FINAL DOCUMENT

Global Harmonization Task Force

Title: Principles of Medical Devices Classification

Authoring Group: Study Group 1 of the Global Harmonization Task Force

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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.

1.0 Introduction

The objective of the Global Harmonization Task Force (GHTF) is to encourage convergence at the global level in the evolution of regulatory systems for medical devices in order to facilitate trade whilst preserving the right of participating members to address the protection of public health by those regulatory means considered the most suitable.

The primary way in which the Global Harmonization Task Force (GHTF) achieves its goals is through the production of harmonized guidance documents suitable for implementation or adoption by member Regulatory Authorities, as appropriate taking into account their existing legal framework, or by nations with developing regulatory programmes. Eliminating differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

This guidance document is one of a series that together describe a global regulatory model for medical devices. Its purpose is to assist a manufacturer to allocate its medical device to an appropriate risk class using a set of harmonized principles. Regulatory Authorities have the responsibility of ruling upon matters of interpretation for a particular medical device. Once assigned, such classification will prescribe how the manufacturer will demonstrate that its device complies with other documents in the series and, in particular, with those entitled *Essential Principles of Safety and Performance of Medical Devices* and *Labelling for Medical Devices* should it be required or requested so to do by a Regulatory Authority, Conformity Assessment Body, user or third party. It seeks to strike a balance between the responsibilities of Regulatory Authorities to safeguard the health of their citizens and their obligations to avoid placing unnecessary burdens upon the industry.

This document should be read in conjunction with the GHTF document on *Principles of Conformity Assessment for Medical Devices* that recommends conformity assessment requirements appropriate to each of the four risk classes proposed herein. This link between documents on classification and conformity assessment is important to ensure a consistent approach across all countries/regions adopting the global regulatory model recommended by the GHTF, so that premarket approval for a particular device may become acceptable globally. Regulatory Authorities who have different classification procedures are encouraged to adopt this GHTF guidance as the opportunity permits.

This document is intended for use by Regulatory Authorities, Conformity Assessment Bodies 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.

Regulatory Authorities that are developing classification schemes or amending existing ones are encouraged to consider the adoption of the system described in this document, as this will help to reduce the diversity of schemes worldwide and facilitate the process of harmonization.

At this time, classification requirements and other regulatory controls assigned to a medical device by different Regulatory Authorities have yet to be harmonized and may vary from the guidance provided in this document.

This guidance document has been prepared by Study Group 1 of the Global Harmonization Task Force (GHTF). Comments or questions about it should be directed to either the Chairman or Secretary of GHTF Study Group 1 whose contact details may be found on the GHTF web page.

2.0 Scope

This document applies to all products that fall within the definition of a medical device that appears within the GHTF document *Information Document Concerning the Definition of the Term 'Medical Device',* **other than those** used for the *in vitro* examination of specimens derived from the human body for which a separate document is being developed.

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3.0 References

GHTF final documents

GHTF/SG1/N12:2000 *Role of Standards in the Assessment of Medical Devices.*

GHTF/SG1/N29:2005 *Information Document Concerning the Definition of the Term 'Medical Device'.*

GHTF/SG1/N40:2006 *Principles of Conformity Assessment for Medical Devices.*

GHTF/SG1/N41:2005 *Essential Principles of Safety and Performance of Medical Devices.*

GHTF/SG1/N43:2005 *Labelling for Medical Devices.*

4.0 Definitions

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. (Source - European Directive 93/42/EEC)

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. (Source - European Directive 93/42/EEC)

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. (Source – based on European Directive 93/42/EEC)

Central circulatory system: For the purpose of this document, central circulatory system means 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: For the purpose of this document, central nervous system means brain, meninges and spinal cord. (Source - European Directive 93/42/EEC)

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:

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.
(Source - European Directive 93/42/EEC - modified)

Harm: Physical injury or damage to the health of people or damage to property or the environment. (Source – ISO/IEC Guide 51:1999)

Hazard: Potential source of harm. (Source – ISO/IEC Guide 51:1999)

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.

Intended use / 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: 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: 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.

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.
(Source - European Directive 93/42/EEC)

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: *Information Document Concerning the Definition of the Term 'Medical Device'* (GHTF/SG1/N29:2005).

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 manufacturer to be reused after appropriate procedures for cleaning and/or sterilisation have been carried out. (Source - European Directive 93/42/EEC – modified)

Risk: Combination of the probability of occurrence of harm and the severity of that harm. (Source – ISO/IEC Guide 51:1999)

5.0 General Principles

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

The GHTF guidance documents *Essential Principles of Safety and Performance of Medical Devices* and *Labelling for Medical Devices* **apply to all devices whatever their risk class**.

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. At the same time, the imposition of regulatory controls should not place an unnecessary burden on regulators or manufacturers.

Therefore:

- there is a need to classify medical devices based on their risk to patients, users and other persons; and
- there is benefit for manufacturers and Regulatory Authorities if a globally harmonized classification system is developed.

The risk presented by a particular 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 device also depends, in part, on its intended user(s), its mode of operation, and/or technologies. In general, the classification rules are intended to accommodate new technologies. Without prejudice to these rules, Regulatory Authorities may wish to require the notification of new devices being placed on the market in their jurisdictions. Such notification may be used in assessing the evidence requirements for use in the conformity assessment process. It may also be used to consider the need, if any, for possible re-classification and/or changes in these harmonized classification rules.

6.0 Recommendations

6.1 Primary Recommendations

- Regulatory Authorities should work towards the establishment of a global classification system.
- This system should consist of four risk classes. Based on experience of GHTF Founding Members, this is sufficient to accommodate all medical devices and allows an efficient and graduated system of conformity assessment controls.
- The initial determination of class should be based on a set of rules derived from those features of devices that create risk. In most cases the initial rules based classification will also be the final classification.
- These rules should be sufficiently clear that manufacturers may readily identify the class of their medical devices, subject, as required, to final classification by the Regulatory Authority.
- The rules should be capable of accommodating future technological developments.
- The manufacturer should document its justification for placing its product into a particular risk class, including the resolution of any matters of interpretation where it has asked a Regulatory Authority and/or Conformity Assessment Body for a ruling.
- Decisions on final classifications, which deviate from the initial rules-based classification, should be weighed against the disadvantages of disharmonized international classification.

6.2 Factors Influencing Device Classification

A number of factors, including for example the duration of device contact with the body, the degree of invasiveness, whether the device delivers medicinal products or energy to

the patient, whether they are intended to have a biological affect on the patient and local *versus* systemic effects (e.g. conventional *versus* absorbable sutures) may, alone or in combination, affect device classification.

If, based on the manufacturer's intended purpose, two or more classification rules apply to the device, the device is allocated the highest level of 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 manufacturer, (e.g. a physiological monitor and a separate recorder, or a general purpose syringe and a syringe driver), the classification rules should apply separately to each of the devices.

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.

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.

Accessories intended specifically by manufacturers 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 GHTF guidance documents as apply to the medical device itself (e.g. Essential principles for Safety and Performance, post-market surveillance etc.). For classification purposes an accessory may be classified as though it is a medical device in its own right.

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

Experience gained from the clinical use of a particular type of medical device may suggest that the rules appearing in Section 8.0 of this document are inappropriate. Current GHTF procedures require that all GHTF documents be reviewed at regular intervals. Such a review of this document will provide any participant with an opportunity to suggest a change of text that, in his/her opinion, will address any shortcoming.

The purpose of risk classification is to make sure that the regulatory controls applied to a medical device are proportionate to risk. Statutory conformity assessment authority provides Regulatory Authorities methods to assure compliance with regulatory controls. At this time, conformity assessment requirements and other regulatory controls assigned to each class of device by different Regulatory Authorities have yet to be harmonized and may vary. While Study Group 1 of GHTF continues to support and encourage regulatory harmonization, it recognises that some Regulatory Authorities may have to reflect different local needs or social considerations when they introduce new regulations on classification, for example, in the application of devices covered by the Additional Rules 13 to 16. Study Group 1 hopes any such differences will disappear in the course of time.

6.3 Proposed General Classification System for Medical Devices

Figure 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.

Figure 1: Proposed general classification system for medical devices

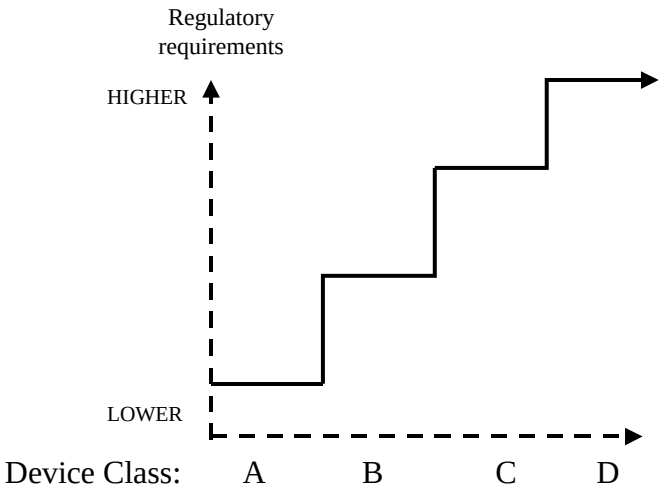
CLASS	RISK LEVEL	DEVICE EXAMPLES
A	Low Risk	Surgical retractors / tongue depressors
B	Low-moderate Risk	Hypodermic Needles / suction equipment
C	Moderate-high Risk	Lung ventilator / bone fixation plate
D	High Risk	Heart valves / implantable defibrillator

Figure 2 shows a conceptual illustration of increasing levels of regulatory requirements as the device risk class increases. These regulatory controls may include, for example: -

- operation of a quality system (recommended for all devices);
- technical data;
- product testing using in-house or independent resources;
- documentation of clinical evidence to support the manufacturer's claims;
- the need for and frequency of independent external audit of the manufacturer's quality system; and
- independent external review of the manufacturer's technical data.

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

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



7.0 The Determination of Device Class using this Rules-based System

The manufacturer should:

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

   NOTE: Medical devices that are used for the *in vitro* examination of specimens derived from the human body are not covered by the classification rules within this document (see Scope).

2. Document the intended use of the medical device.

3. 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.**

4. Determine if the device is subject to special national rules that apply within a particular jurisdiction..

NOTES:

- Once a rules-based system has been adopted, modifications **may occasionally be required**. For example, where through post-market experience, a level of risk for a type of medical device, classified using the criteria found in this guidance document is

no longer appropriate, consideration should be given to re-classification of the device type by a change to the rules.

- Similarly, the historical knowledge of a device may necessitate a different class than the one assigned by the initial classification. Unlike the principle of reclassification after post-market experience with a device, this principle of historical knowledge should be applied immediately when the initial classification yields an inappropriate result.

- 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.

8.0 Initial Classification Rules

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 emphasised 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***	
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 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. 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. **NOTE:** in some jurisdictions, blood bags have a special rule that places them within a different risk 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 (see note to comment for Rule 4). They are normally used in conjunction with an active device within the scope of either Rule 9 or 11. Examples: haemodializers; devices to remove white blood cells from whole blood. **NOTE**: for the purpose of this part of the rule, 'modification' does not include simple, mechanical filtration or centrifuging which are covered below.
unless the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class 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.
➢ ***INVASIVE DEVICES***	
Rule 5. All invasive devices with respect to body orifices (other than	Such devices are invasive in body orifices and are not surgically invasive (refer to definition in

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.	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 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 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. **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	Example: catheter incorporating/containing

form of ionizing radiation, in which case they are in Class C; or	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 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	
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 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	Example: brachytherapy device.

energy in the form or ionizing radiation, 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; 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. **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: 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	**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.	
➢ ***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. **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 Class C.	Examples: external feedback systems for 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: a) monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for	Example: monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnoea monitors.

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: 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: diagnostic X-ray source; 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 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 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.
➢ ***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. **NOTE:** Such medical devices may be subject to additional conformity assessment procedures according to the regional or national requirements of medicinal product Regulatory Authorities.
Rule 14. All devices manufactured from or incorporating animal or human	**NOTE:** In some jurisdictions such products: - are considered to be outside the scope of the

cells/tissues/derivatives thereof, whether viable or non-viable, are Class D,	medical device definition; - may be subject to different controls. It is likely the regulations controlling these devices will be the subject of future harmonization efforts. Examples: porcine heart valves; catgut sutures.
unless such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only, where they are in Class A.	Examples: leather components of orthopaedic appliances.
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.	In some jurisdictions solutions for use with contact lenses: - are considered to be outside the scope of the medical devices definition; - may be subject to different controls.
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 devices are shown in Appendix A.

8.1 Rationale for the inclusion of the Additional Rules into 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). 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 (see Clause 6.2, above). Therefore, four Additional Rules are provided (Rules 13 to 16).

Matters that may need to be considered are: -

Rule 13: Devices incorporating a medicinal product

- The regulations applying to medicinal products require different acceptance procedures to those for medical devices.
- The behavior of a medicinal product used in conjunction with a medical device may differ from that covered by its approved use as a medicinal product alone.

Rule 14: Devices incorporating animal or human tissues

- There is an absence of global regulatory controls for such devices.
- Classification needs to acknowledge the diversity of opinions on such devices, globally.
- The possible risks associated with the transmission of infectious agents through materials used in such devices, e.g. Bovine Spongiform Encephalopathies (BSE) and Creutzfeldt-Jacob disease (CJD), demand classification at a higher risk level.

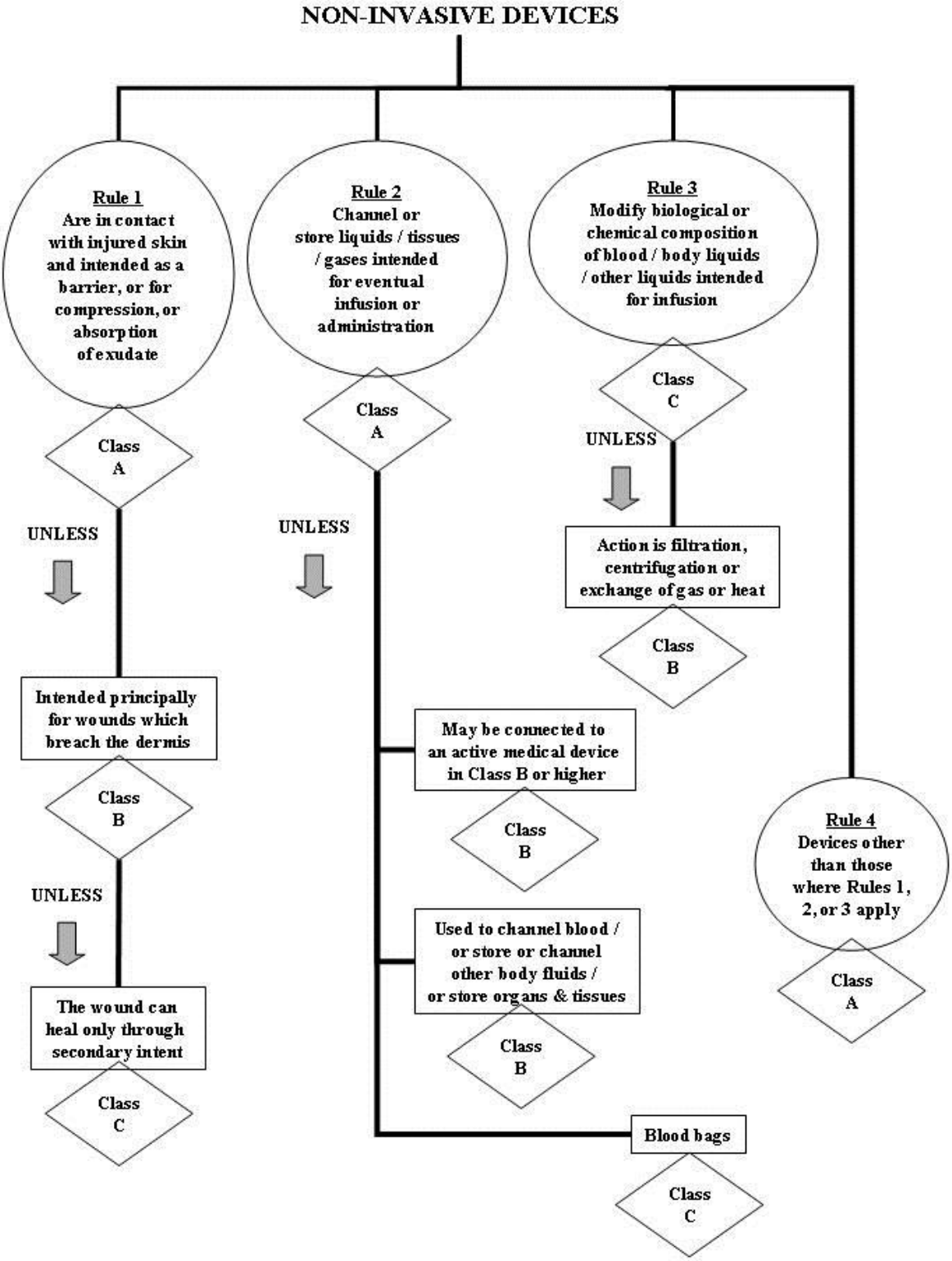
Rule 15 Disinfectants

- The particular concerns relating to those disinfectants that are used with contact lenses, due to sensitivity and vulnerability of the eye.

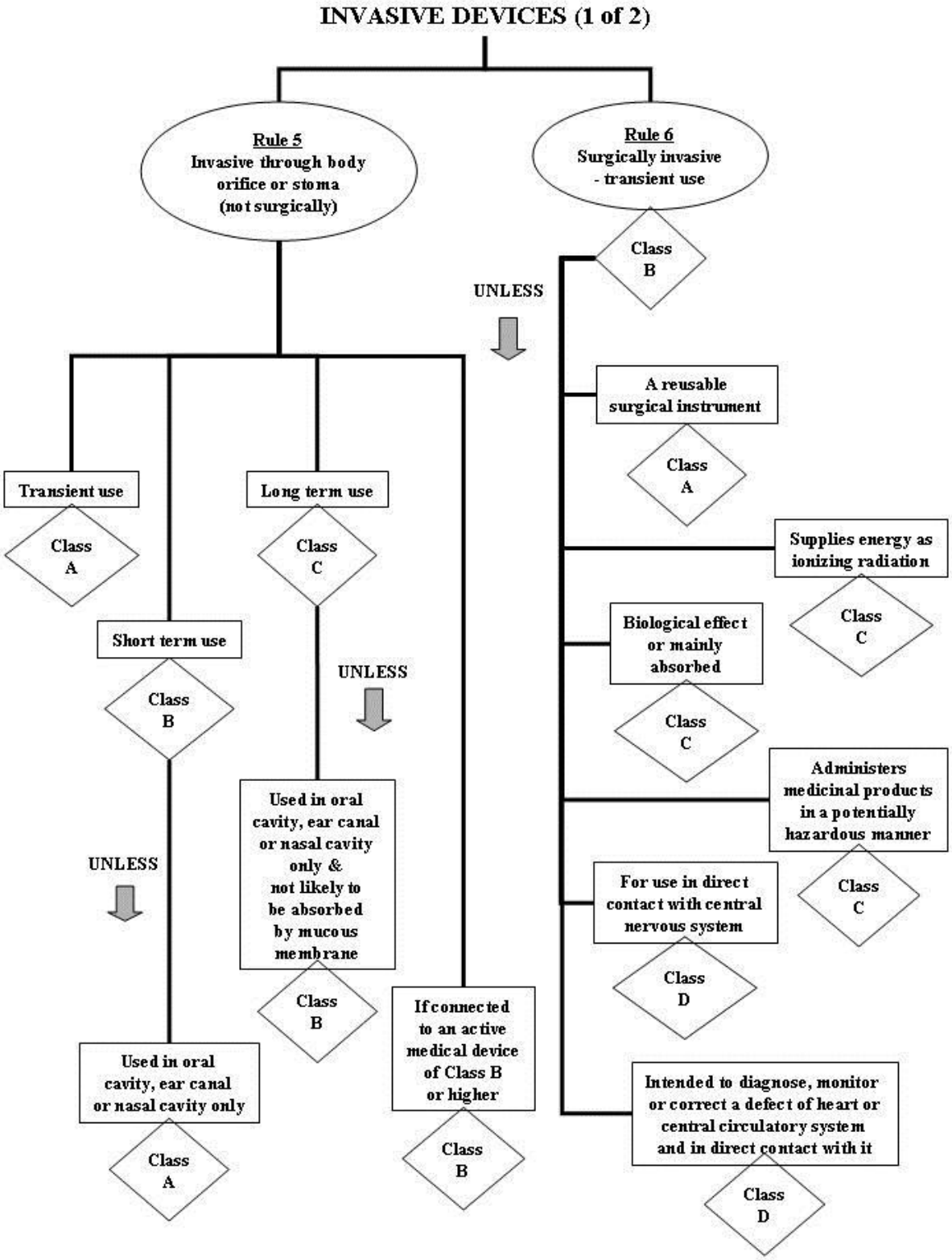
Rule 16 Contraceptive devices

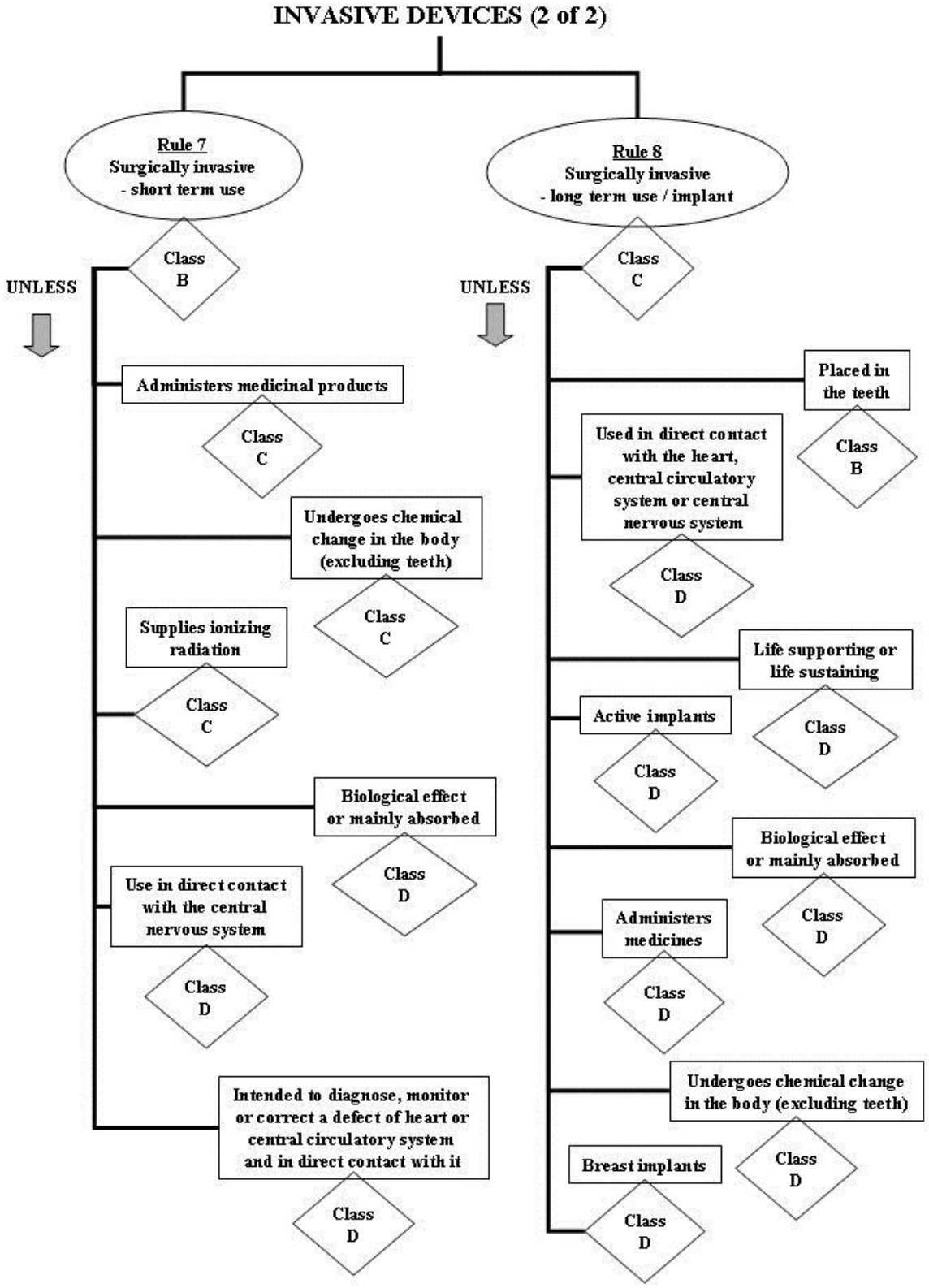
- The risks associated with unwanted pregnancy if caused by mechanical failure of the device.
- The need to safeguard public health through the use of condoms to reduce the prevalence of sexually transmitted diseases.
- User expectation that contraceptive devices are perfectly reliable and safe despite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

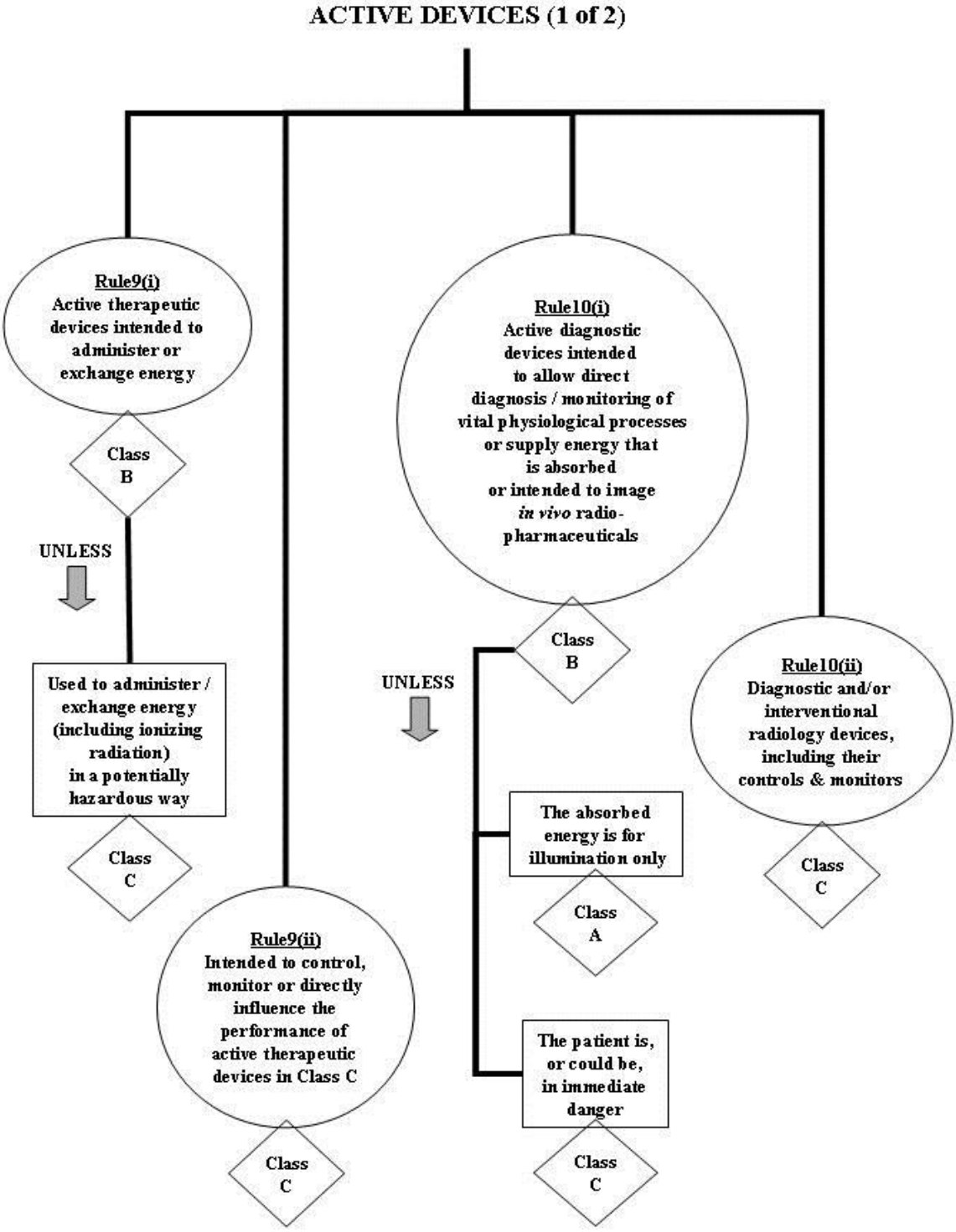
Appendix A: Decision trees to demonstrate how the rules may be used to classify specific devices.

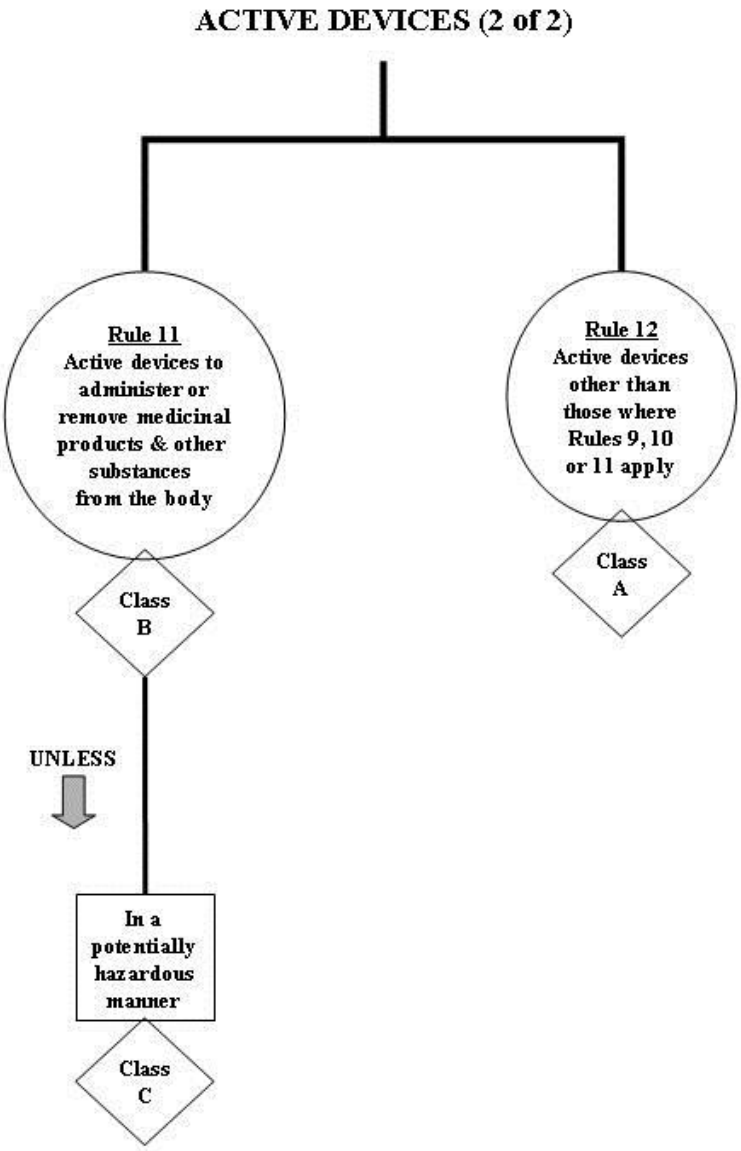


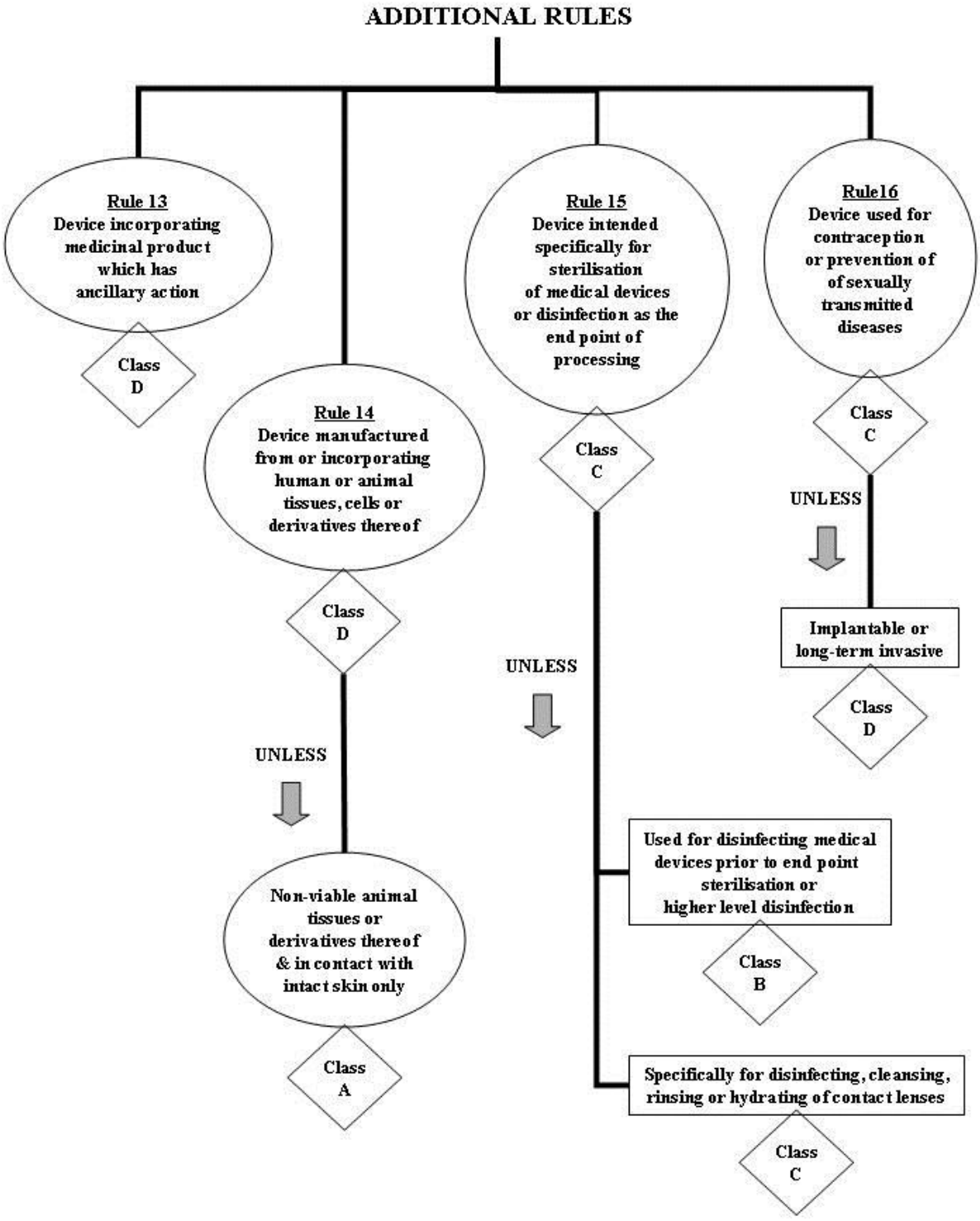
NOTE: This diagram and those that follow are for illustrative purposes only and the determination of risk class for a particular device should be made by referring to the rules themselves and not the decision trees. Where a medical device has features that place it into more than one class, conformity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


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
Long term use
Class C
Short term use
Class B
UNLESS
Used in oral cavity, ear canal or nasal cavity only
Class A
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