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MEDICAL DEVICE GUIDANCE DOCUMENT

GUIDANCE ON THE RULES OF CLASSIFICATION FOR GENERAL MEDICAL DEVICES

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

a) Medical Device Act 2012 (Act 737);

b) Medical Device Regulations 2012.

In this Guidance Document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” indicates a possibility or a capability.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

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GUIDANCE ON THE RULES OF CLASSIFICATION FOR GENERAL MEDICAL DEVICE

1 Introduction

Regulatory controls are intended to safeguard the health and safety of patients, users and others by ensuring that manufacturers of medical devices follow specified procedures during design, manufacturing and marketing.

The level of controls will depend on the identified risks associated with devices, and the identification of a suitable way of generating a sustainable set of rules is an important feature of any regulatory control system.

The risk associated with using medical devices can range from little to significant potential risks inherent in the type of device. The level of premarket intervention by the regulator is proportional to the level of potential risk and established through a classification system based on that potential risk. The level of regulatory control increases with the increasing degree of risk, considering of the benefits offered by use of the device.

The classification of medical device is determined from:

a) The manufacturer's intended purpose for the medical device,

b) A set of classification rules.

These rules will classify medical devices into one of 4 classes of medical devices. The purposes of risk-based classification are:

a) To make sure that the regulatory controls applied to a medical device are proportionate to risk.

b) To assist a manufacturer to allocate its medical device to an appropriate risk class.

c) Regulatory authorities have the responsibility of ruling upon matters of interpretation for a particular medical device.

The purpose of this document is to provide guidance on how to determine the classification of medical device which has been specified in;

a) Section 3 of Medical Device Act 2012 (Act 737),

b) Paragraph 3(1)(a) of Medical Device Regulation 2012, and

c) First Schedule of Medical Device Regulation 2012.

2 Scope and application

This document applies to all products that fall within the definition of medical device that has been specified in the Guidance Document MDA/GD/0006: Guidance on The Definition of Medical Device, other than those used for the *in vitro* examination of specimens derived from the human body for which a separate document will be referred.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 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 but does not include medical devices intended to transmit energy, substances or other elements between an active medical device and the patients, without any significant change.
Source: Medical Device Regulations 2012

3.2 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 of alleviation of an illness, injury or handicap.

3.3 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 or to support in treating physiological conditions, states of health, illnesses or congenital deformities.

3.5 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.

3.6 central circulatory system

The major internal blood vessels including the following:

- pulmonary veins;
- pulmonary arteries;
- cardiac veins;
- coronary arteries;
- common carotid artery;

- external carotid artery;
- internal carotid artery;
- cerebral arteries;
- brachiocephalic artery;
- superior vena cava;
- inferior vena cava;
- aortic arch;
- thoracic aorta;
- abdominal aorta;
- ascending aorta;
- common iliac arteries;
- descending aorta to the bifurcation of aorta.

3.7 central nervous system

The brain, meninges, spinal cord and cerebrospinal fluid.

3.8 cleaning

Removal of contamination from an item to the extent necessary for its further processing and its intended subsequent use.

3.9 continuous use

a) The entire duration of use of the device without regard to temporary interruption of use during a procedure or, temporary removal for purposes such as cleaning or disinfection of the device.

b) The accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.

NOTE: For example, a scalpel may be used on the same patient throughout an operation that may last for several hours. The uninterrupted use for an intended purpose, i.e. cutting tissue, will normally not last for more than a few seconds at a time. Therefore, a scalpel is a transient use device. However, where usage of a device is discontinued in order for the device to be replaced immediately by the same or an identical device (e.g. replacement of a ureteric catheter) this shall be considered an extension of the continuous use of the device. If it cannot be demonstrated that components of the device are totally eliminated in the interval between uses, this is also considered as an immediate replacement.

3.10 disinfection

Reduction of the number of viable microorganisms on a product to a level previously specified as appropriate for its intended further handling or use.

3.11 duration of use

3.11.1 transient use

Normally intended for continuous use for less than 60 minutes.

3.11.2 short term use

Normally intended for continuous use for between 60 minutes and 30 days.

3.11.3 long term use

Normally intended for continuous use for more than 30 days.

3.12 harm

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

3.13 hazard

Potential source of harm.

3.14 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.

3.15 implantable medical device

Any 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 or any device intended to be partially introduced 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 device.

3.16 intended use

The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

3.17 invasive medical device

A device, which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

3.18 life supporting or life sustaining medical device

A 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.

3.19 medical device

As defined in section 2 of ACT 737 and MDA/GD/0006: Guidance on The Definition of Medical Device.

3.20 reusable surgical instrument

An 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 manufacturer to be reused after appropriate procedures for cleaning and/or sterilisation have been carried out.

3.21 risk

A combination of the probability of occurrence of harm and the severity of that harm.

3.22 radiopharmaceuticals

Unique medicinal formulations containing radioisotopes which are used in major clinical areas for diagnosis and/or therapy.

3.24 surgically invasive medical devices

An invasive device which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation; and a device which produces penetration other than through a body orifice.

NOTE: Devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, should be treated as surgically invasive devices. The term surgical operation used in this definition includes all clinical intervention procedures in which a device is placed into the body through the surface in the context of a surgical operation or other clinical procedure.

4 Principles of classification

4.1 General principles

a) The classification of the device is based on the risk associated to it at the point of usage (The risk to patients, users and other persons).

b) The risk presented by a particular device depends on:

i. Its intended purpose;
ii. The effectiveness of the risk management techniques applied during design, manufacture and use;
iii. Its intended user(s);
iv. Its mode of operation
v. Technologies.

4.2 Factors influencing device classification

a) A number of factors may influence medical device classification. These include:

i. The duration of contact of the device with the body;
ii. The degree of, and site of, invasiveness into the body;
iii. Whether the device deliver medicines or energy to the patient;
iv. Whether the device is intended to have a biological effect on the body;
v. Intended action on the human body;
vi. Local *versus* systemic effects;
vii. Whether the device comes into contact with injured skin;
viii. Whether for diagnosis or treatment;
ix. The ability to be re-used or not; and
x. Combination of devices.

5 Application rules

a) The class of the medical device is determined by its intended use and mechanism of action, and not the specific technical characteristics of the medical device, unless the specific technical characteristics have a direct bearing on the intended use.

NOTES:
1. The accidental use of the medical device does not determine the class of the medical device. Similarly, if a medical practitioner uses the medical device in a manner not intended by the manufacturer, this does not determine or change the class of the medical device for the purpose of conformity assessment.

2. It is the intended use determined and assigned by the manufacturer to the medical device that determines the class of the medical device and not the class assigned to other similar medical devices. For instance, two sutures that have the same composition may have different intended uses.

b) If two or more rules are applicable to the medical device based on the manufacturer's intended use, the medical device is allocated the highest level of classification indicated.

c) The manufacturer must take into consideration all the rules in order to establish the proper classification for its device. It is quite conceivable for instance that one of the general rules that are not specific to active devices, nevertheless applies to such a device. All the device characteristics must be taken into consideration. The characteristic or combination of characteristics in accordance with the intended purpose of the device that rates the highest class determines the class for the device as a whole.

d) The duration of use should be specified for all invasive medical devices as it determines the class of invasive medical device.

e) Accessories intended to be used together with a 'parent' medical device to achieve its intended use should be classified separately from the medical device they are used with (as though it is a medical device in its own right).

f) If a medical device is not used in a specific part of the body, it should be classified on the basis of the most critical specified use.

NOTE. Classification of the medical device will have to be determined on the basis of claims contained in the information provided with the device. The manufacturer must be sufficiently specific in that regard. If the manufacturer wants to avoid the particular higher classification, then it must clearly define on the labelling the intended use in such a way that the device falls into the lower class. The manufacturer must provide as a minimum requirement either appropriate positive or negative indications for use. Otherwise it is deemed to be intended to be used principally for the purpose that is accepted in general medical practice.

g) Software that is incorporated into the medical device itself and intended to drive or influence the use of a medical device should be classified the same classification as the medical device (e.g. software which is used for image enhancement).

h) Where the software is independent of any other medical device, it is classified in its own right using the classification rules for medical devices.

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

j) Classification of an assemblage of medical devices that individually comply with all the relevant regulatory requirements depends on the manufacturer's purpose in packaging and marketing such devices.

For example:

i. If the intended use of combination of devices is different from the individual medical devices, it should be classified according to the new intended use.
ii. If the combination does not change the intended use of the individual medical devices that make it up, the classification allocated to the assemblage for the purpose of a Declaration of Conformity is at the level of the highest classified device included within it.

If one or more of the medical devices that is in the assemblage has yet to comply with all the relevant regulatory requirements, the combination should be classified as a whole according to its intended use.

6. Classification of medical devices

6.1 Table 1 indicates the four risk classes of devices. The examples given are for illustration only and the manufacturer must apply the classification rules to each medical device according to its intended purpose.

Table 1: Classification system for general medical device

CLASS	RISK LEVEL	DEVICE EXAMPLES
A	Low Risk	Surgical retractors / tongue depressors
B	Low-moderate Risk	Hypodermic needle / suction equipment
C	Moderate-high Risk	Lung ventilator / orthopaedic implants
D	High Risk	Heart valves / implantable defibrillator

6.2 In the event of any dispute between an establishment and conformity assessment body over a classification of a medical device, the establishment may request in writing to the Authority within thirty days from the date of dispute to decide on the matter. Authority shall decide on the proper classification of the medical device concerned, whose decision shall be final.

7. Determination of device class using rules-based system

7.1 The manufacturer shall:

a) Decide if the product concerned is a medical device, using the appropriate definition,

b) Determine the intended use of the medical device,

c) Take into consideration all the rules that follow in order to establish the proper classification for the device, noting that where a medical device has features that place it into more than one class, classification and conformity assessment should be based on the highest class indicated.

8. Classification rules for medical devices

8.1 The actual classification of each device depends on the claims made by the manufacturer and on its intended use. While the provision of illustrative examples in the table that follows is helpful when interpreting the purpose of each rule, it must be emphasized that the actual classification of a particular device must be considered individually, taking account of its design and intended use.

Table 2: Graphical summary – medical devices classification guidance chart for initial identification of probable device class

SUBJECTS
Non-invasive medical devices – Rules 1, 2, 3, 4 Invasive medical devices – Rules 5, 6, 7, 8 Active medical devices – Rules 9(i), 9(ii), 10(i), 10(ii), 11, 12 Additional rules – Rules 13, 14, 15, 16

8.2 Decision trees illustrating how these rules may be used to classify specific devices are shown in Appendix A.

RULE	EXPLANATIONS
NON-INVASIVE MEDICAL DEVICES	
RULE 1	
a) All non-invasive devices which come into contact with injured skin:	Medical devices covered by this rule are extremely claim sensitive.
i. 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;	**Examples:** - simple wound dressings - cotton wool - absorbent pads - wound strips - adhesive bandages (sticking plasters, band-aid) - gauze dressings which act as a barrier, maintain wound position or absorb exudates from the wound Note. primary intent implies that the edges of the wound are close enough or pulled together, e.g. by suturing, to allow the wound to heal before formation of granulation tissue.
ii. are in Class B if they are intended to be used principally with wounds which have breached the dermis, including devices principally intended to manage the microenvironment of a wound.	**Examples:** - non-medicated impregnated gauze dressings - hydrogel dressing for wounds or injuries that have not breached the dermis or can only heal by secondary intent - polymer film dressings

RULE	EXPLANATIONS
NON-INVASIVE MEDICAL DEVICES	
iii. **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.	Medical devices used to treat wounds where the subcutaneous tissue is as least partially exposed, and the edges of the wound are not sufficiently close to be pulled together. To close the wound, new tissue must be formed within the wound prior to external closure. The device manufacturer claims that they promote healing through physical methods other than 'primary intent'. **Examples:** - dressings for chronic ulcerated wounds - dressings for severe burns - dressings for severe decubitus wounds - dressings providing a temporary skin substitute NOTES: I. Breached dermis: the wound exposes the subcutaneous tissue at least partly. II. Secondary intent: the wound heals by first being filled with granulation tissue, subsequently the epithelium grows back over the granulation tissue and the wound contracts *III.* For such devices incorporating a medicinal product, see Rule 13. For such devices incorporating an animal/human tissue derivative rendered non-viable, see Rule 14.

RULE	EXPLANATIONS
NON-INVASIVE MEDICAL DEVICES	
RULE 2	
a) All non-invasive medical devices intended for channeling or storing • body liquids or tissues, or • liquids or • gases for the purpose of eventual infusion, administration or introduction into the body are in Class A,	Such medical devices are 'indirectly invasive' in that they channel or store liquids that will eventually be delivered into the body (see Rule 4). Medical devices that provide a simple channeling function, with gravity providing the force to transport the liquid. Medical devices intended to be used for a temporary containment or storage function. **Examples:** - Administration sets for gravity infusion - Empty syringes without needles.
b) **unless** they may be connected to an active medical device in Class B or a higher-class, in which case they are Class B;	**Examples:** - syringes and administration sets for infusion pumps - Medical devices used for channelling gases, e.g antistatic tubing for anaesthesia and anesthesia breathing circuits. NOTES: i. If a device, e.g. tubing, can be used for a purpose that would cause it to be connected to an active device such a device will be automatically in Class B, unless the manufacturer clearly state that it should not be connected to an active device of Class B or higher. *ii.* "May be connected to an active device" Such a connection is deemed to exist between a non-active device and an active device where the non-active device forms a link in the transfer of the substance between the patient and the active device and the safety and performance of one of the devices is influenced by the other device. For instance, this applies to tubing in an extracorporeal circulation system which is downstream from a blood pump and in the same blood flow circuit, but not directly in contact with the pump.

RULE	EXPLANATIONS
NON-INVASIVE MEDICAL DEVICES	
c) **unless** they are intended for use of • channeling blood, or • storing or channeling other body liquids, or • for storing or organs, parts of organs or body tissues, in which case they are Class B.	**Examples:** - Tube used for blood transfusion - Organ storage containers. - to channel blood (e.g. in transfusion, extracorporeal circulation) - for temporary storage and transport of organs for transplantation (i.e. containers, bags) - for long term storage of biological substances and tissues such as corneas, sperm, human embryos, etc. (i.e. containers, bags) - Fridges/freezers specifically intended for storing blood, tissues etc.
d) **unless** they are blood bags, in which case they are Class C.	**Example:** Blood bags that do not incorporate an anti-coagulant. NOTE: in some jurisdictions, blood bags have a special rule that places them within a different risk class.

RULE	EXPLANATIONS
NON-INVASIVE MEDICAL DEVICES	
RULE 3	
a) 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,	This rule covers mostly the more sophisticated elements of extracorporeal circulation sets, dialysis systems and autotransfusion systems as well as devices for extracorporeal treatment of body fluids which may or may not be immediately reintroduced into the body, including, where the patient is not in a closed loop with the device. Such medical devices are indirectly invasive in that they treat or modify substances that will eventually be delivered into the body. They are normally used in conjunction with an active device within the scope of either Rule 9 or 11. **Examples:** - hemodialyzers - devices to remove white blood cells from whole blood - Medical devices intended to separate cells by physical means, e.g. gradient medium for sperm separation - Hemodialysis concentrates

	NOTE: for the purpose of this part of the rule, 'modification' does not include simple, mechanical filtration or centrifuging which are covered below.
b) **unless** the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class B.	**Examples:** - devices to remove carbon dioxide; - particulate filters in an extracorporeal circulation system. - centrifugation of blood to prepare it for transfusion or autotransfusion - warming or cooling the blood in an extracorporeal circulation system.

RULE	EXPLANATIONS
NON-INVASIVE MEDICAL DEVICES	
RULE 4	
a) All other non-invasive medical devices are in Class A.	These medical devices either do not touch the patient or contact intact skin only. **Examples:** - urine collection bottles; - medical devices used to immobilize body parts and/or to apply force or compression on them (e.g. non-sterile dressings used to aid the healing of a sprain, cervical collars, gravity traction devices, compression hosiery) - non-invasive electrodes (electrodes for EEG or ECG) - non-invasive conductive gels - medical devices intended in general for external patient support (e.g. hospital beds, patient hoists, walking aids, wheelchairs, stretchers) - corrective glasses - stethoscopes. - eye occlusion plasters incision drapes

RULE	EXPLANATIONS
INVASIVE MEDICAL DEVICES	
RULE 5	
a) 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.	Such medical devices are invasive in body orifices and are not surgically invasive Medical devices tend to be diagnostic and therapeutic instruments used in ENT, ophthalmology, dentistry, proctology, urology and gynecology. Classification depends on the duration of use and the sensitivity (or vulnerability) of the orifice to such invasion. NOTE: Invasiveness with respect to the body orifices must be considered separately from invasiveness that penetrates through a cut in the body surfaces (surgical invasiveness). For short term use, a further distinction must be made between invasiveness with respect to the less vulnerable anterior parts of the ear, mouth and nose and the other anatomical sites that can be accessed through natural body orifices. Surgically created stoma, which for example allows the evacuation of urine or faeces, should also be considered as a body orifice.
i. are in Class A if they are intended for transient use;	**Examples:** - examination gloves - enema devices - handheld mirrors used in dentistry to aid in dental diagnosis and surgery - dental impression materials - stomach tubes - impression trays - urinary catheters intended for transient use - embryo transfer catheter
ii. are in Class B if they are intended for short-term use;	**Examples:** - Indwelling urinary catheters intended for short term use - tracheal tubes - short term corrective and non-corrective contact lens
iii. **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,	**Examples:** -dentures intended to be removed by the patient -a dressing for nose bleeds Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice are classified as Class B if they are applied in the nasal or oral cavity as far as the

	pharynx, and achieve their intended purpose on those cavities. Example: Nasal solution sprays intended to penetrate, hydrate the nasal passages and sinus cavity for preventive or symptomatic nasal care are Class B. unless saline nasal solution intended for clear, clean, rinsing is Class A.
iv. are in Class C if they are intended for long-term use;	**Examples:** - urethral stent - corrective and non-corrective 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) - urinary catheters intended for long term use
v. **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.	**Examples:** - orthodontic wire - fixed dental prosthesis - wetting or lubricating eye drops
vi. 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 a higher class, are in Class B.	**Examples:** - tracheal tubes connected to a ventilator - suction catheters for stomach drainage - dental aspirator tips. - powered nasal irrigators - some enteral feeding tubes - endoscope. See also Rule 2 b)

RULE	EXPLANATIONS
INVASIVE MEDICAL DEVICES	
RULE 6	
a) All surgically invasive medical devices intended for transient use are in Class B,	A majority of such medical devices fall into several major groups: - surgical swabs - surgical gloves - those that create a conduit through the skin (e.g. syringe needles, lancets) - suckers - surgical instruments (e.g. single-use scalpels, single use scalpel blades, surgical staplers, single-use - aortic punch - drill bits connected to active devices - various types of catheter/sucker etc. NOTES i. A surgical instrument (other than that in Class D) is in Class A if reusable and in Class B if supplied sterile and intended for single use. Also, a surgical instrument connected to an active device is in a higher class than A. ii: If the device incorporates a medicinal substance in a secondary role refer to Rule 13.
b) **unless** they are reusable surgical instruments, in which case they Class A; or	**Examples:** - Manually operated surgical drill bits and saws - Manually operated surgical instruments e.g. scissors, forceps, clamps, blades, hand-held retractor NOTE: refer to definition of reusable surgical instrument in 3.21
c) **unless** intended to supply energy in the form of ionizing radiation, in which case they are in Class C; or	**Example:** - catheter incorporating/containing sealed radioisotopes.
d) **unless** intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class C; or	**Example:** - insufflation gases for the abdominal cavity. NOTES: *i.* The 'biological effect' referred to is an intended one rather than unintentional. The term 'absorption' refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body. *ii.* This part of the rule does not apply to those substances that are excreted without modification from the body.

e) **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	**Example:** - insulin pen for self-administration (supplied without insulin) NOTE: the term 'administration of medicines' implies storage and/or influencing the rate/volume of medicine delivered not just channeling. The term 'potentially hazardous manner' refers to the characteristics of the device and not the competence of the user.
f) **unless** they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D; or	**Examples:** - neuro-endoscopes - brain spatulas - direct stimulation canulae - spinal cord retractors - spinal needles
g) **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.	**Examples:** - angioplasty balloon and related guide wires - dedicated disposable cardiovascular instruments NOTES: i. The expression "correct a defect" does not cover devices that are used accessorily in heart surgery procedures, e.g. clamps, aortic punch instruments. The first indent of this rule does not apply to aortic punches and similar cutting instruments which perform a similar function to a scalpel. ii. Dedicated means that the intended purpose of the device or accessory is to specifically control, diagnose, monitor or correct a defect of the heart or of the central circulatory system.

RULE	EXPLANATIONS
INVASIVE MEDICAL DEVICES	
RULE 7	
a) All surgically invasive medical devices intended for short-term use are in Class B,	Such medical devices are mostly used in the context of surgery or post-operative care, or are infusion devices, or are catheters of various types. **Examples:** - infusion cannula - temporary filling materials - non-absorbable skin closure devices - tissue stabilizers used in cardiac surgery NOTES i. includes devices that are used during cardiac surgery but do not monitor or correct a defect. ii. if the device incorporates a medicinal substance in a secondary role refer to Rule 13.
b) **unless** they are intended to administer medicinal products, in which case they are in Class C; or	NOTE: the term 'administration of medicines' implies storage and/or influencing the rate/volume of medicine delivered not just channeling.
c) **unless** they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class C; or	**Example:** surgical adhesive.
d) **unless** they are intended to supply energy in the form or ionizing radiation, in which case they are in Class C; or	**Example:** brachytherapy device.
e) **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	**Examples:** - absorbable suture - biological adhesive. NOTE: the 'biological effect' referred to is an intended one rather than unintentional. The term 'absorption' refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body.
f) **unless** they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D;	**Example:** neurological catheter.
g) **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.	**Examples:** - cardiovascular catheters - temporary pacemaker leads - carotid artery shunts

RULE	EXPLANATIONS
INVASIVE MEDICAL DEVICES	
RULE 8.	
a) All implantable medical devices, and long-term surgically invasive devices, are in Class C,	Most of the medical devices covered by this rule are implants used in the orthopedic, dental, ophthalmic and cardiovascular fields. **Examples:** - maxilla-facial implants - prosthetic joint replacements - bone cement - non-absorbable internal sutures - posts to secure teeth to the mandibular bone (without a bioactive coating). - intraocular lens - peripheral vascular grafts and peripheral stents - shunts - dental implants and abutments NOTE: if the device incorporates a medicinal substance in a secondary role refer to Rule 13.
b) **unless** they are intended to be placed into the teeth, in which case they are in Class B; or	**Examples:** - bridges; - crowns - dental filling materials
c) unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system (CNS), in which case they are in Class D; or	**Examples:** - prosthetic heart valves - spinal stents - vascular prosthesis and stents - cardiovascular sutures - CNS electrodes - aneurysm clips - central vascular catheter for long term-use

RULE	EXPLANATIONS
INVASIVE MEDICAL DEVICES	
d) **unless** they are intended to be life supporting or life sustaining, in which case they are in Class D; or	
e) **unless** they are intended to be active implantable medical devices, in which case they are Class D; or	**Examples:** - pacemakers, their pacemakers' electrodes and their pacemakers lead; - implantable defibrillators
f) **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	**Examples:** - adhesives and implantable devices claimed to be bioactive through the attachment of surface coatings such as phosphoryl choline) - long-term absorbable suture - elastoviscous fluids for joint movement (e.g. hyaluronan of non-animal origin) - biodegradable Bone Cements
g) **unless** they are intended to administer medicinal products, in which case they are in Class D; or	**Example:** rechargeable non-active drug delivery system.
h) **unless** they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class D; or	NOTE: bone cement is not within the scope of the term 'chemical change in the body' since any change takes place in the short rather than long term.
j) **unless** they are breast implants, in which case they are in Class D.	**Examples:** - breast implants - breast tissue expanders

RULE	EXPLANATIONS
ACTIVE MEDICAL DEVICES	
RULE 9(i).	
a) All active therapeutic medical devices intended to administer or exchange energy are in Class B,	Such medical devices are mostly electrically powered equipment used in surgery; devices for specialized treatment and some stimulators. **Examples:** - muscle stimulators - Transcutaneous electrical nerve stimulation (TENS) devices - powered dental hand pieces - hearing aids - neonatal phototherapy equipment - ultrasound equipment for physiotherapy - powered drills

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 ionizing radiation, taking account of the nature, the density and site of application of the energy, in which case they are in Class C.	**Examples:** - lung ventilators - baby incubators - electrosurgical generators - external pacemakers and defibrillators - surgical lasers - lithotripters - therapeutic X-ray and other sources of ionizing radiation. - blood warmers - electrically powered heat exchangers (with patient's incapable of reacting, communicating /or who are without a sense of feeling) NOTE: the term 'potentially hazardous' refers to the type of technology involved and the intended application.

RULE	EXPLANATIONS
ACTIVE MEDICAL DEVICES	
RULE 9(ii).	
a) All active medical devices intended to control or monitor the performance of active therapeutic devices in Class C, or intended directly to influence the performance of such devices, are in Class C.	**Example:** external feedback systems for active therapeutic devices

RULE	EXPLANATIONS
ACTIVE MEDICAL DEVICES	
RULE 10(i)	
a) Active medical devices intended for diagnosis are in Class B:	Such medical devices include equipment for ultrasonic diagnosis/imaging, capture of physiological signals, interventional radiology and diagnostic radiology.
(i) if they are intended to supply energy which will be absorbed by the human body (except for devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum, in which case they are class A) or	**Examples:** - magnetic resonance equipment - ultrasound in non-critical applications - evoked response stimulators.
(ii) if they are intended to image in vivo distribution of radiopharmaceuticals, or	**Examples**: - gamma/nuclear cameras - positron emission tomography and single photon emission computer tomography

RULE	EXPLANATIONS
ACTIVE MEDICAL DEVICES	
(iii) if they are intended to allow direct diagnosis or monitoring of vital physiological processes,	**Examples:** - electronic thermometers - stethoscopes and blood pressure monitors - electrocardiographs - electroencephalograph Note: Vital physiological processes and parameters include, for example respiration, heart rate, cerebral functions, blood gases, blood pressure and body temperature. Medical devices intended to be used for continuous surveillance of vital physiological processes in anesthesia, intensive care or emergency care are in Class C, whilst medical devices intended to be used to obtain readings of vital physiological signals in routine checkups and in self-monitoring are in Class B. A thermal imaging device intended to monitor blood flow is not considered to be a temperature measuring device.
unless they are specifically intended for: (i) monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger tothe patient, for instance variations in cardiac performance, respiration, activity of central nervous system, or (ii) diagnosing in clinical situations where the patient is in immediate danger, in which case they are in Class C.	**Examples:** - monitors/alarms for intensive biological sensors - oxygen saturation monitor - apnea monitor - patient monitors (intended use: monitor intended for multi-parameter patient monitoring. The device will produce visual and audible alarms if any of the physiological parameters monitored vary beyond pre-set limits and timed alarm recordings will be produced.) for example in intensive care monitoring, e.g. blood pressure, temperature, oxygen saturation. **Example:** ultrasound equipment for use in interventional cardiac procedures.

RULE	EXPLANATIONS
ACTIVE MEDICAL DEVICES	
RULE 10(ii).	
Active medical devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology, including devices which control or monitor such devices, or those which directly influence their performance, are in Class C.	**Examples:** - these include devices for the - control, monitoring or influencing of the emission of ionizing radiation - Diagnostic X-ray machine

RULE	EXPLANATIONS
ACTIVE MEDICAL DEVICES	
Rule 11: a) All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are in Class B,	Such devices are mostly drug delivery systems or anesthesia equipment. **Examples:** - 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
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, in which case they are in Class C.	**Examples:** - infusion pumps - anesthesia equipment - dialysis equipment - hyperbaric chambers - nebulizer where the failure to deliver the appropriate characteristics could be hazardous.
RULE 12. All other active devices are in Class A.	**Examples:** - examination lamps - surgical microscopes - powered hospital beds & wheelchairs - powered equipment for the recording, processing, viewing of diagnostic - Images - dental curing lights

Additional Explanations:

1. The concept “act by converting energy” includes conversion of energy in the device and/or conversion at the interface between the device and the tissues or in the tissues**.** Electrodes intended for E.C.G or E.E.G are normally not active devices because they do not normally act by conversion energy.

2. The concept of “significant change” for energy includes changes in the nature, level and density of energy (see Rule 9(i) and Rule 9(ii)). This means that for instance an electrode is not an active device under this classification system as long as the energy input is intended to be the same as the energy output. For instance, resistance in a wire that causes minor changes between input and output cannot be considered to constitute "significant change". However, electrodes used in electrosurgery for cutting tissues or cauterization are active devices because their operation depends on energy provided by a generator and their action is achieved by conversion of energy at the interface between the device and the tissue or in the tissue.

3. The application of energy from the human body does not make a device "active" unless that energy is stored within the device for subsequent release. For instance, energy generated by human muscle and applied to the plunger of a syringe (thus causing a substance to be delivered to a patient) does not make this syringe an "active device". However, if a drug delivery system depends upon manual winding to preload a spring which is subsequently released to deliver a substance, then the device incorporating the spring is an "active device".

4. Medical devices using prestored gases and/or vacuum as a power source are regarded as active devices, as long as they fulfil both criteria under the definition of e.g. gas mixers with anesthesia machines, aerosol pain relief sprays with a pre-stored propellant gas and gas-powered suction pumps.

5. Heating/cooling pads intended only to release stored thermal energy are not active devices because they do not act by conversion of energy. However, heating/cooling pads which act by chemical action (e.g. endothermic or exothermic reaction) are active devices as they are converting chemical energy into heat energy and/or vice versa.

6. Radioactive sources that are intended to deliver ionizing radiation are regarded as active medical devices (e.g. radioactive isotopes coated beads), unless they are radiopharmaceuticals which may be infused into the body

RULE	EXPLANATIONS
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, and which is liable to act on the human body with action ancillary to that of the devices, are in Class D.	These medical devices incorporate medicinal substances in an ancillary role. **Examples:** - antibiotic bone cements - heparin-coated catheters - wound dressings incorporating antimicrobial agents to provide ancillary action on the wound - blood bags incorporating an anti-coagulant - drug eluting stents NOTES: i. Such medical devices may be subject to additional conformity assessment procedures according to the regional or national requirements of medicinal product Regulatory Authorities. *ii.* For combination products, please refer to Guideline for Registration of Drug-Medical Device and Medical Device-Drug Combination Products.

RULE	EXPLANATIONS
ADDITIONAL RULES	
RULE 14.	
a) All medical devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable, are Class D,	NOTES: In some jurisdictions such products: *i.* are considered to be outside the scope of the medical device definition; *ii.* may be subject to different controls. *It is likely the regulations controlling these devices will be the subject of future harmonization efforts.* **Examples:** - porcine heart valves - catgut sutures. For all non-invasive medical devices consisting of a substance or a mixture of substances intended to be used in vitro in direct contact with human cells, tissues or organs taken from the human body or used in vitro with human embryos before their implantation or administration into the body are classified as Class D.

	Examples: - substances or mixture of substances for transport, perfusion, storage of organs intended for transplantation that do not achieve the principal intended action by pharmacological, immunological or metabolic means - IVF or ART products without principal pharmacological/metabolic action (substances or mixture of substances) - IVF cell media without human albumin)
b) **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.	**Example:** leather components of orthopedic appliances.

RULE	EXPLANATIONS
ADDITIONAL RULES	
RULE 15	
a) All medical devices intended specifically to be used for sterilizing medical devices, or disinfecting as the end point of processing, are in Class C.	**Examples:** - denture disinfecting products - washer-disinfector equipment specifically for disinfecting endoscopes or other invasive devices at the end point of processing (e.g. dental equipment) - disinfectants for the fluid pathways of hemodialysis equipment NOTES i. They are specifically to be used for disinfecting invasive devices. *ii.* This rule does not apply to products that are intended to clean medical devices by means of physical action e.g. washing machines.
b) **unless** they are intended for disinfecting medical devices prior to end point sterilization or higher-level disinfection, in which case they are in Class B; or	**Examples:** - disinfectants specifically intended for non-invasive medical devices and equipment such as sterilizers specifically intended to sterilize medical devices in a medical environment and washer disinfectors - washers-disinfectors intended specifically for disinfecting non-invasive medical devices. - dry heat sterilizer - ultraviolet sterilizer

RULE	EXPLANATIONS
ADDITIONAL RULES	
c) **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.	**Examples:** - contact lens solutions - comfort solutions (also known as rewetting contact lens eye drop)
RULE 16. a) All medical devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class C,	**Examples**: - condoms - contraceptive diaphragms.
b) **unless** they are implantable or long-term invasive medical devices, in which case they are in Class D.	**Example:** - - intrauterine contraceptive device (IUD)

8.3 Rationale for the inclusion of the additional rules

There are a small number of products that fall within the scope of the definition of a medical device and which may need to be classified to take account of factors other than those covered by the general rules (Rules 1 to 12). Therefore, four Additional Rules are provided (Rules 13 to 16).

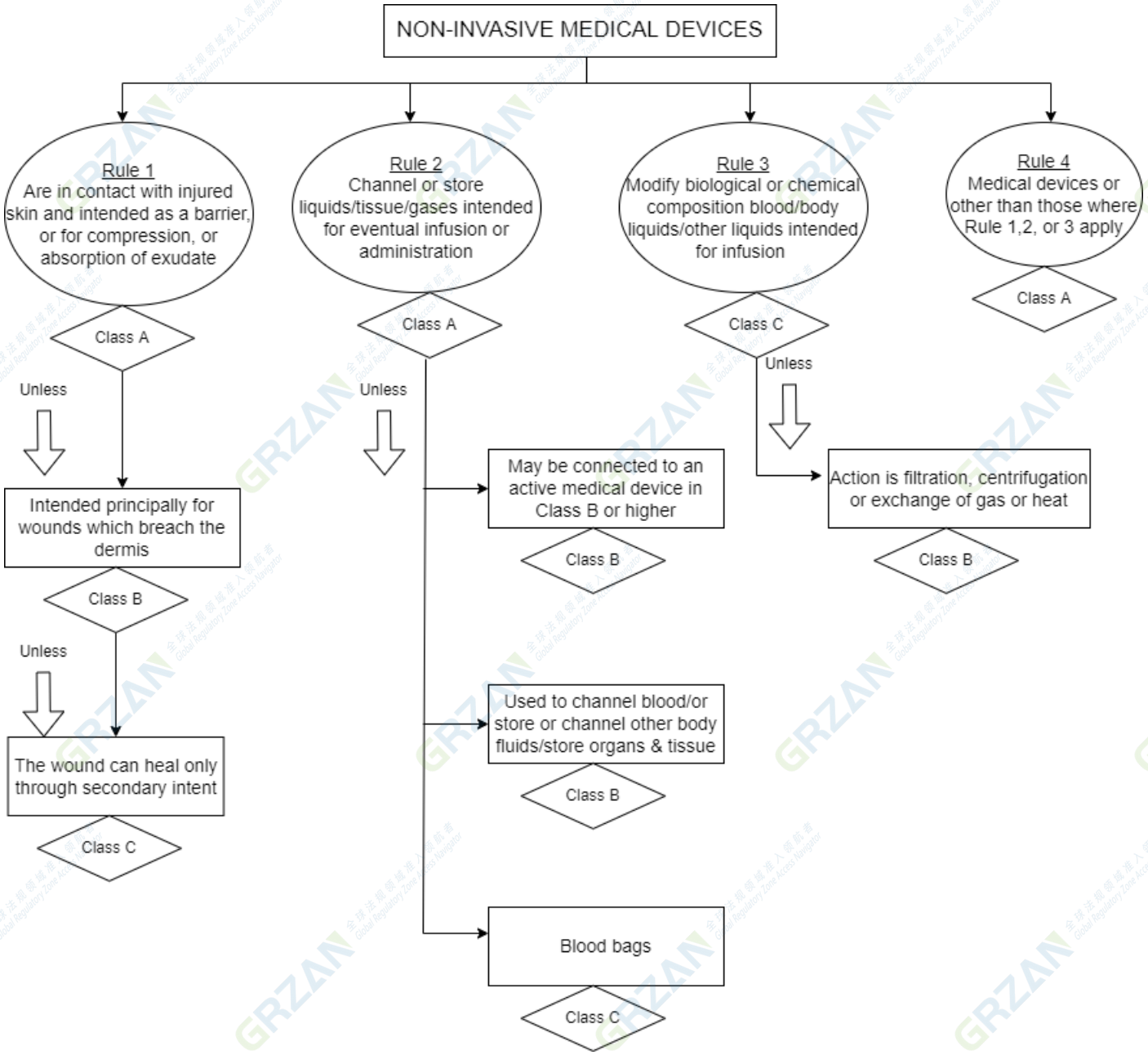
Matters that may need to be considered are:

Rule 13:	Devices incorporating a medicinal product • The regulations applying to medicinal products require different acceptance procedures to those for medical devices. • The behavior of a medicinal product used in conjunction with a medical device may differ from that covered by its approved use as a medicinal product alone.
Rule 14:	Devices incorporating animal or human tissues • There is an absence of global regulatory controls for such devices. • Classification needs to acknowledge the diversity of opinions on such devices, globally. • The possible risks associated with the transmission of infectious agents through materials used in such devices, e.g. Bovine Spongiform Encephalopathy (BSE) and Creutzfeldt-Jacob disease (CJD), demand classification at a higher risk level.
Rule 15:	Disinfectants • The particular concerns relating to those disinfectants that are used with contact lenses, due to sensitivity and vulnerability of the eye.

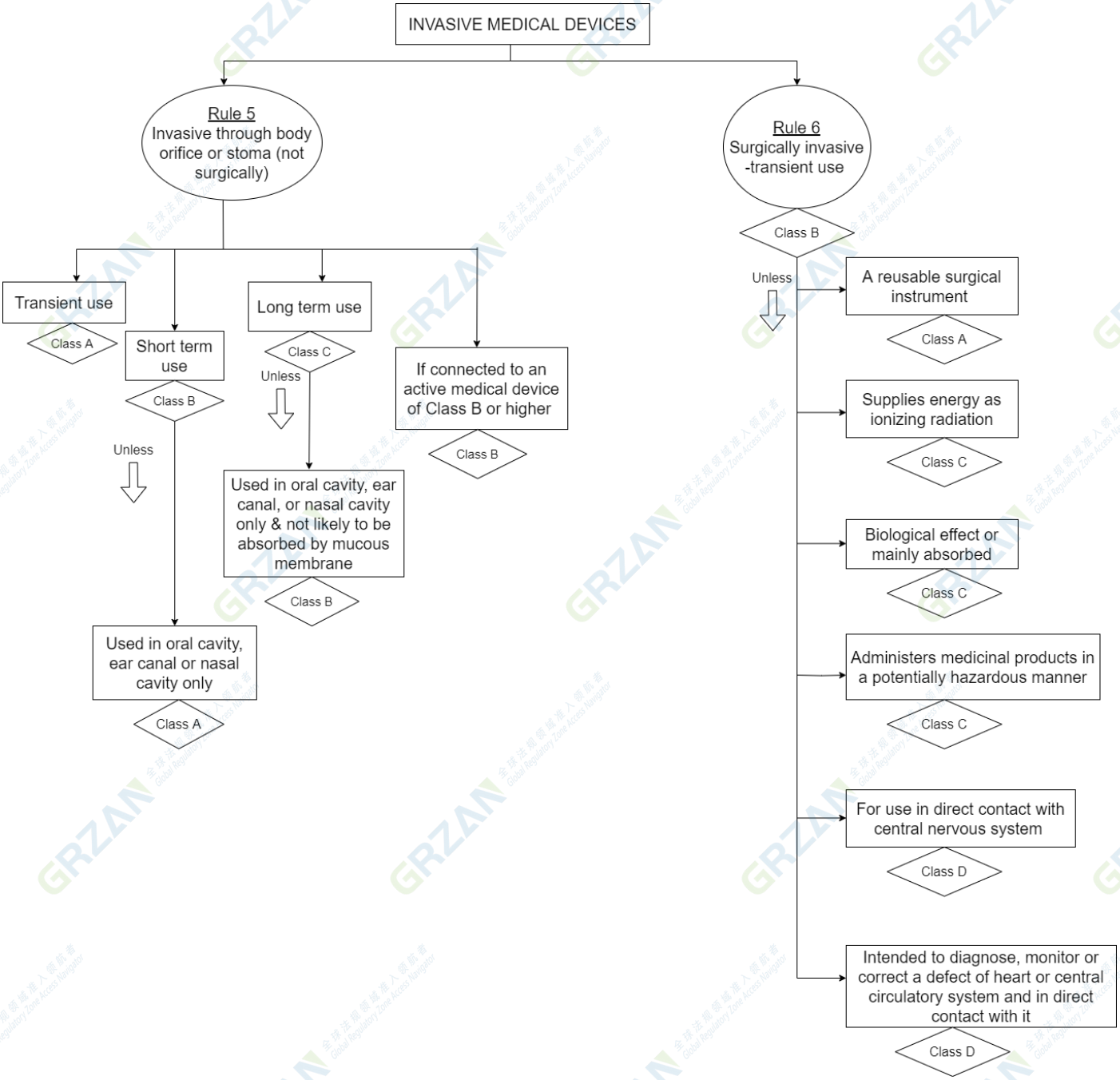
Rule 16:	Contraceptive devices • The risks associated with unwanted pregnancy if caused by mechanical failure of the device. • The need to safeguard public health through the use of condoms to reduce the prevalence of sexually transmitted diseases. • User expectation that contraceptive devices are perfectly reliable and safe despite published data to the contrary.

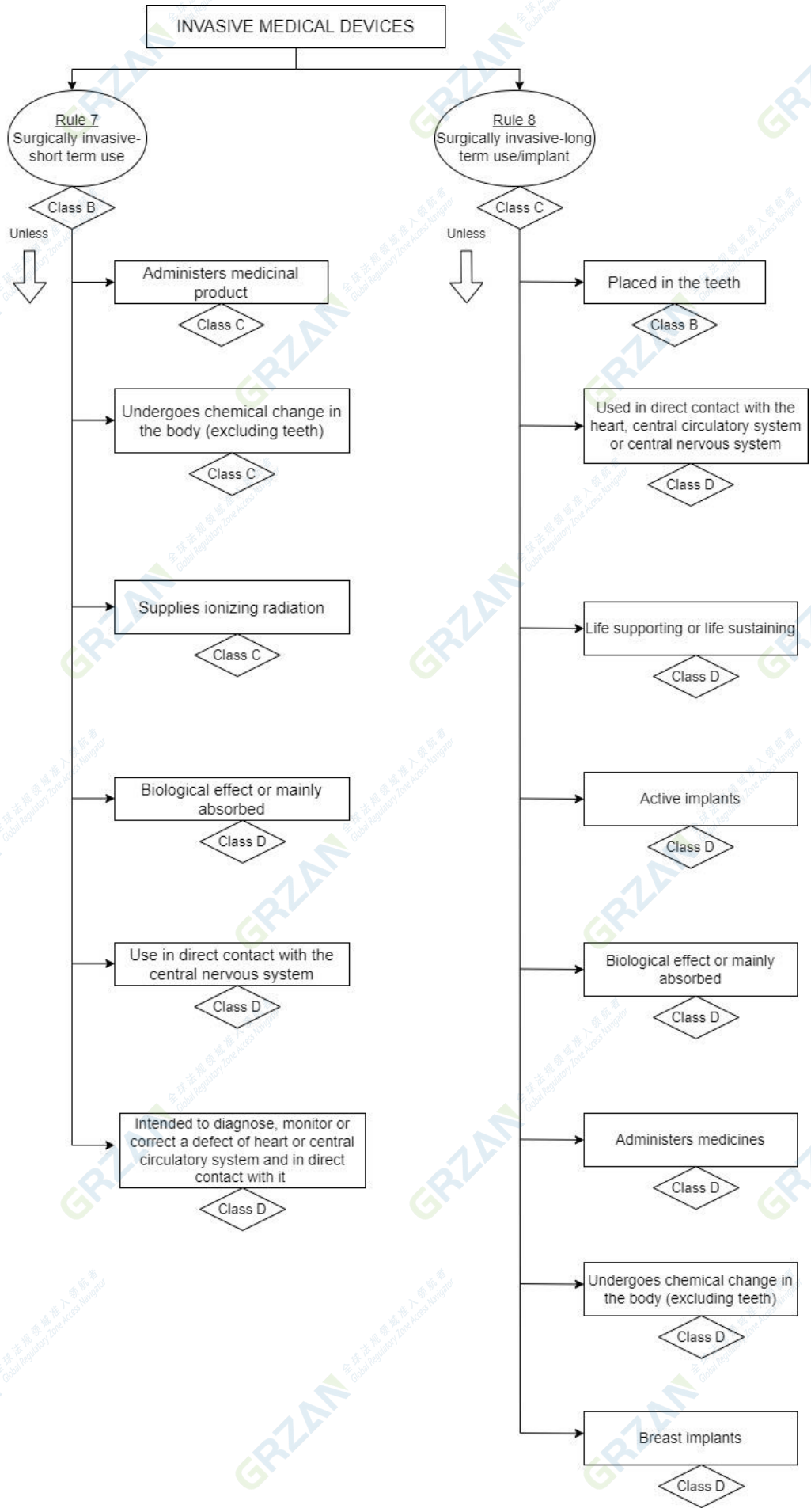
Annex A
(Informative)

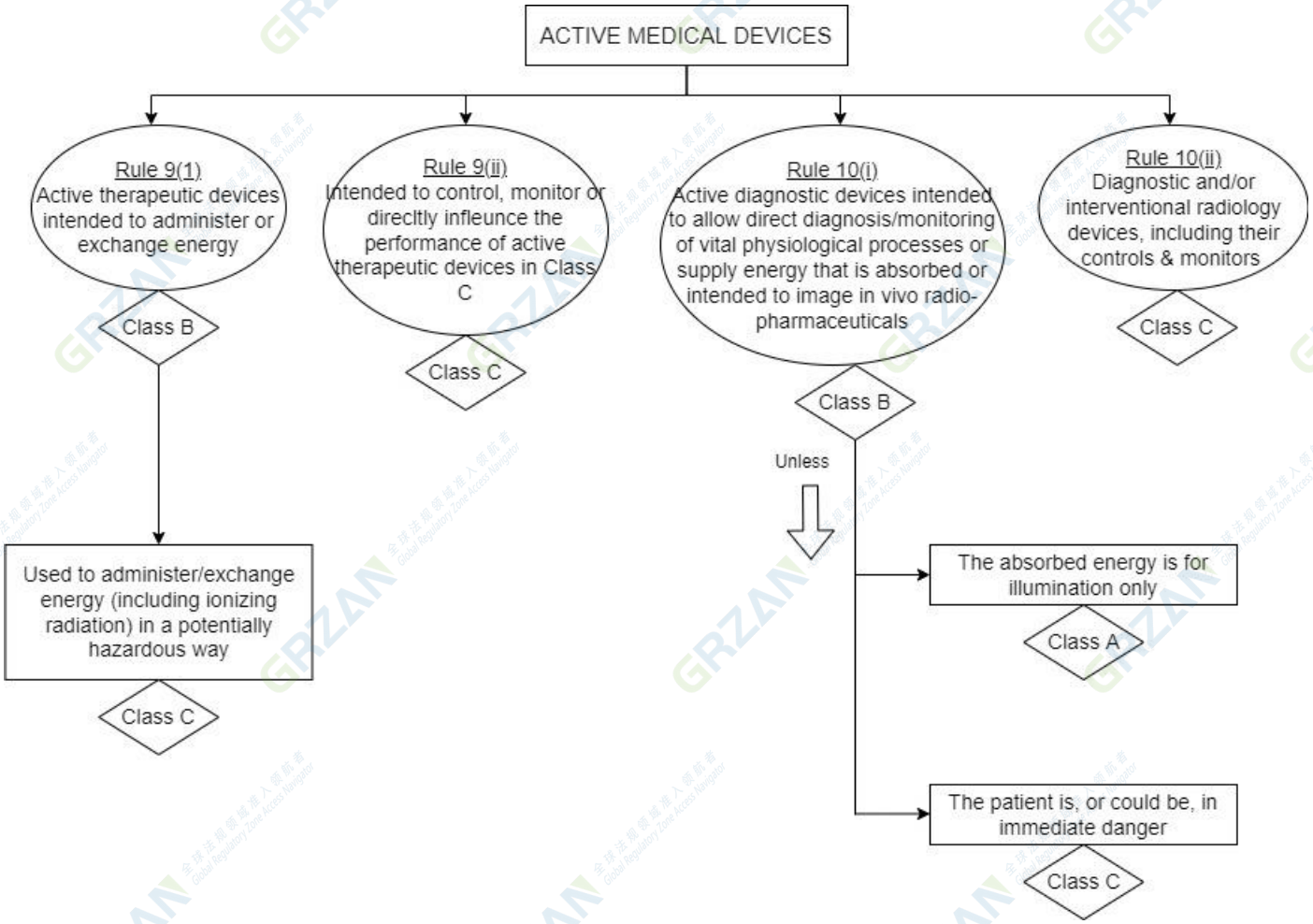
Decision trees to demonstrate how the rules may be used to classify specific devices.

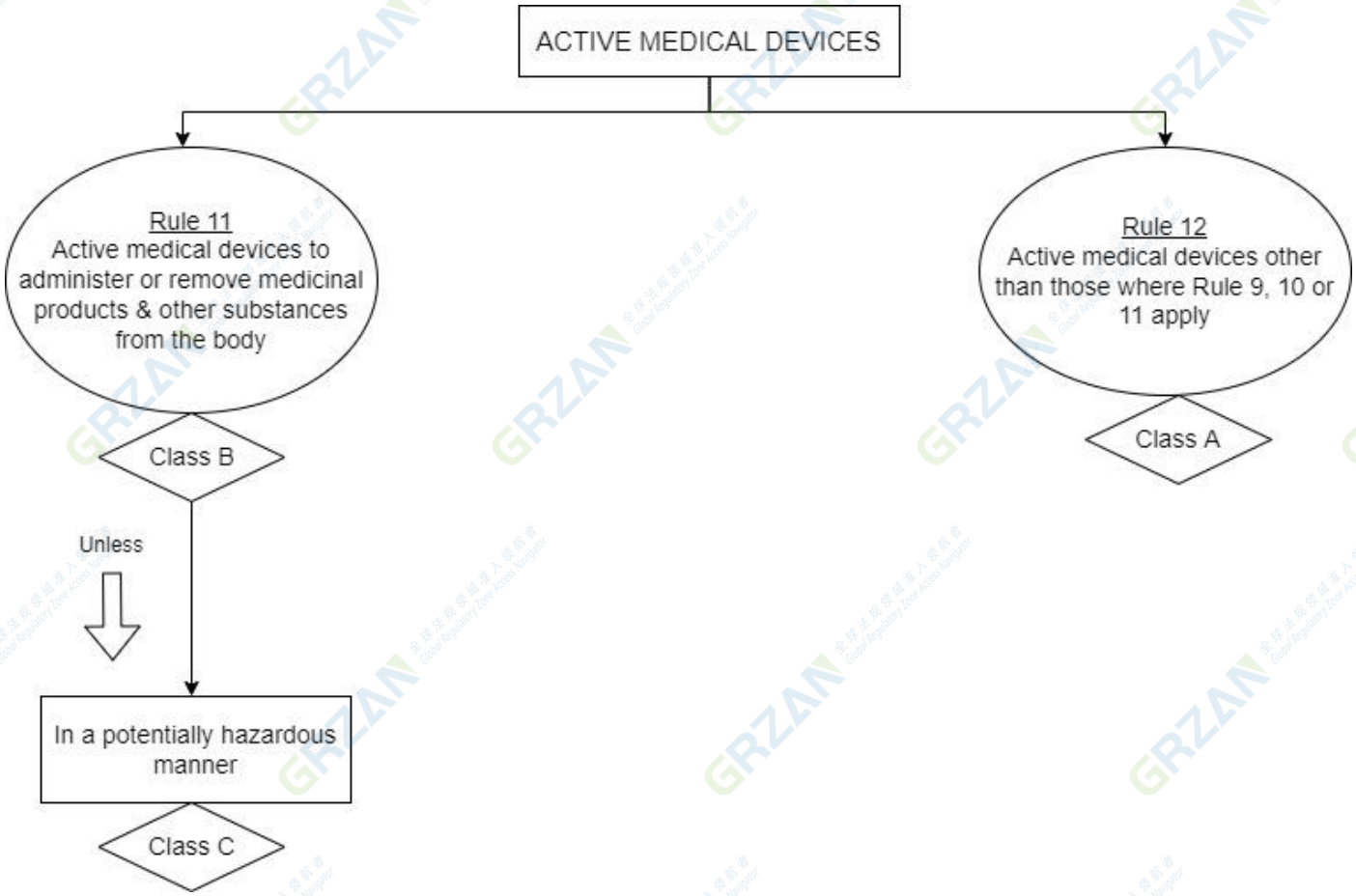


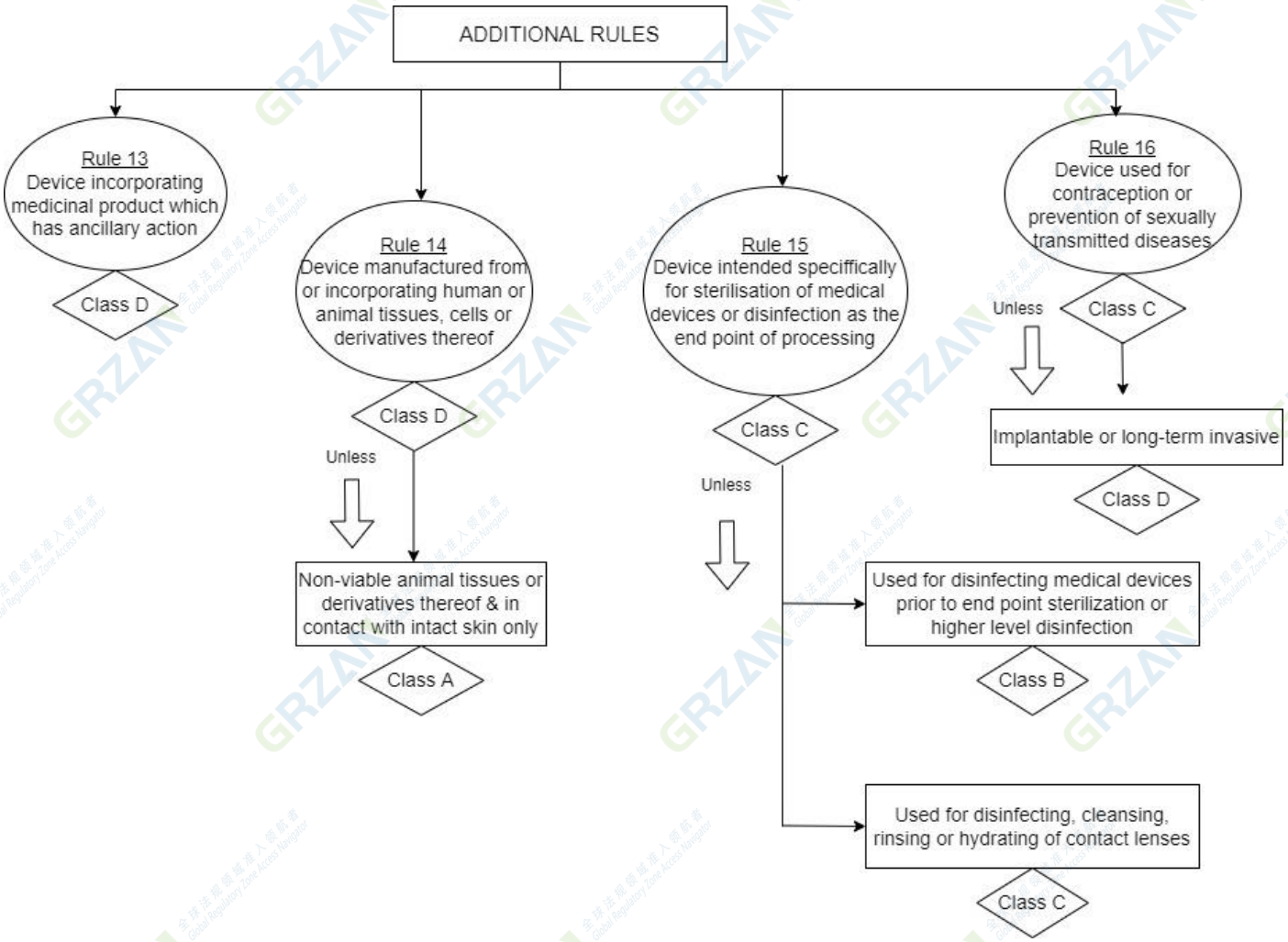
NOTE: This diagram and those that follow are for illustrative purposes only and the determination of risk class for a particular device should be made by referring to the rules themselves and not the decision trees. Where a medical device has features that place it into more than one class, conformity assessment should be based on the highest class indicated.


INVASIVE MEDICAL DEVICES
Rule 5
Invasive through body orifice or stoma (not surgically)
Rule 6
Surgically invasive -transient use
Transient use
Class A
Short term use
Class B
Unless
Used in oral cavity, ear canal or nasal cavity only
Class A
Long term use
Class C
Unless
Used in oral cavity, ear canal, or nasal cavity only & not likely to be absorbed by mucous membrane
Class B
If connected to an active medical device of Class B or higher
Class B
Class B
Unless
A reusable surgical instrument
Class A
Supplies energy as ionizing radiation
Class C
Biological effect or mainly absorbed
Class C
Administers medicinal products in a potentially hazardous manner
Class C
For use in direct contact with central nervous system
Class D
Intended to diagnose, monitor or correct a defect of heart or central circulatory system and in direct contact with it
Class D


INVASIVE MEDICAL DEVICES
Rule 7
Surgically invasive-short term use
Class B
Unless
Administers medicinal product
Class C
Undergoes chemical change in the body (excluding teeth)
Class C
Supplies ionizing radiation
Class C
Biological effect or mainly absorbed
Class D
Use in direct contact with the central nervous system
Class D
Intended to diagnose, monitor or correct a defect of heart or central circulatory system and in direct contact with it
Class D
Rule 8
Surgically invasive-long term use/implant
Class C
Unless
Placed in the teeth
Class B
Used in direct contact with the heart, central circulatory system or central nervous system
Class D
Life supporting or life sustaining
Class D
Active implants
Class D
Biological effect or mainly absorbed
Class D
Administers medicines
Class D
Undergoes chemical change in the body (excluding teeth)
Class D
Breast implants
Class D


ACTIVE MEDICAL DEVICES
Rule 9(1)
Active therapeutic devices intended to administer or exchange energy
Class B
Used to administer/exchange energy (including ionizing radiation) in a potentially hazardous way
Class C
Rule 9(ii)
Intended to control, monitor or directly influence the performance of active therapeutic devices in Class C
Class C
Rule 10(i)
Active diagnostic devices intended to allow direct diagnosis/monitoring of vital physiological processes or supply energy that is absorbed or intended to image in vivo radio-pharmaceuticals
Class B
Unless
The absorbed energy is for illumination only
Class A
The patient is, or could be, in immediate danger
Class C
Rule 10(ii)
Diagnostic and/or interventional radiology devices, including their controls & monitors
Class C


ACTIVE MEDICAL DEVICES
Rule 11
Active medical devices to administer or remove medicinal products & other substances from the body
Class B
Unless
In a potentially hazardous manner
Class C
Rule 12
Active medical devices other than those where Rule 9, 10 or 11 apply
Class A


ADDITIONAL RULES
Rule 13
Device incorporating medicinal product which has ancillary action
Class D
Rule 14
Device manufactured from or incorporating human or animal tissues, cells or derivatives thereof
Class D
Unless
Non-viable animal tissues or derivatives thereof & in contact with intact skin only
Class A
Rule 15
Device intended specifically for sterilisation of medical devices or disinfection as the end point of processing
Class C
Unless
Used for disinfecting medical devices prior to end point sterilization or higher level disinfection
Class B
Used for disinfecting, cleansing, rinsing or hydrating of contact lenses
Class C
Rule 16
Device used for contraception or prevention of sexually transmitted diseases
Unless
Class C
Implantable or long-term invasive
Class D

MEDICAL DEVICE AUTHORITY

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