HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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MEDICAL DEVICE GUIDANCE

GN-13: Guidance on the Risk Classification of General Medical Devices

Revision 1.1

HSA
Health Sciences Authority

PREFACE

R1.1 ►This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action/decision taken or not taken as a result of using this document. The information contained in this document should not be a substitute for professional advice from your own professional and healthcare advisors. ◄ R1.1

1. INTRODUCTION

1.1. Purpose

This document provides guidance to assist product owners to classify medical devices using the appropriate risk-based classification rules.

1.2. Background

Regulatory controls should be proportional to the level of risk associated with a medical device. The level of regulatory control should increase with increasing degree of risk, taking account of the benefits offered by use of the device. Therefore, there is a need to classify medical devices based on their risk to patients, users and other persons

The risk presented by a particular medical device depends substantially on its intended purpose and the effectiveness of the risk management techniques applied during design, manufacture and use.

The risk presented by a medical device also depends, in part, on its intended user(s), its mode of operation, and/or technologies. In general, the risk classification rules are intended to accommodate new technologies.

1.3. Scope

This document is applicable to all device products that fall within the definition of a medical device found in the First Schedule of the Health Products Act 2007 (*Act*), other than those used for *in vitro* examination of specimens derived from the human body. Please refer to the Guidance on the Risk Classification of In Vitro Diagnostic Devices for risk classification of device products used for *in vitro* examination of specimens derived from the human body.

1.4. Definitions

Definitions that do not indicate they are set out in the *Act* and Health Products (Medical Devices) Regulations (*Regulations*) are intended as guidance in this document. These definitions are not taken verbatim from the above legislation and should not be used in any legal context. These definitions are meant to provide guidance in layman terms.

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.

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.

BODY ORIFICE: Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy.

CENTRAL CIRCULATORY SYSTEM: For the purpose of this document, central circulatory system means the major internal blood vessels including the following:

- arteriae pulmonales (pulmonary artery);
- aorta ascendens (ascending aorta);

- arteriae coronariae (coronary artery);
- arteria carotis communis (common carotid artery);
- arteria carotis externa (external carotid artery);
- arteria carotis interna (internal carotid artery);
- arteriae cerebrates (cerebella arteries);
- truncus brachicephalicits (brachiocephalic trunk);
- venae cordis (cardiac veins);
- venae pulmonales (pulmonary vein);
- venae cava superior (superior vena cava);
- venae cava inferior (inferior vena cava);
- arcus aorta (aortic arch);
- thoracica aorta (thoracic aorta);
- abdominalis aorta (abdominal aorta);
- ilica communis (common iliac arteries and veins);
- aorta descendens to the bifurcatio aortae. (descending aorta to the bifurcation of aorta)

CENTRAL NERVOUS SYSTEM: For the purpose of this document, central nervous system refers to the brain, meninges and spinal cord.

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 For the purpose of this document, continuous use means:

- *the entire duration of use of the medical device without regard to temporary interruption of use during a procedure or, temporary removal for purposes such as cleaning or disinfection of the device; or*

- *the accumulated use of a medical device that is intended by the product owner to be replaced immediately with another of the same type.*

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 DEVICE: Any medical device, including those that are partially or wholly absorbed, which is intended: -

- to be totally introduced into the human body or,
- to replace an epithelial surface or the surface of the eye,

by surgical intervention which is intended to remain in place after the procedure.

NOTE Any medical device intended for partial introduction into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

INTENDED PURPOSE: The use for which the medical device is intended according to the specifications of its product owner as stated on any or all of the following:

- the label of the medical device;
- the instructions for use of the medical device;
- the promotional materials in relation to the medical device.

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

LIFE SUPPORTING OR LIFE SUSTAINING: A medical device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

MEDICAL DEVICE: means a medical device as described in the First Schedule of the *Act.*

REUSABLE SURGICAL INSTRUMENT: Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or other surgical procedures, without connection to any active medical device and which are intended by the product owner to be reused after appropriate procedures for cleaning and/or sterilisation have been carried out.

RISK: Combination of the probability of occurrence of harm and the severity of that harm.

SURGICALLY INVASIVE DEVICE: An invasive medical device that penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

NOTE Medical devices other than those referred to in the previous subparagraph and which produce penetration other than through a natural body orifice, should be treated as surgically invasive devices.

2. FACTORS INFLUENCING MEDICAL DEVICE RISK CLASSIFICATION

A number of factors, including for example the duration of medical device contact with the body, the degree of invasiveness, whether the medical device delivers medicinal products or energy to the patient, whether they are intended to have a biological effect on the patient and local *versus* systemic effects (e.g. conventional *versus* absorbable sutures) may, alone or in combination, affect medical device risk classification.

If, based on the product owner's intended purpose, two or more risk classification rules apply to the medical device, the medical device is allocated the highest level of risk classification indicated.

Where one medical device is intended to be used together with another medical device, that may or may not be from the same product owner, (e.g. a physiological monitor and a separate recorder, or a general purpose syringe and a syringe driver), the risk classification rules should apply separately to each of the medical devices.

Risk classification of an assemblage of medical devices that individually comply with all regulatory requirements depends on the product owner's purpose in packaging and marketing such a combination of separate medical devices. For example,

- if the combination results in a product that is intended by the product owner 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 purpose, or
- if the combination is for the convenience of the user but does not change the intended purposes of the individual medical devices that make it up (e.g. a customised kit that provides all the medical devices necessary to carry out a particular surgical procedure), the risk classification allocated to

the assemblage for the purpose of a Declaration of Conformity should be the same as that of the medical device with the highest risk class included within it.

Accessories intended specifically by product owners to be used together with a 'parent' medical device to enable that medical device to achieve its intended purpose, should be subject to all the regulatory requirements that apply to the medical device itself (e.g. Essential principles for Safety and Performance, Post-Market Surveillance). For risk classification purposes, an accessory may be classified as though it is a medical device in its own right.

Most software is incorporated into the medical device itself, for example embedded software to operate an electrocardiogram. Some software applications are not incorporated (embedded) into the medical device itself, such as software applications to analyse electrocardiogram signals on a computer independent of the electrocardiogram. These are deemed to be standalone software. Such standalone software applications that fall within the scope of the definition for a 'medical device' 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 purpose of the combination.
- where it is independent of any other medical device, it is classified in its own right using the rules.
- standalone software is deemed to be an active medical device.

3. GENERAL RISK CLASSIFICATION SYSTEM FOR MEDICAL DEVICES

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

Figure 1: General risk classification system for medical devices

RISK CLASS	RISK LEVEL	MEDICAL DEVICE EXAMPLES
A	Low Risk	Surgical retractors / tongue depressors
B	Low-moderate Risk	Hypodermic Needles / suction equipment
C	Moderate-high Risk	Lung ventilator / bone fixation plate
D	High Risk	Heart valves / implantable defibrillator

4. THE DETERMINATION OF MEDICAL DEVICE RISK CLASS USING THE RULES-BASED SYSTEM

The product owner should:

- decide if the product concerned is a medical device, using the appropriate definition;
- document the intended purpose of the medical device; and
- take into consideration **ALL** the rules that follow in order to establish the proper risk classification for the device, noting that where a medical device has features that place it into more than one risk class, risk classification should be based on the **HIGHEST** risk class indicated.

NOTE Medical devices that are used for the in vitro examination of specimens derived from the human body are not covered by the risk classification rules within this document.

5. RISK CLASSIFICATION RULES

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

RULE	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.
- are in Class A if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates only, i.e. they heal by primary intent;	Examples: simple wound dressings; cotton wool.
- are in Class B if they are intended to be used principally with wounds which have breached the dermis, including devices principally intended to manage the microenvironment of a wound.	Examples: non-medicated impregnated gauze dressings.
Unless they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, in which	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

case they are in Class C.	formed within the wound prior to external closure. The product owner 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 A,	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 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.*
Unless they are intended for use of • channeling blood, or • storing or channeling other body liquids, or • for storing organs, parts of organs or body tissues, in which case they are Class B.	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 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 (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: haemodialysers; 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 extracorporeal 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.
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	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

• are intended for connection to a Class A medical device only.	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 use in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class A,	Examples: dentures intended to be removed by the patient; dressings for nose bleeds.
- 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 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 B.	Examples: orthodontic wire, fixed 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	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.*

medical device in Class B or a higher class, are in Class B.	
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. *NOTE: a surgical instrument (other than those in Class D) is in Class A if reusable and in Class B if supplied sterile and intended for single use. Also, a surgical instrument connected to an active device is in a higher class than A.* *NOTE: 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 A; or	Examples: Manually operated surgical drill bits and saws.
Unless intended to supply energy in the form of ionising radiation, in which case they are in Class C; 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 C; 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.* *NOTE: 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	Example: insulin pen for self-administration.

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	*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	
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.* *NOTE: if the device incorporates a medicinal substance in a secondary role refer to Rule 13.*
Unless they are intended to	*NOTE: the term 'administration of medicines' implies storage and/or influencing the rate/volume*

administer medicinal products, in which case they are in Class C; or	*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 or ionising radiation, in which case they are in Class C; or	Example: brachytherapy device.
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; prosthetic joint replacements; bone cement; non-absorbable 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 B; 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 D; or	Examples: prosthetic heart valves; spinal and vascular stents.
Unless they are intended to be life supporting or life sustaining, in which case they are in Class D; or	
Unless they are intended to be active implantable medical devices, in which case they are Class D; or	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 D; or	Example: implants claimed to be bioactive.
Unless they are intended to	Example: rechargeable non-active drug

administer medicinal products, in which case they are in Class D; or	delivery system.
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	
Unless they are breast implants, in which case they are in Class D.	
ACTIVE DEVICES	
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; transcutaneous Electro-Neuro Stimulator (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 ionising 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 ionising radiation. *NOTE: the term 'potentially hazardous' refers to the type of technology involved and the intended application.*
Rule 9(ii). All active devices	Examples: external feedback systems for

intended to control or monitor the performance of active therapeutic devices in Class C, or intended directly to influence the performance of such devices, are in Class C.	active therapeutic devices.
Rule 10(i). Active devices intended for diagnosis are in Class B:	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 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: • monitoring of vital physio-logical parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance	Example: monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnoea monitors.

variations in cardiac performance, respiration, activity of central nervous system, or • diagnosing in clinical situations where the patient is in immediate danger, in which case they are in Class C.	Example: ultrasound equipment for use in interventional cardiac procedures.
Rule 10(ii). Active devices intended to emit ionising 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: these include devices for the control, monitoring or influencing of the emission of ionising 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 of Class B devices: 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	Examples: infusion pumps; anaesthesia equipment; dialysis equipment; hyperbaric chambers; nebuliser where the failure to deliver the appropriate dosage characteristics could be hazardous.

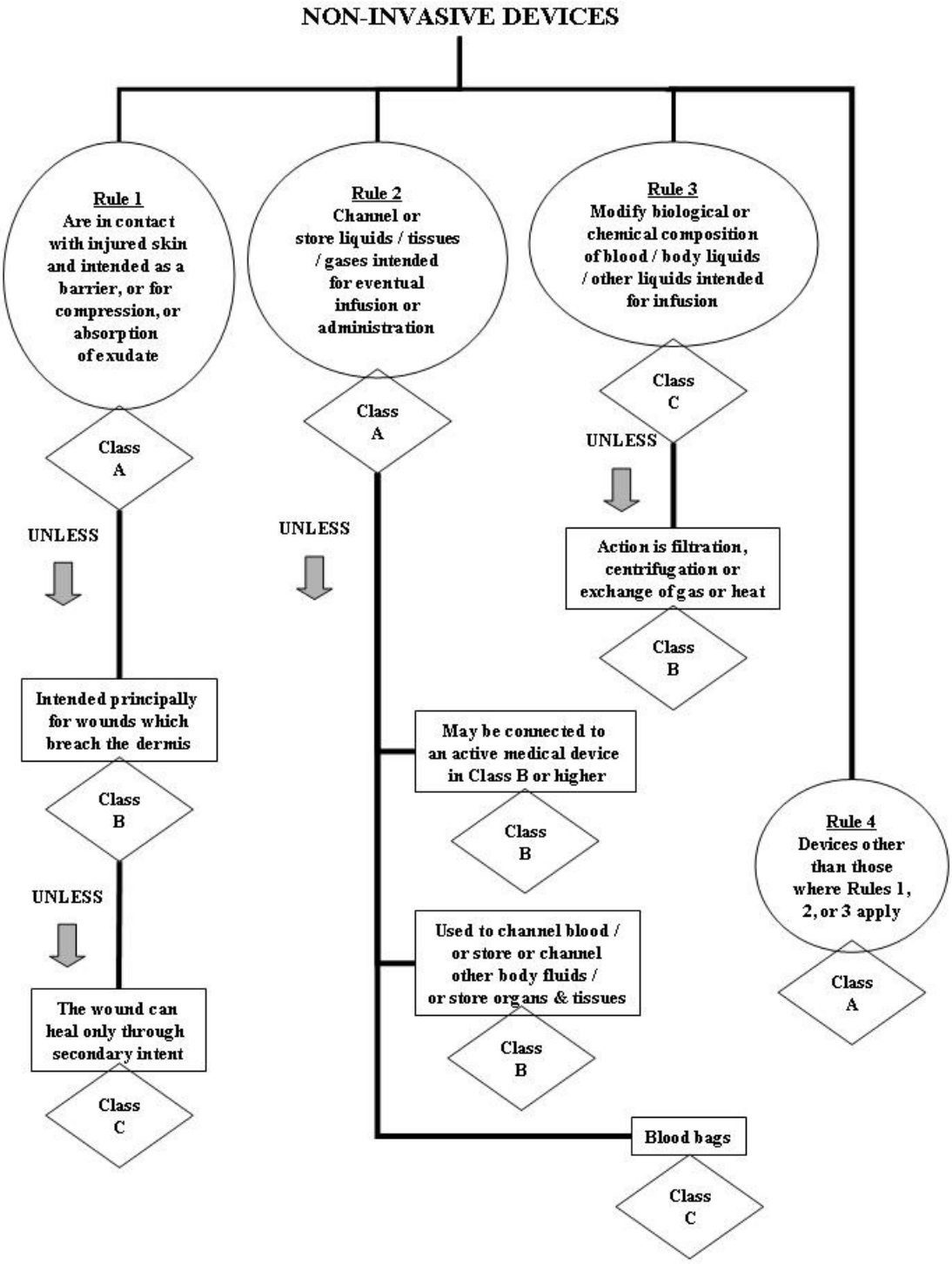
of the mode and route of administration, in which case they are in Class C.	
Rule 12. All other active devices are in Class A.	Examples: examination lamps; surgical microscopes; powered hospital beds & wheelchairs; powered equipment for the recording, processing, viewing of diagnostic images; dental curing lights.
ADDITIONAL RULES	
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.
Rule 14. All devices manufactured from or incorporating • animal or human cells, tissues and/or derivatives thereof, rendered non-viable, or • cells, tissues and/or derivatives of microbial or recombinant origin are Class D,	Examples: porcine heart valves; catgut sutures; dermal fillers based on hyaluronic acid derived from bacterial fermentation processes
Unless such devices are manufactured from or incorporate non-viable animal	Examples: leather components of orthopaedic appliances.

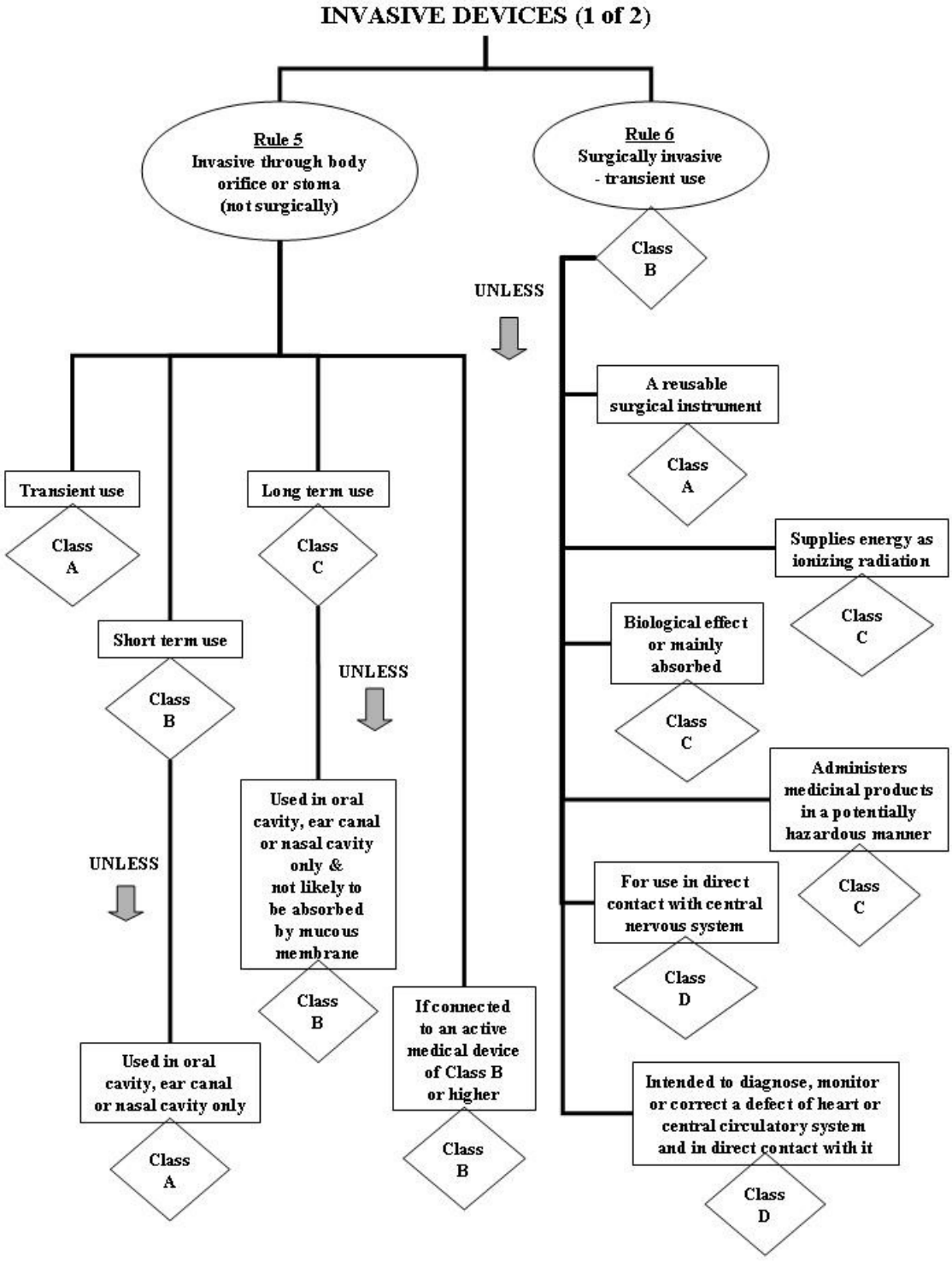
tissues or their derivatives that come in contact with intact skin only, where they are in Class A.	
Rule 15. All devices intended specifically to be used for sterilising medical devices, or disinfecting as the end point of processing, are in Class C.	Examples: devices for disinfecting or sterilising 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 B; 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 C.	
Rule 16. 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.

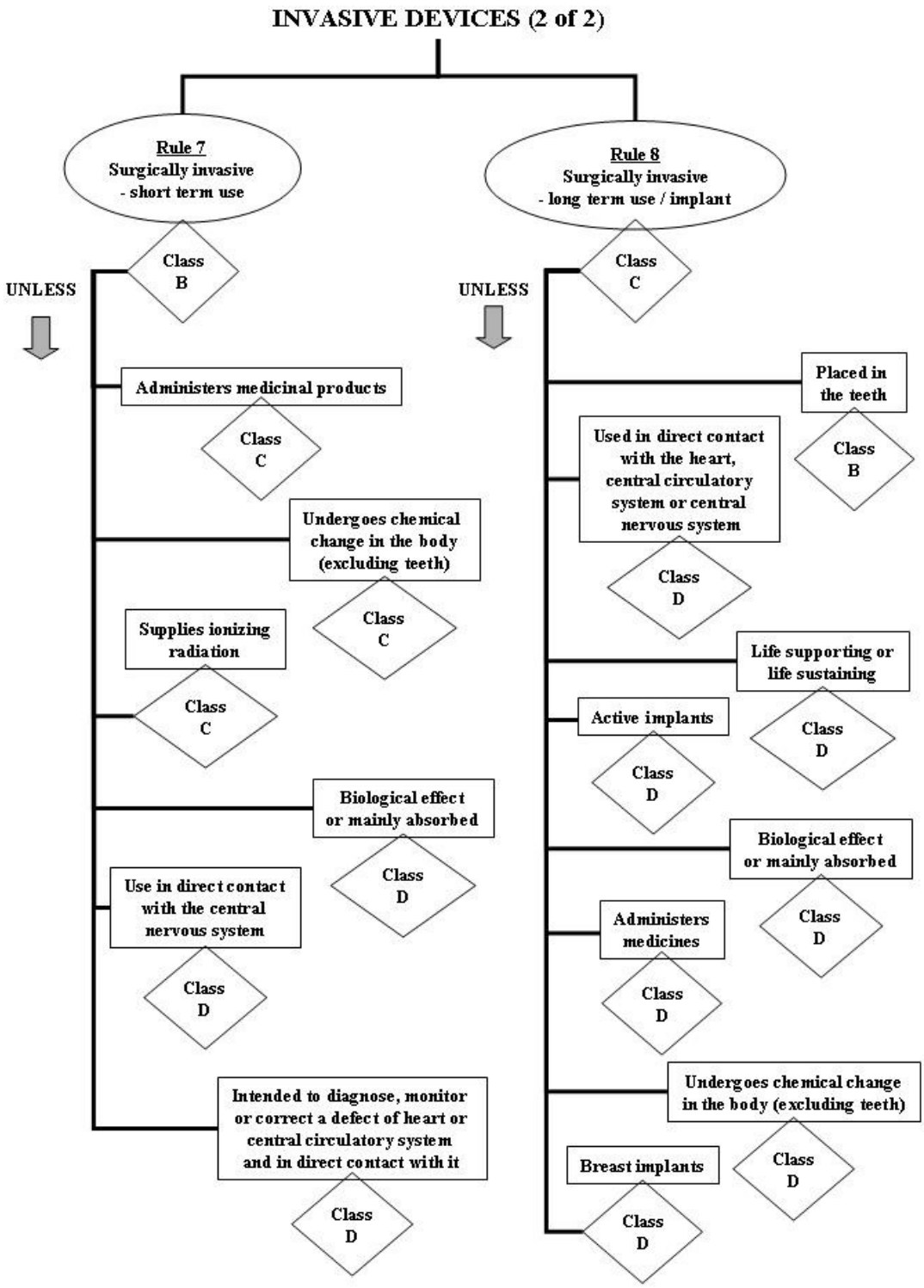
Decision trees illustrating how these rules may be used to classify specific medical devices are shown in **Appendix A**.

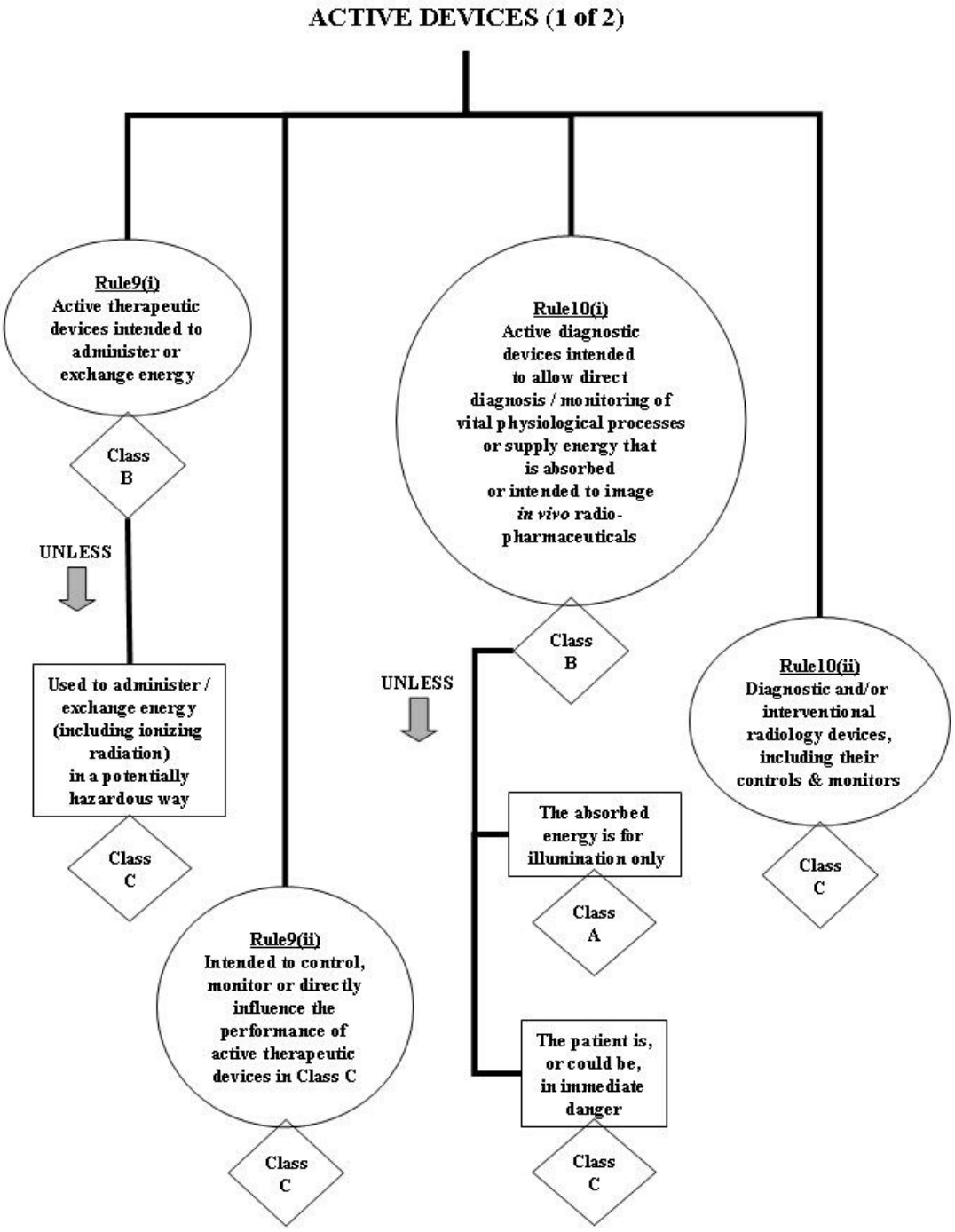
APPENDIX A

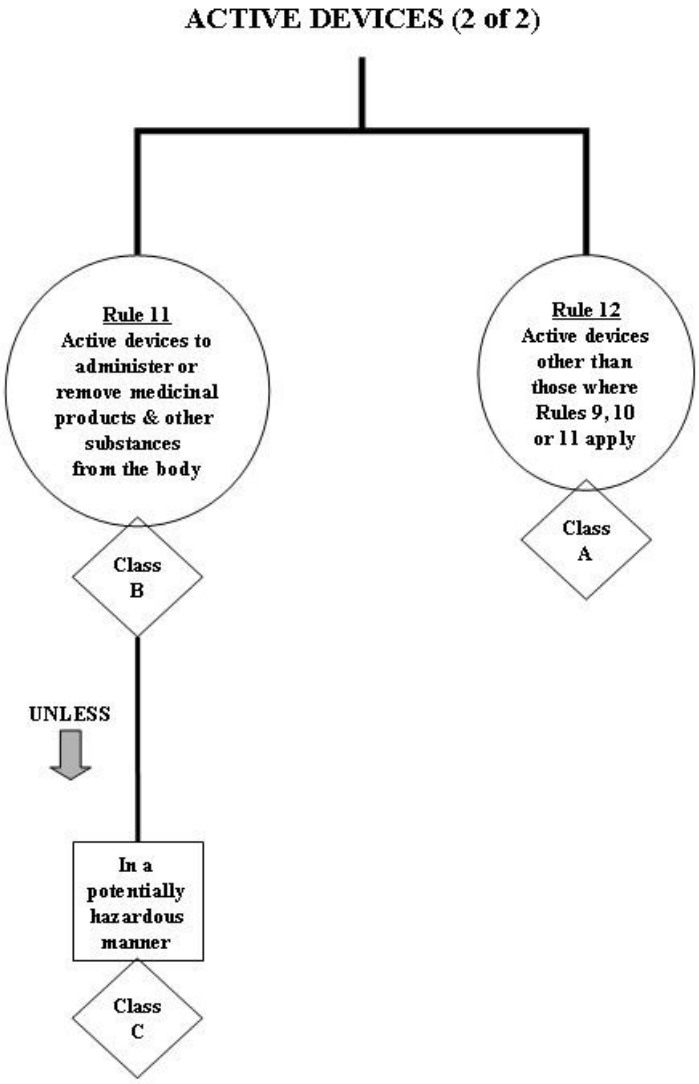
The diagrams that follow are for **illustrative purposes only** and the determination of risk class for a particular medical device should be made through reference to the rules and **not solely the decision trees**. Where a medical device has characteristics that place it into more than one risk class, the final risk classification should be based on the **highest** risk class indicated.

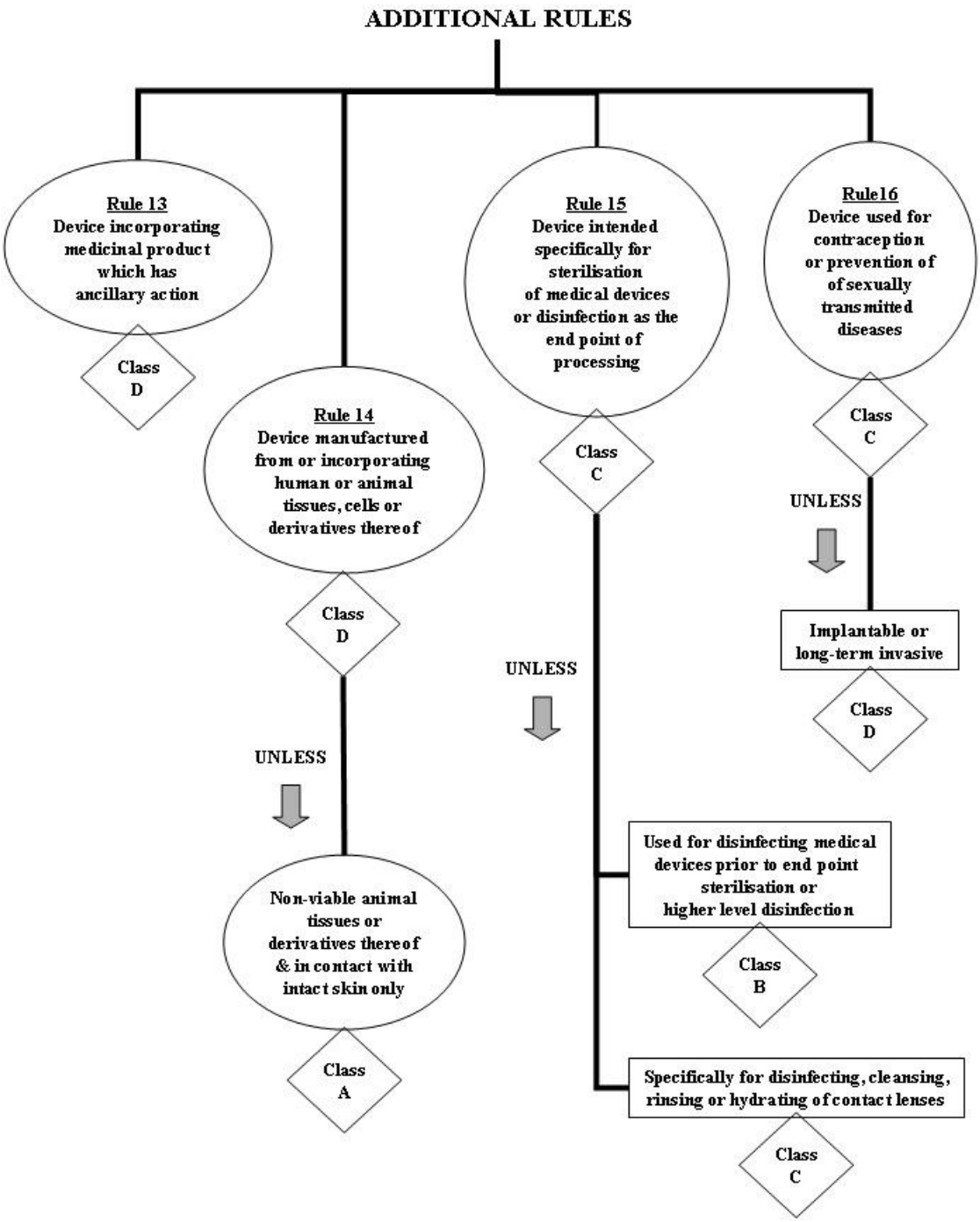

NON-INVASIVE DEVICES
Rule 1
Are in contact with injured skin and intended as a barrier, or for compression, or absorption of exudate
Class A
UNLESS
Intended principally for wounds which breach the dermis
Class B
UNLESS
The wound can heal only through secondary intent
Class C
Rule 2
Channel or store liquids / tissues / gases intended for eventual infusion or administration
Class A
UNLESS
May be connected to an active medical device in Class B or higher
Class B
Used to channel blood / or store or channel other body fluids / or store organs & tissues
Class B
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)
Rule 5
Invasive through body orifice or stoma (not surgically)
Rule 6
Surgically invasive - transient use
Class B
UNLESS
A reusable surgical instrument
Class A
Supplies energy as ionizing radiation
Class C
Biological effect or mainly absorbed
Class C
Administers medicinal products in a potentially hazardous manner
Class C
For use in direct contact with central nervous system
Class D
Intended to diagnose, monitor or correct a defect of heart or central circulatory system and in direct contact with it
Class D
Transient use
Class A
Short term use
Class B
UNLESS
Used in oral cavity, ear canal or nasal cavity only
Class A
Long term use
Class C
UNLESS
Used in oral cavity, ear canal or nasal cavity only & not likely to be absorbed by mucous membrane
Class B
If connected to an active medical device of Class B or higher
Class B


INVASIVE DEVICES (2 of 2)
Rule 7
Surgically invasive
- short term use
Class
B
UNLESS
Administers medicinal products
Class
C
Undergoes chemical change in the body (excluding teeth)
Class
C
Supplies ionizing radiation
Class
C
Biological effect or mainly absorbed
Class
D
Use in direct contact with the central nervous system
Class
D
Intended to diagnose, monitor or correct a defect of heart or central circulatory system and in direct contact with it
Class
D
Rule 8
Surgically invasive
- long term use / implant
Class
C
UNLESS
Placed in the teeth
Class
B
Used in direct contact with the heart, central circulatory system or central nervous system
Class
D
Life supporting or life sustaining
Class
D
Active implants
Class
D
Biological effect or mainly absorbed
Class
D
Administers medicines
Class
D
Undergoes chemical change in the body (excluding teeth)
Class
D
Breast implants
Class
D


ACTIVE DEVICES (1 of 2)
Rule9(i)
Active therapeutic devices intended to administer or exchange energy
Class B
UNLESS
Used to administer / exchange energy (including ionizing radiation) in a potentially hazardous way
Class C
Rule9(ii)
Intended to control, monitor or directly influence the performance of active therapeutic devices in Class C
Class C
Rule10(i)
Active diagnostic devices intended to allow direct diagnosis / monitoring of vital physiological processes or supply energy that is absorbed or intended to image *in vivo* radio-pharmaceuticals
Class B
UNLESS
The absorbed energy is for illumination only
Class A
The patient is, or could be, in immediate danger
Class C
Rule10(ii)
Diagnostic and/or interventional radiology devices, including their controls & monitors
Class C


ACTIVE DEVICES (2 of 2)
Rule 11
Active devices to administer or remove medicinal products & other substances from the body
Class B
UNLESS
In a potentially hazardous manner
Class C
Rule 12
Active devices other than those where Rules 9, 10 or 11 apply
Class A


ADDITIONAL RULES
Rule 13
Device incorporating medicinal product which has ancillary action
Class D
Rule 14
Device manufactured from or incorporating human or animal tissues, cells or derivatives thereof
Class D
UNLESS
Non-viable animal tissues or derivatives thereof & in contact with intact skin only
Class A
Rule 15
Device intended specifically for sterilisation of medical devices or disinfection as the end point of processing
Class C
UNLESS
Used for disinfecting medical devices prior to end point sterilisation or higher level disinfection
Class B
Specifically for disinfecting, cleansing, rinsing or hydrating of contact lenses
Class C
Rule16
Device used for contraception or prevention of of sexually transmitted diseases
Class C
UNLESS
Implantable or long-term invasive
Class D

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Information:

Medical Device Branch
Pre-marketing Division
Health Products Regulation Group
Health Sciences Authority

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