

NON-ACTIVE MEDICAL DEVICES		
<b>CRITERIA 1</b> All medical devices that are not infiltrate into the body which comes in contact with the skin with wound	If intended to cover wounds (mechanical barrier) by pressing on or absorbing the seepage liquid out of the wound only, for example, the tool Doctors use to treat primary wounds (primary intent) → Classified as a class 1 medical device	<ul> <li>simple wound dressings</li> <li>wound dressing such as absorbent pads, island dressings, cotton wool, wound strips, adhesive bandages (sticking plasters, band-aid) and gauze dressings which act as a barrier, maintain wound position or absorb exudates from the wound</li> </ul>
	If intended for use on a ruptured wound to the dermis layer including medical devices intended for micro-environment management (microenvironment) of the wound → Classified as a class 2 medical device	<ul> <li>non-medicated impregnated gauze dressings</li> <li>Have specific properties intended to assist the healing process by controlling the level of moisture at the wound during the healing process and to generally regulate the environment in terms of humidity and temperature, levels of oxygen and other gases and pH values or by influencing the process by other physical means.</li> <li>These devices may specify particular additional healing properties whilst not being intended for extensive wounds requiring healing by secondary intent.</li> <li>Adhesives for topical use</li> <li>polymer film dressings</li> <li>hydrogel dressing</li> </ul>
	If intended for use on a ruptured wound to the dermis layer and can heal wounds. Secondary intent only → Classified as a class 3 medical device	<ul> <li>Dressings for chronic ulcerated wounds</li> <li>Are principally intended to be used with severe wounds that have substantially and extensively breached the dermis, and where the healing process can only be by secondary intent such as</li> <li>dressings for chronic extensive ulcerated wounds</li> <li>dressings for severe burns having breached the dermis and covering an extensive area</li> <li>dressings for severe decubitis wounds</li> <li>dressings incorporating means of augmenting tissue and providing a temporary skin substitute</li> </ul>
CRITERIA 2	ightarrow Classified as a class 1 medical device	<ul> <li>The said medical device indirectly invades the body. because it is the way through or retain body fluids body tissues, other fluids, or gases which will eventually bring such substances into the body. Medical device example</li> <li>administration sets for gravity infusion</li> <li>syringes without needles</li> </ul>
All medical devices that are not infiltrate into the body which is used as a passageway or keep • body fluids or body tissues • other liquids or • Gas If intended for intravenous solution (infusion) or administration (administration) or taking the substance (introduction) into the body	If connected to a powerful medical device Category 2 or higher category → Classified as a class 2 medical device	<ul> <li>syringes and administration sets for infusion pumps</li> <li>anesthesia breathing circuits</li> <li>devices intended to be used as channels in active drug delivery systems (e.g. tubing intended for use with an infusion pump)</li> <li>devices used for channeling (e.g. antistatic tubing for anesthesia, anesthesia breathing circuits, pressure indicator, pressure limiting devices)</li> </ul>
	If the medical device is intended for use in • the passage of blood or • stores or is a passageway for other bodily fluids. Or • Collect organs. Some of the organs. or tissue body → Classified as a class 2 medical device	<ul> <li>tubes used for blood transfusion</li> <li>organ storage containers</li> <li>fridges specifically intended for storing blood, tissues</li> <li>medical device example</li> </ul>
	If it is a bag containing blood → Classified as a class 3 medical device	- blood bags that do not incorporate an anti-coagulant



<b>CRITERIA 3</b> All medical devices that are not invade into the body which is intended for use improve biological composition or the chemistry of • blood or • other bodily fluids, or • Other liquids If intended for intravenous solution Blood entering the body (infusion)	→ Classified as a class 3 medical device	Such medical devices indirectly invade the body. because of purpose for use to improve biological constituents or the chemistry of the substance, which in the end will bring such substances into the body (Details are in the notes to criteria 4) Such medical devices are generally used in conjunction with live medical devices within the scope of rules 9 or 11) - devices to remove white blood cells from whole blood - devices intended to remove undesirable substances out of the blood by exchange of solutes such as hemodialysers - devices intended to separate cells by physical means (e.g. gradient medium for sperm separation) - haemodialysis concentrates Note: For the criteria in this article, the term "intended for biological assembly or the chemistry of the substance" does not cover filtration, simple filtration, mechanical filtration or centrifuge
	If the treatment consists of filtering centrifugation (centrifuging) or gas or heat exchange. → Classified as a class 2 medical device	medical device example - devices to remove carbon dioxide from the blood and/or adding oxygen - particulate filtration of blood in an extracorporeal circulation system. These are used to remove particles and emboli from the blood. - centrifugation of blood to prepare it for transfusion or autotransfusion - warming or cooling the blood in an extracorporeal circulation system
<b>CRITERIA 4</b> All other medical devices that are not has infiltrated the body beyond the rules 1-3	→ Classified as a class 1 medical device	<ul> <li>medical devices according to this guidelines not touching the patient or touching normal skin no wound</li> <li>body liquid collection devices intended to be used in such a way that a return flow in unlikely (e.g. to collect body wastes such as urine collection bottles, ostomy pouches, incontinence pads or collectors used with wound drainage devices). They may be connected to the patient by means of catheters and tubing.</li> <li>Devices used to immobilize body parts and/or to apply force or compression on them (e.g. non-sterile dressing used to aid the healing of a sprain, plaster of Paris, cervical collars, gravity traction devices, compression hosiery)</li> <li>devices intended in general for external patient support (e.g. hospital beds, patient hoists, walking aids, wheelchairs, stretchers, dental patient chair)</li> <li>corrective glasses and frames</li> <li>stethoscopes for diagnosis</li> <li>eye occlusion plasters</li> <li>incision drapes</li> <li>conductive gels</li> <li>non-invasive electrodes (electrodes for EEG or ECG)</li> <li>image intensifying screens</li> <li>permanent magnets for removal of ocular debris</li> </ul>
<b>CRITERIA 5</b> All invasive medical devices enter the body through the body openings (without inclusion of invasion into the body by means of surgery)	If intended to be used for a short time → Classified as a class 1 medical device If intended for use on the outer surface of the eyeball or have a tendency to be absorbed by the epithelium containing mucus	<ul> <li>examination gloves</li> <li>enema devices</li> <li>handheld mirrors used in dentistry to aid in dental diagnosis and surgery</li> <li>dental impression materials</li> <li>tubes used for pumping the stomach</li> <li>impression trays</li> <li>urinary catheters intended for transient use</li> <li>prostatic balloon dilation catheters</li> </ul>
<ul> <li>It is not intended to be connected to a medical device. with strength or</li> <li>Intended to connect to a class of medical device that only 1</li> </ul>	<ul> <li>→ Classified as a class 2 medical device</li> <li>If intended for short term use</li> <li>→ Classified as a class 2 medical device</li> </ul>	<ul> <li>urinary catheters</li> <li>tracheal tubes</li> <li>short term corrective contact lenses</li> <li>stents</li> <li>vaginal pessaries</li> <li>indwelling urinary catheters intended for short term use</li> </ul>



	If the crown is meant to be taken short-term in the oral cavity until	- dentures intended to be removed by the patient
	Throat, ear canal to eardrum, or nasopharynx	- dressings for nose bleeds
	$\rightarrow$ Classified as a class 1 medical device	- materials for manufacturing dentures
		medical device example
	If aiming for long term use	- contact lenses for long-term continuous use (for this device, removal of the lens for cleaning or
	ightarrow Classified as a class 3 medical device	maintenance is considered as part of the continuous use)
		- tracheal cannulae
		- urinary catheters intended for long term use
	If intended for long-term oral use until throat, ear canal to eardrum, or	- orthodontic wire
	nasopharynx and no Tendency to be absorbed by the characteristic	- fixed dental prosthesis
	epithelium, slime	- fissure sealants
	→ Classified as a class 2 medical device	
		- Tracheostomy or tracheal tubes connected to a ventilator
	All medical devices invading the body through the openings of the	- dental aspirator tips
	hody (excluding encroachment into the hody through a surgical	- blood oxygen analyzers placed under the eye-lid
	procedure) that aims to connect to a powerful medical device 2nd or	- powered nasal irrigators
	higher category	- nasopharyngeal airways
	$\rightarrow$ Classified as a class 2 medical device	- some enteral feeding tubes
		- fiber optics in endoscopes connected to surgical lasers
		Note: The duration of invasion depends on the medical device.
		Note
		1. Medical devices used in surgery other than category 4 medical devices
		- If reused It is classified as a class 1 medical device.
		- If sterile and can be used once It is classified as a class 2 medical device.
		- If connected to a powerful medical device classified as a medical device higher category than class 1
		2. If it is a medical device that contains drugs as a component and the drug acts secondary to medical equipment Consider criteria 12
		- syringe needles
		- lancets
		- surgical instruments (e.g. single use scalpels; surgical staplers; single-use aortic punch)
	-> Classified as a class 2 modical device	- surgical gloves
		- various classs of catheters/suckers
CRITERIA 6		- needles used for suturing
Medical devices that invade body with all surgical procedures aimed at for temporary use		- suckers
		- single use scalpel blades
		- support devices in ophthalmic surgery
		- Surgical Swaps
		- etchants
		- tester of artificial heart valves
		- heart valve occluders, sizers and holders
		- swabs to sample exudates
		- single use aortic punches
		- manually operated surgical drill bits and saws.
		- scalpels and scalpel handles
	If it is a surgical medical device that brings recycle	- reamers
	$\rightarrow$ Classified as a class 1 medical device	- drill bits
		- saws, that are not intended for connection to an active device
		- sternum retractors for transient use



	If intended to supply energy in the form of Radiation causing ionization $\rightarrow$ Classified as a class 3 medical device	- catheter incorporating/containing sealed radioisotopes
	If the aim is to have a biological effect or absorbed all or most $ ightarrow$ Classified as a class 3 medical device	<ul> <li>- insufflation gases for the abdominal cavity</li> <li>Note The criteria in this article do not include substances that are eliminated from the body without change element</li> </ul>
	If aiming to administer drugs as a delivery system (delivery system) and operate in a manner that will cause harm by considering the model use $\rightarrow$ Classified as a class 3 medical device	- insulin pen for self-administration
	If you intend to touch directly to the nervous system central $\rightarrow$ Classified as a class 4 medical device	<ul> <li>neuro-endoscopes</li> <li>brain spatulas</li> <li>direct stimulation canulae</li> <li>spinal cord retractors</li> <li>spinal needles</li> </ul>
	If aiming to diagnose, monitor or correct heart defects or circulatory system central, through direct contact with the loud part said of the body → Classified as a class 4 medical device	<ul> <li>- cardiovascular catheters (e.g. angioplasty balloon catheters, stent delivery catheters/systems), including related guidewires, related introducers and dedicated disposable cardiovascular surgical instruments e.g. electrophysiological catheters, electrodes for electrophysiological diagnosis and ablation</li> <li>- catheters containing or incorporating sealed radioisotope where the radioactive isotope is not intended to be released into the body, if used in the central circulatory system</li> <li>- distal protection devices</li> </ul>
	→ Classified as a class 2 medical device	medical equipment Most of these guidelines are used for surgery. or after treatment from surgery or infusion devices or various classs of catheters         - infusion cannulae         - temporary filling materials         - non-absorbable skin closure devices         - tissue stabilizers used in cardiac surgery         - clamps         note         1. Medical devices under this criteria include medical devices used for heart surgery, but not Monitor or correct patient abnormalities         2. If the medical device contains drugs and drugs perform secondary functions medical equipment Consider criteria 13
CRITERIA 7	If aiming to administer medication $\rightarrow$ Classified as a class 3 medical device or	Remark: "Medication administration" means the storage and/or effect on the rate/volume of drug delivered It's not just the way of medicine.
Medical devices invade body with all surgical procedures aimed at for short term use	If aiming to make changes in the way body chemistry (except for medical devices inserted in tooth) → Classified as a class 3 medical device	- surgical adhesive
	If intended to supply energy in the form of radiation causing ionization $\rightarrow$ Classified as a class 3 medical device	- brachytherapy device
	If intended to produce biological effects or to be absorbed all or most of the → Classified as a class 4 medical device	- absorbable suture - biological adhesive
	If intended for direct contact with the system central nervous system $\rightarrow$ Classified as a class 4 medical device or	- neurological catheters - cortical electrodes
	If aiming to diagnose, monitor or correct heart defects or circulatory system central, through direct contact with the loud part said of the body → Classified as a class 4 medical device	<ul> <li>cardiovascular catheters</li> <li>temporary pacemaker leads</li> <li>carotid artery shunts</li> <li>cardiac output probes</li> <li>thoracic catheters intended to drain the heart, including the pericardium</li> <li>ablation catheters</li> </ul>



	→ Classified as a class 3 medical device	Medical devices under this guidelines cover medical devices that are implanted in the body. used in orthopedics, dentistry, ophthalmology and cardiovascular - maxilla-facial implants - prosthetic joint replacements - bone cement - non absorbable internal sutures - posts to secure teeth to the mandibula bone (without a bioactive coating) - ligaments - shunts - shunts - stents and valves (e.g. pulmonary) - nails and plates - intra-ocular lenses - internal closure devices including vascular closure devices - tissue augmentation implants - peripheral vascular catheters - peripheral vascular grafts and stents - penile implants
		<ul> <li>visco-elastic surgical devices intended specifically for ophthalmic anterior segment surgery</li> <li>Note: If a medical device contains a drug and a drug acts as a secondary from medical devices, consider criteria 13</li> <li>bridges</li> </ul>
<b>CRITERIA 8</b> Medical devices implanted in the body all and infiltrate the body by means of surgery intended for long- term use	If aiming to put in the teeth → Classified as a class 2 medical device or	<ul> <li>crown</li> <li>dental filling materials and pins</li> <li>dental alloys, ceramics and polymers</li> </ul>
	If intended for direct contact with the heart, the system central circulatory or the nervous system center → Classified as a class 4 medical device	<ul> <li>prosthetic heart valves</li> <li>spinal and vascular stents</li> <li>aneurysm clips</li> <li>vascular prosthesis and stents</li> <li>central vascular catheters</li> <li>CNS electrodes</li> <li>cardiovascular sutures</li> <li>permanent and retrievable vena cava filters</li> <li>septal occlusion devices</li> <li>intra-aortic balloon pumps</li> <li>external left ventricular assisting devices</li> </ul>
	If intended to support or save lives $\rightarrow$ Classified as a class 4 medical device	
	If intended to be an implantable medical device powerful body $\rightarrow$ Classified as a class 4 medical device	<ul> <li>pacemakers</li> <li>pacemakers's electrodes and leads</li> <li>implantable defibrillators</li> </ul>
	If intended to provide biological effects or absorbed all or most → Classified as a class 4 medical device	<ul> <li>implants claimed to be bioactive</li> <li>absorbable sutures</li> <li>adhesive and implantable devices claimed to be bioactive through the attachment of surface coating such as phosphorylcholine</li> </ul>
	If aiming to administer medication → Classified as a class 4 medical device	- rechargeable non-active drug delivery system
	If aiming to make changes in the way body chemistry (except dental implants) → Classified as a class 4 medical device	
	If it is an artificial breast implanted in the body $\rightarrow$ Classified as a class 4 medical device	



ACTIVE MEDICAL DEVICES			
CRITERIA 9(1)	→ Classified as a class 2 medical device	Most of the medical devices under this Criteria are medical devices currently being used in surgery, medical devices for special treatment (specialized treatment) and a stimulator (stimulators) Electrical and/or magnetic and electromagnetic energy - external bone growth stimulators - eye electromagnets - electrical acupuncture - muscle stimulator - TEN devices Thermal energy - cryosurgery equipment - heat exchangers, except the classs described below Mechanical energy - powered dermatomes - powered drills - dental hand pieces Light - phototherapy for skin treatment and for neonatal aids Sound - hearing aids Ultrasound - equipment for physiotherapy	
Powerful medical devices used in all treatments intended to administer or exchange energy	If aiming to manage or exchange energy enter or take out of the body which tends to Hazards, including radiation causing ruptures. The ionic body when considering nature dense, and a position that manages or trades energy → Classified as a class 3 medical device	Kinetic energy- Lung VentilatorsThermal energy- Incubators for babies- Warming blankets- Blood warmers- Electrically powered heat exchangers (for example, those used with patients incapable of reacting, communicating and/or who are without a sense of feeling)Electrical energy- High-frequency electrosurgical generators, and electrocautery equipment, including their electrodes- External pacemakers and defibrillators- Electroconvulsive therapy equipment.Coherent light- Surgical lasersUltrasound- Lithotriptors, surgical ultrasound devicesIonizing radiation- Radioactive sources for afterloading therapy- Therapeutic cyclotrons and linear accelerators- Therapeutic X-ray sourcesNOTE "Prone to harm" means a class of technology. The relevant and intended use of it is likely to be harmful.	



<b>CRITERIA 9(2)</b> Powerful medical devices all intended to control or monitor the performance of the medical device with the power used to Class III treatment, or aimed at producing an effect directly to the performance of that medical device	ightarrow Classified as a class 3 medical device	<ul> <li>external feedback systems for active therapeutic devices</li> <li>afterloading control devices</li> </ul>
<b>CRITERIA 10(1)</b> Powerful medical devices intended for diagnosis If intended to supply energy absorbed by human body (except medical devices used for only give light to the patient's body. which the light is in visible or near infrared spectral range	<ul> <li>→ Classified as a medical device class 1</li> <li>Or If aiming to create a diffuse image of radiopharmaceuticals in the body (radiopharmaceuticals)</li> <li>Or if intended to diagnose or monitor directly in Physiological processes that are directly important to life (vital physiological processes)</li> <li>→ Classified as a class 2 medical device</li> </ul>	Medical devices under this guidelines include ultrasound machines for diagnose/improve tracking physiological signals radiation therapy (interventional radiology and diagnostic radiology - magnetic resonance equipment - diagnostic ultrasound in non-critical applications - evoked response stimulators - pulp testers - gamma/nuclear cameras - positron emission tomography and single photon emission computer tomography - electronic thermometers - electronic thermometers - electrocardiographs - electronic stethoscopes - electronic stethoscopes - electronic blood pressure measuring equipment - monitors/alarms for intensive care - biological sensors - oxygen saturation monitors - apnea monitors, including apnea monitors in home care - intensive care monitoring and alarm devices (e.g. blood pressure, temperature, oxygen saturation) - blood gas analyzers used in open heart surgery - cardioscopes
	→ Classified as a class 3 medical device	- ultrasound equipment for use in interventional cardiac procedures.
<b>CRITERIA 10(2)</b> Powerful medical devices intended to emit radiation that causes fission ionizing radiation and is intended to diagnostic radiation or combined radiation therapy. (interventional radiology), including controlled medical devices or follow up with such medical devices or tool the doctor directly affects the performance of the tool.	→ Classified as a class 3 medical device	<ul> <li>these include devices for the control, monitoring or influencing of the emission of ionizing radiation</li> <li>diagnostic X-ray sources</li> </ul>
CRITERIA 11 All-powered medical devices intended to administer and/or eliminate drugs, liquids in the body	→ Classified as a class 2 medical device	Most of the medical devices under this Criteria are drug delivery systems or devices. for anesthesia - suction equipment - feeding pumps - jet injectors for vaccination - nebulizer to be used on conscious and spontaneously breathing patients where failure to deliver the appropriate dosage characteristics is not potentially hazardous



or other substances entering or		
looving the body		- anosthosia aquinment
leaving the body		- dialysis equipment
		- hyperbaric chambers
	medical devices under the above paragraph if there is a tendency to	- nebulizer where the failure to deliver the appropriate dosage characteristics could be bazardous
	cause harm considering the nature of the substance involved body parts	- ventilators
	form and channel of administration or eliminated	- anaesthetic vanorisers
	$\rightarrow$ Classified as a class 3 medical device	blood numps for heart-lung machines
		- pressure regulators for medical gases
		- medical gas mixers
		- moisture exchangers in breathing circuits if used on unconscious
		or non-spontaneously breathing patients
		- examination lamps
		- surgical microscopes
		- powered hospital beds & wheelchairs
CRITERIA 12		- powered equipment for the recording, processing, viewing of diagnostic images
		- dental curing lights
Medical devices with strength that	$\rightarrow$ Classified as a class 1 medical device	- active diagnostic devices intended to illuminate the patient's body in the visible spectrum such as
do not fit network of the above-		examination lights or to optically view the body such as surgical microscopes
mentioned criteria		- devices intended in general for external patient support (e.g. hospital beds, patient hoists,
		wheelchairs, dental patient chairs)
		- active diagnostic devices intended for thermography
		- antibiotic bone cements
CRITERIA 13		- heparin-coated catheters
		- wound dressings incorporating antimicrobial agents to provide ancillary action on the wound
Medical devices containing drugs		- blood bags incorporating an anti-coagulant
(according to drug law) as an	Classified as a class 4 medical douise	- condom with spermicide
integrated ingredient It is part of		- endodontic materials with antibiotics
the medical device, to supplement		- ophthalmic irrigation solutions principally intended for irrigation, which contain components which
the functioning of medical devices		support the metabolism of the endothelial cells of the cornea
on the body		- contraceptive intrauterine devices (IUDs) containing copper or silver
,		- drug eluting stents (e.g. coronary, pulmonary)
CRITERIA 14		- Porcine heart valves
		- catgut sutures
		- dermal fillers based on hyaluronic acid derived from bacterial fermentation processes
All medical devices produced or	$\rightarrow$ Classified as a class 4 medical device	- surgical sealants containing human serum
nave these included		- Biological heart valves
Cells, tissues and/or derivatives of		- Porcine xenograft dressing
grow or		- Implants and dressing made from collageal
• Cells tissues and/or microhial	If the medical device is manufactured or is part of non-viable animal	
derivatives or by combining new	tissues or derivatives from animal tissues are included and touch with	- leather components of orthopedic appliances
gene structures	normal skin (intact skin) only	
		- aevices for disinfecting or sterilizing endoscopes
CRITERIA 15	$\rightarrow$ Classified as a class 3 medical device	- aisinfectants intended to be used with medical devices
		NOTE: This guideline does not include machines intended for cleaning medical devices by physical
All medical devices specifically		means such as wasning machines
intended to be used for making	In aiming to disinfect medical equipment before the end Ultimate Sterile	
medical devices sterilized or	Classified as a class 2 modical device or	- Washer Uishneddus
sterilized at the end of the	Classified as a class 2 medical device of	
procedure.	for contact long	- contact lens solutions
	$\rightarrow$ Classified as a class 3 medical device	- comfort solutions



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CRITERIA 16	ightarrow Classified as a class 3 medical device	- condoms - contraceptive diaphragms
All medical devices used for contraception or prevent infectious diseases from intercourse	If it is a medical device that is implanted in the body or penetrates into the body for a long time $\rightarrow$ Classified as a class 4 medical device	- intrauterine contraceptive device

Notes

(1) in the case of medical devices may be classified in more than one category in accordance with the above rules; to classify that medical device It is the class with the highest risk.

(2) in the case of a medical device designed to be used in conjunction with other medical devices as well Classify shared medical devices. that by considering and categorizing each item according to the medical device (3) in the case of a medical device having more than one purpose of use; Classify such medical devices according to Purpose of Use with the Highest Risk

References

1. Guidance document: Classification of Medical Devices MEDDEV 2.4/1 Rev 9, June 2010.

2. GN-13: Guidance on the Risk Classification of General Medical Devices: Revision 1.1, May 2014, Health. Sciences Authority (HSA), Singapore