates referred to in Article 57; the electronic system on clinical investigations referred to in Article 73; the electronic system on vigilance and post-market surveillance referred to in Article 92; the electronic system on market surveillance referred to in Article 100.	MDR (EU) 2017/745EC 2021
European Medical Device Nomenclature (EMDN)	The European Medical Device Nomenclature (EMDN) is a nomenclature for medical devices and in vitro diagnostic medical devices.	EC 2023a
External reprocessor	The entity reprocessing single-use devices at the request of a health institution.	EC 2020b
Fully refurbishing	Fully refurbishing, for the purposes of the definition of manufacturer, means the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device.	MDR (EU) 2017/745
Health care provider	An organisation or person who delivers appropriate health care in a systematic way professionally to any individual in need of health care services.	WHO CC 2023
Health institution	An organisation the primary purpose of which is the care or treatment of patients or the promotion of public health.	MDR (EU) 2017/745
Hospital Acquired Infection	Infections acquired in a hospital by a patient who was admitted for a reason other than that infection. Any infectious agent has the potential to be transmitted nosocomially, whether a bacterium, virus, fungus, parasite, or prion.	WHO 2002

Term	Definition	Source
Implantable device	Any device, including those that are partially or wholly absorbed, which is intended: » to be totally introduced into the human body, or » to replace an epithelial surface or the surface of the eye, by clinical intervention and which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device.	MDR (EU) 2017/745
Importer (IM)	Any natural or legal person established within the Union that places a device from a third country on the Union market.	MDR (EU) 2017/745MDCG 2021-27
Informed consent	A subject's free and voluntary expression of his or her willingness to participate in a particular clinical investigation, after having been informed of all aspects of the clinical investigation that are relevant to the subject's decision to participate or, in the case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical investigation.	MDR (EU) 2017/745
In-house reprocessing	Reprocessing done by the health institution (e.g.: hospital).	EC 2020a
Intended purpose (IP)	The use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation.	MDR (EU) 2017/745
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.	MDR (EU) 2017/745
Label	The written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices.	MDR (EU) 2017/745
Legacy device	Devices, which, in accordance with Article 120(3) MDR and Article 110(3) IVDR, are placed on the market after MDR or IVDR dates of application respectively and until 26 May 2024, or until the relevant certificate becomes void, if certain conditions are fulfilled: » devices which are class I devices under Directive 93/42/EEC, for which a declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure under the MDR requires the involvement of a notified body; » devices covered by a valid certificate issued in accordance with Directives 90/385/EEC or 93/42/EEC prior to 26 May 2021; » devices covered by a valid certificate issued in accordance with Directive 98/79/EC prior to 26 May 2022.	MDCG 2021-13
Making available on the market	Any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.	MDR (EU) 2017/745
Manufacturer (MF)	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 his name or trademark.	MDR (EU) 2017/745
Market surveillance	The activities carried out and measures taken by competent authorities to check and ensure that devices comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection.	MDR (EU) 2017/745
MDD	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. This EU Directive was valid until 25 May 2021 and was replaced by the MDR.	MDD 1993

Term	Definition	Source
Medical device (MD)	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: » diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease, » diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, » investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state, » providing information by means of in vitro examination of specimens derived from the human body, including organ, blood, and tissue donations, 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. The following products shall also be deemed to be medical devices: » devices for the control or support of conception » 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.	MDR (EU) 2017/745
Medical Device Coordination Group (MDCG)	A group of experts, selected based on their expertise and experience in the field of medical devices and in vitro diagnostic medical devices, representing the competent authorities of the Member States and performing the specific tasks set out in Article 105 to Regulation (EU) 2017/745.	MDR (EU) 2017/745
Medical Device Regulation (MDR)	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices	MDR (EU) 2017/745
New Approach Notified and Designated Organisations (NANDO)	This information system, maintained by the Directorate General Internal Market, Industry, Entrepreneurship and SMEs of the European Commission, provides an overview and information on Notified Bodies of the European Union.	EC 2023b
Non-EU manufacturer / Foreign manufacturer	A manufacturer of medical devices outside the European Union (EU) or European Economic Area (EEA). For trade in medical devices of the Non-EU manufacturer within the EU/EEA, the manufacturer must have an authorised representative whose place of business must be in one of the EU/EEA Member States.	EC 2020cMedical Devices Glossary 2022
Notified body (NB)	A conformity assessment body designated in accordance with MDR.	MDR (EU) 2017/745
Original device	A new, unused single-use device.	WHO & PAHO 2016
Outsourcing	The assignment of tasks to an external provider.	ECHAlliance Group 2021
Placing on the market	The first making available of a device, other than an investigational device, on the Union market.	MDR (EU) 2017/745
Prion diseases	A disease due to a prion, a proteinaceous infectious particle that lacks nucleic acids.	MedicineNet
Prions	A disease-causing agent that is neither bacterial nor fungal nor viral and contains no genetic material. Prions are composed largely, if not entirely, of an altered formal (an abnormal isoform) of a normal cellular protein.	MedicineNet
Putting into service	The stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose.	MDR (EU) 2017/745
Refurbishing	Refurbishing is the extensive re-manufacturing of a medical device, which goes beyond reprocessing.	EC 2020a

Term	Definition	Source
Remanufacturing	The processing, conditioning, renovating, repackaging, restoring, or any other act done to a finished medical device that significantly changes the finished device's performance or safety specifications, or intended use.	FDA 2022
Reprocessing	The process carried out on a used device in order to allow its safe re-use including cleaning, disinfection, sterilisation, and related procedures, as well as testing and restoring the technical and functional safety of the used device.	MDR (EU) 2017/745
Reprocessing cycle	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.	EC 2020b
Reprocessor	The health institution and the external reprocessor reprocessing single-use devices.	EC 2020b
Reusable medical devices	A medical device that is intended for repeated or multiple uses, for which instructions for reprocessing (decontamination, cleaning, disinfection or sterilization) between uses as well as the limits for reprocessing and reuse are provided.	WHO 2019
Reuse	The repeated use or multiple use of any medical device including devices intended for reuse or single use, with reprocessing (cleaning, disinfection, or sterilization) between uses.	FDA 2001
Risk	The combination of the probability of occurrence of harm and the severity of that harm.	MDR (EU) 2017/745
Risk classes for medical devices	The classification of a device according to its intended purpose and the Annex VIII of the MDR. The risk classes, from low to high risk, are: » Class I - Class I medical devices with a measuring function (Im) - Class I sterile medical devices (Is) - Class I reusable surgical instruments (Ir) » Class IIa » Class IIb » Class III	MDR (EU) 2017/745
Single registration number (SRN)	The registration number that is automatically assigned by EUDAMED to manufacturers, authorised representatives, system and procedure pack producers and importers through the release of an EUDAMED application in the Actor Module by the competent authority in accordance with Articles 31 MDR and 28 IVDR.	MDCG 2021-13
Single-use device	A device that is intended to be used on one individual during a single procedure.	MDR (EU) 2017/745
Small and medium-sized enterprises (SMEs)	Enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million. » Within the SME category, a small enterprise is defined as an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million. » Within the SME category, a microenterprise is defined as an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million.	EC2003
Stakeholder	A person or organisation with a legitimate interest in a topic related to health care. Stakeholders may be: » Medical devices or pharmaceutical manufacturers » Equipment suppliers » Patient organisations » Organisations representing health care professionals » Other health care organisations » Civil society organisations	WHO CC 2023

Term	Definition	Source
Sterilisation	A validated process used to render the product free from viable micro-organisms. *Note: In a sterilisation process, the nature of microbial inactivation is described as 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.*	FDA 2015
Sustainability	The capacity to meet the needs of the present without compromising the ability to meet future needs.	WHO CC 2023
System/procedure pack producers (SPPP)	A natural or legal person who manufactures systems or procedure packs according to MDR.	MDR (EU) 2017/745
Traceability	The ability to fully trace a device through its entire lifecycle, from when it is manufactured through to end of life.	HPRA 2010
Unique Device Identification (UDI)	A series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market.	MDR (EU) 2017/745
Withdrawal	Any measure aimed at preventing a device in the supply chain from being further made available on the market.	MDR (EU) 2017/745

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