MDCG 2019-14

Explanatory note on MDR codes

December 2019

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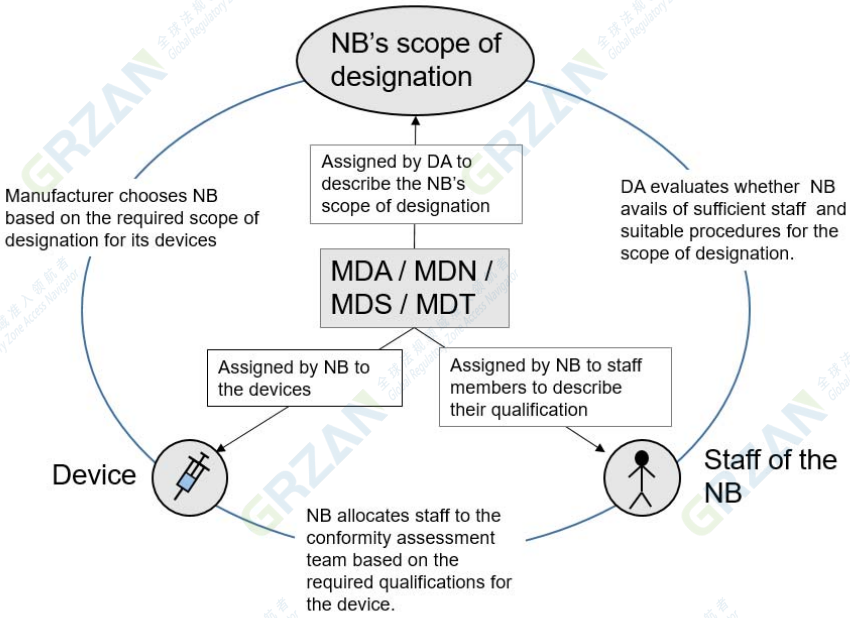
1 Introduction

Commission Implementing Regulation 2017/2185 establishes the codes for the designation of notified bodies in medical devices under Regulation (EU) 2017/745 and *in vitro* diagnostic medical devices under Regulation (EU) 2017/746. These codes are primarily used by designating authorities to define the notified body scope of designation but they are also used by the notified body to:

1) describe the individual qualification of the NBs staff members

2) describe the qualification required for assessing a device

These codes may be very broad and, furthermore, unequivocal authorisation of personnel to codes and the assignment of codes to a device is not always straightforward. However, the notified body's system needs to ensure, in all cases, that the authorisation of personnel and team allocation for the conformity assessment of a device ensures adequate knowledge and expertise.



2 Scope

The lists of codes and corresponding types of devices established by the above mentioned Regulation takes into account various device types which can be characterised by design and intended purpose, manufacturing processes and technologies used, such as sterilisation and the use of nanomaterials.

These lists of codes should be used in a way that provides for a multi-dimensional application to all typology of devices. This will ensure that notified bodies as well as the staff assigned to conformity assessment are fully competent for the devices they are required to assess.

This guidance is intended to explain the different level of codes and how they should be used, including the use of conditions with a view to ensure a harmonised use of the codes especially for the allocation of resources to conformity assessment activities.

3 Assignment of codes to devices within the conformity assessment procedure

When a manufacturer lodges an application with a notified body, the type of devices and technologies subject to conformity assessment activities are to be indicated. Usually, at the application review stage (as defined in section 4.3 of Annex VII MDR), notified bodies will verify the assignment of codes provided by the manufacturer or will assign these codes to the devices themselves. This verification is carried out in order to ensure that the notified body is able to assess the application based on its designation, and that it has available resources to carry out the relevant conformity assessment activities (feasibility evaluation). Thefinal assignment is made by the NB.

After this application review, and signing of the contract, the notified body will allocate appropriately qualified and authorised personnel to carry out audit activities or product reviews.

The following table presents an overview of the different types of codes and a summary of the main characteristics of each of them for the assignment to specific devices and the allocation of resources.

Type Code	Assignment of codes to the device	Relevance for allocation of conformity assessment team
MDA / MDN **Codes reflect design and intended purpose of device**	Exactly 1 code per device. The codes should be selected according to their hierarchical order in Regulation 2017/2185. If more than 1 MDA/ MDN code is applicable, the one that is highest in the list should be selected.	Allocation of personnel involved in the review of technical documentation (e.g. product reviewers) or in audits concerning product related aspects.
MDS **Horizontal codes that reflect the specific characteristics of the device**	0 to several per device Assign all codes applicable to the device. Select once an MDN/MDA code has been assigned.	Allocation of personnel involved in the review of technical documentation (e.g. product reviewers of sterilisation validation). May also be applicable to **staff performing audits concerning** certain special processes (e.g. sterilization).*
MDT **Horizontal codes that describe technologies or processes**	1 to several per device Assign the codes which describe the main production technologies or processes. Select once an MDN/MDA code has been assigned.	Allocation of personnel involved in audits (e.g. site auditors involved in the auditing of metal processing).

* Note: Assessment of these codes could be performed by Product reviewers or Site auditors depending on their competence

3.1 MDN / MDA-codes

MDA / MDN-codes reflect the design and intended purpose of the device and hence are mostly relevant for the allocation of personnel involved in the review of technical documentation. In some specific cases, the NB may assign product reviewers to assess product performance and safety aspects during an audit. This means that if there are product related issues to be audited and the auditors do not possess the required qualification, product reviewers who are qualified for the device in question should be part of the audit team.

The NB needs to ensure that the personnel allocated to the project are competent to assess for the devices and technologies under assessment. Special attention should be paid in situations such as the one described in example 4 of this section.

The MDA / MDN codes may either specify a field of medical application (e.g. MDA 0309 Active non-implantable ophthalmologic devices) or the physical or technological principle of the device (e.g. MDA 0302 Active non-implantable devices utilising non-ionizing radiation or MDA 0315 Software). Therefore, there are cases where more than one specific code might apply to a device (e.g. surgical laser for refractive surgery of the eye). Also, where there is a broad intended purpose, several codes may apply.

Having these issues in mind, when drafting the Regulation 2017/2185, the codes were put in order such that the MDA/MDN codes that require very specific technological knowledge and experience are highest in the code lists. Therefore, in cases where more than one MDA/MDN code apply, the code highest in the list is to be selected. This approach ensures consistent assignment of codes (and therefore consistent assignment of suitably qualified staff) to devices.

> Example 1: 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.

> Example 2: A screw for orthopaedic surgery is assigned to MDN 1102 Non-active osteo- and orthopaedic implants and not to 1104 Non-active soft tissue and other implants, because MDN 1102 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[1]. In such cases, the intended purpose or the main physical or technological principle of the device should be considered (Example 3). Nonetheless, the notified body needs to ensure that the assigned staff is qualified to assess all components of the device.

> Example 3: 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 (e.g. are not medical devices on their own). 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.

Note that, given the complexity and the diversity of medical devices, in exceptional cases deviations from the guidance given above may be necessary when assigning codes to devices in order to ensure suitably qualified staff in the conformity assessment. In such cases, a brief rationale shall be documented (see Example 4).

> Example 4: 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 Active non-implantable devices utilising hyperthermia/hypothermia is a code that describes physical or technological characteristics higher in the list, according to the rule explained above MDA 0303 should be chosen. Nonetheless, the notified body assigns the device to the code MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis and documents that the risks associated with the HCU are such that the staff having experience in this code is more suitable to assess the device.

It is important to note that Stand-alone software (i.e. software that is not part of a physical medical device) should be assigned to MDA 0315 since assessment of software requires very specific knowledge (see annex VII 3.2.2 5th indent MDR) and also that non-implantable cardiovascular

[1] This description does NOT refer to procedure packs or systems according to MDR Article 2 (10) and (11) since those are combinations of individual CE-marked products that have been subjected to separate conformity assessments.

catheters, guidewires, introducers, filters and related tools shall fall under MDN 1203 (instead of MDN 1201 or MDN 1202).

3.2 MDS codes

MDS codes are horizontal codes that are applicable to devices with specific characteristics. All codes that are applicable need to be assigned to a device in order to ensure that the review team possesses the full set of qualifications necessary for the conformity assessment. The MDS-codes are mainly relevant for the allocation of personnel involved in the review of technical documentation. This is because, generally, the auditing aspects linked to MDS codes have their corresponding MDT code for the relevant technology (e.g. MDS 1001 Devices incorporating medicinal substances vs MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals). However, MDS codes may also be applicable to staff performing audits concerning certain special processes (for example MDS 1005 for staff auditing ethylene oxide sterilization processes).

Example 1: 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:

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

Example 2: An infusion pump should be assigned to MDS 1009 - Devices incorporating software/utilising software/controlled by software […] because the infusion pump is controlled by software.

3.3 MDT codes

MDT codes relate to the technologies and processes that are used in the manufacturing and making available of the devices. MDT codes are relevant for the allocation of site auditors.

Assignment of MDT codes should be done taking into consideration production of the device itself as well as for critical upstream production steps. This means that, even though many codes could be applicable when taking into consideration the processes involved in the entire supply chain of a medical device, these should not be considered for the use of MDT codes (e.g. for an electronic medical thermometer, at one point, metal processing, plastic processing, non-metal mineral processing, chemical processing, manufacture in clean rooms, manufacturing using electronic components, labelling and packaging are necessary to assemble the device from raw materials).

Example 1: An electronic medical thermometer for layman's use should be assigned to the following MDT codes:

1) MDT 2010 Devices manufactured using electronic components including communication devices because the product is assembled from electronic components and
2) MDT 2011 Devices which require packaging, including labelling because the device is packed and labelled.

Example 2: A sterile animal derived bone graft substitute is manufactured using several steps. In the first step, the raw animal bone undergoes a sequence of chemical treatments to remove organic components. In a second step, the remaining mineral bone component is subjected to a heat treatment, then ground and sieved to obtain particles of defined sizes. The material is packed, labelled and sterilized. Therefore the following MDT codes should be assigned:

1) MDT 2008 Devices manufactured in clean rooms and associated controlled environments, because the manufacturing of the implant after the heat treatment is conducted in clean rooms,

2) MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin because the implant is made from animal bone

3) MDT 2011 Devices which require packaging, including labelling because the implant is packed and labelled.

Note: MDT 2006 Devices manufactured using chemical processing and MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics) were not applied since the chemical treatment and (bone) mineral processing are already considered within the scope of processing of animal materials.

Example 3: A calcium phosphate bone cement is provided as a sterile powder composed of a mixture of calcium salts and a vial with sterile saline. The following MDT codes should be assigned:

1) MDT 2008 Devices manufactured in clean rooms and associated controlled environments, because the manufacturing of the implant is in a controlled environment,

2) MDT 2006 Devices manufactured using chemical processing, because the main risks in manufacturing are related to the testing and mixing of the components,

3) MDT 2011 Devices which require packaging, including labelling because the implant is packed and labelled.

Example 4: 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:

1) MDT 2008 Devices manufactured in clean rooms and associated controlled environments, because the manufacturing of the implant is in a controlled environment,

2) MDT 2005 Devices manufactured using biotechnology, because the main risks in manufacturing are related to the production and cross-linking of the hyaluronic acid.

3) MDT 2011 Devices which require packaging, including labelling because the implant is packed and labelled.

Note that, despite the fact that the manufacturer itself does not physically manufacture the device, the MDT codes concerning the manufacturing steps are assigned to the device since they are relevant when auditing suppliers / subcontractors.

4 Competence description: conditions (including limitations)

Conditions should be established by the notified body for individual codes in cases where the qualification of the staff authorised to a certain code is not sufficient to cover the entire spectrum of the devices within this code. The designating authority could also apply conditions to the notified body's designation where the notified body does not have sufficient competence to cover a given code or could seek designation for conformity assessment of only certain devices within a code.

Conditions, including limitations, should be formulated in an unambiguous way (see example 1). Furthermore, since the technical codes basically mirror the competence system of the notified body, the conditions and limitations should concern device characteristics (see example 2).

Example 1: “MDN 1101 Non-active cardiovascular, vascular and neurovascular implants. Condition: heart valves”. This condition is unsuitable since it is not clear whether the notified body is restricted to assessment of heart valves or whether those products are excluded from

the scope of designation. Therefore, the condition should be “excluding heart valves” or “including only heart valves”.

Example 2: “MDN 1102 Non-active osteo- and orthopaedic implants. Condition: excluding class III devices”. The scope of designation is intimately linked to the qualification of the staff that the notified body needs to have available. Conditions serve to exclude the devices for which the notified body does not have competent staff and/or suitable procedures; therefore, they need to be expressed in a way that they relate to knowledge and experience of staff and/or procedures. The condition “excluding class III devices” does not allow this and therefore it is unsuitable. In this case, the designating authority has to determine, based on the qualification of the notified body’s staff, which devices are included in the scope. This might result, for example, in the following condition: “including only orthopaedic plates and screws; excluding implants that are applied in or on the spine”.

Further examples of conditions are illustrated in the final column of the table below. Considerations of the conditions should be based on the demonstrated competence of the applicant body.

5 Specific clarifications linked to individual codes

The devices included in the third and fourth columns <u>are only</u> a few examples of the devices covered in the relevant code. The third column is not intended to provide an exhaustive list of devices included in each code.

MDA CODE	Active implantable devices	Devices covered and Specific Considerations[1]	Examples of conditions
MDA 0101	Active implantable devices for stimulation / inhibition / monitoring	Implanted defibrillator Spinal cord stimulator Implantable cardiac pacemakers Implantable bladder stimulators	Excluding brain stimulation
MDA 0102	Active implantable devices delivering drugs or other substances	Implanted drug delivery pump	
MDA 0103	Active implantable devices supporting or replacing organ functions	Artificial heart Cochlear implants	
MDA 0104	Active implantable devices utilising radiation and other active implantable devices	Prostate radioactive seed implant	

[1] The assessment also should consider Section 5.1 of Annex IX applies as well as Validation of SSCP acc. Article 32.

MDA CODE	Active non-implantable devices for imaging, monitoring and / or diagnosis	Devices covered and Specific Considerations	Examples of conditions
MDA 0201	Active non-implantable imaging devices utilising ionizing radiation	X-ray computer tomography equipment Gamma cameras Fluoroscopy equipment PET scanner	Restricted to X-ray and gamma cameras
MDA 0202	Active non-implantable imaging devices utilising non-ionizing radiation	MRI computer tomograph	
MDA 0203	Active non-implantable devices for monitoring of vital physiological parameters	Blood pressure monitor Medical thermometer Pulse oximeter Apnoea monitors Intensive care patient monitoring system Spirometers Electrocardiographs Electroencephalographs	
MDA 0204	Other active non-implantable devices for monitoring and / or diagnosis	Ocular tonometer Audiometers Retinal cameras	

MDA CODE	Active non-implantable therapeutic devices and general active non-implantable devices	Devices covered and Specific Considerations	Examples of conditions
MDA 0301	Active non-implantable devices utilising ionizing radiation	Radioactive sources for cancer after loading therapy Therapeutic cyclotrons and linear accelerators	
MDA 0302	Active non-implantable devices utilising non-ionizing radiation	Surgical laser for refractive surgery of the eye Laser for pain treatment	Including only microwave and magnetotherapy medical devices
MDA 0303	Active non-implantable devices utilising hyperthermia / hypothermia	Medical heating blanket Warming and cooling blankets Blood warmers Paraffin bath	
MDA 0304	Active non-implantable devices for shock-wave therapy (lithotripsy)	Extracorporeal shock wave lithotripsy device	
MDA 0305	Active non-implantable devices for stimulation or inhibition	Automated external defibrillator Device for the transcranial magnetic brain stimulation Device for transcutaneous electrical nerve stimulation (TENS) Muscle stimulators Electrical acupuncture External bone growth stimulators	

MDA 0306	Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Haemodialysis machine and equipment Cardiopulmonary bypass pump Infusion pumps Feeding pumps Jet injectors for vaccination Blood pumps for heart-lung machines Anaesthesia machines	
MDA 0307	Active non-implantable respiratory devices	Medical ventilator Hyperbaric chambers Nebulisers	
MDA 0308	Active non-implantable devices for wound and skin care	Water jet for wound debridement	
MDA 0309	Active non-implantable ophthalmologic devices	Aspiration pump for opthalmological use (removal of crystalline residue)	
MDA 0310	Active non-implantable devices for ear, nose and throat	Hearing aids	
MDA 0311	Active non-implantable dental devices	Powered dental surgical unit and hand pieces Surgical suction device for dental use Ultrasonic scalers Chairs with equipment	
MDA 0312	Other active non-implantable surgical devices	RF electrosurgical generator Electrosurgical instrument Cauterization devices. Powered surgical drills and saws	

MDA 0313	Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Hospital beds Patient hoists Electric Wheelchairs Active limb prostheses Exoskeletons	
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)	IVF cryopreservation systems blood bank refrigerator	
MDA 0315	Software	Radiotherapy planning system.	
MDA 0316	Medical gas supply systems and parts thereof	Medical gas supply system in a hospital Gas manifold and line pressure regulator for medical regulators Medical gas supply pipeline systems	
MDA 0317	Active non-implantable devices for cleaning, disinfection and sterilisation	Sterilizers like autoclaves etc Washer disinfector for medical devices.	
MDA 0318	Other active non-implantable devices		

MDN CODE	Non-active implants and long term surgically invasive devices	Devices covered and Specific Considerations	Examples of conditions
MDN 1101	Non-active cardiovascular, vascular and neurovascular implants	Cardiac vascular stent Peripheral vascular stent Artificial heart valve Cardiac Valve Prostheses, Vascular and neurovascular grafts, shunts, vascular stents, cardiovascular patches Sutures for cardiovascular surgery For biological heart valves MDS 1003 should be applied. For drug eluting stents - MDS 1001 should be applied	Including only cardiac stents
MDN 1102	Non-active osteo- and orthopaedic implants	Artificial spinal disc Spinal cage Bone graft substitute for orthopaedic indications Prosthetic joint replacements (i.e knee, hip implants) Bone cement Hyaluronic acid implant for intra-articular use Orthopaedic nails, screws,plates Bone graft substitute for maxillofacial indications sutures, suture anchors, staples for orthopedic surgery spacers, ligament reconstruction products For antibiotic bone cements- MDS 1001 should be applied For absorbable substances MDS 1008 should be applied	

MDN 1103	Non-active dental implants and dental materials	Dental implant Dental fillers Root canal filler Abutments	

MDN 1104	Non-active soft tissue and other implants	Hyaluronic acid dermal fillers Intraocular lenses Intrauterine dispositive- IUD Breast implant Hernia mesh Urethral stent implants Sutures (not falling within the above codes) Eyelid implants Bariatric surgery devices: Intragastric Balloons, Gastric Bands, Anti-Reflux implants. Lung Volume Reduction devices: Coils, Valves, Sealants. Biliary and Pancreatic stents For contraceptive intrauterine devices containing copper or silver – MDS 1001 should be applied	Excluding breast implants
MDN CODE	**Non-active non-implantable devices**	**Devices covered and specific conditions**	**Examples of conditions**
MDN 1201	Non-active non-implantable devices for anaesthesia, emergency and intensive care	Device for pleural drainage Masks, tubes for the administration of gases. Endotracheal tube Tracheostomy tubes Endotracheal tube introducers	

MDN 1202	Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Intravenous line Hypodermic needle Syringe tubing, bags for injection or transfusion Dialysis filter Dialysis solution Epidural catheters, Urinary Catheter Amnioscopic needles	

MDN 1203	Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	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	Wound dressing Cotton wool Gauze dressings Bandages Sutures for dermal wound closure (of less than 30 days) Surgical gloves For dressings incorporating an antimicrobial agent - MDS 1001 should be applied	
MDN 1205	Non-active non-implantable orthopaedic and rehabilitation devices	Orthoses Crutches Wheelchairs	

MDN 1206	Non-active non-implantable ophthalmologic devices	Contact lenses Eye drops Instrument for ophthalmologic surgery Solutions for contact lenses.	
MDN 1207	Non-active non-implantable diagnostic devices	Thermal expansion thermometer	
MDN 1208	Non-active non-implantable instruments	Instruments for general use in surgery: Forceps, clamps, scalpels, dental instruments	
MDN 1209	Non-active non-implantable dental materials	Etching solution for dental use Braces Dental cements (when not considered long term surgically invasive) Dental impression materials	
MDN 1210	Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	Condom Contraceptive diaphragms	
MDN 1211	Non-active non-implantable devices for disinfecting, cleaning and rinsing	Solutions for disinfecting medical devices Contact lens care, catheter lock solutions	
MDN 1212	Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Freezing solution for egg cells Embryo transfer catheters Artificial insemination probes Media, substances or mixture of substances intended for washing, separating, sperm immobilizing, cryoprotecting solutions.	

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		
MDN 1214	General non-active non-implantable devices used in health care and other non-active non-implantable devices	Ultrasound gels	

MDS CODE	Devices with specific characteristics	Devices covered and specific conditions	Examples of conditions
MDS 1001	Devices incorporating medicinal substances	Devices incorporating medicinal products including herbal substances and human blood derivatives are included in this code.	
MDS 1002	Devices manufactured utilising tissues or cells of human origin, or their derivatives	Section 5.3.1 of Annex IX applies	
MDS 1003	Devices manufactured utilising tissues or cells of animal origin, or their derivatives	Section 5.3.2 of Annex IX applies Devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non- viable or rendered non-viable, unless such devices are intended to come into contact with intact skin only	
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[1]		
MDS 1005	Devices in sterile condition		Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam, formaldehyde sterilisation, moist heat sterilisation, radiation (gamma, x-ray, electron beam), sterilisation with hydrogen peroxide, sterilisation with liquid chemical sterilising agents, thermic sterilisation with dry heat

[1] Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) (OJ L 157 9.6.2006, p. 24).

MDS 1006	Reusable surgical instruments	Reusable surgical instruments according to art. 52 (7) c) MDR	
MDS 1007	Devices incorporating or consisting of nanomaterial		
MDS CODE	**Devices with specific characteristics**	**Devices covered and specific conditions**	**Examples of conditions**
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	Section 5.4 of Annex IX applies for devices intended to be introduced into the human body via a body orifice or applied to the skin and devices at are systemically absorbed by the human body in order to achieve their intended purpose	
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		
MDS 1010	Devices with a measuring function		
MDS 1011	Devices in systems or procedure packs		
MDS 1012	Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745		

MDS 1013	Class III custom-made implantable devices		
MDS 1014	Devices incorporating as an integral part an *in vitro* diagnostic device		

MDT CODE	Devices for which specific technologies or processes are used	Examples of device manufacturing technologies
MDT 2001	Devices manufactured using metal processing	3 d printing, Casting, Welding 3d printing (metal), turning (metal), anodization, passivation, polishing, surface modification, laser tube cutting, honing
MDT 2002	Devices manufactured using plastic processing	Injection molding, Extrusion, Bonding polymer compounding, 3d printing (plastics), thermoforming, blow moulding, turning (plastics)
MDT 2003	Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)	Ceramic sintering, ceramic compounding,
MDT 2004	Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)	Weaving, knitting
MDT 2005	Devices manufactured using biotechnology	Fermentation using cell cultures, enzymatic production processes, purification and modification of biomolecules
MDT 2006	Devices manufactured using chemical processing	Compounding, buffering
MDT 2007	Devices which require knowledge regarding the production of pharmaceuticals	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	
MDT 2009	Devices manufactured using processing of materials of human, animal, or microbial origin	Handling, dissection, storage, processing, inactivation and sterilization of human and animal tissues
MDT 2010	Devices manufactured using electronic components including communication devices	
MDT 2011	Devices which require packaging, including labelling	

MDT 2012	Devices which require installation, refurbishment	Installation of devices at the point of use by or under the manufacturer's responsibility
MDT 2013	Devices which have undergone reprocessing	