

GUIDANCE

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**CODES ASSIGNMENT REFERRED
TO IN THE IMPLEMENTING
REGULATION 2017/2185**
IN THE CONTEXT OF A REQUEST
FOR CERTIFICATION ACCORDING
TO THE REGULATION (EU) 2017/745

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I CONTEXT

Commission Implementing Regulation 2017/2185 establishes the codes for the definition of notified bodies' scope of designation in medical devices under Regulation (EU) 2017/745.

In order to determine whether the request for certification within the framework of a CE marking according to Regulation 2017/745 is eligible compared to the designation codes for which GMED is designated as a notified body, the manufacturer must describe the type of device and technology concerned and identify the corresponding codes.

The assigned codes are then verified by GMED to ensure their coherency in view of the design and intended purpose of the device and the technologies and processes used.

The purpose of this guide is to clarify the different types of codes and their method of assignment in order to ensure the consistency of the codes assigned to a type of medical device.

This guide is based on the document MDCG 2019-14, Explanatory note on MDR codes of December 2019, available on the European Commission website (<https://ec.europa.eu>).

II METHOD FOR THE ASSIGNMENT OF CODES

The Implementing Regulation 2017/2185 defines three types of codes:

- MDA/MDN codes: Codes reflecting the design and intended purpose of the device,
- MDS codes: Horizontal codes reflecting the specific characteristics of the device,
- MDT codes: Horizontal codes describing the technologies or processes used.

1 → MDA/MDN Codes

MDA / MDN-codes reflect the design and intended purpose of the device. Only one code must be assigned to each device. In the case where several codes are applicable, the highest code in the list of Regulation 2017/2185 must be assigned.

EXAMPLE : *A surgical laser for refractive surgery of the eye is assigned to “MDA 0302 Active non-implantable devices utilising non-ionizing radiation” and not to “MDA 0309 Active non-implantable ophthalmologic devices” because, even though both codes are specific for the device, since MDA 0302 is higher in the list.*

Devices may be composed of different components which, if they were products on their own, would belong to different MDA/MDN codes. In such cases, the intended purpose or the main physical or technological principle of the device should be considered.

EXAMPLE : *A medical devices is composed of a suture anchor (a bone screw attached to a surgical suture to reattach ruptured tendons) as well as a single use deployment instrument and a single use bone drill. The components are provided sterile in a blister, are covered by the same technical documentation and are not available individually. This product is assigned to “MDN 1102 Non-active osteo- and orthopaedic implants” and not to “MDN 1208 Non-active non-implantable instruments” because the implanted component of the device is associated with the intended purpose rather than the deployment instrument and the drill.*

In certain exceptional cases, GMED may have to deviate from the above-mentioned rule so that the code assigned reflects the risk linked to the most critical technology (in particular in terms of skills associated to carry out the conformity assessment). This aspect is then discussed by the different parties and a justification for the choice made is documented by GMED.

EXAMPLE : *A heater-cooler unit (HCU) for cardiac surgery is a device through which blood circulates, and which changes the circulating blood's temperature in order to achieve hypo- or hyperthermia. Both the codes "MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia" and "MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis" are specific to the device. Since MDA 0303 is a code higher in the list, according to the rule explained above it should be chosen. Nonetheless, it was decided to assign the code MDA 0306 by documenting that the highest risks associated with HCU are mainly linked to this code.*

Two specific cases are identified for which a clear assignment is given:

- Stand-alone software should be assigned to the code MDA 0315.
- Non-implantable cardiovascular catheters, guide-wires, introducers, filters and related tools are to be assigned to the code MDN 1203.

2 MDS Codes

MDS codes are horizontal codes which reflect the specific characteristics of the device. All applicable codes must be assigned to a device.

EXAMPLE : *A partially resorbable, sterile surgical implant that contains an antibiotic to prevent post-surgical infection will need to be assigned to the following MDS codes:*

- "MDS 1005 - Devices in sterile condition": because it is provided sterile,
- "MDS 1008 - Devices utilising [...] being wholly or mainly absorbed or locally dispersed in the human body [...]": because it is absorbed, and
- "MDS 1001 - Devices incorporating medicinal substances": because it contains an antibiotic.

3 MDT Codes

MDT codes are horizontal codes associated with the technologies or processes used in the manufacturing and making available of the devices.

Assignment of MDT codes should be done taking into consideration production of the device itself as well as for critical production steps. This means that only critical processes are to be considered.

The processes considered critical by GMED are the internal and/or subcontracted manufacturing processes having the most impact on the performance and safety of medical devices. The same process can be considered as critical or non-critical depending on the type of device concerned. For illustration, the primary packaging process for a sterile product will be critical, which is not necessarily the case for a non-sterile product. Or the injection method of an implantable part will be critical, which will not necessarily be the case of the injection method for a protective casing of electro-medical equipment.

EXAMPLE : *An electronic medical thermometer for layman's use should be assigned to the following MDT codes:*

- *“MDT 2010 Devices manufactured using electronic components including communication devices” because the product is assembled from electronic components and*
- *“MDT 2011 Devices which require packaging, including labelling” because the device is packed and labelled.*

It is important to note that the MDT codes are assigned to the devices, whether the manufacturing or making available activities are carried out by the manufacturer himself or that they are subcontracted.

EXAMPLE : *A manufacturer of cross-linked hyaluronic acid implants has no in-house manufacturing. The finished, labelled implant is bought from a supplier. The implant raw material (hyaluronic acid) is produced by fermentation using bacteria. The following MDT codes should be assigned:*

- *“MDT 2008 Devices manufactured in clean rooms and associated controlled environments”, because the manufacturing of the implant is in a controlled environment,*
- *“MDT 2005 Devices manufactured using biotechnology”, because the main risks in manufacturing are related to the production and cross-linking of the hyaluronic acid.*
- *“MDT 2011 Devices which require packaging, including labelling” because the implant is packed and labelled.*



4 → Overview

The assignment of codes is carried out by following the steps below using the list of codes as published in the Implementing Regulation (EU) 2017/2185 of November 23, 2017.

| | CODE | CODE type | ASSIGNATION DES CODES A UN DISPOSITIF |
|-----------------------|---------|---|--|
| 1 ST STAGE | MDA/MDN | Codes reflecting the design and intended purpose of the device. | Exactly 1 code per device The codes should be assigned according to their hierarchical order in Regulation 2017/2185. If more than one MDA/ MDN code is applicable, the one that is highest in the list should be selected. |
| 2 ND STAGE | MDS | Codes reflecting the specific characteristics of the device. | Between 0 to several per device Assign all codes applicable to the device. |
| 3 RD STAGE | MDT | Horizontal codes describing the technologies or processes used. | Between 1 to several per device Assign the codes which describe the main production technologies or critical processes. |

III EXAMPLES FOR CODES ASSIGNMENT

A Active devices codes

1 → Active implantable devices

| ACTIVE IMPLANTABLE DEVICES | | |
|----------------------------|---|---|
| MDA CODE | CORRESPONDING TYPES OF DEVICES | EXAMPLES OF DEVICES COVERED |
| MDA 0101 | Active implantable devices for stimulation / inhibition / monitoring | <ul style="list-style-type: none"> • Implantable cardiac defibrillators • Implantable endocardial bipolar pacing lead • Implantable pacemaker • Neuro-stimulators • Diaphragm stimulator • Implantable bladder stimulator • Implantable artificial sphincter |
| MDA 0102 | Active implantable devices delivering drugs or other substances | <ul style="list-style-type: none"> • Implantable pumps (insulin...) |
| MDA 0103 | Active implantable devices supporting or replacing organ functions | <ul style="list-style-type: none"> • Cochlear implant • Brainstem implant • Motorized gastric bands • Artificial heart |
| MDA 0104 | Active implantable devices utilising radiation and other active implantable devices | <ul style="list-style-type: none"> • Radioactive seeds implant |

2 → Active non-implantable devices for imaging, monitoring and /or diagnosis

| ACTIVE NON-IMPLANTABLE DEVICES FOR IMAGING, MONITORING AND / OR DIAGNOSIS | | |
|---|---|---|
| MDA CODE | CORRESPONDING TYPES OF DEVICES | EXAMPLES OF DEVICES COVERED |
| MDA 0201 | Active non-implantable imaging devices utilising ionizing radiation | <ul style="list-style-type: none"> • Devices for radiology and tomography • Nuclear medicine workstation for nuclear medicine diagnostic imaging system • PET/SPECT imaging system • Mammographic systems • X-ray tube • Gamma cameras • Fluoroscopy equipment |
| MDA 0202 | Active non-implantable imaging devices utilising non-ionizing radiation | <ul style="list-style-type: none"> • MRI • Near-infrared spectroscopic imaging • Optical tomography • Optical imaging system |
| MDA 0203 | Active non-implantable devices for monitoring of vital physiological parameters | <ul style="list-style-type: none"> • Respiratory Polygraph, apnea monitors • Devices for ECG/ EEG • Oximetry sensor • Aneroid sphygmomanometer/tensiometer • Electronic thermometers • Devices for hemodynamic measurement • Spirometer |
| MDA 0204 | Other active non-implantable devices for monitoring and / or diagnosis | <ul style="list-style-type: none"> • Polysomnograph • Ultrasound diagnostics devices and associated probes / Echographs • Digital manometers • Connected insole • Curameters • Devices for the diagnostic of visual functions (pupillometers, refractometers, tonometers, pachymeters, topographers, aberrometers) • Devices for the diagnostic of hearing functions |



3 → ACTIVE NON-IMPLANTABLE THERAPEUTIC DEVICES AND GENERAL ACTIVE NON-IMPLANTABLE DEVICES

| ACTIVE NON-IMPLANTABLE THERAPEUTIC DEVICES AND GENERAL ACTIVE NON-IMPLANTABLE DEVICES | | |
|---|--|--|
| MDA CODE | CORRESPONDING TYPES OF DEVICES | EXAMPLES OF DEVICES COVERED |
| MDA 0301 | Active non-implantable devices utilising ionizing radiation | <ul style="list-style-type: none"> • Therapeutic cyclotrons and linear accelerator • Radiotherapy equipment |
| MDA 0302 | Active non-implantable devices utilising non-ionizing radiation | <ul style="list-style-type: none"> • Remote transmitter for implantable cardiac devices (radio frequency) • Phototherapy devices • Surgical laser for refractive surgery of the eye • Laser for pain treatment |
| MDA 0303 | Active non-implantable devices utilising hyperthermia / hypothermia | <ul style="list-style-type: none"> • Devices in the treatment of venous disease by endothermal techniques • Devices for patient heating (heating blankets, heating cradles...) • Cryotherapy equipment • Paraffin bath |
| MDA 0304 | Active non-implantable devices for shock-wave therapy (lithotripsy) | <ul style="list-style-type: none"> • Extracorporeal lithotripters |
| MDA 0305 | Active non-implantable devices for stimulation or inhibition | <ul style="list-style-type: none"> • Automated external defibrillator • Nerve stimulation devices • Muscle stimulators • Electrostimulators for treatment of urinary incontinence • Ionopheresis treatment device • Electrical acupuncture • External bone growth stimulators |
| MDA 0306 | Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis | <ul style="list-style-type: none"> • Hemodialysis devices • Infusion pumps • Electric breast pump • Hardware and software for incorporating into infusion pump to control the administration of anesthetic agent • Anesthesia workstation (manifold block, syringes pumps, gas mixers...) • Jet injectors for vaccination • Blood pumps for heart-lung machines |
| MDA 0307 | Active non-implantable respiratory devices | <ul style="list-style-type: none"> • Devices for ventilation, oxygen-therapy and for the treatment of sleep apnea. • Devices for functional respiratory exploration • Hyperbaric chamber • Nebulisers |
| MDA 0308 | Active non-implantable devices for wound and skin care | <ul style="list-style-type: none"> • Wound treatment devices • Mesotherapy devices • Pressotherapy/Vacuometry devices • Water jet for wound debridement |

→ **Active non-implantable therapeutic devices and general active non-implantable device (afterpart)**

| ACTIVE NON-IMPLANTABLE THERAPEUTIC DEVICES AND GENERAL ACTIVE NON-IMPLANTABLE DEVICES | | |
|---|--|--|
| MDA CODE | CORRESPONDING TYPES OF DEVICES | EXAMPLES OF DEVICES COVERED |
| MDA 0309 | Active non-implantable ophthalmologic devices | <ul style="list-style-type: none"> • Electromagnet for Eye Surgery • Ultrasound probe for phacoemulsification (cataract treatment) • Aspiration pump for ophtalmological use |
| MDA 0310 | Active non-implantable devices for ear, nose and throat | <ul style="list-style-type: none"> • Hearing aids |
| MDA 0311 | Active non-implantable dental devices | <ul style="list-style-type: none"> • Dental drills • Surgical suction device for dental use • Ultrasonic scalers • Chairs with equipment • Apex locator • Endodontology microengine |
| MDA 0312 | Other active non-implantable surgical devices | <ul style="list-style-type: none"> • RF Electrosurgical equipment • Electrosurgery instruments • Robotic high intensity ultrasound therapy equipment • Computer assisted surgical devices • Laparoscopic insufflator • Cauterization devices |
| MDA 0313 | Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport | <ul style="list-style-type: none"> • Active medical beds and wheelchairs • Immobilization, mobilization and testing devices of the human joints • Patient lift • Exoskeleton |
| MDA 0314 | Active non-implantable devices for processing and preservation of human cells, tissues or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART) | <ul style="list-style-type: none"> • Cryobiological storage container • IVF cryopreservation systems • Blood bank refrigerator |
| MDA 0315 | Software | <ul style="list-style-type: none"> • Data conversion software • Monitoring software • Pre-implant planning software for surgery • Medical imaging software |
| MDA 0316 | Medical gas supply systems and parts thereof | <ul style="list-style-type: none"> • Medical gas supply system in a hospital • Gas manifold and line pressure regulator for medical regulators |
| MDA 0317 | Active non-implantable devices for cleaning, disinfection and sterilisation | <ul style="list-style-type: none"> • Disinfecting chambers using for MD • Steam cleaner and disinfectant for MD |
| MDA 0318 | Other active non-implantable devices | <ul style="list-style-type: none"> • Electronic tourniquets • Devices for electrotherapy/magnetotherapy • Surgical tables |



B Non-active devices codes

1 → Non-active implants and long term surgically invasive devices

| NON-ACTIVE IMPLANTS AND LONG TERM SURGICALLY INVASIVE DEVICES | | |
|---|--|--|
| MDN CODE | CORRESPONDING TYPES OF DEVICES | EXAMPLES OF DEVICES COVERED |
| MDN 1101 | Non-active cardiovascular, vascular and neurovascular implants | <ul style="list-style-type: none"> • Vascular prosthesis, stents • Heart valves, heart prosthesis, annuloplasty rings • Valves and catheters for hydrocephalus • Embolization agent, glue • Implant for the treatment of intracranial aneurysm • Vena cava filter • Vascular implantable ports, vascular implantable catheters • Sutures for cardiovascular surgery |
| MDN 1102 | Non-active osteo- and orthopaedic implants | <ul style="list-style-type: none"> • Artificial spinal disc • Spinal cage • Orthopedic cement • Orthopedic implants (shoulders, knees, hips, spine...) • Implants for osseous filling, for osteotomy • Hyaluronic acid implant for intra-articular use • Bone substitute • Orthopedic nails, plates, screws • Sutures, suture anchors, staples for orthopedic surgery • Artificial ligaments • Medullary plugs |
| MDN 1103 | Non-active dental implants and dental materials | <ul style="list-style-type: none"> • Dental implants • Dental fillers • Root canal filler • Abutments |
| MDN 1104 | Non-active soft tissue and other implants | <ul style="list-style-type: none"> • Tissue or organs support and reinforcements (mesh) • Implants for urological surgery (ureteral stent...) • Cosmetic implants (breast, calves, pecs, penis...) • Staples, clips, sutures (not falling in above codes) • Hyaluronic acid dermal fillers • Intraocular lens and phacoemulsification • Intra-uterine device – IUD • Eyelid implant • Bariatric surgery devices: Gastric rings, gastric balloons, gastric bands... • Biliary stents, pharyngeal stents • Lung volume reduction devices: coils, valves, sealants. • Implantable ports (excluding vascular) solution |

2 → Non-active non-implantable devices

| NON-ACTIVE NON-IMPLANTABLE DEVICES | | |
|------------------------------------|--|--|
| MDN CODE | CORRESPONDING TYPES OF DEVICES | EXAMPLES OF DEVICES COVERED |
| MDN 1201 | Non-active non-implantable devices for anesthesia, emergency and intensive care | <ul style="list-style-type: none"> • Devices for tracheostomy and laryngectomy • Masks, breathing balls and ventilation circuits • Devices for pleural drainage • Devices for anesthesia - intensive care • Cryoanesthetic agents |
| MDN 1202 | Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis | <ul style="list-style-type: none"> • Hemodialysis kits : filter, solution • Needles • Devices for infusion, for puncture • Epidural catheters, urinary catheter • Dosing spoons • Syringes • Manual breast pump |
| MDN 1203 | Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools | <ul style="list-style-type: none"> • Vascular filter catheter • Embolectomy catheter • Cardiovascular guidewires and catheters • Neurovascular catheters • Central venous catheter |
| MDN 1204 | Non-active non-implantable devices for wound and skin care | <ul style="list-style-type: none"> • Dressings, compresses • Liquid dressings • Solutions for wound care (Eosin 2%, NaCl...) • Fat tulle • Devices in the form of cream: healing, treatment of hemorrhoids • Sutures for dermal wound closure (<30 days) • Surgical gloves |
| MDN 1205 | Non-active non-implantable orthopaedic and rehabilitation devices | <ul style="list-style-type: none"> • Orthosis, corsets, orthopedic soles, lumbar and abdominal bearing belts, cervical collar • Crutches • Wheelchairs • Ancillaries, trial implants |
| MDN 1206 | Non-active non-implantable ophthalmologic devices | <ul style="list-style-type: none"> • Solutions for ophthalmic rinsing • Solutions for hydration/lubrication of the eye • Systems for implants injection for ophthalmology • Contact lenses and rinse solution • Instruments for ophthalmologic surgery • Iris retractor |
| MDN 1207 | Non-active non-implantable diagnostic devices | <ul style="list-style-type: none"> • Recording chart paper for physiological waveform • Thermal expansion thermometer |
| MDN 1208 | Non-active non-implantable instruments | <ul style="list-style-type: none"> • Surgical devices (Pliers, loops, scalpels, trocars...) • Surgical kits |
| MDN 1209 | Non-active non-implantable dental materials | <ul style="list-style-type: none"> • Gingival retraction cord • Devices for orthodontics • Dental impression material • Dental adhesive • Etching solution for dental use • Braces • Dental cements (when not considered long term surgically invasive) |



→ **Non-active non-implantable devices (afterpart)**

| NON-ACTIVE NON-IMPLANTABLE DEVICES | | |
|------------------------------------|---|--|
| MDN CODE | CORRESPONDING TYPES OF DEVICES | EXAMPLES OF DEVICES COVERED |
| MDN 1210 | Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases | <ul style="list-style-type: none"> • Condoms • Contraceptive diaphragms |
| MDN 1211 | Non-active non-implantable devices for disinfecting, cleaning and rinsing | <ul style="list-style-type: none"> • Disinfectant solutions • Disinfectant wipes |
| MDN 1212 | Non-active non-implantable devices for processing and pre-preservation of human cells, tissue or organs including in vitro fertilization (IVF) and assisted reproductive technologies (ART) | <ul style="list-style-type: none"> • Bag for organ transport and refrigeration • Organ preservation solutions • Blood platelet storage solutions • Pocket systems for cord blood and / or stem cells, phlebotomy bags • Blood bags • Freezing solution for egg cells • Embryo transfer catheters • Artificial insemination probes • Devices for oocyte and sperm preservation |
| MDN 1213 | Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route | <ul style="list-style-type: none"> • Nasal, auricular, oral solution (single dose, spray ...) • Devices in the form of suppositories • Devices for oral care |
| MDN 1214 | General non-active non-implantable devices used in health care and other non-active non-implantable devices | <ul style="list-style-type: none"> • Warming relaxing patch • Surgical drapes • Acupuncture needles • Tubes (feeding...) • Ultrasound gels |

C Horizontal codes

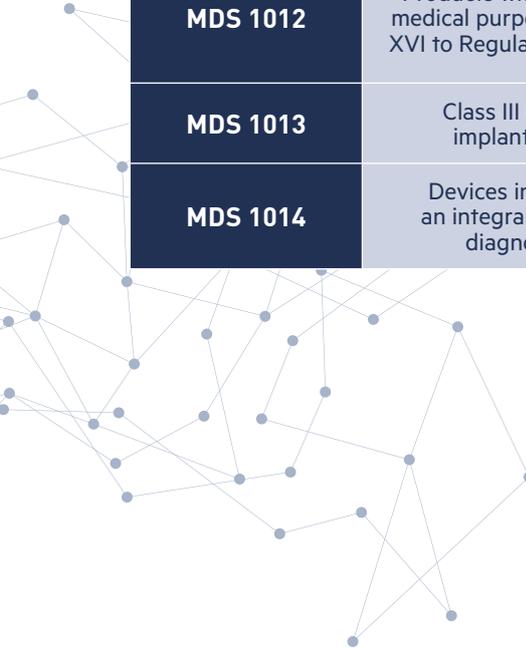
1 → Devices with specific characteristics

| DEVICES WITH SPECIFIC CHARACTERISTICS | | |
|---------------------------------------|--|--|
| MDS CODE | CORRESPONDING TYPES OF DEVICES | EXAMPLES OF DEVICES COVERED |
| MDS 1001 | Devices incorporating medicinal substances | <ul style="list-style-type: none"> • Hormonal intra-uterine devices • Chlorhexidine dressing • Heparin coated vascular prosthesis |
| MDS 1002 | Devices manufactured utilising tissues or cells of human origin, or their derivatives | <ul style="list-style-type: none"> • Tissue engineering products from tissues of human origin (bone...) |
| MDS 1003 | Devices manufactured utilising tissues or cells of animal origin, or their derivatives | <ul style="list-style-type: none"> • Bone substitute • Xenogeneic heart valves • Matric for dermal regeneration |
| MDS 1004 | Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council | <ul style="list-style-type: none"> • Medical robot • Electronic wheelchair • Scanner |
| MDS 1005 | Devices in sterile condition | <ul style="list-style-type: none"> • Devices sterilized by ETO, radiation, steam, aseptic filtration... |
| MDS 1006 | Reusable surgical instruments | <ul style="list-style-type: none"> • Biomedical equipment • Surgical instruments |
| MDS 1007 | Devices incorporating or consisting of nanomaterial | <ul style="list-style-type: none"> • Devices made of nanomaterials (implants, needle, trocar ...) |
| MDS 1008 | Devices utilising biologically active coatings and / or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body | <ul style="list-style-type: none"> • Joint implants covered with hydroxyapatite • Reinforcement implant covered with collagen • Medullary plugs • Absorbable sutures |
| MDS 1009 | Devices incorporating software / utilising software / controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices | <ul style="list-style-type: none"> • Devices linked to a software |



→ **Devices with specific characteristics (afterpart)**

| DEVICES WITH SPECIFIC CHARACTERISTICS | | |
|---------------------------------------|--|--|
| MDS CODE | CORRESPONDING TYPES OF DEVICES | EXAMPLES OF DEVICES COVERED |
| MDS 1010 | Devices with a measuring function | <ul style="list-style-type: none"> • Measuring spoons • Recording chart paper for physiological waveform • Measuring syringes |
| MDS 1011 | Devices in systems or procedure packs | <ul style="list-style-type: none"> • Nutrition / respiratory systems • Care sets |
| MDS 1012 | Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 | <ul style="list-style-type: none"> • Color contact lens • Body implants • Pre-filled syringe for filling wrinkles • Aspiration for liposuction |
| MDS 1013 | Class III custom-made implantable devices | <ul style="list-style-type: none"> • Custom-made orthopedic implants • Orthodontic appliance |
| MDS 1014 | Devices incorporating as an integral part an <i>in vitro</i> diagnostic device | <ul style="list-style-type: none"> • Dialysis device incorporating a device for measuring creatinine |



2 → Devices for which specific technologies or processes are used

| DEVICES FOR WHICH SPECIFIC TECHNOLOGIES OR PROCESSES ARE USED | | |
|---|---|---|
| MDT CODE | CORRESPONDING TYPES OF DEVICES | DEVICE MANUFACTURING TECHNOLOGIES |
| MDT 2001 | Devices manufactured using metal processing | <ul style="list-style-type: none"> • 3D printing (metal), casting, welding • Turning (metal), anodization, passivation, polishing, surface modification, laser tube cutting, honing |
| MDT 2002 | Devices manufactured using plastic processing | <ul style="list-style-type: none"> • Injection molding, extrusion, bonding • Polymer compounding, 3D printing (plastics), thermoforming, blow molding, turning (plastics) |
| MDT 2003 | Devices manufactured using non-metal mineral processing (e.g. glass, ceramics) | <ul style="list-style-type: none"> • Ceramic sintering, ceramic compounding |
| MDT 2004 | Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper) | <ul style="list-style-type: none"> • Weaving, knitting |
| MDT 2005 | Devices manufactured using biotechnology | <ul style="list-style-type: none"> • Fermentation using cell cultures, enzymatic production processes, purification and modification of biomolecules |
| MDT 2006 | Devices manufactured using chemical processing | <ul style="list-style-type: none"> • Compounding, buffering |
| MDT 2007 | Devices which require knowledge regarding the production of pharmaceuticals | <ul style="list-style-type: none"> • Production, handling and incorporation into a device of substances which, if used separately, can be considered to be a medicinal product |
| MDT 2008 | Devices manufactured in clean rooms and associated controlled environments | <ul style="list-style-type: none"> • Manufacturing of sterile or clean devices |
| MDT 2009 | Devices manufactured using processing of materials of human, animal, or microbial origin | <ul style="list-style-type: none"> • Tissue engineering from tissues of human/animal origin (bone...) |
| MDT 2010 | Devices manufactured using electronic components including communication devices | <ul style="list-style-type: none"> • Manufacturing of active devices |
| MDT 2011 | Devices which require packaging, including labelling | <ul style="list-style-type: none"> • Packaging, labelling |
| MDT 2012 | Devices which require installation, refurbishment | <ul style="list-style-type: none"> • Installation of biomedical equipment |
| MDT 2013 | Devices which have undergone reprocessing | <ul style="list-style-type: none"> • Manufacturing of surgical devices (Pliers, loops, scalpels, trocars...), endoscope |





→ HEADQUARTER

GMED SAS

1 rue Gaston Boissier
75015 PARIS • FRANCE
+33 (0)1 40 43 37 00
info@lne-gmed.com

→ FRENCH REGIONAL OFFICE

GMED SAS

19 D rue de la Télématique
42000 SAINT-ETIENNE • FRANCE
+33 (0)4 77 10 11 11

→ NORTH AMERICAN SUBSIDIARY

GMED NORTH AMERICA, INC

6550 Rock Spring Drive - Suite # 280
BETHESDA, MD 20817 • USA
+1 (301) 495 0477
gmedna@lne-gmed.com

