NOTIFICATION OF THE MINISTRY OF PUBLIC HEALTH
RE: RISK CLASSIFICATION OF MEDICAL DEVICES,
B.E. 2562 (2019)*

In order to ensure that the control and regulation of medical devices are efficient and consistent with the control of medical devices at the ASEAN region and international levels, it is expedient to classify classes of medical devices or medical devices or medical devices according to the level of their risks of danger to the health, body or life of human or impacts on public health with a view to ensuring safety in the use of medical devices and appropriate consumer protection.

By virtue of the provisions of section 5 paragraph one of the Medical Devices Act, B.E. 2551 (2008) and section 6 (1) of the Medical Devices Act, B.E. 2551 (2008) as amended by the Medical Devices Act (No. 2), B.E. 2562 (2019), the Minister of Public Health, upon recommendation of the Board of Medical Devices, hereby issues the Notification as follows.

Clause 1. Medical devices shall be classified into 2 classes:

(1) in vitro diagnostic medical devices;

(2) non-in vitro diagnostic medical devices.

Clause 2. In vitro diagnostic medical devices shall be classified according to the level of individual and public health risks from low to high levels as follows:

(1) type 1 medical device means a medical device with low individual and public health risks;

(2) type 2 medical device means a medical device with a moderate individual risk or a low public health risk;

(3) type 3 medical device means a medical device with a high individual risk or a moderate public health risk;

(4) type 4 medical device means a medical device with high individual and public health risks.

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* Published in the Government Gazette, Vol. 136, Special Issue, Part 308d, page 53, dated 18th December B.E. 2562 (2019)

The classification of in vitro diagnostic medical devices according to the level of risks under clause 1 shall be in accordance with Document No. 1 annexed to this Notification.

Clause 3. Non-in vitro diagnostic medical devices shall be classified according to the level of risks that may be caused from low to high levels as follows:

(1) type 1 medical device means a medical device with a low risk;

(2) type 2 medical device means a medical device with a low-moderate risk;

(3) type 3 medical device means a medical device with a moderate-high risk;

(4) type 4 medical device means a medical device with a high risk.

The classification of non-in vitro diagnostic medical devices according to the level of risks shall be in accordance with Document No. 2 annexed to this Notification.

Clause 4. In the case where there is a problem as to the classification of medical devices, the Secretary-General of the Food and Drug Administration shall have the power to make a decision thereon.

Clause 5. The risk classification of medical devices under this Notification shall be in accordance with the following measures to control classes of medical devices or medical devices:

(a) classes of medical devices or medical devices for which manufacturers or importers are required to obtain a license are medical devices under clause 2 (4) or clause 3 (4);

(b) classes of medical devices or medical devices of which manufacturers or importers are required to declare specifications are medical devices under clause 2 (2) or (3) or clause 3 (2) or (3);

(c) classes of medical devices or medical devices in respect of which manufacturers or importers are required to make a notification are medical devices under clause 2 (1) or clause 3 (1).

The classes of medical devices or medical devices subject to the requirement of license, declaration of specifications or notification shall be as prescribed by the Notification of the Minister upon recommendation of the Board of Medical Devices.

For the purpose of consumer protection, the Minister upon recommendation of the Board of Medical Devices shall have the power to prescribe by Notification classes of medical devices or medical devices which are different from paragraph one.

Clause 6. This Notification shall come into force as from the day of its publication in the Government Gazette.

Announced on the 14th day of November B.E. 2563 (2020)
Anutin Charnvirakul
Minister of Public Health

Document No. 1

Risk Classification of In Vitro Diagnostic Medical Devices
Annexed to the Notification of the Ministry of Public Health Re: Risk Classification of Medical Devices, B.E. 2562 (2019)

In the risk classification of in vitro diagnostic medical devices, regard shall be had to factors affecting the level of risks, such as intended purposes and instruction for use of the medical device as specified by the product owner, skills of the users of the medical device, and importance and impacts of information received from the medical device to individuals and public health.

1. In this Document:

"Medical device" means a medical device for humans, and does not include that for animals.

"In vitro diagnostic (IVD) medical device" means any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system or any other article, whether used alone, together or in combination with another medical device, that is intended by the product owner to be used for examination of a specimen derived from the human body, including donated blood and organs, for the purpose of providing information—

(1) concerning a physiological or pathological state or a congenital abnormality;

(2) to determine the safety and compatibility of tissue donation with a potential recipient of the organ; or

(3) to monitor therapeutic measures, including a specimen receptacle.

"Instrument" means equipment or apparatus intended by the product owner to be used as an IVD medical device.

"Reagent" means any chemical, biological or immunological components, solutions or preparations intended by the product owner to be used as an IVD medical device.

"IVD medical device for self-testing" means any IVD medical device intended by the product owner for use by lay persons.

"Specimen receptacle" means an IVD medical device, whether vacuum-type or not, specifically intended by the product owner for the primary containment of specimens derived from the human body.

"Product owner" means any natural person or juristic person who—

(1) sells the medical device under his or her own name, or under any trademark, design, trade name or other name or mark owned or controlled by such person; and

(2) is responsible for designing, manufacturing, assembling, processing, labelling, packaging, or assigning to it a purpose, whether those tasks are performed by such person or under the assignment of such person.

"Lay person" means a person who does not have formal training in a relevant field or discipline.

"Examination" means a set of operations to determine the value of a property or an attribute.

Note:

Examination of an analyte in a biological sample is commonly referred to as a test, assay, or analysis.

"Near patient testing" means any test performed outside a laboratory by a health care professional not necessarily a laboratory professional, generally near to, or at the side of, the patient, which may also be referred to as Point-of-Care (POC).

"Self-testing" means a test performed by a lay person.

"Transmissible agent" means an agent capable of being transmitted or communicated to a person that causes a communicable disease or an infectious disease.

"Transmission" means the conveyance of disease to a person.

2. Rules of Risk Classification for IVD Medical Devices

Rule 1. IVD medical devices intended for the following purposes are classified as type 4 medical devices:

- medical devices intended for detecting the presence of or exposure to a transmissible agent in blood, blood components, blood derivatives, cells, tissues or organs in order to assess their suitability for transfusion or transplantation; or
- medical devices intended for detecting the presence of or exposure to a transmissible agent that causes a life-threatening, incurable disease with a high risk of propagation.

Principles and Rationale: These medical devices are IVD medical devices intended to be used to ensure the safety of blood and blood components for transfusion or for transplantation of cells, tissues and organs. In most cases, the result of the test is the major determinant as to whether the donation or product will be used. As serious diseases arising from blood transfusion or transplantation of cells, tissues and organs are those that result in death or long-term disability, which are incurable or require therapeutic interventions, an accurate diagnosis is therefore vital to mitigate the public health impact.

Examples: Tests to detect infection by HIV, HCV, HBV, HTLV. This Rule applies to first-line assays, confirmatory assays and supplemental assays.

Rule 2. IVD medical devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissues or organs for blood transfusion or transplantation are classified as type 3 medical devices.

However, IVD medical devices used for blood grouping in ABO system [A (ABO1), B (ABO2), AB (ABO3)], rhesus system [RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e)], Kell system [Kel1 (K)], Kidd system [JK1 (Jka), JK2 (Jkb)] and Duffy system [FY1 (Fya), FY2 (Fyb)] are classified as type 4 medical devices.

Principles and Rationale: These medical devices are medical devices with a high risk to an individual, where an erroneous result would put the patient in a life-threatening situation, and are therefore classified as type 4 medical devices. The rule divides blood-grouping IVD medical devices into 2 categories, i.e., type 3 medical devices or type 4 medical devices, depending on the nature of the blood group antigen the IVD medical device is capable to detect, and the importance of the blood group antigen in a transfusion setting.

Examples: HLA, Duffy system (other Duffy systems except those listed in the rule as type 4 medical devices) are type 3 medical devices.

Rule 3. IVD medical devices intended for any of the following uses are classified as type 3 medical devices:

- in detecting the presence of or exposure to a sexually transmitted agent (e.g. *Chlamydia trachomatis*, *Neisseria gonorrhoeae*);
- in detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation (e.g. *Neisseria meningitidis* or *Cryptococcus neoformans*);
- in detecting the presence of an infectious agent where there is a high risk that an erroneous result would cause death or severe disability to the patient or fetus (e.g. diagnostic assay for Cytomegalovirus (CMV), *Chlamydia pneumoniae*, Methycillin Resistant *Staphylococcus aureus*);
- in pre-natal screening of women in order to determine their immune status towards transmissible agents (e.g. immune status tests for Rubella or Toxoplasmosis);
- in determining infectious disease status or immune status, and where there is a risk that an erroneous result will lead to a therapy decision resulting in a life-threatening

situation for the patient (e.g. Enteroviruses, CMV and Herpes simplex virus (HSV) in transplant patients);

- in screening for selection of patients for selective therapy and management, or for disease staging, or in the diagnosis of cancer (e.g. personalized medicine);

Note:

The abovementioned IVD medical devices where further investigation and monitoring must be undertaken before making a therapy decision would be classified as type 2 medical devices under Rule 6.

- in human genetic testing (e.g. Huntington's Disease, Cystic Fibrosis);
- in monitoring levels of medicinal drugs, substances or biological components, when there is a risk that an erroneous result will lead to a therapy decision resulting in an immediate life-threatening situation for the patient (e.g. Cardiac markers, cyclosporin, prothrombin time testing);
- in the therapy of patients suffering from a life-threatening infectious disease (e.g. HCV viral load, HIV Viral Load and HIV and HCV geno- and subtyping);
- in screening for congenital disorders in the fetus (e.g. Spina Bifida or Down Syndrome).

Principles and Rationale: The IVD medical devices in this class present a high individual risk or a moderate public health risk, where an erroneous result would put the patient in a life-threatening situation, or would have a major negative impact. The IVD medical devices in this class provide the critical, or sole, determinant for the correct diagnosis. They may also present a high individual risk because of the stress and anxiety resulting from the information and the nature of the possible follow-up measures.

Rule 4. IVD medical devices intended for self-testing are classified as type 3 medical devices. Medical devices from which the result is not determining a medically critical status, or is preliminary and requires follow-up with the appropriate laboratory test are classified as type 2 medical devices. IVD medical devices intended for blood gases and blood glucose determinations for near-patient testing are classified as type 3 medical devices. Other IVD medical devices intended for near-patient testing are classified in accordance with the medical device classification rules.

Principles and Rationale: Users of the IVD medical devices in this class are persons with no technical expertise and thus the labelling and instructions for use are critical to the correctness of the outcome of the test.

Examples: An IVD medical device intended for self-testing classified as type 3 is a blood glucose monitoring kit.

Examples: IVD medical devices intended for self-testing classified as type 2 are pregnancy self-test, fertility testing, and urine test strip.

Rule 5. The following IVD medical devices are classified as type 1 medical devices:

- reagents or other substances that possess specific characteristics intended by the product owner to make them suitable for in-vitro diagnostic procedures related to a specific examination;
- instruments intended by the product owner specifically to be used for in-vitro diagnostic procedures;
- specimen receptacles.

Note:

Any products for general laboratory use which are not manufactured, sold or represented for use specifically in in-vitro diagnostic applications are not classified as IVD medical devices.

Principles and Rationale: These IVD medical devices present a low individual risk and no or minimal public health risk.

Examples: Selective/differential microbiological media (excluding the dehydrated powders which are considered not to be a finished IVD medical device), identification kits for cultured microorganisms, wash solutions, instruments and plain urine cup.

Note:

(1) The performance of software or an instrument that has specific assessment criteria will be assessed at the same time as the test kit.

(2) The interdependence of the instrument and the test methodology prevents the instrument from being assessed separately, even though the instrument itself is classified as a type 1 medical device.

Rule 6. IVD medical devices other than those specified in Rules 1 - 5 are classified as type 2 medical devices.

Principles and Rationale: This class of IVD medical devices present a moderate individual risk as their erroneous result would not cause death or severe disability, or have a major negative impact on the therapy, or put the patient in immediate danger. The IVD medical

devices give results that are usually one of several determinants. If the test result is the sole determinant however other information is available, such as presenting signs and symptoms or other clinical information that may guide the therapy of a physician, such medical devices are classified as type 2 medical devices. Other appropriate controls may also be put in place to validate the results. Type 2 medical devices also include the IVD medical devices that present a low public health risk, because they detect infectious agents that are not easily propagated in a population.

Examples: Blood gases, *H. pylori* and physiological markers, such as hormones, vitamins, enzymes, metabolic markers, specific IgE assays and celiac disease markers.

Rule 7. IVD medical devices that are controls without a quantitative or qualitative assigned value are classified as type 2 medical devices.

Principles and Rationale: For IVD medical devices which are controls, the user, not the product owner, assigns the qualitative or quantitative value.

3. In cases where a medical device may be classified into more than one type of medical device according to the aforementioned rules, it shall be classified into the type representing the highest risk.

4. In cases where a medical device is designed to be used in combination with another medical device, each of the medical devices used in the combination shall be classified separately.

5. In cases where a medical device has more than one intended purpose, the medical device shall be classified according to the intended purpose with the highest risk.

Document No. 2

Risk Classification of Non-In Vitro Diagnostic Medical Devices Annexed to the Notification of the Ministry of Public Health Re: Risk Classification of Medical Devices, B.E. 2562 (2019)

In the risk classification of non-in vitro diagnostic medical devices, regard shall be had to factors affecting the risks, such as level of invasiveness, duration inside the body, nature of the use and biological effect.

1. In this Document:

"Medical device" means a medical device for humans, and does not include that for animals.

"Active medical device" means any medical device, operation of which depends on a source of electrical energy or any other source of power other than that directly generated by the human body or gravity and which acts by converting such energy. However, a medical device intended to transmit energy, substances or other elements between an active medical device and the patients without any significant change, are not deemed to be an active medical device. Standalone software (which falls within the definition of a medical device) is deemed to be an active medical device.

"Active therapeutic medical device" means any active medical device, whether used alone or in combination with other medical devices, to support, back or upkeep, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.

"Active medical device intended for diagnosis" means any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or to support in treating physiological conditions, states of health, illnesses or congenital deformities.

"Implantable medical device" means any medical device, including a medical device that is 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 of such medical device. Any medical device intended for partial introduction into the human body through surgical intervention and intended to remain in place for at least 30 days is also deemed to be an implantable medical device.

"Invasive medical device" means a medical device, which, in whole or in part, penetrates inside the body, either through a body orifice or through the skin.

"Life supporting or life sustaining" means 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.

"Surgically invasive medical device" means an invasive medical device that penetrates inside the body through the skin with the aid of a surgical operation, in whole or in part. Medical devices other than the aforementioned which produce penetration other than through a natural body orifice, are classified as surgically invasive medical devices.

"Reusable surgical instrument" means an instrument which is 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 is intended by the product owner to be reused after appropriate procedures for cleaning or sterilization have been carried out.

"Product owner" means any natural person or juristic person who—

(1) sells the medical device under his or her own name, or under any trademark, design, trade name or other name or mark owned or controlled by such person; and,

(2) is responsible for designing, manufacturing, assembling, processing, labelling, packaging, or assigning to it a purpose, whether those tasks are performed by such person or under the assignment of such person.

"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 or permanent tracheotomy.

"Central circulatory system" in this Document means the major internal blood vessels including the following:

(1) arteriae pulmonales (pulmonary artery);
(2) aorta ascendens (ascending aorta);
(3) arteriae coronariae (coronary artery);
(4) arteria carotis communis (common carotid artery);
(5) arteria carotis externa (external carotid artery);
(6) arteria carotis interna (internal carotid artery);
(7) arteriae cerebrates (cerebella arteries);
(8) truncus brachiocephalicus (brachiocephalic trunk);
(9) venae cordis (cardiac veins);
(10) venae pulmonales (pulmonary vein);
(11) venae cava superior (superior vena cava);
(12) venae cava inferior (inferior vena cava);

(13) arcus aorta (aortic arch);

(14) thoracica aorta (thoracic aorta);

(15) abdominalis aorta (abdominal aorta);

(16) arteriae ilica communis (common iliac arteries);

(17) aorta descendens to the bifurcatio aortae (descending aorta to the bifurcation of aorta).

"Central nervous system" means the brain, meninges and spinal cord.

"Continuous use" in relation to a medical device means:

(1) 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 certain purposes such as cleaning or disinfection; or

(2) 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" means:

(1) transient is a state of normal and continuous use for less than 60 minutes;

(2) short term is a state of normal and continuous use for between 60 minutes and 30 days;

(3) long term is a state of normal and continuous use for more than 30 days.

"Harm" means physical injury or damage to the health of people, properties or the environment.

"Hazard" means potential source of harm;

"Immediate danger" means a situation where the patient is at risk of losing life or an important physiological function if no immediate preventative measure is taken.

"Risk" means combination of the probability of occurrence of harm and the severity of that harm.

2. Rules of Risk Classification for Non-IVD Medical Devices

2.1 Non-Invasive Medical Devices

Rule 1. All non-invasive medical devices which come into contact with injured skin are classified as type 1 medical devices if they are intended to be used as a mechanical barrier for compression or for absorption of exudates leaked from the wound only, e.g. medical devices used to heal by primary intent.

They are classified as type 2 medical devices if they are intended to be used with wounds which have breached the dermis, including medical devices intended to manage the microenvironment of a wound.

They are classified as type 3 medical devices if they are intended to be used with wounds which have breached the dermis and can only heal by secondary intent.

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

- body liquids or body tissues;
- other liquids; or
- gases,

are classified as type 1 medical devices if they are intended for the purpose of infusion, administration or introduction into the body.

They are classified as type 2 medical devices if they are connected to a type 2 active medical device or a higher type.

They are classified as type 2 medical devices if they are intended for use of—

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

They are classified as type 3 medical devices if they are blood bags.

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

- blood; or
- other body liquids; or
- other liquids.

are classified as type 3 medical devices if they are intended for infusion into the body.

They are classified as type 2 medical devices if the treatment consists of filtration, centrifuging or exchanges of gas or of heat.

Rule 4. All other non-invasive medical devices other than those in Rules 1 – 3 are classified as type 1 medical devices.

2.2 Invasive Medical Devices

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

- are not intended for connection with an active medical device; or

- are intended for connection with a type 1 medical device;

are classified as type 1 medical devices if they are intended for transient use.

They are classified as type 2 medical devices if they are for use on the external surface of any eyeball or are liable to be absorbed by the mucous membrane.

They are classified as type 2 medical devices if they are intended for short-term use.

They are classified as type 1 medical devices if 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.

They are classified as type 3 medical devices if they are intended for long-term use.

They are classified as type 2 medical devices if 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.

All invasive medical devices with respect to body orifices (other than those which are surgically invasive) that are intended to be connected to a type 2 active medical device or a higher type, are classified as type 2 medical devices.

Rule 6. All surgically invasive medical devices intended for transient use are classified as type 2 medical devices.

If they are reusable surgical instruments, they are classified as type 1 medical devices; or

If they are intended to supply energy in the form of ionizing radiation, they are classified as type 3 medical devices; or

If they are intended to have a biological effect or be wholly or mainly absorbed, they are classified as type 3 medical devices; or

If they are intended to administer medicinal drugs by means of a delivery system, and this is done in a manner that is potentially hazardous, taking account of the mode of application, they are classified as type 3 medical devices; or

If they are intended for use in direct contact with the central nervous system, they are classified as type 4 medical devices; or

If they are intended for diagnosis, monitoring or correction of a defect of the heart or of the central circulatory system through direct contact with such part of the body, they are classified as type 4 medical devices.

Rule 7. All surgically invasive medical devices intended for short-term use are classified as type 2 medical devices.

If they are intended to administer medicinal drugs, they are classified as type 3 medical devices; or

If they are intended to undergo chemical change in the body (except if the medical devices are placed in the teeth), they are classified as type 3 medical devices; or

If they are intended to supply energy in the form or ionizing radiation, they are classified as type 3 medical devices; or

If they are intended to have a biological effect or to be wholly or mainly absorbed, they are classified as type 4 medical devices; or

If they are intended to be in direct contact with the central nervous system, they are classified as type 4 medical devices.

If they are intended for diagnosis, monitoring or correction of a defect of the heart or of the central circulatory system through direct contact with these parts of the body, they are classified as type 4 medical devices.

Rule 8. All implantable medical devices, and long-term surgically invasive medical devices are classified as type 3 medical devices.

If they are intended to be placed into the teeth, they are classified as type 2 medical devices; or

If they are intended to be in direct contact with the heart, the central circulatory system or the central nervous system, they are classified as type 4 medical devices; or

If they are intended to be life supporting or life sustaining, they are classified as type 4 medical devices; or

If they are intended to be active implantable medical devices, they are classified as type 4 medical devices; or

If they are intended to have a biological effect or be wholly or mainly absorbed, they shall be classified as type 4 medical devices; or

If they are intended to administer medicinal drugs, they are classified as type 4 medical devices; or

If they are intended to undergo chemical change in the body (except if the medical devices are placed in the teeth), they are classified as type 4 medical devices; or

If they are breast implants, they are classified as type 4 medical devices.

2.3 Active Medical Devices

Rule 9 (1). All active therapeutic medical devices intended to administer or exchange energy are classified as type 2 medical devices.

If they are intended to administer or exchange energy to or from the body in a potentially hazardous way, including ionizing radiation, taking account of the nature, the density and site of the administration or exchange of the energy, they are classified as type 3 medical devices.

Rule 9 (2). All active medical devices intended to control or monitor the performance of type 3 active therapeutic medical devices, or intended directly to influence the performance of such medical devices are classified as type 3 medical devices.

Rule 10 (1). Active medical devices intended for diagnosis are classified as type 2 medical devices—

if they are intended to supply energy which is absorbed by the human body (except for medical devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum, in which case they are classified as type 1 medical devices); or

if they are intended to image in vivo distribution of radiopharmaceuticals; or

if they are intended for direct diagnosis or monitoring of vital physiological processes.

If they are specifically intended for—

- monitoring of vital physiological parameters, where the nature of variations could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of central nervous system, they are classified as type 3 medical devices; or
- diagnosing in clinical situations where the patient is in immediate danger, they are classified as type 3 medical devices.

Rule 10 (2). Active medical devices intended to emit ionizing radiation and intended for diagnostic radiology or interventional radiology, including medical devices which control or monitor such medical devices, or medical devices which directly influence their performance are classified as type 3 medical devices.

Rule 11. All active medical devices intended to administer and/or remove medicinal drugs, body liquids or other substances to or from the body are classified as type 2 medical devices.

If the medical devices under the previous paragraph are potentially hazardous, they are type 3 medical devices, 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.

Rule 12. Active medical devices that do not fall into the abovementioned criteria are classified as type 1 medical devices.

2.4 Additional Rules

Rule 13. All medical devices incorporating as their integral part medicinal drugs (under the law on drugs) that act on the body with action ancillary to that of the medical devices, are classified as type 4 medical devices.

Rule 14. All medical devices manufactured from or incorporating the following are classified as type 4 medical devices:

- animal cells, tissues and/or derivatives thereof which are non-viable; or
- cells, tissues and/or derivatives of microbial or recombinant origin.

If such medical devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only, they are classified as type 1 medical devices.

Rule 15. All medical devices intended specifically to be used for sterilizing medical devices, or disinfecting as the end point of processing are classified as type 3 medical devices.

If they are intended for disinfecting medical devices prior to end point sterilization or higher-level disinfection, they are classified as type 2 medical devices; or

If they are intended specifically for disinfecting, cleaning, rinsing or hydrating contact lenses, they are classified as type 3 medical devices.

Rule 16. All medical devices used for contraception or the prevention of the transmission of sexually transmitted infectious diseases are classified as type 3 medical devices.

If they are implantable or long-term invasive medical devices, they are type 4 medical devices.

3. In cases where a medical device may be classified into more than one type of medical devices according to the aforementioned rules, it shall be classified into the type representing the highest risk.

4. In cases where a medical device is designed to be used in combination with another medical device, each of the medical devices used in the combination shall be classified separately.

5. In cases where a medical device has more than one intended purpose, the medical device shall be classified according to the intended purpose with the highest risk.