Glossary of medical devices availability terms

Working definitions of terms for the "Study supporting the monitoring of availability of medical devices on the EU market"

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Medical devices (MD) and in vitro diagnostic medical devices (IVD) are essential for a well working health care system, as they have a crucial role in the prevention, diagnosis, monitoring, prediction, prognosis and treatment of acute and chronic illness and disease, as well as patient rehabilitation.

In the context of the implementation of Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices, the European Commission's Directorate-General for Health and Food Safety (DG SANTE) – via the European Health and Digital Executive Agency (HaDEA) – commissioned a **study supporting the monitoring of availability of 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 and Civic Consulting.

This glossary provides **working definitions** for the study and includes terms related to the Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices valid for the European Economic Area. It also includes definitions of relevant terms from the Medical Devices Glossary 2022 and from the online glossary of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies.

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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Gesundheit Österreich Beratungs GmbH · Areté The Agri-food Intelligence Company · CIVIC CONSULTING · European Commission

Glossary of terms related to availability of medical devices

Term	Definition	Source
Active 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.	MDR (EU) 2017/745
Actor	Umbrella term for persons and entities which comprises authorities, market players and stakeholders.	WHO CC 2022
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, IVDR].	MDR (EU) 2017/745 IVDR (EU) 2017/746
Authority responsible for notified bodies	Any Member State that intends to designate a conformity assessment body as a notified body, or has designated a notified body, to carry out conformity assessment activities under this Regulation shall appoint an authority ('authority responsible for notified bodies'), which may consist of separate constituent entities under national law and shall be 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 2022
Availability	In the context of this study, availability of medical devices relates to the terminology "making them available on the market", as applied in the MDR. This refers to 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 IVDR (EU) 2017/746
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 EU Regulation 2017/745 and EU Regulation 2017/746 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 IVDR (EU) 2017/746 Medical Devices Glossary 2022
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 IVDR (EU) 2017/746
Conformity assessment	The process demonstrating whether the requirements according to MDR and IVDR relating to a device have been fulfilled. For class I products, the manufacturer carries out the conformity assessment himself; for class II and above, an external notified body is required.	MDR (EU) 2017/745 IVDR (EU) 2017/746
Conformity assessment body	A body that performs third-party conformity assessment activities including calibration, testing, certification and inspection.	MDR (EU) 2017/745

Term	Definition	Source
Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws relating to active implantable medical devices (AIMDD)	As part of the European Union (EU) regulatory framework on medical devices, it sought to harmonise national legislation on active implantable medical devices. This ensured universally high safety standards for patients, giving the public confidence in the system. It allowed the products to be placed on the market in any EU country. This EU directive was valid until 25 May 2021 and was replaced by the MDR.	AIMDD 1990
Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD)	The aim of this Directive was to ensure a high level of protection for human health and safety and the proper functioning of the internal market in the European Union (EU) and to achieve the results for which medical devices are intended. The Directive harmonised national legislation on medical devices. This ensured a high level of protection for patients as well as public confidence. It allowed products to be used on the market in any EU country. This EU directive was valid until 25 May 2021 and was replaced by the MDR.	MDD 1993
Custom-made device (CMD)	Any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs. However, mass-produced devices which need to be adapted to meet the specific requirements of any professional user, and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person shall not be considered to be custom-made devices.	MDR (EU) 2017/745
Declaration of conformity (DoC)	The EU declaration of conformity shall state that the requirements specified in this Regulation have been fulfilled in relation to the device that is covered. The manufacturer shall continuously update the EU declaration of conformity. The EU declaration of conformity shall, as a minimum, contain the information set out in Annex IV and shall be translated into an official Union language or languages required by the Member State(s) in which the device is made available.	MDR (EU) 2017/745
Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (IVDD)	The Directive laid down the essential safety, health, design and manufacturing requirements that in vitro diagnostic medical devices and their accessories had to meet. This ensured generally high safety standards and established public confidence. The Directive allowed the products to be used in any country of the European Union. This EU Directive was valid until 25 May 2022 and was replaced by the IVDR.	IVDD 1998
Economic operator (EO)	Under MDR: A manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3) MDR. Under IVDR: A manufacturer, an authorised representative, an importer or a distributor.	MDR (EU) 2017/745 IVDR (EU) 2017/746
End user	A patient, consumer, or a professional who directly uses the medical device on a patient or a consumer.	WHO CC 2022

Term	Definition	Source
European Database on Medical Devices (EUDAMED)	EUDAMED is the IT system established by Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnosis medical devices. EUDAMED is integral part of the implementation of the two Medical Devices Regulations. The Commission, after consulting the MDCG, shall set up, maintain and manage the European database on medical devices ('Eudamed') for the following purposes: a) to enable the public to be adequately informed about devices placed on the market, the corresponding certificates issued by notified bodies and about the relevant economic operators; b) to enable unique identification of devices within the internal market and to facilitate their traceability; c) to enable the public to be adequately informed about clinical investigations and to enable sponsors of clinical investigations to comply with obligations under Articles 62 to 80, Article 82, and any acts adopted pursuant to Article 81; d) to enable manufacturers to comply with the information obligations laid down in Articles 87 to 90 or in any acts adopted pursuant to Article 91; e) to enable the competent authorities of the Member States and the Commission to carry out their tasks relating to this Regulation on a well-informed basis and to enhance the cooperation between them. Eudamed shall include the following electronic systems: a) the electronic system for registration of devices referred to in Article 29(4); b) the UDI-database referred to in Article 28; c) the electronic system on registration of economic operators referred to in Article 30; d) the electronic system on notified bodies and on certificates referred to in Article 57; e) the electronic system on clinical investigations referred to in Article 73; f) the electronic system on vigilance and post-market surveillance referred to in Article 92; g) the electronic system on market surveillance referred to in Article 100. The Commission Implementing Regulation (EU) 2021/2078 of 26 November 2021 lays down the detailed arrangements necessary for the setting up and maintenance of EUDAMED.	MDR (EU) 2017/745 Commission Implementing Regulation (EU) 2021/2078
European Economic Area (EEA)	One of the three original European Community organisations, along with the European Coal and Steel Community (ECSC) and the European Atomic Energy Community (EURATOM), whose institutions were merged by the Merger Treaty (which came into force in 1967). The European Community (EC) emerged from the European Economic Community (EEC), the name was introduced by the Maastricht Treaty.	Parliament 2022
European Medical Device Nomenclature (EMDN)	The European Medical Device Nomenclature (EMDN) aims at supporting the functioning of the European database on medical devices (EUDAMED). Among its various uses, it will be utilised by manufacturers for the registration of medical devices in EUDAMED, where it will be associated to each Unique Device Identifier – Device Identifier (UDI-DI). As the EMDN primarily serves regulatory purposes to support MDR and IVDR requirements, it also plays a key role in MDR/IVDR device documentation and technical documentation, sampling of technical documentation conducted by notified bodies, post-market surveillance, vigilance and post-market data analysis, etc. It is intended to support all actors in their activities under the MDR/IVDR and provides key device descriptions to patients as regards their own devices and all other devices available on the market and registered in EUDAMED.	European Commission 2023a
Generic device group	A set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.	MDR (EU) 2017/745

Term	Definition	Source
		IVDR (EU) 2017/746
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 IVDR (EU) 2017/746
Health technology assessment (HTA)	Health technology assessment' or 'HTA' means a multidisciplinary process that summarises information about the medical, patient and social aspects and the economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner**.**	Regulation (EU) 2021/2282 on health technology assessment
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) 2017/745 IVDR (EU) 2017/746 MDCG 2021-27
In vitro diagnostic medical device (IVD)	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 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: a) concerning a physiological or pathological process or state; b) concerning congenital physical or mental impairments; c) concerning the predisposition to a medical condition or a disease; d) to determine the safety and compatibility with potential recipients; e) to predict treatment response or reactions; f) to define or monitoring therapeutic measures. Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices.	IVDR (EU) 2017/746
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 IVDR (EU) 2017/746
Legacy devices	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 MDCG 2022-8

Term	Definition	Source
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 IVDR (EU) 2017/746
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 its name or trademark.	MDR (EU) 2017/745 IVDR (EU) 2017/746
Market surveillance	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 IVDR (EU) 2017/746
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)	An expert panel that is based on the MDR and IVDR. The members of the MDCG are selected based on their expertise and experience in the field of medical devices and in vitro diagnostic medical devices and they represent the competent authorities of the Member States. The specific tasks are set out in Article 105 of the MDR and Article 99 of the IVDR.	MDR (EU) 2017/745 IVDR (EU) 2017/746
New Approach Notified and Designated Organisations (NANDO)	The NANDO (New Approach Notified and Designated Organisations) 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.	European Commission 2023b
Non-EU manufacturer / Foreign manufacturer	A manufacturer of medical devices outside the European Union (EU)/European Economic Area (EEA). For trade in medical devices of the Non-EU manufacturer within the EU/EEA, this manufacturer must have an authorised representative whose place of business must be in one of the EU/EEA Member States.	European Commission 2020
Notified body (NB)	A conformity assessment body designated in accordance with MDR/IVDR.	MDR (EU) 2017/745 IVDR (EU) 2017/746
Old devices	Devices placed on the market according to the medical devices Directives or the in vitro diagnostic medical devices Directive before the date of application of the MDR and IVDR or placed on the market before the Directives entered into force. *Note: MDCG Guideline 2022-8 provides guidance as regards the applicability of IVDR requirements to legacy devices and old devices.*	MDCG 2021-13 MDCG 2022-8

Term	Definition	Source
Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices (Medical Device Regulation, MDR)	The MDR came into force on 25 May 2017 and, after a four-year transition period, has replaced the two EU Directives 90/385/EEC and 93/42/EEC with effect from 26 May 2021. Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. The aim of the Regulation: » It updates the rules on placing, making available and putting into service medical devices* for human use and their accessories on the European Union (EU) market. » It also contains rules on how clinical investigations* concerning such devices and accessories are carried out in the EU. » It aims to improve patient safety by introducing more stringent procedures for conformity assessment (to ensure that unsafe or non-compliant devices do not end up on the market) and post-market surveillance. » Amending Regulation (EU) 2020/561 was adopted to allow EU Member States and their authorities and institutions to prioritise the fight against the COVID-19 pandemic. It defers the application of certain rules of Regulation (EU) 2017/745 by 1 year, in order to ensure the smooth functioning of the EU's internal market, to maintain a high level of protection of public health and patient safety, to provide legal certainty and to avoid potential market disruption during the pandemic.	MDR (EU) 2017/745
Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (In Vitro Diagnostics Regulation, IVDR)	The IVDR entered into force on 25 May 2017 and has replaced EU Directive 98/79/EC after a five-year transitional period with an effective date of 26 May 2022. The purpose of the Regulation: » The Regulation updates the rules for the placing on the market, making available on the market of the European Union (EU) and putting into service of in vitro diagnostic medical devices and their accessories intended for human use. » The Regulation also lays down rules concerning performance studies carried out in the EU on in vitro diagnostic medical devices (or their accessories). » The aim is to improve patient safety by introducing stricter procedures for conformity assessment (to ensure that unsafe or non-compliant products are not placed on the market) and post-market surveillance.	IVDR (EU) 2017/746
Risk classes for in vitro diagnostic medical devices	The classification according to risk classes is based on the classification rules in Annex VIII of the IVDR. The application of the classification rules depends on the intended purpose of the products: » Class A » Class B » Class C » Class D Class A products have a low risk, Class D products have a high risk.	IVDR (EU) 2017/746
Risk classes for medical devices	The classification according to risk classes is based on the classification rules in Annex VIII of the MDR. The application of the classification rules depends on the intended purpose of the devices: » Class I - Class I medical devices with a measuring function (Class Im) - Class I sterile medical devices (Class Is) - Reusable surgical instruments of class Ir » Class IIa » Class IIb » Class III Class I products have a low risk, Class III products have a high risk.	MDR (EU) 2017/745 MDCG 2021-24 MDCG 2022-5

Term	Definition	Source
Single registration number (SRN)	The registration number that is automatically assigned by EUDAMED to manufacturers, authorised representatives, system and procedure pack producer 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
Small and medium-sized enterprises (SMEs)	This category consists of 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.	European Commission 2003
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 2022
Sustainability	The capacity to meet the needs of the present without compromising the ability to meet future needs.	WHO CC 2022
System/procedure pack producers (SPPP)	A natural or legal person who manufactures systems or procedure packs according to MDR or IVDR.	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 IVDR (EU) 2017/746

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