ETHIOPIAN FOOD AND DRUG AUTHORITY

GUIDELINE FOR CLASSIFICATION OF MEDICAL DEVICES OTHER THAN IVD MEDICAL DEVICES

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1. INTRODUCTION

Regulatory controls are intended to ensure a high level of protection of public health and safety. Thus, they 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 regulatory 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, taking into account of the benefits offered by use of the device.

2. DEFINITION

Active medical device

Mean 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.

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

Applicant

The person or entity who submits a registration application of medical devices to the Authority and responsible for the product information.

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.

Biological Effects

Impacts on health as a result of adverse reactions of a medical devices.

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 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.

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.

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.

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.

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.

Risk

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

Surgically invasive medical device

Is an invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation. (***NOTE 1:*** *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.)*

Transient use

Normally intended for continuous use for less than 60 minutes.

Short term use

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

Long term use

Normally intended for continuous use for more than 30 days.

3. OBJECTIVES

The objective of this guideline to assist applicant and assessor to provide guidance based on rules to identify the specific class of medical device other than IVD.

4. PURPOSE

The purpose of this guideline is:

1) To assist a manufacturer/applicant to allocate its medical devices into appropriate risk class according to the classification system, based on medical device intended use and classification principles.
2) To provide guidance to assessors on how to verify the classification of medical devices other than IVD determined by the applicant.
3) To allow the Authority to act on the matters of interpretation for a particular medical device classification when appropriate.

5. SCOPE

This guideline is applicable for classification of all medical devices other than IVD.

6. MEDICAL DEVICE CLASSIFICATIONS OTHER THAN IVD

In order to ensure that conformity assessment implementation is effective, manufacturers should be able to determine the classification of their product as early as possible in the device development. The manufacturer must use a systematic approach to apply the classification

rules described within this Guideline.

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

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

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

iii. To indicate the Authority's responsibility regarding ruling upon matters of interpretation for a medical device classification.

6.1. General principles

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

The risk presented by a particular medical device and its classification is determined from:

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

b) The effectiveness of the risk management techniques applied during design, manufacture and use

c) Its intended user(s)

d) Its mode of operation set of classification rules (principles)

6.2. Factors influencing device classification

Several factors may influence medical device classification. These include:

- The duration of contact of the device with the body.
- The degree of, and site of, invasiveness into the body.
- Whether the device deliver medicines or energy to the patient.
- Whether the device is intended to have a biological effect on the body.

- Intended action on the human body.
- Local versus systemic effects.
- Whether the device comes into contact with injured skin.
- Whether for diagnosis or treatment,
- The ability to be re-used or not, and
- Combination of devices.

6.3. Medical Device Classification Rules

The classification rules are based on various criteria, such as the duration of contact with the patient, the degree of invasiveness and the part of the body affected by the use of the device, intended purpose, and duration.

a. **Duration of contact**: based on the duration f contact, medica device could be either transient, short-term devices or long-term devices.

b. **Invasiveness:** Any device which, in whole or in part, penetrates inside the body, either through a natural body orifice or through the surface of the body, is an invasive device. A surgically invasive device always implies that it enters through an artificially created opening. This can be a large opening, such as a surgical incision, or it can be a pinprick opening created by a needle. Therefore, surgical gloves and needles used with syringes are surgically invasive. The concept of surgically invasive should be understood as covering also liquids that are in invasive contact with organs, tissue, or other parts of the body if the access for such liquids is through a surgically created opening.

   In the context of invasiveness, however, a surgically created stoma used in urostomy, colostomy, ileostomy, or permanent tracheostomy is considered to be a body orifice. Therefore, devices introduced into such a stoma are not surgically invasive. A surgically created opening to allow access to the circulatory system, in contrast, should not be considered to be such a "body orifice." Devices introduced into such an opening are surgically invasive.

c. **Implant:** One of the key elements in defining an implantable device is the concept of "procedure." Thus, an implantable device must remain in the patient after the procedure. A "procedure" must be understood in this context to include the surgical procedure during which the implant is placed into the body and the immediate post-operative care

that is associated with the procedure. The "procedure" does not extend to the conclusion of the therapeutic treatment, e.g., the removal of an implant must be considered to be another "procedure." Thus, a plate used to reduce a fracture of the bone is an implant even if it is taken out after the fracture has healed. In this case, the placing of the plate and its explanations are two different surgical procedures.

d. **Implantable devices:** Some partially implanted devices are deemed to be implants. For instance, if an operation is carried out specifically to place an infusion port into the body, then such an infusion port would remain for at least 30 days after the procedure and, consequently, be an implant. However, a non-tunneled central venous catheter which is intended for use for temporary vascular access and intended to be removed after 7–10 days is not a long-term implantable device. Nor would a suture used for skin wound closure that is taken out prior to 30 days be considered an implant.

e. **Energy:** 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.

   A device that administers energy to the body should not be considered as invasive if only energy penetrates the body, and not the device itself. Energy, as such, is not a device and, therefore, it cannot be classified. Only the device generating the energy must be classified. However, if a device administers a substance, whether this substance is a medicine or a medical device, such a substance must be assessed in its own right (e.g., substances administered by a jet injector).

f. **Active devices:** Medical devices using pre-stored gases and/or vacuum as a power source are regarded as active devices, e.g., gas mixers with anesthesia machines and gas-powered suction pumps.

   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.

Radioactive sources that are intended to deliver ionizing radiation are regarded as active medical devices, unless they are radiopharmaceuticals where they are considered as medicinal products and not medical devices.

The classification of medical devices is a risk based system based on the vulnerability of the human body, taking account of the potential risks associated with the devices. This approach allows the use of a set of criteria that can be combined in various ways in order to determine classification, e.g., duration of contact with the body, degree of invasiveness, and local vs. systemic effect.

It is recognized that although the existing rules will adequately classify the vast majority of existing devices, a small number of products may be more difficult to classify. Such cases may, in particular, include devices which are borderline cases between two different classes of medical devices. In addition, there may be devices that cannot be classified by the existing rules because of their unusual nature or situations where the classification would result in the wrong level of conformity assessment in light of the hazard represented by the device. In such cases, the applicant will consult the authority and the authority will review on a case by case basis. For a procedure pack that is a device in its own right, the classification is normally determined by the intended use. In those cases where the intended use of the procedure pack is not specific enough to determine the classification, the classification of the pack is at the level of the highest classified device included in the pack.

6.4. Applicable Rules

In terms of further interpretation of the classification rules, the following should be considered:

1. 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 e.g., incorporation of an ancillary substance, tissue of animal origin, etc.

NOTE:

i. 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.

ii. *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.

2. 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.
3. If a medical device is intended to be used in combination with other medical device, the classification rules should be applied separately to each of the medical device.

NOTE:

i. Multi-application equipment such as laser printers and identification cameras, which may be used in combination with medical devices, are not medical devices unless their manufacturer places them on the market with specific intended purpose as medical devices.

4. The duration of use should be specified for all invasive medical devices as it determines the class of invasive medical device.
5. 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).
6. 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.
7. 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).
8. 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:

i. 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.

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

9. 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:

a) 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.

b) 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.

10. 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.

11. For a device to be "specifically intended" for the purpose referenced in a particular classification rule, the manufacturer must clearly indicate that the device is intended for such a specific purpose in the information accompanying the device. Otherwise, it is deemed to have the intended use which is principally used and accepted in general medical practice.

12. As an alternative to classifying the system as a whole, the determination of the class of a particular device may be made with respect to the simplest configuration that can still be considered, in view of its proper functional features, as a device in its own right. A device that is part of a system, e.g., a tube in an extra corporeal circulation set, may be classed as a device in its own right rather than classifying the system as a whole. The device, however, must be assessed in its own right as a separate device in such instances.

6.5. Classification of medical devices

The general approaches for medical device classification other than IVD medical devices are given in the following table (Table 1). This table 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.

Class	Risk Level	Device Example
I	Low Risk	Surgical retractors / tongue depressors
II	Low–Moderate Risk	Hypodermic needle / suction equipment
III	Moderate–High Risk	Lung ventilator / orthopaedic implants
IV	High Risk	Heart valves / implantable defibrillator

Table 1: General classification system for medical devices

6.6. Determination of device class using rules-based system

The manufacturer should:

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, nothing 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,

d) Determine that the device is not subject to special national rules that apply within a particular jurisdiction,

6.7. Classification rules for medical devices

The actual classification of each device depends on the claims made by the manufacturer and on its intended use. The explanations of individual classification rules are given in the following table (Table 2). 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.

Any special terms used are explained, and practical issues related to the rule are clarified. It must be emphasized that even if a particular device type is given as an example, this does not mean that such devices are in all cases in the class indicated by the example. It is always possible that some manufacturer will assign to a device an entirely different intended use than what was used in the context of the example.

Rule	Explanation	Illustrative examples of devices that may conform with a rule
NON-INVASIVE DEVICES		
Rule 1	All non-invasive devices which come into contact with injured skin:	Devices covered by this rule are extremely claim sensitive.
	a) are in Class I, 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
	b) are in Class II 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.
	c) are in Class III if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent	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.
Rule 2	All non-invasive 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 I	Such devices are 'indirectly invasive' in that they channel or store liquids that will eventually be delivered into the body (see comment for Rule 4). Examples: administration sets for gravity infusion; syringes without needles.
	unless they may be connected to an active medical device in Class II or a higher class, in which case they are Class II;	Examples: syringes and administration sets for infusion pumps; anaesthesia breathing circuits. NOTE: "Connection" to an active device covers those circumstances where the safety and performance of the active device is influenced by the non-active device and 'vice versa'.
	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 II.	Examples: tubes used for blood transfusion, organ storage containers.
	unless they are blood bags, in which case they are Class III.	Example: Blood bags that do not incorporate an anti-coagulant.
Rule 3	All non-invasive 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 III,	Such devices are indirectly invasive in that they treat or modify substances that will eventually be delivered into the body (see note to comment for Rule 4). They are normally used in conjunction with an active device within the scope of either Rule 9 or 11. Examples: haemodializers; devices to remove white blood cells from whole blood. NOTE: for the purpose of this part of the rule, 'modification' does not include simple, mechanical filtration or centrifuging which are covered below.

	unless the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class II.	Examples: devices to remove carbon dioxide; particulate filters in an extracorporial circulation system.
Rule 4	All other non-invasive devices in contact with injured skin or mucous membrane are in Class I.	These devices either do not touch the patient or contact intact skin only. Examples: urine collection bottles; compression hosiery; non-invasive electrodes, hospital beds.
INVASIVE DEVICES		
Rule 5	All invasive 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 I medical device only.	Such devices are invasive in body orifices and are not surgically invasive. Devices tend to be diagnostic and therapeutic instruments used in ENT, ophthalmology, dentistry, proctology, urology and gynaecology. Classification depends on the duration of use and the sensitivity (or vulnerability) of the orifice to such invasion.
	a) are in Class I if they are intended for transient use;	Examples: examination gloves; enema devices.
	b) are in Class II if they are intended for short-term use;	Examples: urinary catheters, tracheal tubes.
	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 I,	Examples: dentures intended to be removed by the patient; dressings for nose bleeds.
	c) are in Class III if they are intended for long-term use;	Example: urethral stent; contact lenses for long-term continuous use (for this device, removal of the lens for cleaning or maintenance is considered as part of the continuous use).
	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 II.	Examples: orthodontic wire, fixed dental prosthesis.
	All invasive devices with respect to body orifices (other than those which are surgically invasive) that are intended for	Examples: tracheal tubes connected to a ventilator; suction catheters for stomach drainage; dental aspirator tips.

	connection to an active medical device in Class II or a higher class, are classified as Class II.	NOTE: independent of the time for which they are invasive.
Rule 6	All surgically invasive devices intended for transient use are in Class II,	A majority of such devices fall into several major groups: those that create a conduit through the skin (e.g. syringe needles; lancets), surgical instruments (e.g. single use scalpels; surgical staplers; single-use aortic punch); surgical gloves; and various types of catheter/sucker etc. NOTE: 1. a surgical instrument (other than those in Class IV) is in Class A if reusable and in Class II if supplied sterile and intended for single use. Also, a surgical instrument connected to an active device is in a higher class than I. 2. if the device incorporates a medicinal substance in a secondary role refer to Rule 13.
	Unless they are reusable surgical instruments, in which case they are in Class I; or	Examples: Manually operated surgical drill bits and saws.
	unless intended to supply energy in the form of ionizing radiation, in which case they are in Class III; or	Example: catheter incorporating/containing sealed radioisotopes.
	unless intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class III; or	***NOTES:*** a) 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. b) This part of the rule does not apply to those substances that are excreted without modification from the body. Example: Insufflation gases for the abdominal cavity.
	unless intended to administer medicinal products by means of a delivery system, if this is done in a manner that is potentially	Example: insulin pen for self-administration. **NOTE**: the term 'administration of

	hazardous taking account of the mode of application, in which they are in Class III; or	medicines'implies storage and/or influencing the rate/volume of medicine delivered not just channelling. The term 'potentially hazardous manner' refers to the characteristics of the device and not the competence of the user.
	unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class IV; 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 IV.	Examples: angioplasty balloon catheters and related guide wires; dedicated disposable cardiovascular surgical instruments.
Rule 7	All surgically invasive devices intended for short-term use are in Class II,	Such 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 cannulae; temporary filling materials; non-absorbable skin closure devices; tissue stabilisers used in cardiac surgery. **NOTE**: a) includes devices that are used during cardiac surgery but do not monitor or correct a defect. b) if the device incorporates a medicinal substance in a secondary role refer to Rule 13.
	unless they are intended to administer medicinal products, in which case they are in Class III; or	**NOTE**: the term 'administration of medicines' implies storage and/or influencing the rate/volume of medicine delivered not just channelling.
	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 III; or	Example: surgical adhesive.
	unless they are intended to supply energy in the form or ionizing radiation, in which case they are in Class III; or	Example: brachytherapy device.
	unless they are intended to have a	Example: absorbable suture; biological adhesive.

	biological effect or to be wholly or mainly absorbed, in which case they are in Class IV; or	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.
	unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class IV;	Example: neurological catheter.
	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 IV.	Examples: cardiovascular catheters; temporary pacemaker leads; carotid artery shunts.
Rule 8	All implantable devices, and long term surgically invasive devices, are in Class III,	Most of the devices covered by this rule are implants used in the orthopaedic, dental, ophthalmic and cardiovascular fields. Example: maxilla-facial implants; prosthetic joint replacements; bone cement; nonabsorbable internal sutures; posts to secure teeth to the mandibula bone (without a bioactive coating). NOTE: if the device incorporates a medicinal substance in a secondary role refer to Rule 13.
	unless they are intended to be placed into the teeth, in which case they are in Class II; or	Examples: bridges; crowns; dental filling materials.
	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 IV; or	Examples: prosthetic heart valves; spinal and vascular stents.
	unless they are intended to be active implantable medical devices or their accessories, in which case they are Class IV; or	Example: pacemakers, their electrodes and their leads; implantable defibrillators.
	unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class IV; or	Example: implants claimed to be bioactive. NOTE: hydroxy-apatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer.
	unless they are intended to administer medicinal products, in which case they are	Example: rechargeable non-active drug delivery system.

	in Class IV; or	
	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 IV; 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.
	unless they are breast implants or surgical meshes in which case they are in Class IV.	
	Unless They are total or partial joint replacements in which case, they are in class IV with the exception of ancillary components such as screws, wedges, plates, and instruments	
	Unless they are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified in class IV with the exception of ancillary components such as screws, wedges, plates, and instruments	
ACTIVE DEVICES		
Rule 9	All active therapeutic devices intended to administer or exchange energy are in Class II,	Such devices are mostly electrically powered equipment used in surgery; devices for specialised treatment and some stimulators. Examples: muscle stimulators; TENS devices; powered dental hand pieces; hearing aids; neonatal phototherapy equipment; ultrasound equipment for physiotherapy.
	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 III.	Examples: lung ventilators; baby incubators; electrosurgical generators; external pacemakers and defibrillators; surgical lasers; lithotriptors; therapeutic X-ray and other sources of ionizing radiation. NOTE: the term 'potentially hazardous' refers to the type of technology involved and the intended application.
	All active devices intended to control or monitor the performance of active therapeutic devices in Class III, or intended directly to influence the performance of such devices, are in Class III.	Examples: external feedback systems for active therapeutic devices.

	All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are classified as class III.	
	All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class IV.	
Rule 10	Active devices intended for diagnosis and monitoring are in Class II:	Such devices include equipment for ultrasonic diagnosis/imaging, capture of physiological signals, interventional radiology and diagnostic radiology.
	• 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 I), or	Examples: magnetic resonance equipment; diagnostic ultrasound in non-critical applications; evoked response stimulators.
	• if they are intended to image in vivo distribution of radiopharmaceuticals, or	Example: gamma/nuclear cameras.
	• if they are intended to allow direct diagnosis or monitoring of vital physiological processes,	Example: electronic thermometers, stethoscopes and blood pressure monitors; electrocardiographs.
	unless they are specifically intended for: a) 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 b) diagnosing in clinical situations where the patient is in immediate danger, in which case they are in Class III.	Example: monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnoea monitors. Example: ultrasound equipment for use in interventional cardiac procedures.
	Active devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology, including devices which	Example: these include devices for the control, monitoring or influencing of the emission of ionizing radiation.

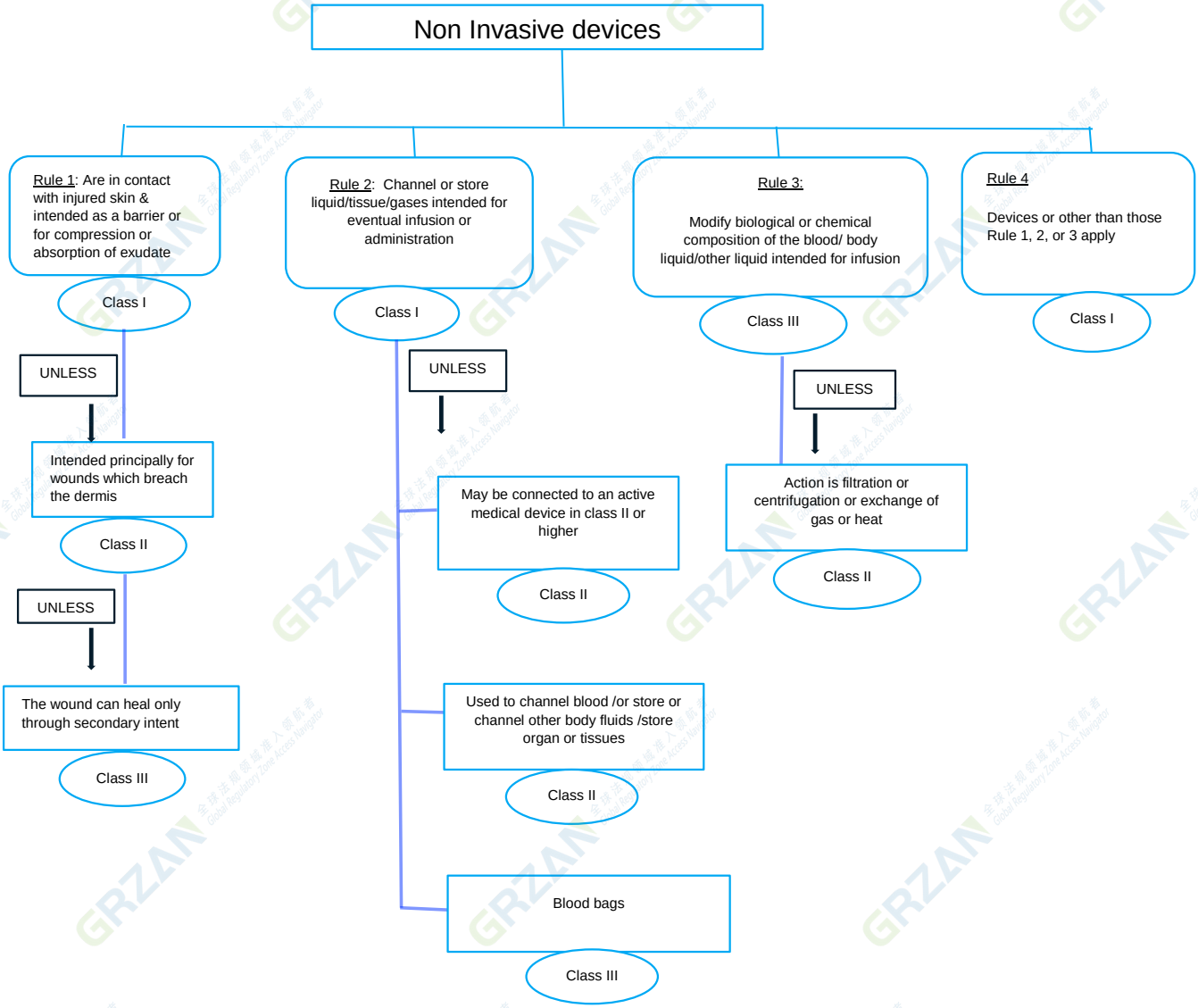
	control or monitor such devices, or those which directly influence their performance, are in Class III.	
Rule 11	Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class II,	
	except if such decisions have an impact that may cause: • death or an irreversible deterioration of a person's state of health, in which case it is in class IV; or • a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class III.	
	Software intended to monitor physiological processes is classified as class II,	
	except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class III.	
	All other software is classified as class I.	
Rule 12	All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are in Class II,	Such devices are mostly drug delivery systems or anaesthesia equipment. Examples: suction equipment; feeding pumps; jet injectors for vaccination; nebuliser to be used on conscious and spontaneously breathing patients where failure to deliver the appropriate dosage characteristics is not potentially hazardous.
	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 III.	Examples: infusion pumps; anaesthesia equipment; dialysis equipment; hyperbaric chambers; nebuliser where the failure to deliver the appropriate dosage characteristics could be hazardous.

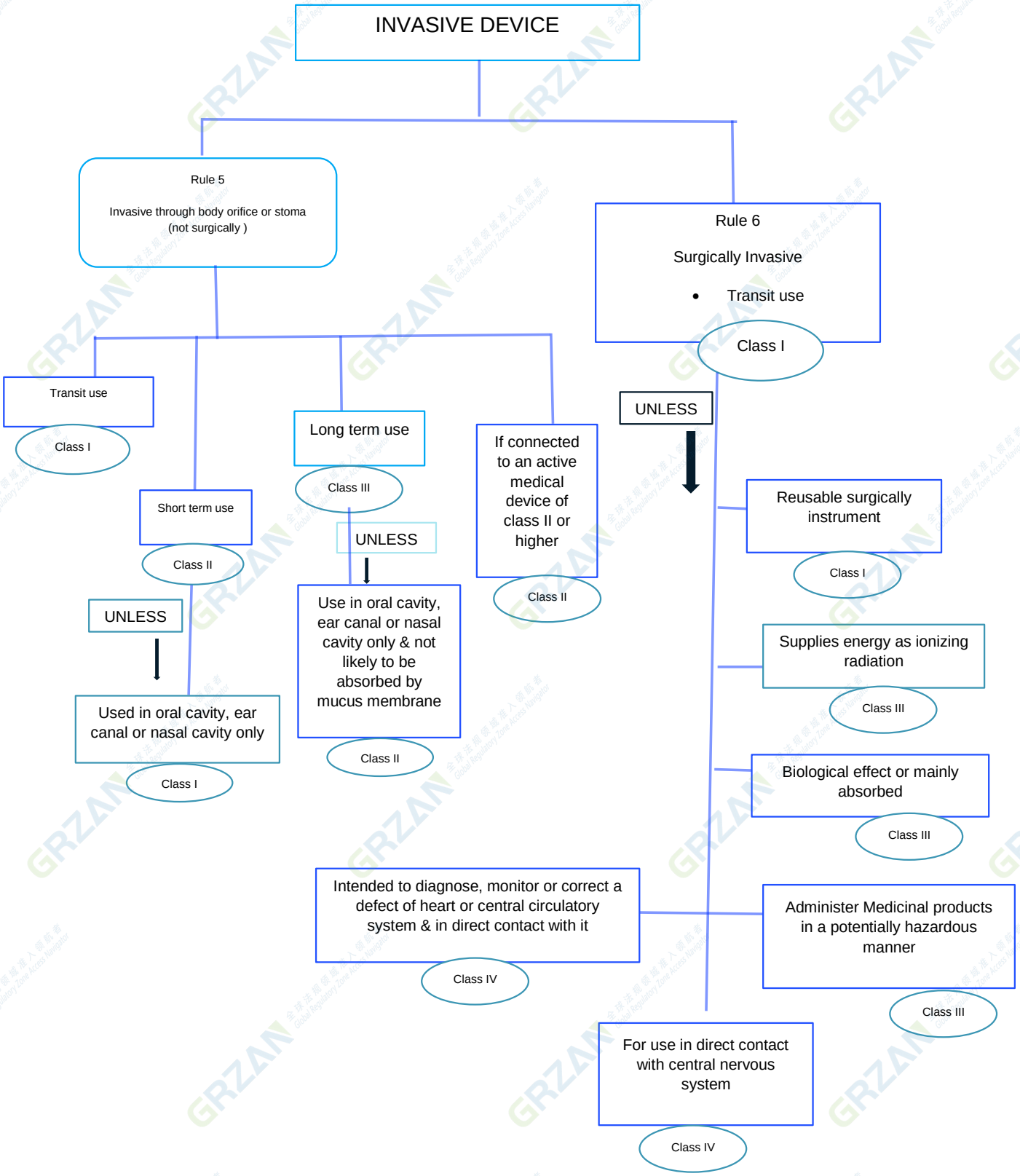
Rule 13	All other active devices are in Class I.	Examples: examination lamps; surgical microscopes; powered hospital beds & wheelchairs; powered equipment for the recording, processing, viewing of diagnostic images; dental curing lights.
SPECIAL RULES		
Rule 14	All devices incorporating, as an integral 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 IV.	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.
Rule 15	All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class III,	Examples: condoms; contraceptive diaphragms.
	unless they are implantable or long-term invasive devices, in which case they are in Class IV.	Example: intrauterine contraceptive device.
Rule 16	All devices intended specifically to be used for sterilizing medical devices, or disinfecting as the end point of processing, are in Class III.	Examples: devices for disinfecting or sterilising endoscopes; disinfectants intended to be used with medical devices. NOTE: This rule does not apply to products that are intended to clean medical devices by means of physical action e.g. washing machines.
	unless they are intended for disinfecting medical devices prior to end point sterilisation or higher level disinfection, in which case they are in Class II; or	Example: washer disinfectors.
	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 III.	
Rule 17	Devices specifically intended for recording of diagnostic images generated by X-ray radiation are classified as class II.	
Rule	All devices manufactured from or incorporating animal or human	NOTE: In some jurisdictions such products: • are considered to be outside the scope of the

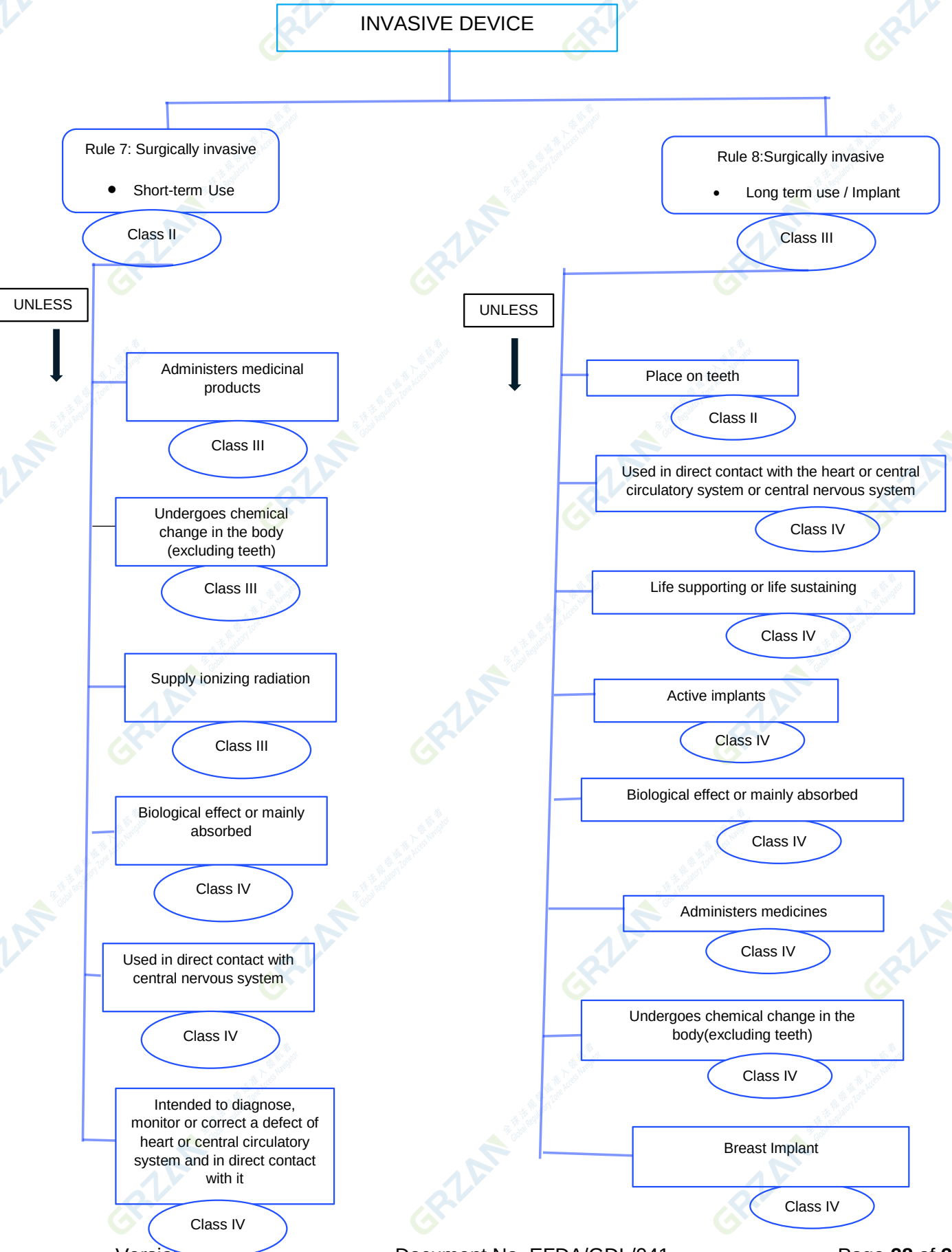
18	cells/tissues/derivatives thereof, whether viable or non-viable, are Class IV,	medical device definition; • may be subject to different controls. It is likely the regulations controlling these devices will be the subject of future harmonization efforts. Examples: porcine heart valves; catgut sutures.
	unless such 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 I.	Examples: leather components of orthopaedic appliances.
Rule 19	All devices incorporating or consisting of nanomaterial are classified as:	
	• class IV if they present a high or medium potential for internal exposure;	
	• class III if they present a low potential for internal exposure; and	
	• class II if they present a negligible potential for internal exposure.	
Rule 20	All invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation are classified as class II,	
	unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product or they are intended to treat life- threatening conditions, in which case they are classified as class III	
Rule 21	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 or applied to the skin and that are absorbed by or locally dispersed in the human body are classified as:	

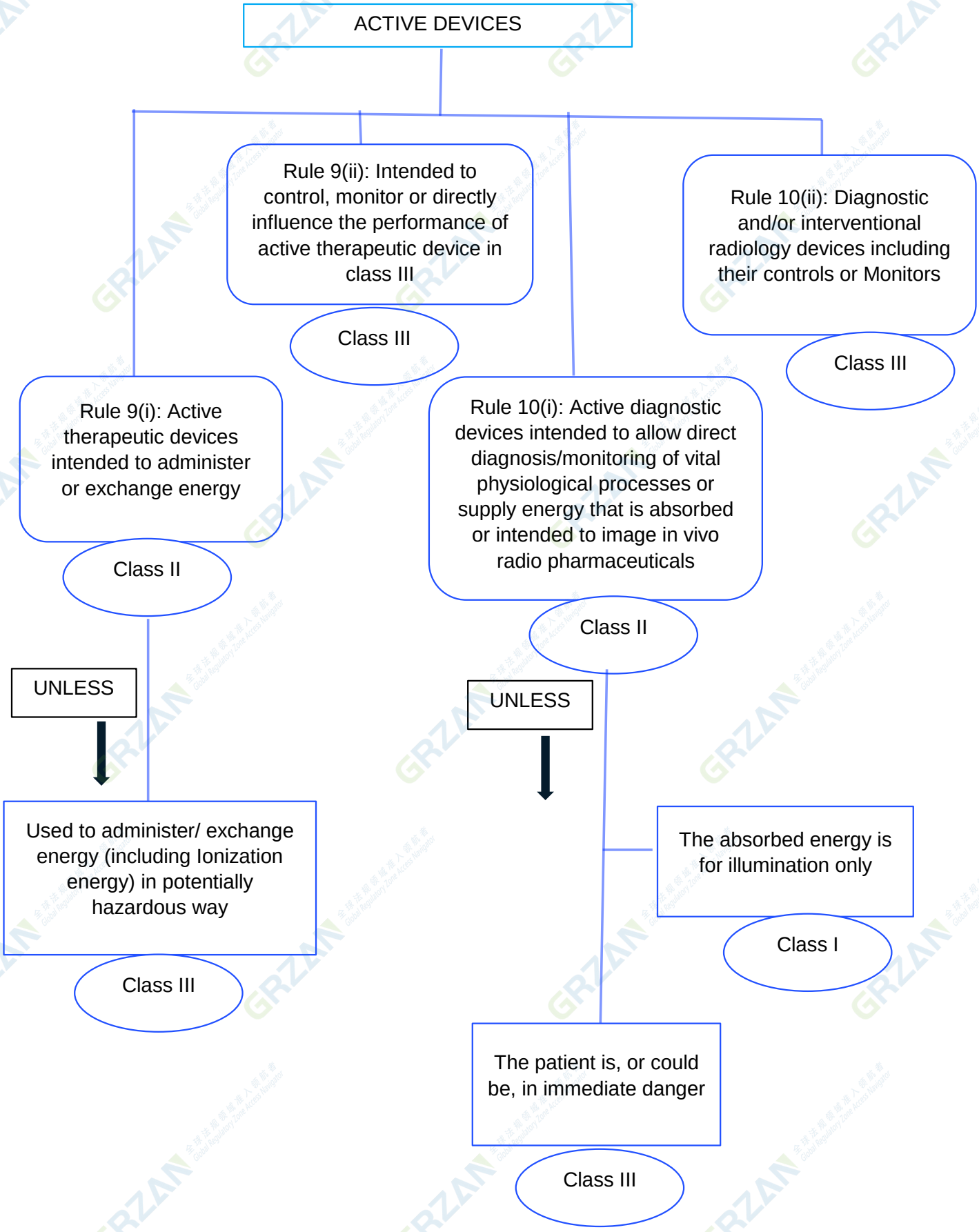
	• class IV if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;	
	• class IV if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body;	
	• class II if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities; and	
	• class III in all other cases.	
Rule 22	Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class IV.	

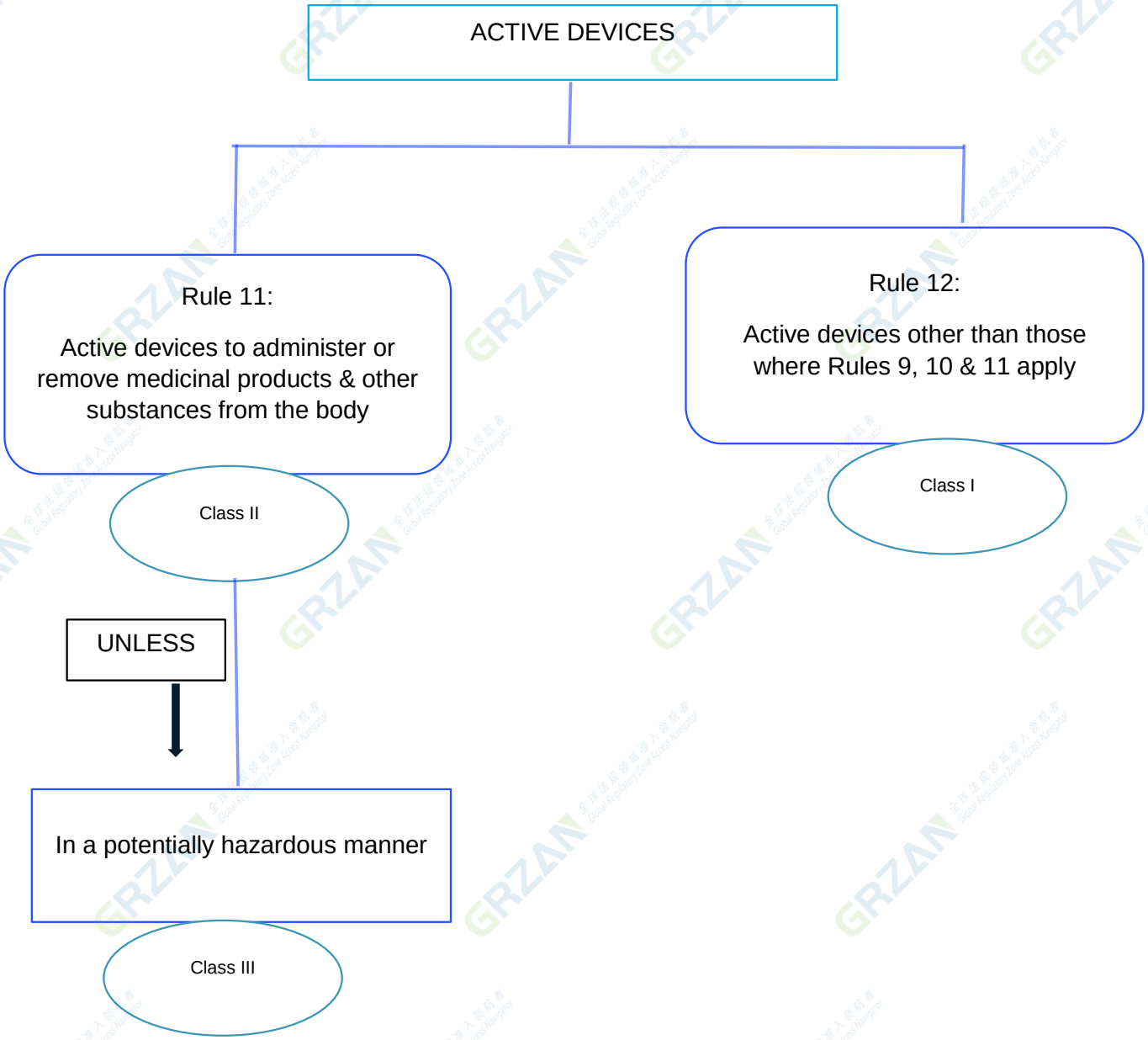
Annex I: Decision trees to demonstrate how the rules may be used to classify specific devices.

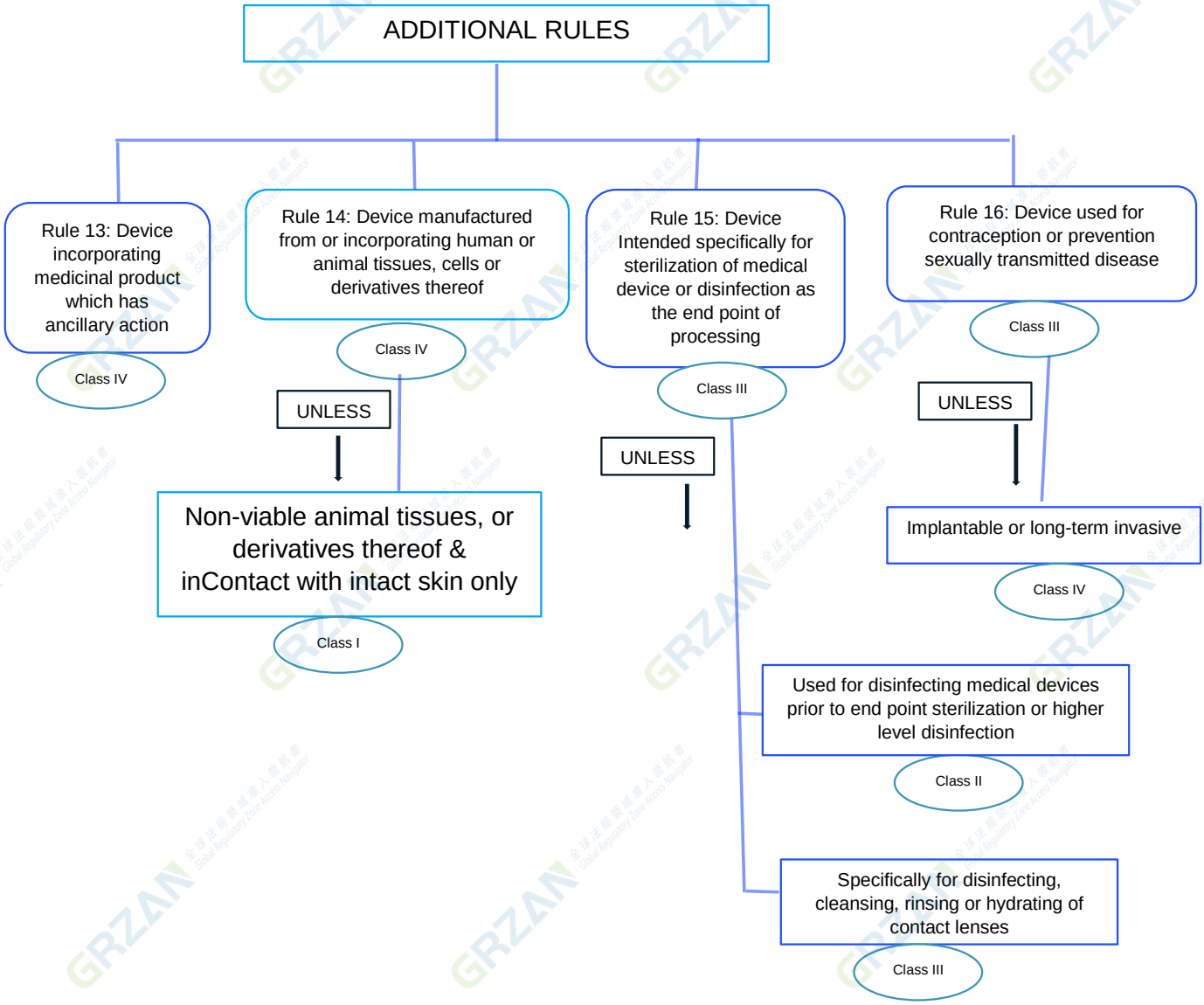



INVASIVE DEVICE
Rule 5
Invasive through body orifice or stoma (not surgically)
Rule 6
Surgically Invasive
Transit use
Class I
Transit use
Class I
Short term use
Class II
UNLESS
Used in oral cavity, ear canal or nasal cavity only
Class I
Long term use
Class III
UNLESS
Use in oral cavity, ear canal or nasal cavity only & not likely to be absorbed by mucus membrane
Class II
If connected to an active medical device of class II or higher
Class II
UNLESS
Reusable surgically instrument
Class I
Supplies energy as ionizing radiation
Class III
Biological effect or mainly absorbed
Class III
Intended to diagnose, monitor or correct a defect of heart or central circulatory system & in direct contact with it
Class IV
Administer Medicinal products in a potentially hazardous manner
Class III
For use in direct contact with central nervous system
Class IV


INVASIVE DEVICE
Rule 7: Surgically invasive
Short-term Use
Class II
UNLESS
Administers medicinal products
Class III
Undergoes chemical change in the body (excluding teeth)
Class III
Supply ionizing radiation
Class III
Biological effect or mainly absorbed
Class IV
Used in direct contact with central nervous system
Class IV
Intended to diagnose, monitor or correct a defect of heart or central circulatory system and in direct contact with it
Class IV
Rule 8:Surgically invasive
Long term use / Implant
Class III
UNLESS
Place on teeth
Class II
Used in direct contact with the heart or central circulatory system or central nervous system
Class IV
Life supporting or life sustaining
Class IV
Active implants
Class IV
Biological effect or mainly absorbed
Class IV
Administers medicines
Class IV
Undergoes chemical change in the body(excluding teeth)
Class IV
Breast Implant
Class IV


ACTIVE DEVICES
Rule 9(ii): Intended to control, monitor or directly influence the performance of active therapeutic device in class III
Class III
Rule 10(ii): Diagnostic and/or interventional radiology devices including their controls or Monitors
Class III
Rule 9(i): Active therapeutic devices intended to administer or exchange energy
Class II
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 II
UNLESS
Used to administer/ exchange energy (including Ionization energy) in potentially hazardous way
Class III
UNLESS
The absorbed energy is for illumination only
Class I
The patient is, or could be, in immediate danger
Class III


ACTIVE DEVICES
Rule 11:
Active devices to administer or remove medicinal products & other substances from the body
Class II
UNLESS
In a potentially hazardous manner
Class III
Rule 12:
Active devices other than those where Rules 9, 10 & 11 apply
Class I


ADDITIONAL RULES
Rule 13: Device incorporating medicinal product which has ancillary action
Class IV
Rule 14: Device manufactured from or incorporating human or animal tissues, cells or derivatives thereof
Class IV
UNLESS
Non-viable animal tissues, or derivatives thereof & inContact with intact skin only
Class I
Rule 15: Device Intended specifically for sterilization of medical device or disinfection as the end point of processing
Class III
UNLESS
Used for disinfecting medical devices prior to end point sterilization or higher level disinfection
Class II
Specifically for disinfecting, cleansing, rinsing or hydrating of contact lenses
Class III
Rule 16: Device used for contraception or prevention sexually transmitted disease
Class III
UNLESS
Implantable or long-term invasive
Class IV