



MDR Classification:

(Reference Medical Device Regulation EU 2017/745, Annex VIII)

Product:

Product Name

1. DURATION OF USE		
MDR ID:	Definition:	Applicable:
-	Invasive Device:	Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to 2. Invasive and Active Devices
a8_001_1	Transient' means normally intended for continuous use for less than 60 minutes.	Yes: <input type="checkbox"/>
a8_001_2	Short term' means normally intended for continuous use for between 60 minutes and 30 days.	Yes: <input type="checkbox"/>
a8_001_3	Long term' means normally intended for continuous use for more than 30 days.	Yes: <input type="checkbox"/>
2. INVASIVE AND ACTIVE DEVICES		
MDR ID:	Definition:	Applicable:
-	Invasive and active devices:	Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to the Rules
a8_002_1	Body orifice' means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.	Yes: <input type="checkbox"/>



a8_002_2_1	Surgically invasive device' means: (a) an invasive device which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation; and	Yes: <input type="checkbox"/>
a8_002_2_2	(b) a device which produces penetration other than through a body orifice.	Yes: <input type="checkbox"/>
a8_002_3	Reusable surgical instrument' means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out.	Yes: <input type="checkbox"/>
a8_002_4	Active therapeutic device' means any active device used, whether alone or in combination with other devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or disability.	Yes: <input type="checkbox"/>
a8_002_5	Active device intended for diagnosis and monitoring' means any active device used, whether alone or in combination with other devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.	Yes: <input type="checkbox"/>
a8_002_6	Central circulatory system' means the following blood vessels: arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior.	Yes: <input type="checkbox"/>
a8_002_7	Central nervous system' means the brain, meninges and spinal cord.	Yes: <input type="checkbox"/>
a8_002_8	Injured skin or mucus membrane' means an area of skin or a mucus membrane presenting a pathological change or change following disease or a wound.	Yes: <input type="checkbox"/>
a8_003_1	Application of the classification rules shall be governed by the intended purpose of the devices.	Yes: <input type="checkbox"/>
a8_003_2	If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories for a medical device and for a product listed in Annex XVI shall be classified in their own right separately from the device with which they are used.	Yes: <input type="checkbox"/>
a8_003_3_1	Software, which drives a device or influences the use of a device, shall fall within the same class as the device.	Yes: <input type="checkbox"/>
a8_003_3_2	If the software is independent of any other device, it shall be classified in its own right.	Yes: <input type="checkbox"/>
a8_003_4	If the device is not intended to be used solely or principally in a specific part of the body, it shall be considered and classified on the basis of the most critical specified use.	Yes: <input type="checkbox"/>
a8_003_5	If several rules, or if, within the same rule, several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and sub-rule resulting in the higher classification shall apply.	Yes: <input type="checkbox"/>



a8_003_6_1	In calculating the duration referred to in Section 1, continuous use shall mean: (a) the entire duration of use of the same device without regard to temporary interruption of use during a procedure or temporary removal for purposes such as cleaning or disinfection of the device. Whether the interruption of use or the removal is temporary shall be established in relation to the duration of the use prior to and after the period when the use is interrupted, or the device removed; and	Yes: <input type="checkbox"/>	
a8_003_6_2	(b) the accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.	Yes: <input type="checkbox"/>	
a8_003_7	A device is considered to allow direct diagnosis when it provides the diagnosis of the disease or condition in question by itself or when it provides decisive information for the diagnosis.	Yes: <input type="checkbox"/>	
3. NON-INVASIVE DEVICES			
MDR ID:	Rules:	Applicable:	Class:
a8_004	NON-INVASIVE DEVICES	Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to Rule 5	-
a8_004_1	Rule 1 All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies.	Yes: <input type="checkbox"/> No: <input type="checkbox"/>	Class I
a8_004_2	Rule 2 All non-invasive devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified as class IIa: – if they may be connected to a class IIa, class IIb or class III active device; or – if they are intended for use for channelling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags; blood bags are classified as class IIb.	Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to Rule 3	Class IIa
		Yes: <input type="checkbox"/>	Class IIb
	In all other cases such devices are classified as class I.	Yes: <input type="checkbox"/>	Class I
a8_004_3	Rule 3 All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body are classified as class IIb,	Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to Rule 4	Class IIb
	unless the treatment for which the device is used consists of filtration, centrifugation or exchanges of gas, heat, in which case they are classified as class IIa.	Yes: <input type="checkbox"/>	Class IIa
	All non-invasive devices consisting of a substance or a mixture of substances intended to be used in vitro in direct contact with human cells, tissues or organs taken from the human body or used in vitro with human embryos before their implantation or administration into the body are classified as class III.	Yes: <input type="checkbox"/>	Class III



a8_004_4	Rule 4 All non-invasive devices which come into contact with injured skin or mucous membrane are classified as: – class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;	Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to Rule 9	Class I
	– class IIb if they are intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent;	Yes: <input type="checkbox"/>	Class IIb
	– class IIa if they are principally intended to manage the micro-environment of injured skin or mucous membrane; and	Yes: <input type="checkbox"/>	Class IIa
	– class IIa in all other cases.	Yes: <input type="checkbox"/>	Class IIa
4. INVASIVE DEVICES			
MDR ID:	Definition:	Applicable:	
a8_005	INVASIVE DEVICES	Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to Rule 9	-
a8_005_1	Rule 5 All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device are classified as: – class I if they are intended for transient use;	Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to Rule 6	Class I
	– class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity, in which case they are classified as class I; and	Yes: <input type="checkbox"/> → expect if, Yes: <input type="checkbox"/>	Class IIa Class I
	– class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are classified as class IIa.	Yes: <input type="checkbox"/> → expect if, Yes: <input type="checkbox"/>	Class IIb Class IIa
	All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to a class IIa, class IIb or class III active device, are classified as class IIa.	Yes: <input type="checkbox"/>	Class IIa



a8_005_2	<p>Rule 6 All surgically invasive devices intended for transient use are classified as class IIa unless they:</p>	<p>Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to Rule 7</p>	Class IIa
	– are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;	Yes: <input type="checkbox"/>	Class III
	– are reusable surgical instruments, in which case they are classified as class I;	Yes: <input type="checkbox"/>	Class I
	– are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;	Yes: <input type="checkbox"/>	Class III
	– are intended to supply energy in the form of ionising radiation in which case they are classified as class IIb;	Yes: <input type="checkbox"/>	Class IIb
	– have a biological effect or are wholly or mainly absorbed in which case they are classified as class IIb; or	Yes: <input type="checkbox"/>	Class IIb
	– are intended to administer medicinal products by means of a delivery system, if such administration of a medicinal product is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are classified as class IIb.	Yes: <input type="checkbox"/>	Class IIb
a8_005_3	<p>Rule 7 All surgically invasive devices intended for short-term use are classified as class IIa unless they:</p>	<p>Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to Rule 8</p>	Class IIa
	– are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;	Yes: <input type="checkbox"/>	Class III
	– are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;	Yes: <input type="checkbox"/>	Class III
	– are intended to supply energy in the form of ionizing radiation in which case they are classified as class IIb;	Yes: <input type="checkbox"/>	Class IIb



	– have a biological effect or are wholly or mainly absorbed in which case they are classified as class III;	Yes: <input type="checkbox"/>	Class III
	– are intended to undergo chemical change in the body in which case they are classified as class IIb, except if the devices are placed in the teeth; or	Yes: <input type="checkbox"/>	Class IIb
	– are intended to administer medicines, in which case they are classified as class IIb.	Yes: <input type="checkbox"/>	Class IIb
a8_005_4	Rule 8 All implantable devices and long-term surgically invasive devices are classified as class IIb unless they:	Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to Rule 9	Class IIb
	– are intended to be placed in the teeth, in which case they are classified as class IIa;	Yes: <input type="checkbox"/>	Class IIa
	– are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as class III;	Yes: <input type="checkbox"/>	Class III
	– have a biological effect or are wholly or mainly absorbed, in which case they are classified as class III;	Yes: <input type="checkbox"/>	Class III
	– are intended to undergo chemical change in the body in which case they are classified as class III, except if the devices are placed in the teeth;	Yes: <input type="checkbox"/>	Class III
	– are intended to administer medicinal products, in which case they are classified as class III.	Yes: <input type="checkbox"/>	Class III
	– are active implantable devices or their accessories, in which cases they are classified as class III;	Yes: <input type="checkbox"/>	Class III
	– are breast implants or surgical meshes, in which cases they are classified as class III;	Yes: <input type="checkbox"/>	Class III
	– are total or partial joint replacements, in which case they are classified as class III, with the exception of ancillary components such as screws, wedges, plates and instruments; or	Yes: <input type="checkbox"/>	Class III



	– are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III with the exception of components such as screws, wedges, plates and instruments	Yes: <input type="checkbox"/>	Class III
(a8_004_4)	Proof if Rule 4 is applicable. Because this rule applies also to the invasive devices that come into contact with injured mucous membrane.	Yes: <input type="checkbox"/> → Go to Rule 4 No: <input type="checkbox"/> → Go to Rule 9	-



5. ACTIVE DEVICES			
MDR ID:	Rules:	Applicable:	Class:
a8_006	ACTIVE DEVICES	Yes: <input type="checkbox"/> No: <input type="checkbox"/> → Go to Rule 14	-
a8_006_1	Rule 9 All active therapeutic devices intended to administer, or exchange energy are classified as class IIa unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class IIb.	Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to Rule 10	Class IIa
	All active devices intended to control or monitor the performance of active therapeutic class IIb devices, or intended directly to influence the performance of such devices are classified as class IIb.	Yes: <input type="checkbox"/>	Class IIb
	All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.	Yes: <input type="checkbox"/>	Class IIb
	All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class III.	Yes: <input type="checkbox"/>	Class III
a8_006_2	Rule 10 Active devices intended for diagnosis and monitoring are classified as class IIa:	Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to Rule 11	Class IIa
	– if they are intended to supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body, in the visible spectrum, in which case they are classified as class I;	Yes: <input type="checkbox"/>	Class I
	– if they are intended to image in vivo distribution of radiopharmaceuticals; or – if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate danger, in which cases they are classified as class IIb.	Yes: <input type="checkbox"/>	Class IIb



	Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.	Yes: <input type="checkbox"/>	Class IIb
a8_006_3	Rule 11 Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:	Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to Rule 12	Class IIa
	– death or an irreversible deterioration of a person's state of health, in which case it is in class III; or	Yes: <input type="checkbox"/>	Class III
	– a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.	Yes: <input type="checkbox"/>	Class IIb
	Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.	Yes: <input type="checkbox"/> → expect if, Yes: <input type="checkbox"/>	Class IIa Class IIb
	All other software are classified as class I.	Yes: <input type="checkbox"/>	Class I
a8_006_4	Rule 12 All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are classified as class IIa, unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are classified as class IIb.	Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to Rule 13	Class IIa
		Yes: <input type="checkbox"/>	Class IIb
a8_006_5	Rule 13 All other active devices are classified as class I.	Yes: <input type="checkbox"/> No: <input type="checkbox"/>	Class I



6. SPECIAL RULES			
a8_007_1	Rule 14 All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the devices, are classified as class III.	Yes: <input type="checkbox"/> No: <input type="checkbox"/>	Class III
a8_007_2	Rule 15 All devices used for contraception or prevention of the transmission of sexually transmitted diseases are classified as class IIb, unless they are implantable or long term invasive devices, in which case they are classified as class III.	Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to Rule 16	Class IIb
		Yes: <input type="checkbox"/>	Class III
a8_007_3	Rule 16 All devices intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses are classified as class IIb.	Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to Rule 17	Class IIb
	All devices intended specifically to be used for disinfecting or sterilising medical devices are classified as class IIa, unless they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing, in which case they are classified as class IIb.	Yes: <input type="checkbox"/> → expect if,	Class IIa
	(This rule does not apply to devices that are intended to clean devices other than contact lenses by means of physical action only.)	Yes: <input type="checkbox"/>	Class IIb
a8_007_4	Rule 17 Devices specifically intended for recording of diagnostic images generated by X-ray radiation are classified as class IIa.	Yes: <input type="checkbox"/> No: <input type="checkbox"/>	Class IIa
a8_007_5	Rule 18 All devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable, are classified as class III, unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable and are devices intended to come into contact with intact skin only.	Yes: <input type="checkbox"/> No: <input type="checkbox"/>	Class III
a8_007_6	Rule 19 All devices incorporating or consisting of nanomaterial are classified as: – class III if they present a high or medium potential for internal exposure;	Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to Rule 20	Class III
	– class IIb if they present a low potential for internal exposure; and	Yes: <input type="checkbox"/>	Class IIb
	– class IIa if they present a negligible potential for internal exposure.	Yes: <input type="checkbox"/>	Class IIa
a8_007_7	Rule 20 All invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal	Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to Rule 21	Class IIa



	products by inhalation are classified as class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product or they are intended to treat life-threatening conditions, in which case they are classified as class IIb.	Yes: <input type="checkbox"/>	Class IIb
a8_007_8	Rule 21 Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body are classified as: – class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;	Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to Rule 22	Class III
	– class III if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body;	Yes: <input type="checkbox"/>	Class III
	– class IIa if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities; and	Yes: <input type="checkbox"/>	Class IIa
	– class IIb in all other cases.	Yes: <input type="checkbox"/>	Class IIb
a8_007_9	Rule 22 Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III.	Yes: <input type="checkbox"/> No: <input type="checkbox"/>	Class III
-	Device classified above as CLASS I	Yes: <input type="checkbox"/> → Continue No: <input type="checkbox"/> → Go to final result	-
-	Sterile	Yes: <input type="checkbox"/>	Class Is
-	Measuring function	Yes: <input type="checkbox"/>	Class Im
-	FINAL RESULT:	Rule X	Class X