



## List of COVID-19 essential Medical Devices (MDs and IVDs)

Device	EMDN <sup>1</sup> /CND <sup>2</sup> code	EMDN/CND term	(unofficial) EMDN definition
<b>Gloves, examination or surgical</b>	Multiple codes apply. Ex. T0101 or T0102	GLOVES	They are single-use sterile devices used to cover healthcare professionals' hands during surgery or other procedures (eg. examination). They could be made up of latex or synthetic materials such as polychloroprene, nitrile, polyisoprene or another synthetic latex free material not otherwise classified in this nomenclature.
<b>Gowns and other dressing elements for non surgical use (e.g. cover boots and shoes, caps and coglets)</b>	T0205	NON-SURGICAL GOWNS	These include devices that can be both sterile and non-sterile which are used in the course of non-surgical procedures by medical and paramedical staff in order to ensure protection for the patient and the operator. They can be composed of both synthetic or natural material and are available in various shapes and sizes. The devices described can be disposable or reusable.  Other nomenclature codes apply for surgical gowns.
<b>Medical face masks</b>	Multiple codes apply. Ex. T0206	Multiple terms apply	Multiple definitions apply
<b>Ventilator for critical care, invasive and non-invasive</b>	Multiple codes apply. Ex. Z12030105	INTENSIVE CARE VENTILATORS	Multiple definitions apply depending on device function/modes and if invasive/non-invasive.
<b>Non-invasive ventilators for ventilator-dependent patients, CPAP and BiPAP</b>	Multiple codes apply. Ex. Z12030105 or Z12030102	INTENSIVE CARE VENTILATORS	Multiple definitions apply depending on device function/modes.
<b>Ventilator for transport and emergency</b>	Z12030104	TRANSPORTABLE VENTILATOR	Pulmonary ventilators specifically built for ventilation of the patient during transport or during out-of-hospital emergency.

<sup>1</sup> European Medical Device Nomenclature, <https://ec.europa.eu/docsroom/documents/39009/attachments/1/translations/en/renditions/native>

<sup>2</sup> Classificazione Nazionale dei Dispositivi medici, [http://www.salute.gov.it/portale/temi/p2\\_6.jsp?lingua=italiano&id=328&area=dispositivi-medici&menu=classificazione](http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=328&area=dispositivi-medici&menu=classificazione), <https://ec.europa.eu/docsroom/documents/39007/attachments/1/translations/en/renditions/native>



<b>Extracorporeal membrane oxygenation (ECMO) , equipment and disposables (cannula, oxygenators, and tubing)</b>	Multiple codes apply. Ex. Z12050201 or C0301 or Z12050285	Multiple terms apply	Multiple definitions apply
<b>Anaesthetic ventilator</b>	Z1203010101	ANESTHESIA UNITS	Devices which allow to anaesthetise and ventilate the patient with suitable gas mixtures.
<b>Filters for ventilators (patient and machine filters)</b>	Multiple codes apply. Ex. R0401 or Z1203010585	Multiple terms apply	Multiple definitions apply
<b>Colorimetric end tidal CO2 detector</b>	R010380	ENDOTRACHEAL TUBES - ACCESSORIES	They are sterile or non-sterile devices, used with endotracheal tubes and are primarily represented by: fittings and connectors (for connection with breathing circuits); caps (for sealing pipes to the tracheal wall); deblockers (to remove the secretions attached to the internal walls from the pipes); bands of fixation (for holding the tube to the patient's skin); guides and introducers; spindles. The devices described can be both disposable and reusable.
<b>Flowmeter and oxygen sensors</b>	Multiple codes apply. Ex. Z120309 or Z1203020408	Multiple terms apply	Multiple definitions apply
<b>Flow-splitter, for oxygen supply</b>	Z120309	MEDICAL/MEDICINAL GAS SYSTEMS AND RELATED ACCESSORIES	Complete systems that include the power plant, the distribution network and the terminal units at the points where the medical gases pass or where clearing of anaesthesia gases may be required.
<b>Oxygen Humidifier for oxygen therapy</b>	R060202	HUMIDIFYING SYSTEMS, OXYGEN ADMINISTRATION	They are sterile or non-sterile devices, used in the course of oxygen administration procedures to ensure the correct humidification of the medical gas inhaled by the patient. They are usually presented in plastic containers connected to the oxygen flow meter and to the patient tube. The devices described can be disposable or reusable.
<b>Oxygen concentrator/generator</b>	Z12159004	OXYGEN CONCENTRATORS	These devices increase the concentration of oxygen in the air inspired by the patient by treating the ambient air with resins, exchange of ions or membranes that allow the separation of nitrogen in the air.



<b>Oxygen delivery devices, e.g. oxygen masks, venturi masks, oxygen tents, oxygen head boxes, bag valve masks (BVM)</b>	Multiple codes apply. Ex. R03010201 or R03010202 or R03010104 or R03020201	Multiple terms apply	Multiple definitions apply
<b>Medical gas cylinder</b>	N/A	N/A	N/A
<b>Medical gas supply systems</b>	Z120309	MEDICAL/MEDICINAL GAS SYSTEMS AND RELATED ACCESSORIES	Complete systems that include the power plant, the distribution network and the terminal units at the points where the medical gases pass or where clearing of anaesthesia gases may be required.
<b>Endotracheal intubation devices and kits</b>	Multiple codes apply. Ex. R0101 or R0102 or R0103 or R0104 or R0105 or R0106 or R0199	Multiple terms apply	Multiple definitions apply
<b>Laryngoscope</b>	Z12021003	LARYNGOSCOPES	Rigid or flexible endoscopes that are inserted into the patient through the mouth to allow direct exploration of the larynx for diagnostic or therapeutic purposes.
<b>Nasal prongs</b>	R03010203	AIR/OXYGEN NASAL CANNULAS	They are sterile or non-sterile devices used in the course of oxygen administration procedures for a therapeutic purpose. They are built of plastic material and have a semi-rigid structure. They are introduced into the nostrils of the patient, directing the flow of oxygen directly into the nasal cavities. The devices described are single use.
<b>Nasopharyngeal airway devices</b>	R010101	NASOPHARYNGEAL TUBES	They include devices that can be both sterile and non-sterile, used to ensure patency of the upper airway that connects the nose to the pharynx. They are made of rubber or plastic polymers which can be inserted in one or both nostrils. Externally they can be connected, via a connector to external equipment (e.g. to the oxygen distribution network). They are available in various dimensions (lengths and diameters) according to the specific clinical need. The described devices can be both disposable and reusable.
<b>Oropharyngeal airway devices</b>	R010102	AIRWAY GUEDEL TUBES	They are sterile or non-sterile devices, used to ensure the patency of the oral cavity thanks to the compressive action exerted on the tongue (which in this way cannot obstruct the upper airways). They are generally built from rubber or plastic polymers. They allow the passage of cannulas for ventilation or aspiration.



			They are available in various sizes (lengths and diameters) according to the specific clinical need. The devices described can be disposable or reusable.
<b>Needles, catheters, cannulae, connectors and the like</b>	Multiple codes apply	Multiple terms apply	Multiple definitions apply
<b>Disposable emergency cricothyrotomy set</b>	R0106	PERCUTANEOUS TRACHEOSTOMY KITS	Multiple definitions apply
<b>Infusion pump and giving sets and accessories</b>	Z12030301	INFUSION PUMPS	These devices infuse fluids or medicinal products into the patient's body through different methods (parenteral (venous or arterial), subcutaneous, epidural etc). These devices are used universally in surgical departments. They are generally divided according to the administration mechanism: volumetric pumps, peristaltic or drop. Based on the number of independent lines, the volumes differ in: single-channel or multi-channel (generally 2-4). An acoustic / visual alarm is generated in the event of a malfunction (occlusion or achievement of the programmed limit value). Other codes might apply to giving sets and accessories.
<b>Syringe pumps</b>	Z12030302	SYRINGE PUMPS	Infuses fluids or medicinal products in a controlled manner into the patient's body through various infusion methods (parenteral (venous or arterial), subcutaneous, epidural etc.) using a standard syringe removable together with the whole infusion line.
<b>Enteral feeding pumps and naso gastric tubes</b>	Multiple codes apply. Ex. Z12030303 or A030103 or G02020101	Multiple terms apply	Multiple definitions apply
<b>Fiberscopes</b>	Z12029006	INTUBATION FIBERSCOPES	Special laryngoscopes indicated for performing difficult endotracheal intubations in anesthesiology. They can be optical or video flexible, or, if they are blade shaped, can include a battery light source usually contained in the handle.
<b>Multiparametric Patient Monitoring devices</b>	Z120302	VITAL SIGNS MONITORING INSTRUMENTS	Multiple definitions apply
<b>Blood Pressure monitoring kits</b>	C0104	ANGIOGRAPHY AND HEMODYNAMIC DEVICES	Multiple definitions apply



<b>Computed tomography (CT) scanners</b>	Z110306	COMPUTED TOMOGRAPHY SCANNING SYSTEMS (CT)	The computerized axial tomographs are completely digital systems that allow to obtain a series of contiguous two-dimensional images of the human body (with appropriate integrated software are obtained three-dimensional reconstructions). The X-ray table-tube system moves in a coordinated way to allow a circular or helical scan following the levels of radiation intensity received by during the scan, the data is obtained for subsequent digital processing.
<b>Ultrasound machines, and accessories</b>	Z110401	ULTRASOUND SCANNERS	Multiple definitions apply
<b>Electrocardiograph, and accessories</b>	Z120503	ELECTROCARDIOGRAPHS	Multiple definitions apply
<b>Manual resuscitator</b>	R030202	HAND-OPERATED VENTILATION BALLOONS	Multiple definitions apply
<b>Dialysis machine and bloodlines, including CRRT machines</b>	Z12090201 or F0201	HEMODIALYSIS UNITS	Equipment carrying out the extracorporeal dialysis process, in the absence of renal function. The device consists of a dialyzer filter, extracorporeal blood circuit, and liquid dialysis circuit, monitor for management the preparation of the dialysis liquid and for the control of all the functions and parameters related to conduction of the dialysis session.
<b>Pulse oximeter</b>	Z1203020408	PULSE OXIMETER	Device generally used in operating rooms and in intensive care units, they allow non-invasive measurement of oxygen saturation in the blood (spo2), exploiting the partial transparency of the tissues. A photodetector converts a light signal (led) into an electrical signal proportional to the absorption. They could be produced in a handy compact version which is battery operated rendering it suitable for emergency use. When equipped with appropriate sensors, (for the finger, the forehead etc.) they can also be intended for paediatric use.



<b>Thermometers</b>	V030101	THERMOMETERS	Multiple definitions apply
<b>Wound dressings</b>	M	DEVICES FOR GENERIC AND SPECIALISTIC MEDICATION	Multiple definitions apply
<b>Syringes, with or without needles</b>	A02	SYRINGES	Multiple definitions apply depending on access pathway required may it be cutaneous, subcutaneous, venous or arterial.
<b>Blood gas syringes</b>	A020105 or W0501010103	Multiple terms apply	Multiple definitions apply
<b>Medical drills for vascular access</b>	Multiple codes apply	Multiple terms apply	Multiple definitions apply
<b>Hemofiltration equipment and sets</b>	Z12090301 or F0201	HEMOFILTRATION UNITS	Equipment carrying out hemofiltration in the absence of renal function. These devices automatically run arterial or venous blood, the passage of which goes through a membrane filter for the removal of extra-cellular liquid and the infusion of the replacement liquid is performed.
<b>Active humidifier</b>	R060201	HUMIDIFYING SYSTEMS, ACTIVE VENTILATION	They are sterile or non-sterile devices used during mechanical ventilation procedures to ensure the correct humidification of the medical gas inhaled by the patient. They are usually presented in containers made of a plastic material which is connected from one side to the oxygen flow meter and the other side to the patient tube. The devices described can be disposable or reusable.
<b>Specially designed positioning beds</b>	Z120307	CRITICAL CARE PATIENT BEDS	Multiple definitions apply



<b>Nursing material for positioning</b>	Y1236	PATIENT LIFTING DEVICES	Multiple definitions apply
<b>Anti-decubitus mattress</b>	Y033306	PRESSURE ALLEVIATION MATTRESSES AND UNDERPADS	They are non-sterile devices intended to better distribute pressure and support the patient's body or to massage the epidermis. They contain materials that ensure uniformly distributed softness and come in various shapes and sizes depending on the use. The devices described are reusable.
<b>Suction devices</b>	R0501	ESPIRATORY SUCTION, PROBES AND SYSTEMS	They are sterile or non-sterile devices, used for the aspiration of liquid or semi-solid materials from the respiratory tract (pharynx, larynx and bronchi). They are generally made of plastic or other polymer materials. They may or may not have control valves. They are available in various sizes (lengths and diameters) depending on the specific clinical need. The devices described are single use.
<b>Disinfectors/ sterilisators /equipment for virus inactivation</b>	Multiple codes apply. D or S or Z120113	Multiple terms apply	Multiple definitions apply
<b>Software/App qualified as medical device in Covid-19 context</b>	Multiple codes apply.	Multiple terms apply	Multiple definitions apply
<b>COVID-19 Test Kit PCR</b>	W0105040519	CORONAVIRUS-NA REAGENTS	Diagnostic kits for the in vitro detection of the presence of the Coronavirus genome in samples coming from from the human body. The presence of the genome is used in the diagnosis of respiratory infections.
<b>COVID-19 Test Kit Antigen, including rapid tests</b>	W0105040619 or W0105099099	CORONAVIRUS	Diagnostic kits for the in vitro serological diagnosis of Coronaviruses in samples from the human body. There Serological diagnosis (antigen research and antibody titration) is used in the diagnosis of respiratory infection.
<b>COVID-19 Test Kit Antibody, including rapid tests</b>	W0105099099	OTHER - OTHER VIROLOGY - RT & POC	Diagnostic kits for the in vitro one-step qualitative determination of antibodies against other viruses in samples coming from the human body. They are rapid tests for the detection of other viruses that do not find a place in specific terminal branches of the nomenclature.
<b>CRP and other markers of inflammation tests</b>	W01021109	C-REACTIVE PROTEIN	Diagnostic kits for the quantitative in vitro determination of reactive Protein C (CRP) in samples coming from the human body. The CRP quantity is used in the diagnosis and treatment of inflammatory diseases of an infectious or non-infectious nature and various processes of tissue aggression. Different codes apply for 'other inflammation markers'.



<b>Analysers / PCR equipment e.g. thermocycler/real time PCR analyser</b>	W0205	NUCLEIC ACID TESTING INSTRUMENTS	Multiple definitions apply
<b>Blood Gas Analyser</b>	W02010401	BLOOD GAS ANALYSER	Medical devices for the automated in vitro execution of blood gas analysis tests.
<b>Blood Counting Analyser</b>	W020201	CELL COUNTING	Multiple definitions apply
<b>Analysers and equipment for blood coagulation related measurements, i.e. ACT, PTT, INR</b>	W02020201	COAGULOMETERS	Multiple definitions apply
<b>Nasopharyngeal and other swabs</b>	Multiple codes apply. Ex. V9013	Multiple terms apply	Multiple definitions apply depending on the intended purpose.
<b>Tube for Nasopharyngeal Swabs</b>	W05020199	SAMPLES TRANSPORT, CONTAINERS - OTHERS	They include devices that can be both sterile and non-sterile, which represent a miscellany of containers for the transport of samples not otherwise classifiable, in addition to those for which they were created specific classes (bags, boxes, bottles, jars, envelopes and bags, biopsy cassettes). The devices described can be both disposable and reusable.
<b>Viral transport medium</b>	W0104010203	TRANSPORT MEDIA	Ready-to-use sterile media, packed in tubes of different volumes and with caps. They are used for the temporary in vitro conservation of bacteria present in samples from the human body for transport to the laboratory.
<b>Sampling kits</b>	Multiple codes apply	Multiple terms apply	Multiple definitions apply
<b>Analyser / PCR / test specific consumables and other laboratory consumables</b>	Multiple codes apply	Multiple terms apply	Multiple definitions apply
<b>Calibrators and control materials</b>	Multiple codes apply	Multiple terms apply	Multiple definitions apply
<b>Nucleic Acid Extraction Kit</b>	W0105900101	REAGENTS FOR DNA AND/OR RNA EXTRACTION AND PREPARATION: BACTERIA AND/OR VIRUS	Diagnostic kits for the extraction and in vitro preparation of genomes of bacterial and / or viral origin from sample coming from the human body. The extraction and preparation of the genome is fundamental for the subsequent step of gene amplification and identification.
<b>Reagents, including lysis buffer and PCR enzymes</b>	Multiple codes apply. Ex. W0105900101 or W0105900102	Multiple terms apply	Multiple definitions apply