MEDICAL DEVICES RISK CLASSIFICATION IN THAI FDA

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.

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