



Notification Scope



NOTIFIED BODY 1282

ECM - Notified Body 1282

ECM - Ente Certificazione Macchine is EU Notified Body No. 1282 and ISO 17025 Accredited Testing Laboratory offering several options for quality and safety related services.


ECM boasts over twenty-five years of experience in the certification of products, providing countless global small, medium and large companies with compliance services to get their products EC certified for markets requiring the CE mark.

Codes and Descriptions	Examples	Exclusions
MDA 0202 - Active-non implantable imaging devices using non-ionizing radiation	<ul style="list-style-type: none">• Videoendoscopy	Excluding Class III Medical Devices. Limited to video endoscopes
MDA 0203 - Active-non implantable devices for monitoring vital physiological parameters	<ul style="list-style-type: none">• Blood pressure monitor• Medical thermometer• Pulse oximeter• Apnoea monitors• Intensive care patient monitoring system	Excluding Class III medical devices
MDA 0204 - Other non-implantable active devices for monitoring and/or diagnosis	<ul style="list-style-type: none">• Ocular tonometer• Audiometers• Retinal cameras	Excluding Class III Medical Devices
MDA 0302 - Active non-implantable devices using non-ionizing radiation	<ul style="list-style-type: none">• Surgical laser for refractive surgery of the eye• Laser for pain treatment	Excluding Class III Medical Devices
MDA 0303 - Active-non implantable devices for hyperthermia/hypothermia	<ul style="list-style-type: none">• Medical heating blanket• Warming and cooling blankets• Blood warmers• Paraffin bath	Excluding Class III Medical Devices
MDA 0305 - Active-non implantable devices for stimulation or inhibition	<ul style="list-style-type: none">• Automated external defibrillator• Device for the transcranial magnetic brain simulation• Device for transcutaneous electrical nerve stimulation (TENS)	
MDA 0306 - Active non-implantable devices for extracorporeal circulation, administration or removal of substances and emaphrases	<ul style="list-style-type: none">• Haemodialysis machine and equipment• Infusion pumps• Feeding pumps• Jet injectors for vaccination• Anaesthesia machines	Excluding Class III Medical Devices. Excluding non-implantable active devices for extracorporeal circulation
MDA 0307 - Active non-implantable devices for the respiratory system	<ul style="list-style-type: none">• Medical ventilator• Nebulisers	Excluding Class III Medical Devices. Hyperbaric chambers excluded
MDA 0308 - Active non-implantable devices for the treatment of lesions and skin	<ul style="list-style-type: none">• Water jet for wound debridement	Excluding Class III Medical Devices
MDA 0312 - Other active non-implantable devices for surgical use	<ul style="list-style-type: none">• RF electrosurgical generator• Electrosurgical instrument Cauterization devices• Powered surgical drills and saws	Excluding Class III Medical Devices
MDA 0313 - Active non- implantable prostheses, rehabilitation devices and devices for positioning and transport patients	<ul style="list-style-type: none">• Hospital beds• Patients hoists• Electric Wheelchairs	Excluding Class III Medical Devices. Excluding non-implantable active prostheses
MDA 0315 - Software	<ul style="list-style-type: none">• Radiotherapy planning system	
MDA 0317 - Active non-implantable devices for cleaning, disinfection and sterilization	<ul style="list-style-type: none">• Sterilizers like autoclaves etc• Washer disinfectors for medical devices	Excluding Class III Medical Devices. Limited to non-implantable active devices for cleaning, disinfection and moist heat and dry heat sterilizers
MDA 0318 - Other active non-implantable devices		Excluding Class III Medical Devices


CONTACTS

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 [ECM - Medical Device](#)

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Codes and Descriptions	Examples	Exclusions
MDN 1103 - Non-active dental implants and materials	<ul style="list-style-type: none">Dental implantDental fillersRoot canal fillerAbutments	
MDN 1201 - Non-implantable, non-active devices for anesthesia, emergency care and intensive care	<ul style="list-style-type: none">Device for pleural drainageMasks, tubes for the administration of gasesEndotracheal tubeTracheostomy tubesEndotracheal tube introducers	Excluding Class III medical devices
MDN 1202 - Non-implantable, non-active devices for the administration, channeling and removal of substances, including dialysis devices	<ul style="list-style-type: none">Intravenous lineHypodermic needleSyringe tubing, bags for injection or trasfusionDialysis filterDialysis solutionUrinary catheter	Excluding Class III Medical Devices
MDN 1204 - Non-implantable, non-active devices for the treatment of skin lesions	<ul style="list-style-type: none">Wound dressingCotton woolGauze dressingBandagesSuture for dermal wound closure (of less than 30 days)Surgical gloves	Excluding Class III Medical Devices
MDN 1208 - Non-implantable, non-active devices	<ul style="list-style-type: none">Instruments for general use in surgery: forceps, clamps, scalpels, dental instruments	Excluding Class III Medical Devices
MDN 1209 - Non-implantable, non-active dental materials	<ul style="list-style-type: none">Etching solutions for dental useBracesDental cements (when not considered long term surgically invasive)Dental impression materials	
MDN 1211 - Non-implantable, non-active devices for disinfection, cleaning and rinsing	<ul style="list-style-type: none">Solutions for disinfecting medical devicesContact lens careCatheter lock solutions	Excluding Class III Medical Devices
MDN 1213 - Non-implantable, non-active devices consisting of substances intended to be introduced into the human body through a body orifice or through the skin		Excluding Class III Medical Devices
MDN 1214 - Non-implantable, non-active devices for general use in the healthcare sector and other non-implantable, non-active devices	<ul style="list-style-type: none">Ultrasound gels	Excluding Class III Medical Devices

Codes and Descriptions	Exclusions
MDS 1004 - Devices that are machinery within the meaning of Article 2(a) of Directive 2006/42/EC of the European Parliament and of the Council	
MDS 1005 - Sterile devices	Limited to aseptic treatment, ETO, moist heat sterilization, radiation sterilization
MDS 1006 - Reusable surgical instruments	
MDS 1008 - Devices that use biologically active coatings and/or materials, or that are wholly or largely absorbed by the human body or locally dispersed within it, or that are intended to undergo chemical modification after introduction into the body	
MDS 1009 - Devices that contain/use/are controlled by software, including devices intended to control, monitor or directly influence the performance of active devices or active implantable devices	
MDS 1010 - Devices with measuring function	
MDS 1011 - Devices that are part of systems or procedural kits	
MDS 1012 - Products without medical use listed in Annex XVI of Regulation (EU) 2017/745	
All MDT codes excluding MDT 2009 - Devices manufactured using processing of materials of human, animal or microbial origin	

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