FINAL DOCUMENT

Global Harmonization Task Force

(Revision of GHTF/SG1/N15:2006)

Title: Principles of Medical Devices Classification

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This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

The document is intended to provide non-binding guidance to regulatory authorities for use in the regulation of medical devices, and has been subject to consultation throughout its development.

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Preface

The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device Regulatory Authorities and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

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1.0 Introduction

The primary way in which the GHTF achieves its goals is through the production of a series of guidance documents that together describe a global regulatory model for medical devices. The purpose of such guidance is to harmonize the documentation and procedures that are used to assess whether a medical device conforms to the regulations that apply in each jurisdiction. Eliminating differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

This document has been developed to encourage and support global convergence of regulatory systems. It is intended for use by Regulatory Authorities (RAs), Conformity Assessment Bodies (CABs) and industry, and will provide benefits in establishing, in a consistent way, an economic and effective approach to the control of medical devices in the interest of public health. It seeks to strike a balance between the responsibilities of RAs to safeguard the health of their citizens and their obligations to avoid placing unnecessary burdens upon the regulated industry.

This document should be read in conjunction with the GHTF document entitled *Principles of Conformity Assessment for Medical Devices* that prescribes conformity assessment requirements appropriate to each of the four classes proposed herein. The link between device classification and conformity assessment is fundamental to the development of an effective global regulatory model. If such is adopted in a consistent manner by all jurisdictions, the goal of a premarket approval for a particular device being accepted globally, may be achieved.

This document **supersedes** GHTF/SG1/N15:2006 which provided guidance on the same topic. It has been modified to:

- clarify the basis of allocating medical devices to one of four classes;
- change the rule applying to sterilisation and disinfection devices;
- remove the inconsistency with GHTF/SG1/N011 *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)*;
- add a Section on the reclassification of medical devices; and
- incorporate changes resulting from the public scrutiny process.

Where other guidance documents within the series are referenced within this text, their titles are italicised for clarity.

Study Group 1 of the Global Harmonization Task Force (GHTF) has prepared this guidance document. Comments or questions about it should be directed to either the Chair or Secretary of GHTF Study Group 1 whose contact details may be found on the GHTF website[1].

[1] www.ghtf.org

2.0 Rationale, Purpose and Scope

2.1 Rationale

It is widely accepted that there should be a method to separate medical devices into a small number of groups, or classes, and subsequently apply different conformity assessment techniques to each class. The global adoption of a rules-based classification procedure would offer significant benefits to manufacturers, users, patients, and RAs and support global convergence of regulatory systems.

2.2 Purpose

To stipulate a series of principles and rules that allow a medical device to be assigned to one of four classes based on its intended use, and thereby:

- assist a manufacturer to allocate its medical device to an appropriate class using a set of classification rules; and
- allow RAs to pronounce upon matters of interpretation for a particular medical device, when required so to do.

Subsequently, such classification will determine the conformity assessment procedures that will be applied to the device.

This document is intended for use by RAs, CABs and the regulated Industry,

2.3 Scope

This document applies to all products that fall within the definition of the term 'medical device', other than IVD medical devices, for which a separate classification document is available on the GHTF website.

3.0 References[2]

GHTF/SG1/N44:2008 *Role of Standards in the Assessment of Medical Devices.*

GHTF/SG1/N68:2012 *Essential Principles of Safety and Performance of Medical Devices.*

GHTF/SG1/N70:2011 *Label and Instructions for Use for Medical Devices.*

GHTF/SG1/N071:2012 *Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'.*

GHTF/SG1/N78:2012 *Principles of Conformity Assessment for Medical Devices.*

[2] The listed documents are subject to periodic review and may be superseded by later versions. The reader is encouraged to refer to the GHTF website to confirm whether the referenced documents remain current.

4.0 Definitions

Accessory to a medical device: Means an article intended specifically by its manufacturer to be used together a particular medical device to enable or assist that device to be used in accordance with its intended use.

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

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

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

Central circulatory system: The major internal blood vessels including the following: pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, carotid arteries (common, internal and external), cerebral arteries, brachiocephalic artery, aorta (includes all segments of the aorta), inferior and superior vena cava and common iliac arteries.

Central nervous system: The brain, meninges, and spinal cord.

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

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.

Duration of use

Transient: Normally intended for continuous use for less than 60 minutes.

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

Long term: Normally intended for continuous use for more than 30 days.

NOTE: continuous use means:

a) The entire duration of use of the same 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.

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

Hazard: Potential source of harm.

Intended use / Intended purpose: 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 devices

Invasive 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.

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.

Surgically invasive device:

(a) 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.

(b) A medical device which produces penetration other than through a body orifice.

Implantable 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.

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.

Lay person: Individual that does not have formal training in a relevant field or discipline**.**

Life supporting or life sustaining: 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.

Medical device: See GHTF guidance document: *Definition of the Term 'Medical Device'*.

Reusable medical device: Means a device intended for repeated use either on the same or different patients, with appropriate decontamination and other reprocessing between uses.

Reusable surgical instrument: Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar 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: Combination of the probability of occurrence of harm and the severity of that harm.

Sterilisation: Validated process used to render product free from viable microorganisms.

NOTE: In a sterilisation process, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

Vital physiological process: Means a process that is necessary to sustain life, the indicators of which may include any one or more of the following:

- respiration;
- heart rate;
- cerebral function;
- blood gases;
- blood pressure;
- body temperature.

5.0 General Principles

Manufacturers of medical devices are subject to regulatory controls overseen by national RAs. The RA specifies procedures to be followed by manufacturers during the design, manufacture, and marketing of each device, and describes the manner in which a manufacturer should demonstrate conformity to such procedures. It is widely accepted that oversight of these procedures by the RA should increase in line with the potential of a medical device to cause harm to a patient or user (i.e. the hazard it presents), and to do so without placing an unwarranted increase in the cost of regulatory compliance for either the manufacturer or RA, or delay market entry. In practice, this is best achieved by assigning every medical device into one of four groups – or 'classes' - by applying the classification rules described in this guidance document, and specify in separate guidance[3] the different conformity assessment procedures that should apply to each group of devices.

Customarily, a classification system of this type is referred to as a 'risk-based classification scheme' but this is a misnomer since the rules take account only of the hazard presented by a particular device and not the probability harm will occur[4].

The RA takes account of the probability that harm will occur by modifying the evidence requirements at the conformity assessment stage rather than modifying the classification rules. Probability of harm is influenced by factors such as whether:

- the technology is regarded as mature;
- the device type is the source of many adverse event reports;

[3] See GHTF/SG1/N78:2012 *Principles of Conformity Assessment for Medical Devices.*

[4] See the internationally accepted definition of' risk' in Section 4.0.

- the device's manufacturer has a long experience of the device and the technologies it embodies;
- the device user is a lay person.

The hazard presented by a particular medical device depends substantially on its intended use and the technology it utilises. Consequently, the classification rules stipulated in Section 7.0 of this guidance document take factors into account such as, whether the device:

- is life supporting or sustaining;
- is invasive and if so, to what extent and for how long;
- incorporates medicinal products, or human/animal tissues/cells;
- is an active medical device;
- delivers medicinal products, energy or radiation;
- could modify blood or other body fluids;
- is used in combination with another medical device.

A further advantage of a rules-based system of classification is that it is easily adapted to accommodate new technologies.

6.0 Classification System for Medical Devices

6.1 Structure of the Classification Rules

a) RAs should establish a device classification system consisting of four classes where Class A represents the lowest hazard and Class D the highest.

b) The determination of class should be based on rules derived from the potential of a medical device to cause harm to a patient or user (i.e. the hazard it presents) and thereby on its intended use and the technology/ies it utilises.

c) These rules should allow a manufacturer to readily identify the class of its particular medical device subject, where appropriate, to the RA resolving any matters of interpretation.

d) The rules should be capable of accommodating future technological developments.

e) The manufacturer should document its justification for placing its product into a particular class, including the resolution of any matters of interpretation where it has asked a RA for a ruling.

f) An accessory to a medical device may be classified separately using the classification rules in this guidance document.

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

h) Where one medical device is intended to be used together with a different medical device, that may or may not be from the same manufacturer, (e.g. a pulse oximeter and a replaceable sensor sourced from a different manufacturer, or a general purpose syringe and a syringe driver), the classification rules should apply separately to each of the devices.

i) Classification of an assemblage of medical devices that individually comply with all regulatory requirements depends on the manufacturer's purpose in packaging and marketing such a combination of separate devices. For example:

- If the combination results in a product that is intended by the manufacturer to meet a purpose different from that of the individual medical devices that make it up, the combination is a new medical device in its own right and should be classified according to the new intended use.

- If the combination is for the convenience of the user but does not change the intended uses of the individual medical devices that make it up (e.g. a customised kit that provides all the devices necessary to carry out a particular surgical procedure), 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.

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

k) While most software is incorporated into the medical device itself, some is not. Provided such standalone software falls within the scope of the definition for a 'medical device', it is deemed to be an active device and should be classified as follows:

- Where it drives or influences the use of a separate medical device, it should be classified according to the intended use of the combination.

- Where it is independent of any other medical device, it is classified in its own right using the rules in Section 7.0 of this document.

l) The historical experience of a RA may require a particular type of medical device to be allotted a different classification from that assigned through the application of these classification rules.

6.2 Diagrammatic Representation of the Classification System

CLASS	LEVEL	DEVICE EXAMPLES
A	Low Hazard	Bandages / tongue depressors
B	Low-moderate	Hypodermic Needles / suction equipment

	Hazard	
C	Moderate-high Hazard	Lung ventilator / bone fixation plate
D	High Hazard	Heart valves / implantable defibrillator

Figure 1: Classification System for Medical Devices

Note: The examples of medical devices provided in Figure 1 are for illustration only and a manufacturer of such a device should not rely on it appearing as an example but should instead make an independent decision on classification taking account of its particular design and intended use.

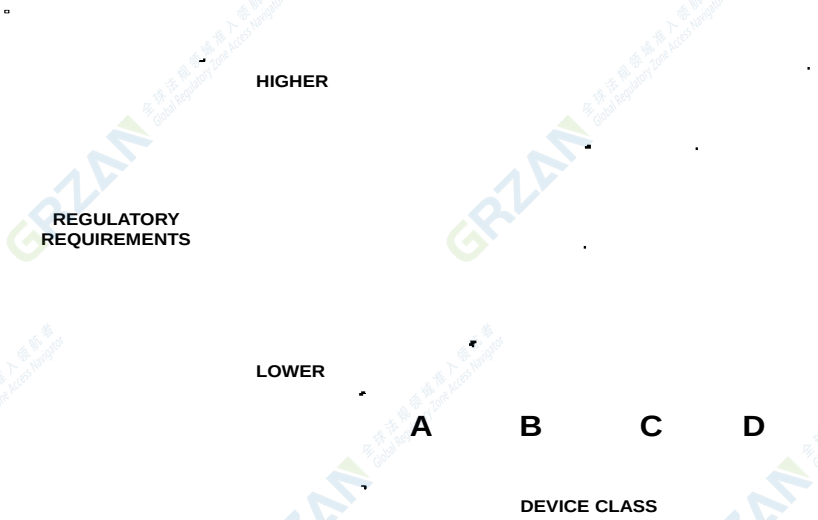


Figure 2: Conceptual illustration of regulatory controls increasing with device class

Figure 2 indicates increasing regulatory controls as the device class progresses from Class A to Class D. Such controls may require, for example:-

- the manufacturer to apply an independently audited quality management system to the design and development process as well as to manufacturing;
- the RA or CAB to review the manufacturer's Summary Technical Documentation, including the clinical evidence provided, to verify conformity to all relevant Essential Principles, prior to the device being placed on the market;
- the manufacturer to undertake post-market evaluation and testing of marketed devices.

The concept is expanded in the GHTF guidance document entitled *Principles of Conformity Assessment for Medical Devices*.

6.3 Manufacturer's Determination of Device Class

The manufacturer should:

a) Refer to the GHTF guidance document entitled *Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'* to confirm the product concerned is a medical device.

b) Document 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.**

d) Determine if the device is subject to special national rules that apply within a particular jurisdiction and whether this affects the device class.

e) Ask the RA to resolve any matter of interpretation, if such exists.

7.0 Classification Rules

The actual classification of each device depends on the claims made by the manufacturer for its intended use and the technology/ies it utilises. As an aid to interpreting the purpose of each rule, illustrative examples of medical devices that should conform to the rule have been provided in the table below. However, it must be emphasised that a manufacturer of such a device should not rely on it appearing as an example but should instead make an independent decision on classification taking account of its particular design and intended use.

As an aid to understanding how these rules may be applied, a series of decision trees are provided in Appendix A. These are for illustrative purposes only and are **not intended to be a substitute for the rules themselves**.

Manufacturers, RAs and CABs are advised to refer to the definitions in Section 4.0 of this document for a proper understanding of the terms used within these rules.

7.1 Non-Invasive Devices

RULE	ILLUSTRATIVE EXAMPLES
Rule 1. All non-invasive devices which come into contact with injured skin:	Devices covered by this rule are extremely claim sensitive.
- 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: bandages; cotton wool.

RULE	ILLUSTRATIVE EXAMPLES
- 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.	Example: non-medicated impregnated gauze dressings.
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.	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(i). All non-invasive devices intended for channelling or storing • liquids, or • gases for the purpose of eventual infusion, administration or introduction into the body are in Class A,	Such devices are 'indirectly invasive' in that they channel or store liquids that will eventually be delivered into the body. Examples: administration sets for gravity infusion; syringes without needles.
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; 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*.
Rule 2(ii). All non-invasive devices intended to be used for • channeling blood, or • storing or channeling other body liquids, or • storing organs, parts of organs or body tissues, for the purpose of eventual infusion, administration or introduction into the body are Class B.	Examples: tubes used for blood transfusion, organ storage containers.
unless they are blood bags, in which case they are Class C.	Example: Blood bags that do not incorporate an anti-coagulant.

RULE	ILLUSTRATIVE EXAMPLES
	NOTE: In some jurisdictions, blood bags have a special rule that places them within a different class.
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 C,	Such 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: 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 B.	Examples: devices to remove carbon dioxide; particulate filters in an extracorporial circulation system.
Rule 4. All other non-invasive devices are in Class A.	These devices either do not touch the patient or contact intact skin only. Examples: urine collection bottles; compression hosiery; non-invasive electrodes, hospital beds.

7.2 Invasive Devices

RULE	ILLUSTRATIVE EXAMPLES
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 A medical device only.	Such devices are invasive in body orifices and are not surgically invasive (refer to definition in Section 4). 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.
- are in Class A if they are intended for transient use;	Examples: examination gloves; enema devices.
- are in Class B if they are intended for short-term use;	Examples: urinary catheters, tracheal tubes.
unless they are intended for short-term	Examples: dressings for nose bleeds.

RULE	ILLUSTRATIVE EXAMPLES
use in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class A,	
- are in Class C if they are intended for long-term use;	Example: urethral stent; contact lenses for long-term continuous use (for this device, removal of the lens for cleaning 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 B.	Examples: orthodontic materials, removable dental prosthesis.
All invasive 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. **NOTE:** Independent of the time for which they are invasive.
Rule 6. All surgically invasive devices intended for **transient use** are in Class B,	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.
unless they are reusable surgical instruments, in which case they are in Class A; or	Examples: Manually operated surgical drill bits and saws. **NOTE**: A surgical instrument connected to an active device is in a higher class than A.
unless intended to supply energy in the form of ionizing radiation, in which case they are in Class C; or	Example: catheter containing sealed radioisotopes.
unless intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class C; 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

RULE	ILLUSTRATIVE EXAMPLES
	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 hazardous taking account of the mode of application, in which they are in Class C; or	Example: insulin pen for self-administration. **NOTE**: The term 'administration of 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 D; or	Example**:** spinal needle.
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 catheters and related guide wires; dedicated disposable cardiovascular surgical instruments.
Rule 7. All surgically invasive devices intended for **short-term use** are in Class B,	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:** Includes devices that are used during cardiac surgery but do not monitor or correct a defect.
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 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 C; or	Example: surgical adhesive.
unless they are intended to supply energy in the form of ionizing radiation,	Example: brachytherapy device.

RULE	ILLUSTRATIVE EXAMPLES
in which case they are in Class C; or	
unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or	Example: 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.
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.
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 8. All implantable devices, and **long-term surgically invasive** devices, are in Class C,	Most of the devices covered by this rule are implants used in the orthopaedic, dental, ophthalmic, and cardiovascular fields. Example: maxilla-facial implants; bone plates and screws; bone cement; non-absorbable internal sutures; posts to secure teeth to the mandibula bone (without a bioactive coating).
unless they are intended to be placed into the teeth or on prepared tooth structure, in which case they are in Class B; or	Examples: materials for inlays, crowns, and bridges; 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 D; or	Examples: prosthetic heart valves; cardiovascular stents; pacemaker leads and electrodes; deep brain stimulation electrodes; cerebrospinal catheter.
unless they are intended to be life supporting or life sustaining, in which case they are in Class D; or	
unless they are intended to be active implantable medical devices, in which	Example: pacemakers; implantable defibrillators.

RULE	ILLUSTRATIVE EXAMPLES
case they are Class D; or	
unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or	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 in Class D; or	Example: subcutaneous infusion ports for long-term use.
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	Example: surgical adhesives intended for long term use. **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, in which case they are in Class D.	

7.3 Active Devices

RULE	ILLUSTRATIVE EXAMPLES
Rule 9(i). All active therapeutic devices intended to administer or exchange energy are in Class B,	Such devices are mostly electrically powered equipment used in surgery; devices for specialised treatment and some stimulators. Examples: muscle stimulators; 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 C.	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.
Rule 9(ii). All active 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	Examples: external feedback systems for active therapeutic devices.

RULE	ILLUSTRATIVE EXAMPLES
Class C.	
Rule 10(i). Active devices intended for diagnosis are in Class B:	Such devices include equipment for ultrasonic diagnosis/imaging, capture of physiological signals.
- 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; 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 C.	Example: monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnoea monitors. Example: ultrasound equipment for use in interventional cardiac procedures.
Rule 10(ii). Active 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.	Example: devices for the control, monitoring or influencing of the emission of ionizing radiation.
Rule 11. 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 anaesthesia equipment. Examples: suction equipment; feeding pumps; jet injectors for vaccination; nebuliser to be used

RULE	ILLUSTRATIVE EXAMPLES
	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 C.	Examples: infusion pumps; anaesthesia equipment; dialysis equipment; hyperbaric chambers; nebuliser where the failure to deliver the appropriate dosage 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.

7.4 Additional Rules

RULE	ILLUSTRATIVE EXAMPLES
Rule 13. 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 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. **NOTE:** In some jurisdictions such products: - are considered to be outside the scope of the medical device definition; - may be subject to different controls.
Rule 14. All devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable, are in Class D,	Example: porcine heart valves. **NOTE:** In some jurisdictions such products: - are considered to be outside the scope of the medical device definition; - may be subject to different controls.
unless such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only in which case they are in Class A.	Examples: leather components of orthopaedic appliances.
Rule 15. All devices intended specifically to be used for sterilising or disinfecting medical devices are in Class B.	Example: desk-top sterilisers for use with dental instruments.
unless they are disinfectant solutions or washer-disinfectors intended specifically for invasive medical devices, as the end point of processing, in which case they are in Class C; or	Examples: solutions intended to be used for the disinfection of medical devices without further processing (for example in a steriliser) including those where the infective agent is a prion; washer-disinfector equipment specifically for disinfecting an endoscope or another invasive device.
unless they are intended to clean medical devices by means of physical action	

RULE	ILLUSTRATIVE EXAMPLES
only, in which case they are in Class A.	
Rule 16. All devices that are intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class C.	**NOTE:** In some jurisdictions such products: - are considered to be outside the scope of the medical device definition; - may be subject to different controls.
Rule 17. All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class C,	Examples: condoms; contraceptive diaphragms.
unless they are implantable or long-term invasive devices, in which case they are in Class D.	Example: intrauterine contraceptive device.

7.5 Rationale for the inclusion of the Additional Rules within this document

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). While GHTF continues to support and encourage regulatory harmonisation, it recognises that a particular RA may have to reflect different local needs or social considerations when it introduces regulations on the classification of a minority of medical devices. Additional rules 13 to 17 provide examples of where this may occur.

For the understanding of those countries that are not Founding Members of GHTF, it is felt important to offer guidance on the classification of such devices. Therefore, five Additional Rules are provided (Rules 13 to 17).

Matters that may need to be considered are: -

Rule 13: Devices incorporating a medicinal substance

- The regulations applying to medicinal products require different acceptance procedures to those for medical devices.
- The behavior of a medicinal substance 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 transmission of infectious agents to human beings by the use of devices incorporating animal or human tissues (e.g. Bovine Spongiform Encephalopathies (BSE) and Creutzfeldt-Jacob disease (CJD)) demands classification at a higher level.

Rule 15: Disinfection as the end point of processing

- Classification of disinfection solutions and washer-disinfector equipment intended for the treatment of invasive devices **as the end point of processing** rather than as an intermediate step before sterilisation.

Rule 16: Fluids used with contact lenses

- The particular concerns relating to disinfectant solutions and other fluids that are used with contact lenses, due to sensitivity and vulnerability of the eye.

Rule 17: Contraceptive devices

- The hazard 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.

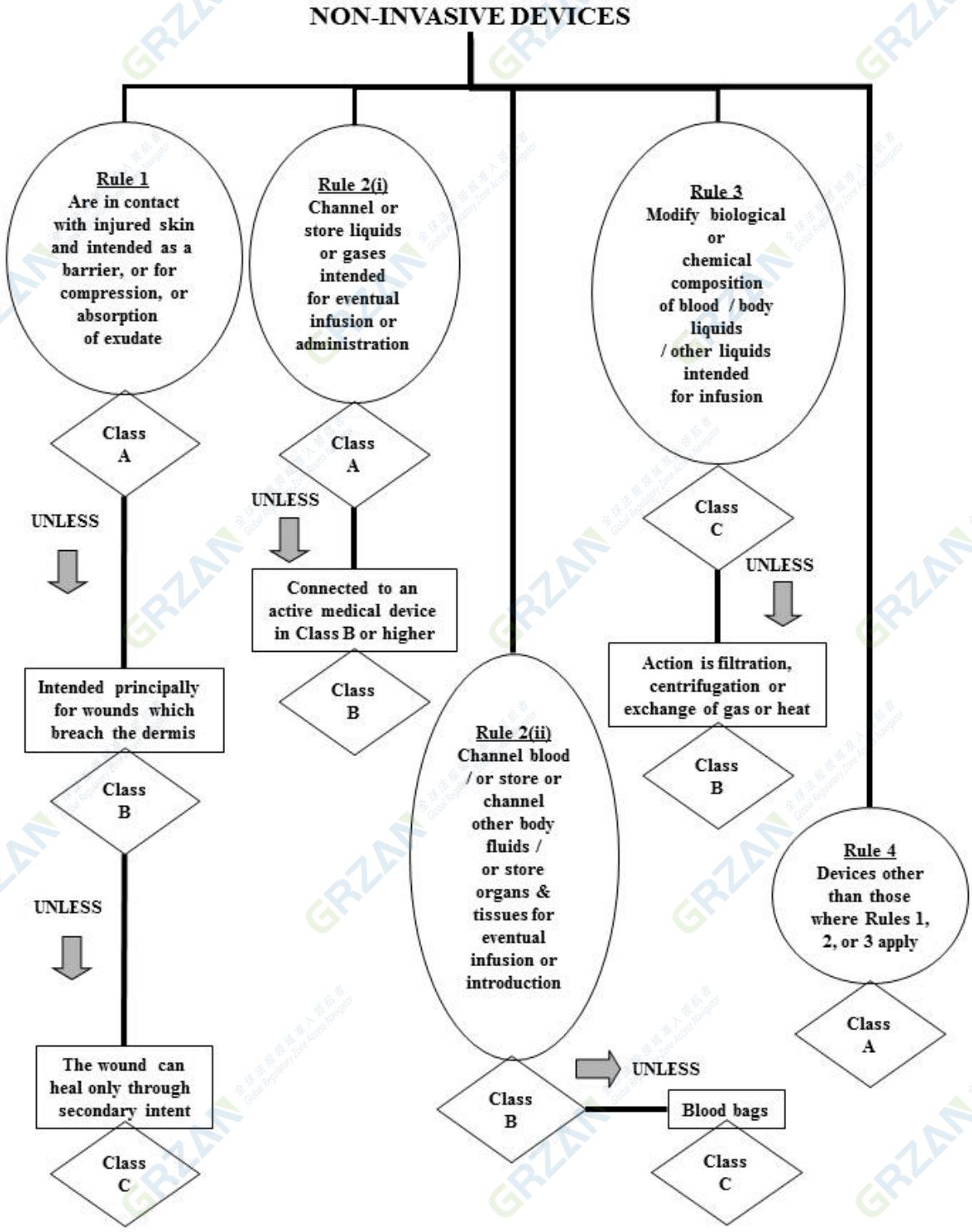
8.0 Reclassification of Medical Devices

Once a rules-based system has been adopted, modifications may occasionally be required. For example, where post-market experience with a particular device type suggests the classification rule recommended through this guidance document is no longer appropriate. In such a circumstance, consideration should be given to a change to the classification of the device type by a change to the rules.

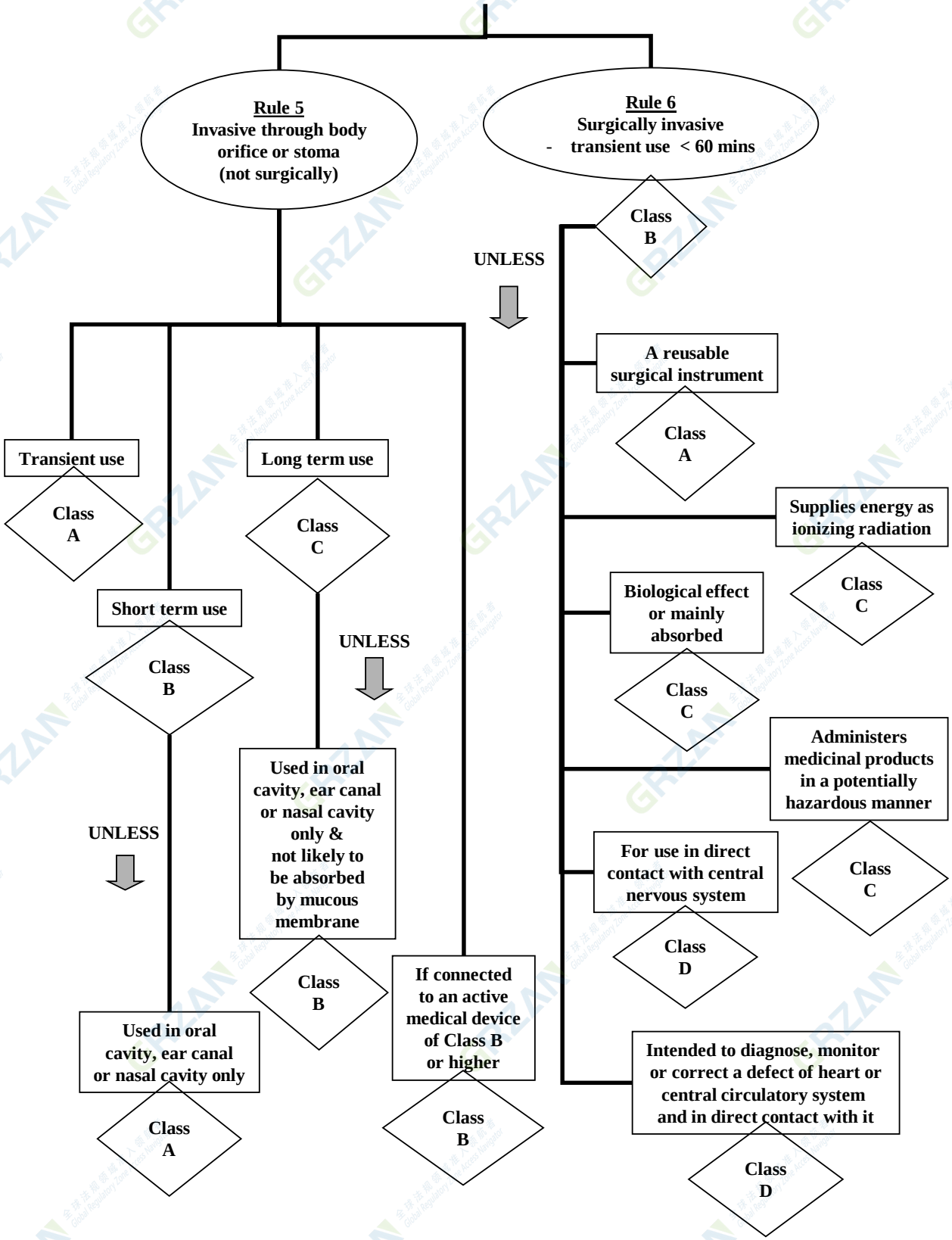
Current GHTF procedures require that all GHTF documents be reviewed at regular intervals. Such a review of this document will provide an opportunity to change the classification of a particular device type by a changing the appropriate rule

Appendix A: Decision trees to illustrate how the rules may be used to classify specific devices.

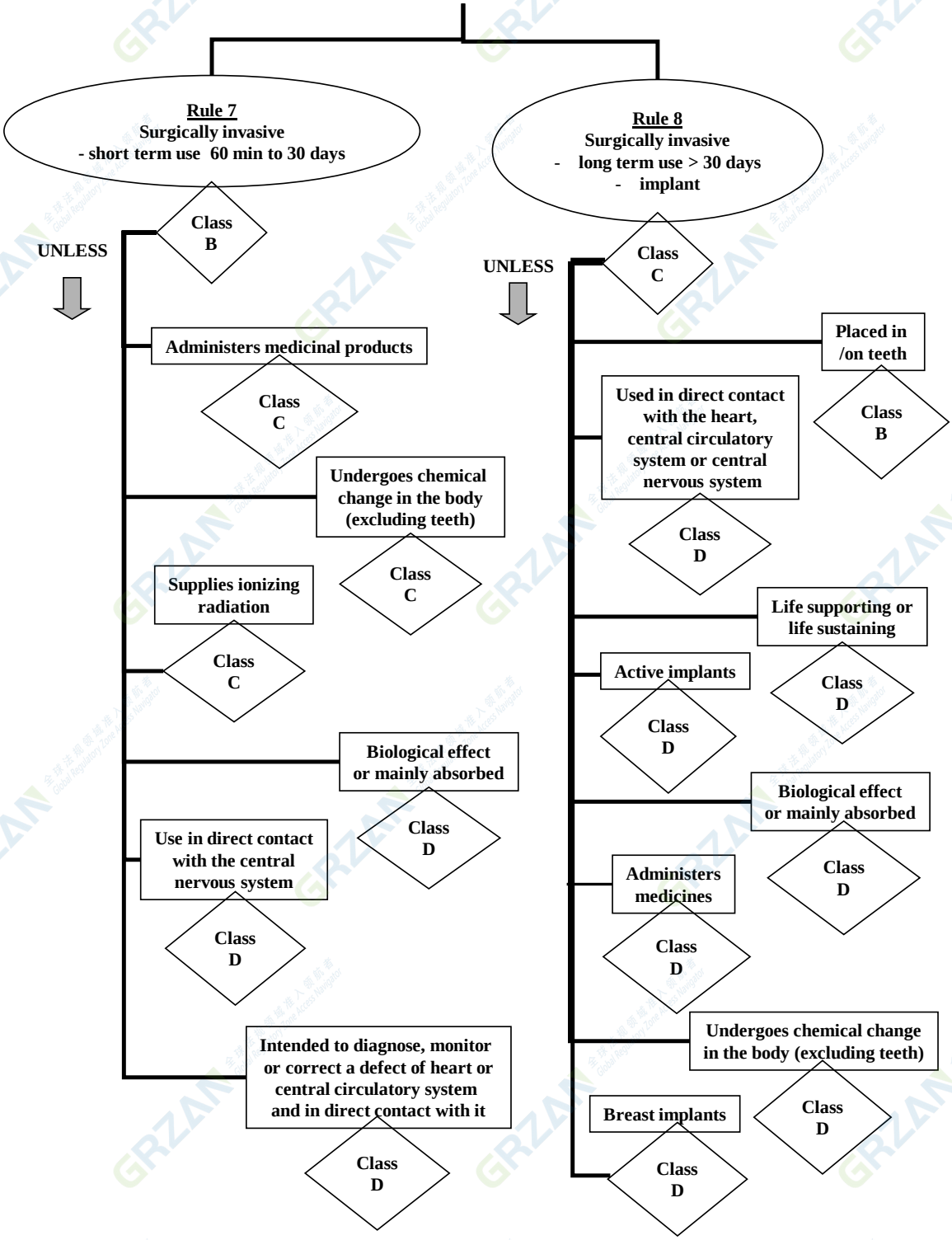
NOTE: The diagrams in this appendix are for illustrative purposes only and the determination of class for a particular device should be made by referring to the rules themselves and not the decision trees. Where a medical device has features that place it into more than one class, conformity assessment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


NON-INVASIVE DEVICES
Rule 1
Are in contact with injured skin and intended as a barrier, or for compression, or absorption of exudate
Class A
UNLESS
Intended principally for wounds which breach the dermis
Class B
UNLESS
The wound can heal only through secondary intent
Class C
Rule 2(i)
Channel or store liquids or gases intended for eventual infusion or administration
Class A
UNLESS
Connected to an active medical device in Class B or higher
Class B
Rule 2(ii)
Channel blood / or store or channel other body fluids / or store organs & tissues for eventual infusion or introduction
Class B
UNLESS
Blood bags
Class C
Rule 3
Modify biological or chemical composition of blood / body liquids / other liquids intended for infusion
Class C
UNLESS
Action is filtration, centrifugation or exchange of gas or heat
Class B
Rule 4
Devices other than those where Rules 1, 2, or 3 apply
Class A

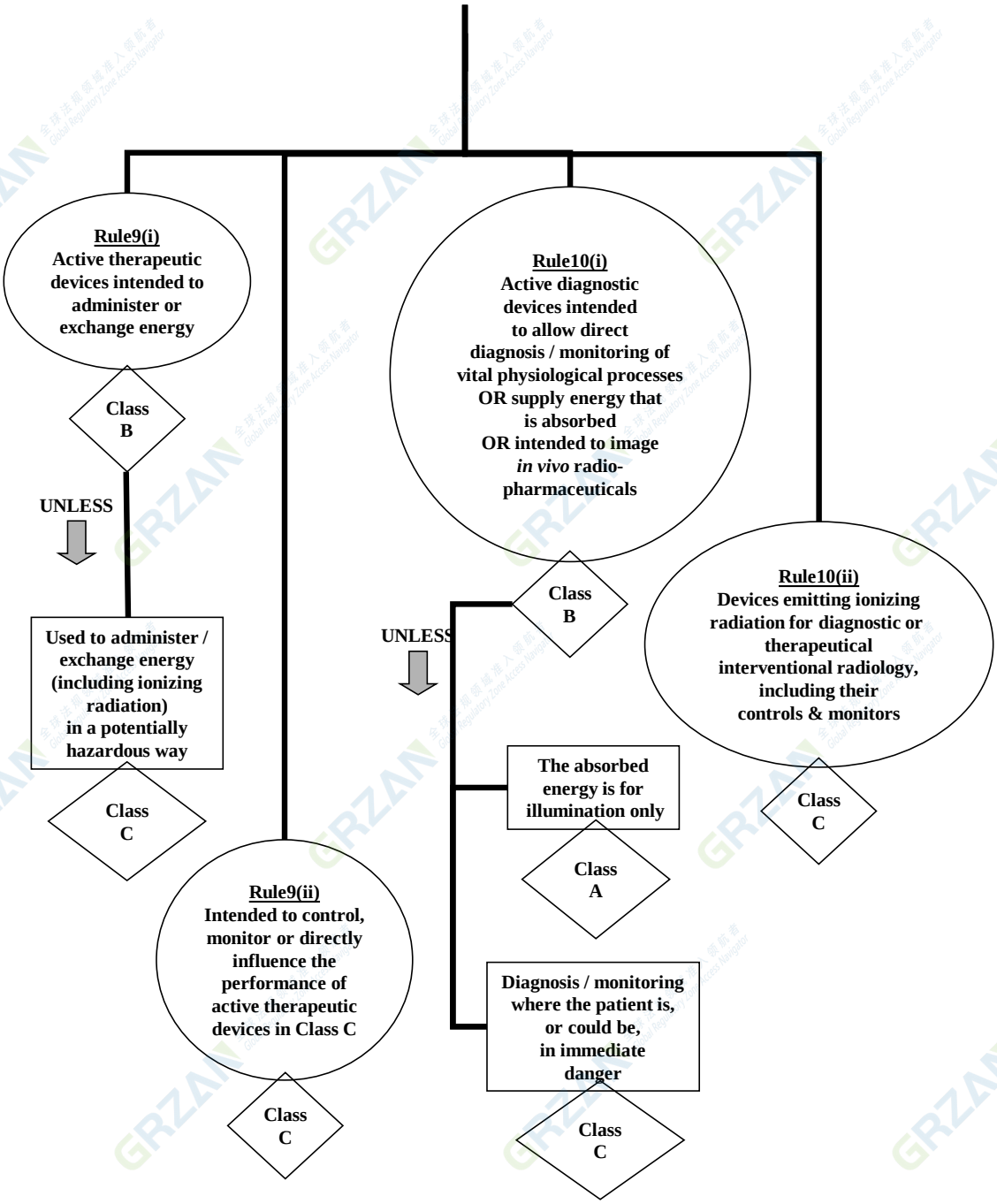
INVASIVE DEVICES (1 of 2)



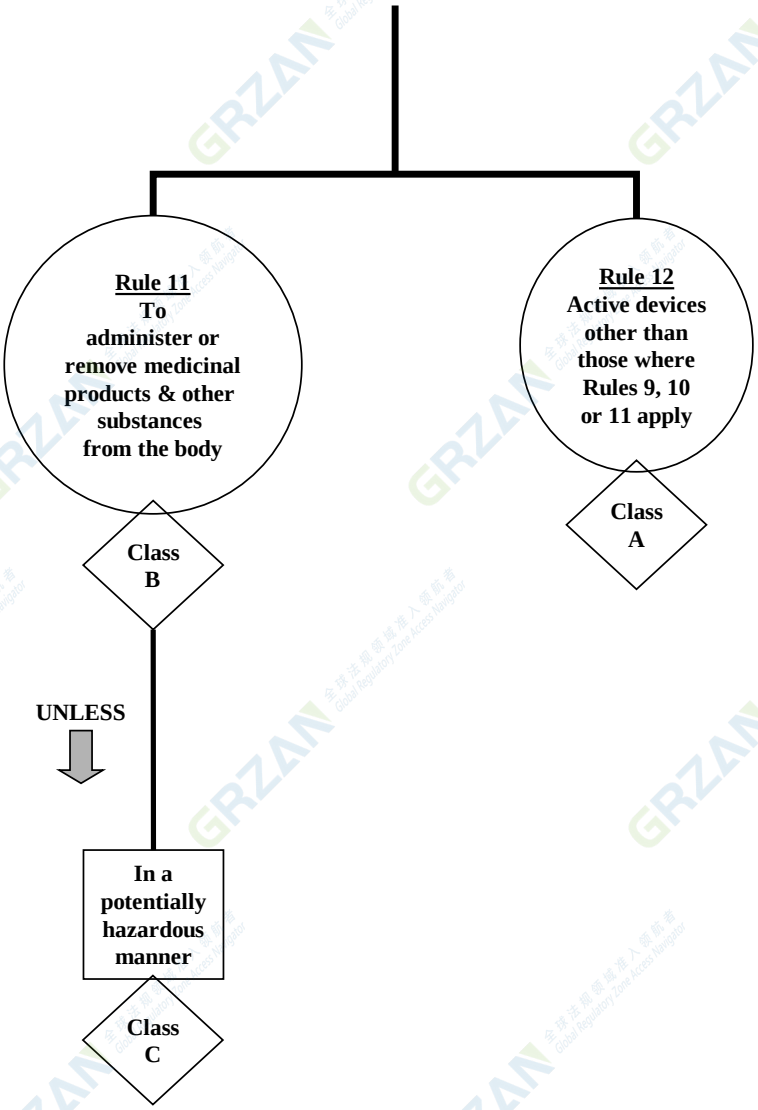
INVASIVE DEVICES (2 of 2)

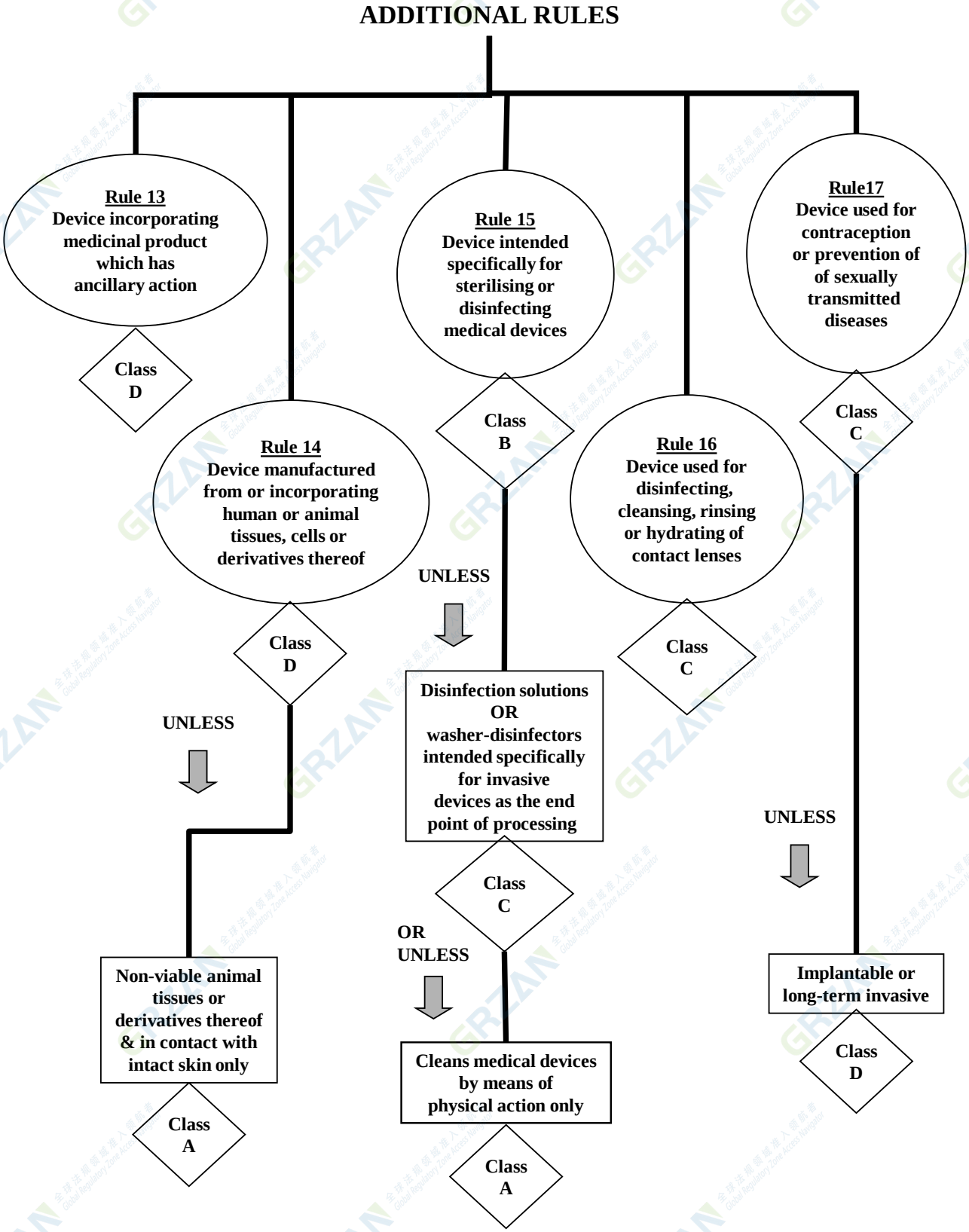


ACTIVE DEVICES (1 of 2)



ACTIVE DEVICES (2 of 2)




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 sterilising or disinfecting medical devices
Class B
UNLESS
Disinfection solutions OR washer-disinfectors intended specifically for invasive devices as the end point of processing
Class C
OR UNLESS
Cleans medical devices by means of physical action only
Class A
Rule 16
Device used for disinfecting, cleansing, rinsing or hydrating of contact lenses
Class C
Rule17
Device used for contraception or prevention of of sexually transmitted diseases
Class C
UNLESS
Implantable or long-term invasive
Class D