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: ☐ → Continue No: ☐ → Go to **2. Invasive and Active Devices**
a8_001_1	Transient' means normally intended for continuous use for less than 60 minutes.	Yes: ☐ No: ☐
a8_001_2	Short term' means normally intended for continuous use for between 60 minutes and 30 days.	Yes: ☐ No: ☐
a8_001_3	Long term' means normally intended for continuous use for more than 30 days.	Yes: ☐ No: ☐
2. INVASIVE AND ACTIVE DEVICES		
MDR ID:	**Definition:**	**Applicable:**
-	Invasive and active devices:	Yes: ☐ → Continue No: ☐ → 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: ☐ No: ☐

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: ☐ No: ☐
a8_002_2_2	(b) a device which produces penetration other than through a body orifice.	Yes: ☐ No: ☐
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: ☐ No: ☐
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: ☐ No: ☐
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: ☐ No: ☐
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: ☐ No: ☐
a8_002_7	Central nervous system' means the brain, meninges and spinal cord.	Yes: ☐ No: ☐
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: ☐ No: ☐
a8_003_1	Application of the classification rules shall be governed by the intended purpose of the devices.	Yes: ☐ No: ☐
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: ☐ No: ☐
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: ☐ No: ☐
a8_003_3_2	If the software is independent of any other device, it shall be classified in its own right.	Yes: ☐ No: ☐
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: ☐ No: ☐
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: ☐ No: ☐

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: ☐ No: ☐
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: ☐ No: ☐
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: ☐ No: ☐

3. NON-INVASIVE DEVICES

MDR ID:	Rules:	Applicable:	Class:
a8_004	NON-INVASIVE DEVICES	Yes: ☐ → Continue No: ☐ → 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: ☐ No: ☐	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:	Yes: ☐ → Continue No: ☐ → Go to **Rule 3**	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: ☐ No: ☐	Class IIb
	In all other cases such devices are classified as class I.	Yes: ☐ No: ☐	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: ☐ → Continue No: ☐ → 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: ☐ No: ☐	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: ☐ No: ☐	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: ☐ → Continue No: ☐ → 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: ☐ No: ☐	Class IIb
	– class IIa if they are principally intended to manage the micro-environment of injured skin or mucous membrane; and	Yes: ☐ No: ☐	Class IIa
	– class IIa in all other cases.	Yes: ☐ No: ☐	Class IIa
4. INVASIVE DEVICES			
MDR ID:	**Definition:**	**Applicable:**	
a8_005	INVASIVE DEVICES	Yes: ☐ → Continue No: ☐ → 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: ☐ → Continue No: ☐ → 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: ☐ → expect if,	Class IIa
		Yes: ☐ → For pharynx, ear drum or nasal cavity only No: ☐	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: ☐ → expect if,	Class IIb
		Yes: ☐ → No absorbed by mucous No: ☐	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: ☐ No: ☐	Class IIa