MEDICAL DEVICES RISK CLASSIFICATION IN THAI FDA

A full description of criteria for Medical Device Risk Classification applied by Thai FDA with examples

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1. DEFINITIONS

ACTIVE MEDICAL DEVICE: Any medical device, operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patients, without any significant change, are not considered to be active medical devices.

NOTE: Standalone software (to the extent it falls within the definition of a medical device) is deemed to be an active device.

ACTIVE THERAPEUTIC DEVICE: Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.

ACTIVE DEVICE INTENDED FOR DIAGNOSIS: Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring orto support in treating physiological conditions, states of health, illnesses or congenital deformities.

BODY ORIFICE: Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy.

CENTRAL CIRCULATORY SYSTEM: For the purpose of this document, central circulatory system means the major internal blood vessels including the following:

- arteriae pulmonales (pulmonary artery);
- aorta ascendens (ascending aorta);
- arteriae coronariae (coronary artery);
- arteria carotis communis (common carotid artery);
- arteria carotis externa (external carotid artery);
- arteria carotis interna (internal carotid artery);
- arteriae cerebrates (cerebella arteries);
- truncus brachiocephalicus (brachiocephalic trunk);
- venae cordis (cardiac veins);
- venae pulmonales (pulmonary vein);
- °venae cava superior (Superior vena cava);
- venae cava inferior (inferior vena cava);
- arcus aorta (aortic arch);
- thoracica aorta (thoracic aorta);
- abdominalis aorta (abdominal aorta);
- arteriae ilica communis (common iliac arteries);
- aorta descendens to the bifurcatio aortae. (descending aorta to the bifurcation of aorta)

CENTRAL NERVOUS SYSTEM: For the purpose of this document, central nervous system refers to the brain, meninges and spinal cord.

CONTINUOUS USE: in relation to a medical device, means

- the uninterrupted use of the medical device, not including any temporary interruption of its use during a procedure or any temporary removal of the medical device for purposes such as cleaning or disinfection; or
- the accumulated use of the medical device by replacing it immediately with another medical device of the same type, as intended by its product owner;

DURATION OF USE

- TRANSIENT: Normally intended for continuous use for less than 60 minutes,
- SHORT TERM: Normally intended for continuous use for between 60 minutes and 30 days
- LONG TERM: Normally intended for continuous use for more than 30 days.

HARM: Physical injury or damage to the health of people or damage to property or the environment.

HAZARD: Potential source of harm.

IMMEDIATE DANGER: A situation where the patient is at risk of either losing life or an important physiological function if no immediate preventative measure is taken.

IMPLANTABLE MEDICAL DEVICE: Any medical device, including those that are partially or wholly absorbed, which is intended:

- to be totally introduced into the human body or,
- to replace an epithelial surface or the surface of the eye, by surgical intervention which is intended to remain in place after the procedure.

NOTE: Any medical device intended for partial introduction into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable medical device.

INVASIVE MEDICAL DEVICE: A medical device, which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

LIFE SUPPORTING OR LIFE SUSTAINING: A medical device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

REUSABLE SURGICAL INSTRUMENT: Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or other surgical procedures, without connection to any active medical device and which are intended by the product owner to be reused after appropriate procedures for cleaning and/or sterilization have been carried out.

RISK: Combination of the probability of occurrence of harm and the severity of that harm.

SURGICALLY INVASIVE MEDICAL DEVICE: An invasive medical device that penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

NOTE: Medical devices other than those referred to in the previous subparagraph and which produce penetration other than through a natural body orifice, should be treated as surgically invasive medical devices.

2. RISK CLASSIFICATION FOR MEDICAL DEVICES

A. NON-INVASIVE MEDICAL DEVICES

Rule 1. All non-invasive medical devices which come into contact with injured skin:

- are in Class A if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates only, i.e. they heal by primary intent
- are in Class B if they are intended to be used principally with wounds which have breached the dermis, including medical devices principally intended to manage the microenvironment of a wound

Unless they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, in which case they are in Class C

Rule 2. All non-invasive medical devices intended for channelling or storing

- body liquids or tissues,
- liquids or
- gases

for the purpose of eventual infusion, administration or introduction into the body are in Class A,

Unless they may be connected to an active medical device in Class B or a higher class, in which case they are Class B;

Unless they are intended for use of

- channeling blood, or
- storing or channeling other body liquids, or
- for storing organs, parts of organs or body tissues,

in which case they are Class B.

Unless they are blood bags, in which case they are Class C.

Rule 3. All non-invasive medical devices intended for modifying the biological or chemical composition of

- blood,
- other body liquids, or
- other liquids

intended for infusion into the body are in Class C.

Unless the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in class A.

Rule 4. All other non-invasive medical devices are in Class A.

B. INVASIVE MEDICAL DEVICES

Rule 5. All invasive medical devices with respect to body orifices (other than those which are surgically invasive) and which:

- are not intended for connection to an active medical device, or
- are intended for connection to a Class A medical device only.

- are in Class A if they are intended for transient use;

Unless they are intended by its product owner for use on the external surface of any eyeball; or it is liable to be absorbed by the mucous membrane, in which case they are in Class B.

- are in Class B if they are intended for short-term use;

Unless they are intended for short-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class A.

- are in Class C if they are intended for long term use

Unless they are intended for long-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear-drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class B.

All invasive medical devices with respect to body orifices (other than those which are surgically invasive) that are intended to be connected to an active medical device in Class B or higher class, are in Class B.

Rule 6. All surgically invasive medical devices intended for transient use are in Class B.

Unless they are reusable surgical instruments, in which case they are inClass A; or

Unless intended to supply energy in the form of ionising radiation, in which case they are in Class C; or

Unless intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class C; or

Unless intended to administer medicinal products by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class C; or

Unless they are intended specifically for use in direct contact with the

Unless intended specifically to diagnose, monitor or correct a defect of the central nervous system, in which case they are in Class D; or

Unless intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D

Rule 7. All surgically invasive medical devices intended for short-term use are in Class B,

Unless they are intended to administer medicinal products, in which case they are in Class C; or

Unless they are intended to undergo chemical change in the body (except if the medical devices are placed in the teeth), in which case they are in Class C; or

Unless they are intended to supply energy in the form or ionising radiation, in which case they are in Class C; or

Unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or

Unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D;

Unless they are intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.

Rule 8. All implantable medical devices, and long-term surgically invasive medical devices, are in Class C,

Unless they are intended to be placed into the teeth, in which case they are in Class B; or

Unless they 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 in Class D; or

Unless they are intended to be life supporting or life sustaining, in which case they are in Class D; or

Unless they are intended to be active implantable medical devices, in which case they are Class D; or

Unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or

Unless they are intended to administer medicinal products, in which case they are in Class D; or

Unless they are intended to undergo chemical change in the body (except if the medical devices are placed in the teeth), in which case they are in Class D; or

Unless they are breast implants, in which case they are in Class D.

C. ACTIVE MEDICAL DEVICES

Rule 9(i). All active therapeutic medical devices intended to administer or exchange energy are in Class B,

Unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionising radiation, taking account of the nature, the density and site of application of the energy, in which case they are in Class C.

Rule 9(ii). All active medical devices intended to control or monitor the performance of active therapeutic medical devices in Class C, or intended directly to influence the performance of such medical devices, are in Class C

RULE 10(i). Active medical devices intended for diagnosis are in Class B:

- if they are intended to supply energy which will be absorbed by the human body (except for medical devices used solely to illuminate the patient's body, with light in the visible or near infrared spectrum, in which case they are Class A), or
- if they are intended to image in viv distribution of radiopharmaceuticals, or
- if they are intended to allow direct diagnosis or monitoring of vital physiological processess

Unless they are specifically intended for:

- monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of central nervous system, or
- diagnosing in clinical situations where the patient is in immediate danger, in which case they are in Class C.

Rule 10(ii). Active medical devices intended to emit ionising radiation and intended for diagnostic and/or interventional radiology, including medical devices which control or monitor such medical devices, or those which directly influence their performance, are in Class C.

Rule 11. All active medical devices intended to administer and/or remove medicinal product, body liquids or other substances to or from the body are in Class B,

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 and route of administration or removal, in which case they are in class C

Rule 12. All other active medical devices are in class A

D. ADDITIONAL RULES

Rule 13. All-medical. Devices incorporating,-as-an integral part, a substance which, if used separately, can be considered to be a medicinal product (as defined by the Member State), and which is liable to act on the human body with action ancillary to that of the medical devices, are in Class C.

Rule 14. All medical devices manufactured from or incorporating

- animal cells, tissues and/or derivatives thereof, rendered non-viable, or
- cells, tissues and/or derivatives of microbial or recombinant origin

are Class D,

Unless such medical devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only, where they are in Class A.

Rule 15. All medical devices intended specifically to be used for sterilizing medical devices, or disinfecting as the end point of processing, are in Class C.

Unless they are intended for disinfecting medical devices prior to end point sterilizationor higher level disinfection, in which case they are in Class B; or

Unless they are intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses, in which case they are in Class C.

Rule 16. All medical devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class C,

Unless they are implantable or long-term invasive medical devices, in which case they are in Class D.

RISK-BASED CLASSIFICATION OF MEDICAL DEVICES

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NON-ACTIVE MEDICAL DEVICES		
CRITERIA 1 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	- simple wound dressings - 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
	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	- non-medicated impregnated gauze dressings - 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. - These devices may specify particular additional healing properties whilst not being intended for extensive wounds requiring healing by secondary intent. - Adhesives for topical use - polymer film dressings - hydrogel dressing
	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	- Dressings for chronic ulcerated wounds - 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 • dressings for chronic extensive ulcerated wounds • dressings for severe burns having breached the dermis and covering an extensive area • dressings for severe decubitis wounds • dressings incorporating means of augmenting tissue and providing a temporary skin substitute
CRITERIA 2 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	→ Classified as a class 1 medical device	- 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 - administration sets for gravity infusion - syringes without needles
	If connected to a powerful medical device Category 2 or higher category → Classified as a class 2 medical device	- syringes and administration sets for infusion pumps - anesthesia breathing circuits - devices intended to be used as channels in active drug delivery systems (e.g. tubing intended for use with an infusion pump) - devices used for channeling (e.g. antistatic tubing for anesthesia, anesthesia breathing circuits, pressure indicator, pressure limiting devices)
	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	- tubes used for blood transfusion - organ storage containers - fridges specifically intended for storing blood, tissues medical device example
	If it is a bag containing blood → Classified as a class 3 medical device	- blood bags that do not incorporate an anti-coagulant

CRITERIA 3 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
CRITERIA 4 All other medical devices that are not has infiltrated the body beyond the rules 1-3	→ Classified as a class 1 medical device	medical devices according to this guidelines not touching the patient or touching normal skin no wound - 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. - 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) - devices intended in general for external patient support (e.g. hospital beds, patient hoists, walking aids, wheelchairs, stretchers, dental patient chair) - corrective glasses and frames - stethoscopes for diagnosis - eye occlusion plasters - incision drapes - conductive gels - non-invasive electrodes (electrodes for EEG or ECG) - image intensifying screens - permanent magnets for removal of ocular debris
CRITERIA 5 All invasive medical devices enter the body through the body openings (without inclusion of invasion into the body by means of surgery) • It is not intended to be connected to a medical device. with strength or • Intended to connect to a class of medical device that only 1	If intended to be used for a short time → Classified as a class 1 medical device	- examination gloves - enema devices - handheld mirrors used in dentistry to aid in dental diagnosis and surgery - dental impression materials - tubes used for pumping the stomach - impression trays - urinary catheters intended for transient use - prostatic balloon dilation catheters
	If intended for use on the outer surface of the eyeball or have a tendency to be absorbed by the epithelium containing mucus → Classified as a class 2 medical device	
	If intended for short term use → Classified as a class 2 medical device	- urinary catheters - tracheal tubes - short term corrective contact lenses - stents - vaginal pessaries - indwelling urinary catheters intended for short term use

	If the crown is meant to be taken short-term in the oral cavity until Throat, ear canal to eardrum, or nasopharynx → Classified as a class 1 medical device	- dentures intended to be removed by the patient - dressings for nose bleeds - materials for manufacturing dentures
	If aiming for long term use → Classified as a class 3 medical device	medical device example -urethral stent - contact lenses for long-term continuous use (for this device, removal of the lens for cleaning or 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 nasopharynx and no Tendency to be absorbed by the characteristic epithelium, slime → Classified as a class 2 medical device	- orthodontic wire - fixed dental prosthesis - fissure sealants
	All medical devices invading the body through the openings of the body (excluding encroachment into the body through a surgical procedure) that aims to connect to a powerful medical device 2nd or higher category → Classified as a class 2 medical device	- Tracheostomy or tracheal tubes connected to a ventilator - suction catheters for stomach drainage - dental aspirator tips - blood oxygen analyzers placed under the eye-lid - powered nasal irrigators - nasopharyngeal airways - some enteral feeding tubes - fiber optics in endoscopes connected to surgical lasers Note: The duration of invasion depends on the medical device.
CRITERIA 6 Medical devices that invade body with all surgical procedures aimed at for temporary use	→ Classified as a class 2 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 13 - syringe needles - lancets - surgical instruments (e.g. single use scalpels; surgical staplers; single-use aortic punch) - surgical gloves - various classs of catheters/suckers - needles used for suturing - suckers - single use scalpel blades - support devices in ophthalmic surgery - surgical swabs - drill bits connected to active devices - etchants - tester of artificial heart valves - heart valve occluders, sizers and holders - swabs to sample exudates - single use aortic punches
	If it is a surgical medical device that brings recycle → Classified as a class 1 medical device	- manually operated surgical drill bits and saws. - scalpels and scalpel handles - reamers - drill bits - saws, that are not intended for connection to an active device - retractors forceps, excavators and chisels - sternum retractors for transient use

	If intended to supply energy in the form of Radiation causing ionization → 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 → Classified as a class 3 medical device	- insufflation gases for the abdominal cavity Note The criteria in this article do not include substances that are eliminated from the body without change element
	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 → Classified as a class 3 medical device	- insulin pen for self-administration
	If you intend to touch directly to the nervous system central → Classified as a class 4 medical device	- neuro-endoscopes - brain spatulas - direct stimulation canulae - spinal cord retractors - spinal needles
	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	- 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 - 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 - distal protection devices
CRITERIA 7 Medical devices invade body with all surgical procedures aimed at for short term use	→ 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
	If aiming to administer medication → 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.
	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 → 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 → 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	- cardiovascular catheters - temporary pacemaker leads - carotid artery shunts - cardiac output probes - thoracic catheters intended to drain the heart, including the pericardium - ablation catheters

CRITERIA 8 Medical devices implanted in the body all and infiltrate the body by means of surgery intended for long-term use	→ 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 - 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 - visco-elastic surgical devices intended specifically for ophthalmic anterior segment surgery Note: If a medical device contains a drug and a drug acts as a secondary from medical devices, consider criteria 13
	If aiming to put in the teeth → Classified as a class 2 medical device or	- bridges - crown - dental filling materials and pins - dental alloys, ceramics and polymers
	If intended for direct contact with the heart, the system central circulatory or the nervous system center → Classified as a class 4 medical device	- prosthetic heart valves - spinal and vascular stents - aneurysm clips - vascular prosthesis and stents - central vascular catheters - CNS electrodes - cardiovascular sutures - permanent and retrievable vena cava filters - septal occlusion devices - intra-aortic balloon pumps - external left ventricular assisting devices
	If intended to support or save lives → Classified as a class 4 medical device	
	If intended to be an implantable medical device powerful body → Classified as a class 4 medical device	- pacemakers - pacemakers's electrodes and leads - implantable defibrillators
	If intended to provide biological effects or absorbed all or most → Classified as a class 4 medical device	- implants claimed to be bioactive - absorbable sutures - adhesive and implantable devices claimed to be bioactive through the attachment of surface coating such as phosphorylcholine
	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 → Classified as a class 4 medical device	

ACTIVE MEDICAL DEVICES		
CRITERIA 9(1) Powerful medical devices used in all treatments intended to administer or exchange energy	→ 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
	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 Ventilators Thermal 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 lasers Ultrasound - Lithotriptors, surgical ultrasound devices Ionizing radiation - Radioactive sources for afterloading therapy - Therapeutic cyclotrons and linear accelerators - Therapeutic X-ray sources NOTE “Prone to harm” means a class of technology. The relevant and intended use of it is likely to be harmful.

CRITERIA 9(2) 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	→ Classified as a class 3 medical device	- external feedback systems for active therapeutic devices - afterloading control devices
CRITERIA 10(1) 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	→ Classified as a medical device class 1 Or If aiming to create a diffuse image of radiopharmaceuticals in the body (radiopharmaceuticals) Or if intended to diagnose or monitor directly in Physiological processes that are directly important to life (vital physiological processes) → Classified as a class 2 medical device	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 - electrocardiographs - electroencephalographs - cardioscopes with or without pacing pulse indicators - electronic stethoscopes - electronic blood pressure measuring equipment
	If specifically aimed at • Follow up on physiological factors that are important to life. (vital physiological parameters), which such change causing harmful effects acute on the patient, for example, changes performance of the heart, breathing, functioning of central nervous system, or • Clinical diagnosis to show that the patient is in Acute Hazardous Conditions → Classified as a class 3 medical device	- 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 - ultrasound equipment for use in interventional cardiac procedures.
CRITERIA 10(2) 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	- these include devices for the control, monitoring or influencing of the emission of ionizing radiation - diagnostic X-ray sources
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 leaving the body	medical devices under the above paragraph, if there is a tendency to cause harm considering the nature of the substance involved body parts form and channel of administration or eliminated → Classified as a class 3 medical device	- infusion pumps - anesthesia equipment - dialysis equipment - hyperbaric chambers - nebulizer where the failure to deliver the appropriate dosage characteristics could be hazardous - ventilators - anaesthetic vaporisers blood pumps 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
CRITERIA 12 Medical devices with strength that do not fit network of the above-mentioned criteria	→ Classified as a class 1 medical device	- examination lamps - surgical microscopes - powered hospital beds & wheelchairs - powered equipment for the recording, processing, viewing of diagnostic images - dental curing lights - active diagnostic devices intended to illuminate the patient's body in the visible spectrum such as examination lights or to optically view the body such as surgical microscopes - devices intended in general for external patient support (e.g. hospital beds, patient hoists, wheelchairs, dental patient chairs) - active diagnostic devices intended for thermography
CRITERIA 13 Medical devices containing drugs (according to drug law) as an integrated ingredient It is part of the medical device. to supplement the functioning of medical devices on the body	→ Classified as a class 4 medical device	- antibiotic bone cements - heparin-coated catheters - wound dressings incorporating antimicrobial agents to provide ancillary action on the wound - blood bags incorporating an anti-coagulant - condom with spermicide - endodontic materials with antibiotics - ophthalmic irrigation solutions principally intended for irrigation, which contain components which support the metabolism of the endothelial cells of the cornea - contraceptive intrauterine devices (IUDs) containing copper or silver - drug eluting stents (e.g. coronary, pulmonary)
CRITERIA 14 All medical devices produced or have these included • Cells, tissues and/or derivatives of animal origin. which is unable to grow, or • Cells, tissues and/or microbial derivatives. or by combining new gene structures	→ Classified as a class 4 medical device	- Porcine heart valves - catgut sutures - dermal fillers based on hyaluronic acid derived from bacterial fermentation processes - surgical sealants containing human serum - Biological heart valves - Porcine xenograft dressing - Implants and dressing made from collageal
	If the medical device is manufactured or is part of non-viable animal tissues or derivatives from animal tissues are included and touch with normal skin (intact skin) only → Classified as a class 1 medical device	- leather components of orthopedic appliances
CRITERIA 15 All medical devices specifically intended to be used for making medical devices sterilized or sterilized at the end of the procedure.	→ Classified as a class 3 medical device	- devices for disinfecting or sterilizing endoscopes - disinfectants intended to be used with medical devices NOTE: This guideline does not include machines intended for cleaning medical devices by physical means such as washing machines
	If aiming to disinfect medical equipment before the end Ultimate Sterile Process or before sterilization at a higher level → Classified as a class 2 medical device or	- washer disinfectors
	If specifically intended for disinfection, cleaning, washing or moistening for contact lens → Classified as a class 3 medical device	- contact lens solutions - comfort solutions

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