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MEDICAL DEVICE GUIDANCE DOCUMENT

**GUIDANCE ON THE RULES OF CLASSIFICATION FOR
GENERAL MEDICAL DEVICES**



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Preface

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

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

- a) Medical Device Act 2012 (Act 737); and
- b) Medical Device Regulations 2012.

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

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission; and
- “can” indicates a possibility or a capability.

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

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

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

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RULES OF CLASSIFICATION FOR GENERAL MEDICAL DEVICES

1 Introduction

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

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

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

The classification of medical device is determined from:

- (i) The manufacturer's intended purpose for the medical device, (ii) A set of classification rules.

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

2 Purpose

The purpose of this document is to provide guidance on how to determine the classification of medical device which has been specified in; i- Section 3 of Medical Device Act 2012 (Act 737), ii- Paragraph 3(1)(a) of Medical Device Regulation 2012, and iii- First Schedule of Medical Device Regulation 2012.

3 Scope

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

4 Terms and definitions

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

4.1 Active medical device

Any medical device, operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy but does not include medical devices intended to transmit energy, substances or other elements between an active medical device and the patients, without any significant change.

4.2 Active therapeutic device

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

4.3 Active device intended for diagnosis

Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or to support in treating physiological conditions, states of health, illnesses or congenital deformities.

4.4 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.

4.5 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.

4.6 Harm

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

4.7 Hazard

Potential source of harm.

4.8 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.

4.9 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.

4.10 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.

4.11 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.

4.12 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.

4.13 Medical device

As defined in MDA/GD/0006: Guidance on The Definition of Medical Device

4.14 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.

4.15 Risk

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

4.16 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.

4.17 Duration of use

4.17.1 Transient use

Normally intended for continuous use for less than 60 minutes.

4.17.2 Short term use

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

4.17.3 Long term use

Normally intended for continuous use for more than 30 days.

NOTE 2:

For the purpose of this document, continuous use means:

- a) The entire duration of use of the device without regard to temporary interruption of use during a procedure or, temporary removal for purposes such as cleaning or disinfection of the device.*
- b) The accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.*

5 General principles

- (i) The classification of the device is based on the risk associated to it at the point of usage (The risk to patients, users and other persons).
- (ii) The risk presented by a particular device depends on
 - (a) Its intended purpose
 - (b) The effectiveness of the risk management techniques applied during design, manufacture and use
 - (c) Its intended user(s)
 - (d) Its mode of operation

6 Factors influencing device classification

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

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

7 Application Rules

7.17 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.

NOTE 3:

- 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.*

7.18 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.

7.19 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 4:

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.

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

7.21 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).

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

NOTE 5:

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.

7.23 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).

7.24 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 6:

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

7.25 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.

7.26 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.

8 Classification of medical devices

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

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

Table 1: General classification system for medical devices

9 Determination of device class using rules-based system

The manufacturer should:

- (i) Decide if the product concerned is a medical device, using the appropriate definition,
- (ii) Determine the intended use of the medical device,
- (iii) 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,
- (iv) Determine that the device is not subject to special national rules that apply within a particular jurisdiction,

Where special national rules are applied, resulting in a device class other than that suggested by the present rules, then a different conformity assessment

procedure may be indicated. This may have an effect on the acceptability of such devices for free movement in countries where these present rules have been adopted unless other, or additional, conformity assessment procedures are carried out.

10 Classification rules for medical devices

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

RULE	ILLUSTRATIVE EXAMPLES OF DEVICES THAT MAY CONFORM WITH A RULE
NON-INVASIVE DEVICES	
<p>RULE 1.</p> <p>All non-invasive devices which come into contact with injured skin:</p>	<p>Devices covered by this rule are extremely claim sensitive.</p>
<ul style="list-style-type: none"> • 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; 	<p>Examples: simple wound dressings; cotton wool.</p>
<ul style="list-style-type: none"> • 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. <p>unless they are intended to be used principally with wounds which have</p>	<p>Examples: non-medicated impregnated gauze dressings.</p> <p>Devices used to treat wounds where the subcutaneous tissue is as least partially</p>

<p>breached the dermis and can only heal by secondary intent, in which case they are in Class C.</p>	<p>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'.</p> <p>Examples: dressings for chronic ulcerated wounds; dressings for severe burns.</p>
<p>RULE 2.</p> <p>All non-invasive devices intended for channelling or storing</p> <ul style="list-style-type: none"> • body liquids or tissues, • liquids or • gases <p>for the purpose of eventual infusion, administration or introduction into the body are in Class A,</p>	<p>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).</p> <p>Examples: administration sets for gravity infusion; syringes without needles.</p>
<p>unless they may be connected to an active medical device in Class B or a higher class, in which case they are Class B;</p>	<p>Examples: syringes and administration sets for infusion pumps; anaesthesia breathing circuits.</p> <p><i>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'.</i></p>
<p>unless they are intended for use of</p> <ul style="list-style-type: none"> • 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. 	<p>Examples: tubes used for blood transfusion, organ storage containers.</p>
<p>unless they are blood bags, in which case they are Class C.</p>	<p>Example: Blood bags that do not incorporate an anti-coagulant.</p> <p><i>NOTE: in some jurisdictions, blood bags have a special rule that places them within a different risk class.</i></p>

<p>RULE 3.</p> <p>All non-invasive devices intended for modifying the biological or chemical composition of</p> <ul style="list-style-type: none"> • blood, • other body liquids, or • other liquids <p>intended for infusion into the body are in Class C,</p>	<p>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.</p> <p>Examples: haemodialyzers; devices to remove white blood cells from whole blood.</p> <p><i>NOTE: for the purpose of this part of the rule, 'modification' does not include simple, mechanical filtration or centrifuging which are covered below.</i></p>
<p>unless the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class B.</p>	<p>Examples: devices to remove carbon dioxide; particulate filters in an extracorporeal circulation system.</p>
<p>RULE 4.</p> <p>All other non-invasive devices are in Class A.</p>	<p>These devices either do not touch the patient or contact intact skin only.</p> <p>Examples: urine collection bottles; compression hosiery; non-invasive electrodes, hospital beds.</p>
INVASIVE DEVICES	
<p>RULE 5.</p> <p>All invasive devices with respect to body orifices (other than those which are surgically invasive) and which:</p> <ul style="list-style-type: none"> • are not intended for connection to an active medical device, or • are intended for connection to a Class A medical device only. 	<p>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.</p>
<p>(i) are in Class A if they are intended for transient use;</p> <p>(ii) are in Class B if they are</p>	<p>Examples: examination gloves; enema devices.</p> <p>Examples: urinary catheters, tracheal</p>

<p>intended for short-term use;</p> <p>unless they are intended for shortterm 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,</p>	<p>tubes.</p> <p>Examples: dentures intended to be removed by the patient; a dressing for nose bleeds.</p>
<p>(iii) are in Class C if they are intended for long-term use;</p>	<p>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).</p>
<p>unless they are intended for longterm 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.</p>	<p>Examples: orthodontic wire, fixed dental prosthesis.</p>
<p>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.</p>	<p>Examples: tracheal tubes connected to a ventilator; suction catheters for stomach drainage; dental aspirator tips.</p> <p><i>NOTE: independent of the time for which they are invasive.</i></p>
<p>RULE 6.</p> <p>All surgically invasive devices intended for transient use are in Class B,</p>	<p>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. singleuse scalpels; surgical staplers; single-use aortic punch); surgical gloves; and various types of catheter/sucker etc.</p> <p><i>NOTE: a surgical instrument (other than that in Class D) is in Class A if reusable and in Class B if supplied sterile and intended for single use. Also, a surgical instrument connected to an active device is in a higher class than A.</i></p> <p><i>NOTE: if the device incorporates a medicinal substance in a secondary role refer to Rule 13.</i></p>

unless they are reusable surgical instruments, in which case they are	Examples: Manually operated surgical drill bits and saws.
in Class A; or	
unless intended to supply energy in the form of ionizing radiation, in which case they are in Class C; or	Example: catheter incorporating/containing sealed radioisotopes.
unless intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class C; or	<p>NOTES:</p> <p>(i) <i>The 'biological effect' referred to is an intended one rather than unintentional. The term 'absorption' refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body.</i></p> <p>(ii) <i>This part of the rule does not apply to those substances that are excreted without modification from the body.</i></p> <p>Example: Insufflation gases for the abdominal cavity.</p>
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	<p>Example: insulin pen for self-administration.</p> <p><i>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.</i></p>
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.

<p>RULE 7.</p> <p>All surgically invasive devices intended for short-term use are in Class B,</p>	<p>Such devices are mostly used in the context of surgery or post-operative care, or are infusion devices, or are catheters of various types.</p> <p>Examples: infusion cannula; temporary filling materials; non-absorbable skin closure devices; tissue stabilisers used in cardiac</p>
	<p>surgery.</p> <p><i>NOTE: includes devices that are used during cardiac surgery but do not monitor or correct a defect.</i></p> <p><i>NOTE: if the device incorporates a medicinal substance in a secondary role refer to Rule 13.</i></p>
<p>unless they are intended to administer medicinal products, in which case they are in Class C; or</p>	<p><i>NOTE: the term ‘administration of medicines’ implies storage and/or influencing the rate/volume of medicine delivered not just channelling.</i></p>
<p>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</p>	<p>Example: surgical adhesive.</p>
<p>unless they are intended to supply energy in the form of ionizing radiation, in which case they are in Class C; or</p>	<p>Example: brachytherapy device.</p>
<p>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</p>	<p>Example: absorbable suture; biological adhesive.</p> <p><i>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.</i></p>
<p>unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D;</p>	<p>Example: neurological catheter.</p>

<p>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.</p>	<p>Examples: cardiovascular catheters; temporary pacemaker leads; carotid artery shunts.</p>
<p>RULE 8.</p> <p>All implantable devices, and long-term surgically invasive devices, are in Class C,</p>	<p>Most of the devices covered by this rule are implants used in the orthopaedic, dental, ophthalmic and cardiovascular fields.</p> <p>Example: maxilla-facial implants; prosthetic joint replacements; bone cement; nonabsorbable internal sutures; posts to secure teeth to the mandibular bone (without a bioactive coating).</p> <p><i>NOTE: if the device incorporates a medicinal substance in a secondary role refer to Rule 13.</i></p>
<p>unless they are intended to be placed into the teeth, in which case they are in Class B; or</p>	<p>Examples: bridges; crowns; dental filling materials.</p>
<p>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</p>	<p>Examples: prosthetic heart valves; spinal and vascular stents.</p>
<p>unless they are intended to be life supporting or life sustaining, in which case they are in Class D; or</p>	
<p>unless they are intended to be active implantable medical devices, in which case they are Class D; or</p>	<p>Example: pacemakers, their electrodes and their leads; implantable defibrillators.</p>
<p>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</p>	<p>Example: implants claimed to be bioactive.</p> <p><i>NOTE: hydroxy-apatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer.</i></p>

unless they are intended to administer medicinal products, in which case they are in Class D; or	Example: rechargeable non-active drug 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	<i>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.</i>
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; 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 C.	Examples: lung ventilators; baby incubators; electrosurgical generators; external pacemakers and defibrillators; surgical lasers; lithotriptors; therapeutic X-ray and other sources of ionizing radiation. <i>NOTE: the term 'potentially hazardous' refers to the type of technology involved and the intended application.</i>
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 Class C.	Examples: external feedback systems for active therapeutic devices.

<p>RULE 10(i).</p> <p>Active devices intended for diagnosis are in Class B:</p>	<p>Such devices include equipment for ultrasonic diagnosis/imaging, capture of physiological signals, interventional radiology and diagnostic radiology.</p>
<p>(i) if they are intended to supply energy which will be absorbed by the human body (except for devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum, in which case they</p>	<p>Examples: magnetic resonance equipment; diagnostic ultrasound in non-critical applications; evoked response stimulators.</p>
<p>are Class A), or</p>	
<p>(ii) if they are intended to image <i>in vivo</i> distribution of radiopharmaceuticals, or</p>	<p>Example: gamma/nuclear cameras.</p>
<p>(iii) if they are intended to allow direct diagnosis or monitoring of vital physiological processes,</p>	<p>Example: electronic thermometers, stethoscopes and blood pressure monitors; electrocardiographs.</p>
<p>unless they are specifically intended for:</p> <p>(i) 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</p> <p>(ii) diagnosing in clinical situations where the patient is in immediate danger, in which case they are in Class C.</p>	<p>Example: monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnoea monitors.</p> <p>Example: ultrasound equipment for use in interventional cardiac procedures.</p>

<p>RULE 10(ii).</p> <p>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.</p>	<p>Example: these include devices for the control, monitoring or influencing of the emission of ionizing radiation.</p>
<p>RULE 11.</p> <p>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,</p>	<p>Such devices are mostly drug delivery systems or anaesthesia equipment.</p> <p>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.</p>
<p>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.</p>	<p>Examples: infusion pumps; anaesthesia equipment; dialysis equipment; hyperbaric chambers; nebuliser where the failure to deliver the appropriate dosage characteristics could be hazardous.</p>
<p>RULE 12.</p> <p>All other active devices are in Class A.</p>	<p>Examples: examination lamps; surgical microscopes; powered hospital beds & wheelchairs; powered equipment for the recording, processing, viewing of diagnostic images; dental curing lights.</p>
<p>ADDITIONAL RULES</p>	

<p>RULE 13.</p> <p>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.</p>	<p>These medical devices incorporate medicinal substances in an ancillary role.</p> <p>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.</p> <p><i>NOTE: Such medical devices may be subject to additional conformity assessment procedures according to the regional or national requirements of medicinal product Regulatory Authorities.</i></p>
<p>RULE 14.</p> <p>All devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable, are Class D,</p>	<p><i>NOTE: In some jurisdictions such products:</i></p> <ul style="list-style-type: none"> (i) are considered to be outside the scope of the medical device definition; (ii) may be subject to different controls. <p><i>It is likely the regulations controlling these devices will be the subject of future harmonization efforts.</i></p> <p>Examples: porcine heart valves; catgut sutures.</p>
<p>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 A.</p>	<p>Examples: leather components of orthopaedic appliances.</p>
<p>RULE 15.</p> <p>All devices intended specifically to be used for sterilizing medical devices, or disinfecting as the end point of processing, are in Class C.</p>	<p>Examples: devices for disinfecting or sterilising endoscopes; disinfectants intended to be used with medical devices.</p> <p><i>NOTE: This rule does not apply to products that are intended to clean medical devices by means of physical action e.g. washing machines.</i></p>

<p>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</p>	<p>Example: washer disinfectors.</p>
<p>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.</p>	<p>In some jurisdictions solutions for use with contact lenses:</p> <ul style="list-style-type: none"> (i) are considered to be outside the scope of the medical devices definition; (ii) may be subject to different controls.
<p>RULE 16.</p> <p>All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class C,</p>	<p>Examples: condoms; contraceptive diaphragms.</p>
<p>unless they are implantable or longterm invasive devices, in which case they are in Class D.</p>	<p>Example: intrauterine contraceptive device.</p>

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

10.17 Rationale for the inclusion of the additional rules

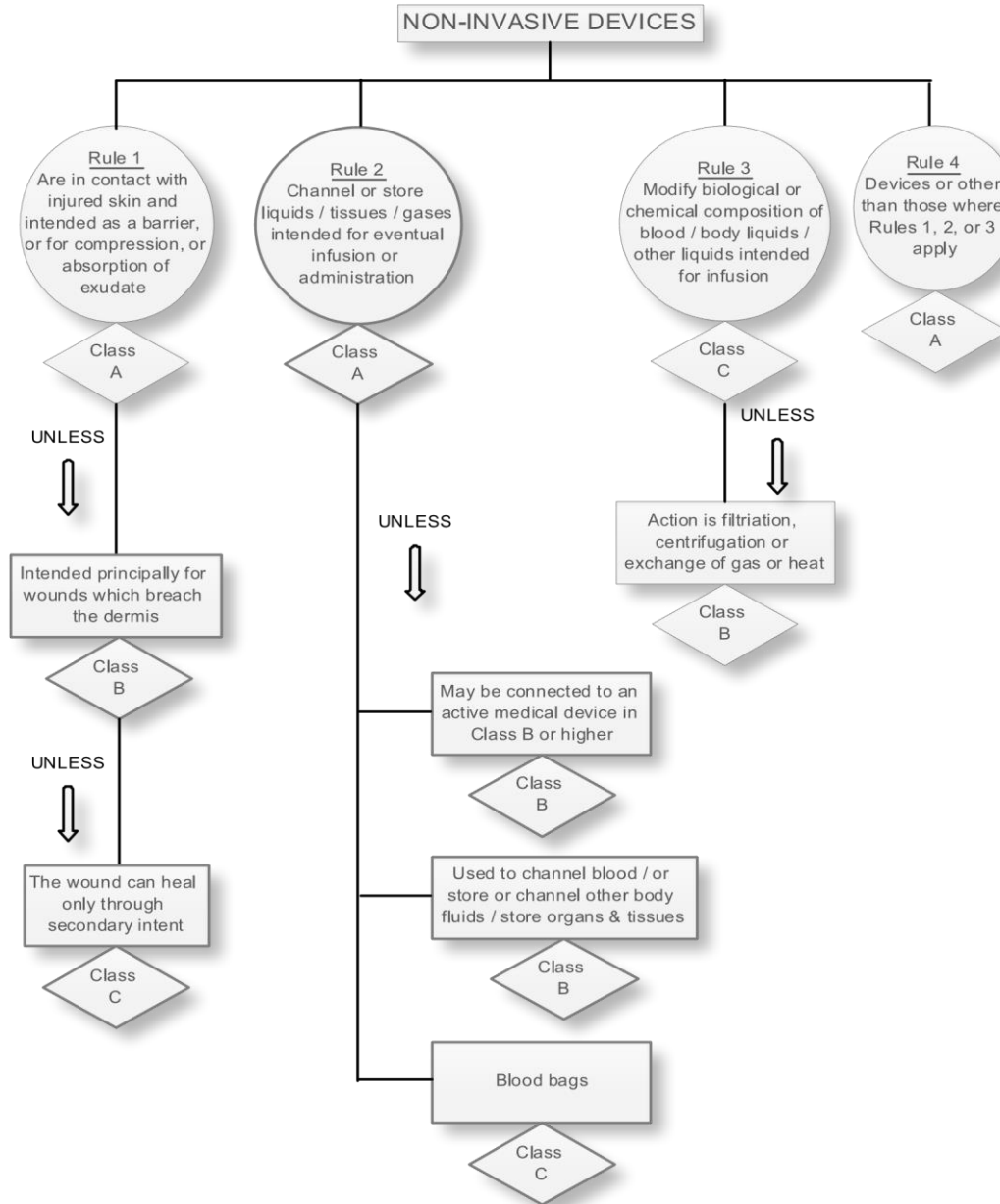
There are a small number of products that fall within the scope of the definition of a medical device and which may need to be classified to take account of factors other than those covered by the general rules (Rules 1 to 12). Therefore, four Additional Rules are provided (Rules 13 to 16).

Matters that may need to be considered are:

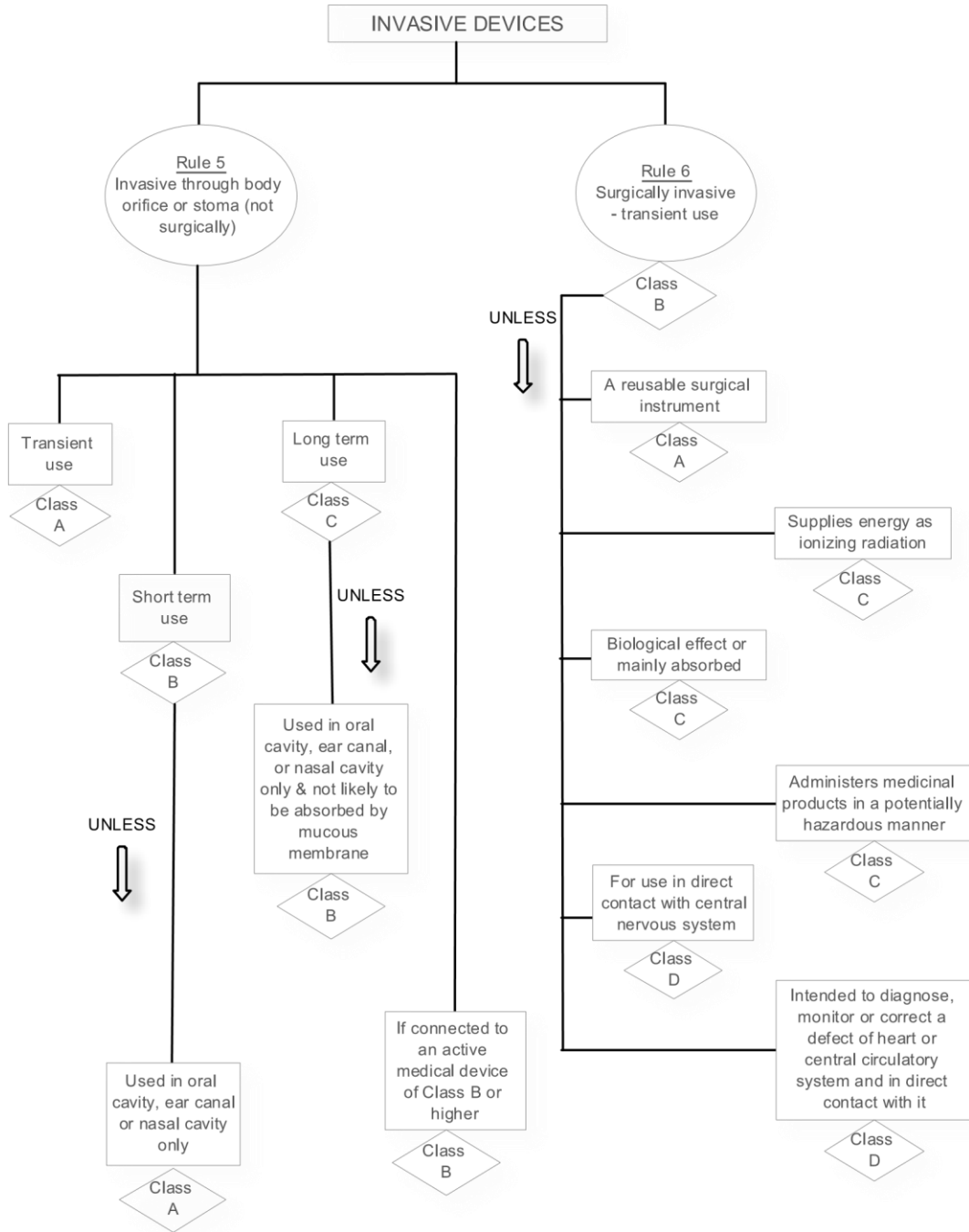
<p>Rule 13:</p>	<p>Devices incorporating a medicinal product</p> <ul style="list-style-type: none"> • The regulations applying to medicinal products require different acceptance procedures to those for medical devices. • The behaviour of a medicinal product used in conjunction with a medical device may differ from that covered by its approved use as a medicinal product alone.
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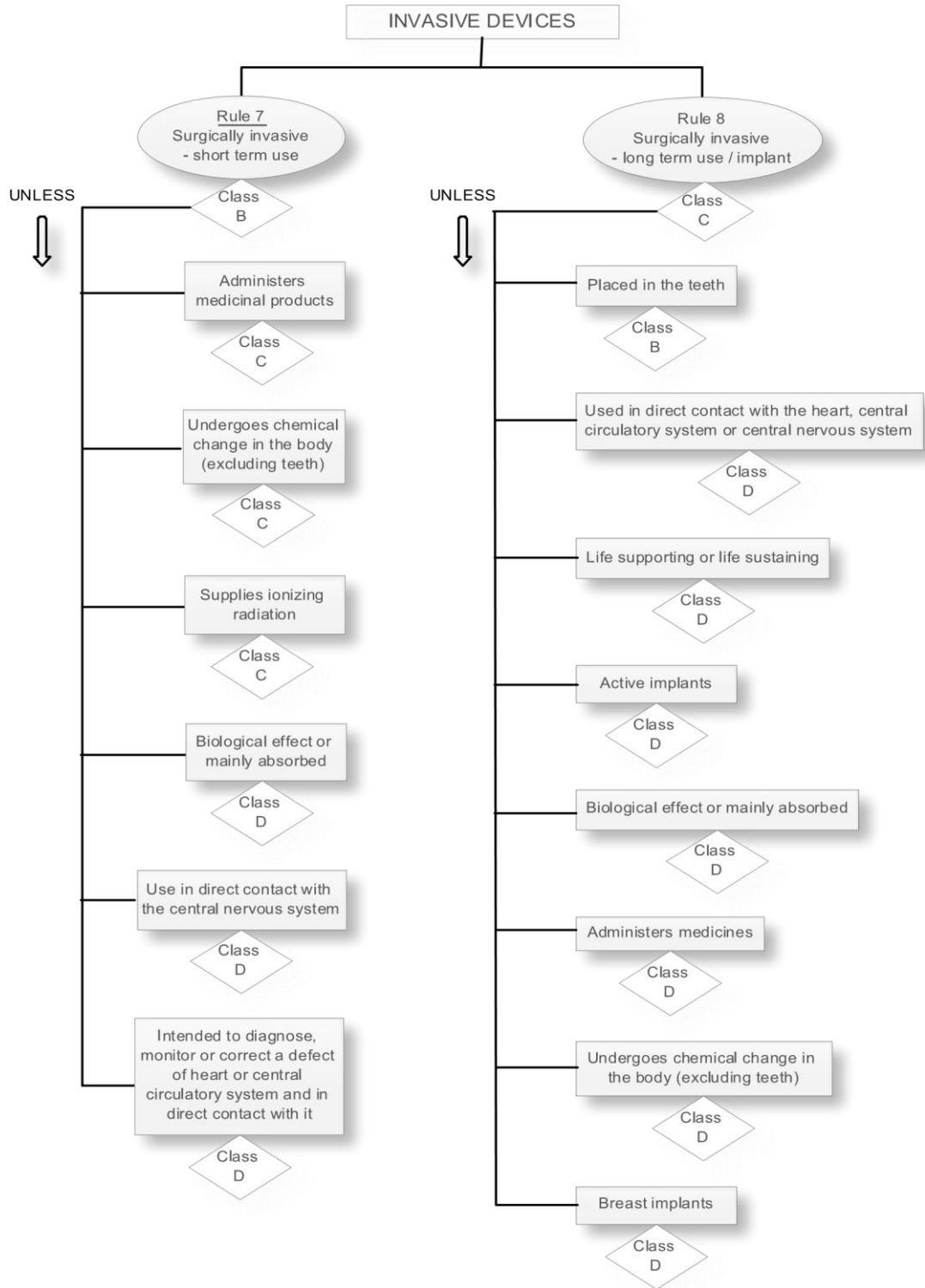
Rule 14:	<p>Devices incorporating animal or human tissues</p> <ul style="list-style-type: none">• There is an absence of global regulatory controls for such devices.• Classification needs to acknowledge the diversity of opinions on such devices, globally.• The possible risks associated with the transmission of infectious agents through materials used in such devices, e.g. Bovine Spongiform Encephalopathy (BSE) and Creutzfeldt-Jacob disease (CJD), demand classification at a higher risk level.
Rule 15:	<p>Disinfectants</p> <ul style="list-style-type: none">• The particular concerns relating to those disinfectants that are used with contact lenses, due to sensitivity and vulnerability of the eye.
Rule 16:	<p>Contraceptive devices</p> <ul style="list-style-type: none">• The risks associated with unwanted pregnancy if caused by mechanical failure of the device.• The need to safeguard public health through the use of condoms to reduce the prevalence of sexually transmitted diseases.• User expectation that contraceptive devices are perfectly reliable and safe despite published data to the contrary.

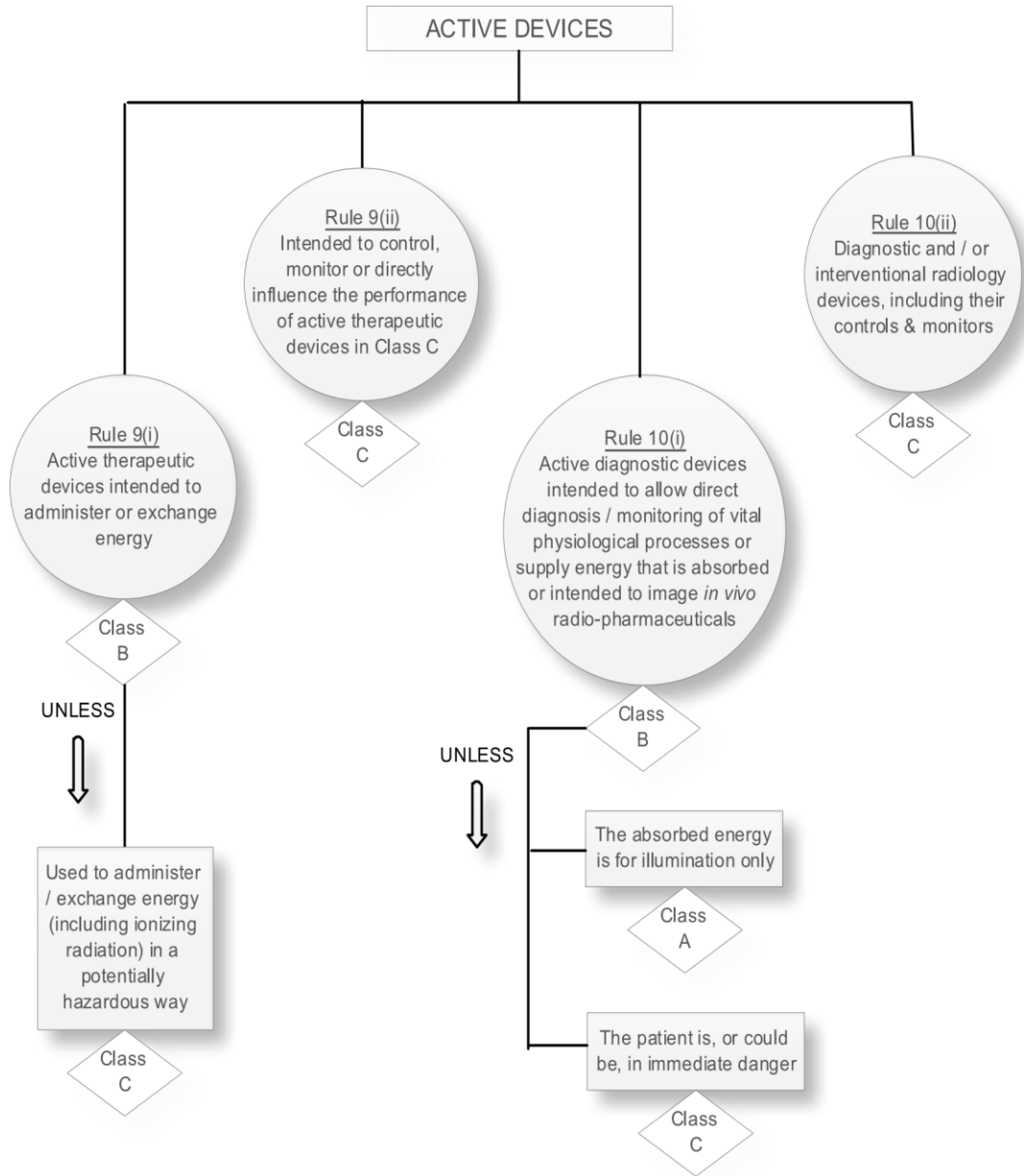
Appendix A - Decision trees to demonstrate how the rules may be used to classify specific devices.

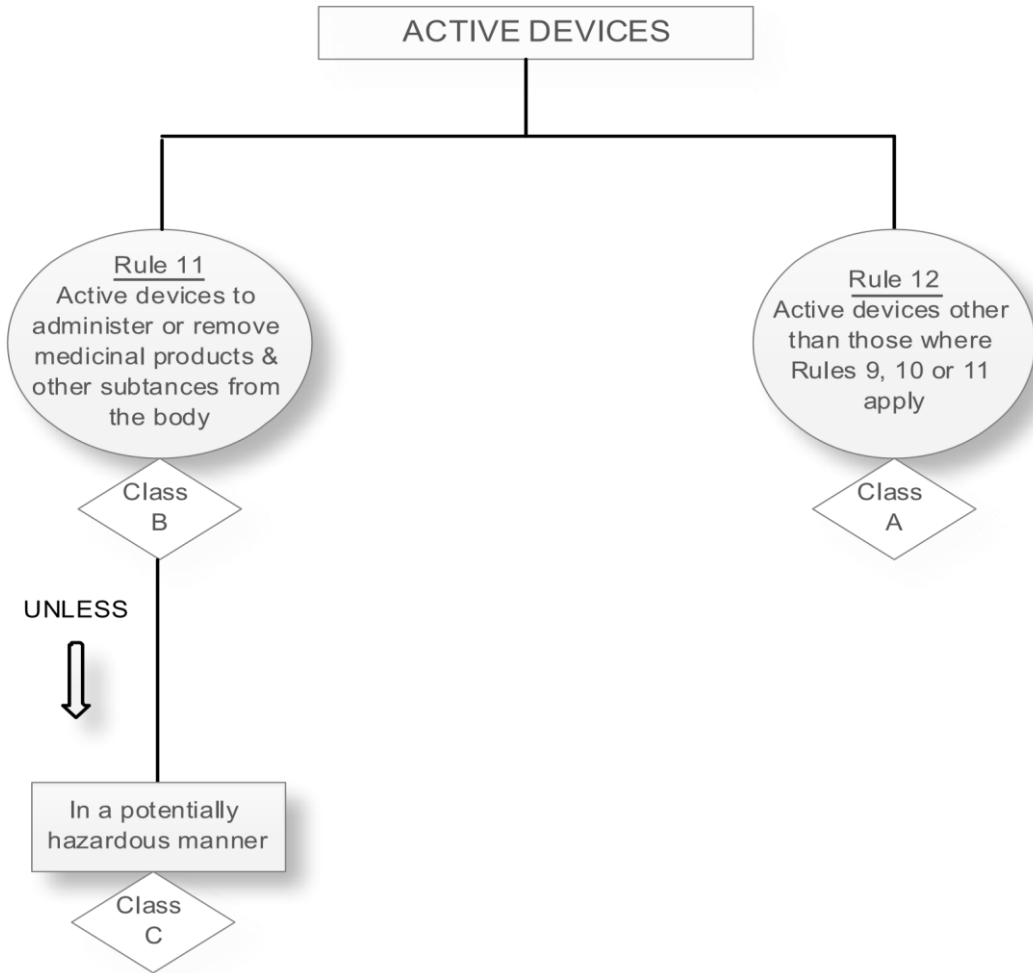


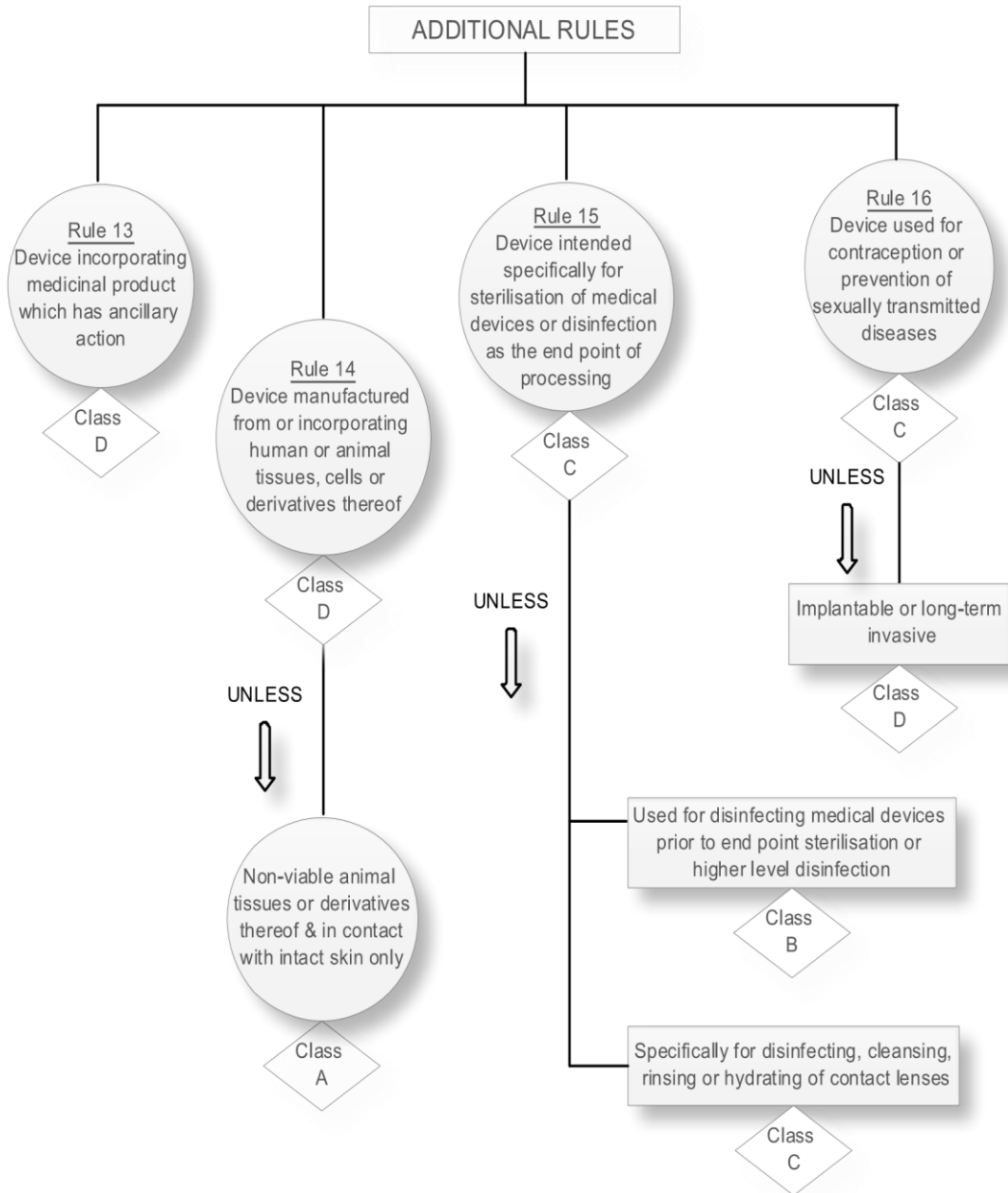
NOTE: This diagram and those that follow are for illustrative purposes only and the determination of risk class for a particular device should be made by referring to the rules themselves and not the decision trees. Where a medical device has features that place it into more than one class, conformity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











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