South African Health Products
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GUIDELINE FOR CLASSIFICATION OF MEDICAL DEVICES AND IVDS

This guideline is intended to provide recommendations to interested persons wishing to submit applications for the licensing of manufacturers, distributors and wholesalers, and registration of medical devices and IVDs. It represents the Authority's current thinking on the safety, quality and performance of medical devices and IVDs. It is not intended as an exclusive approach. The Authority reserves the right to request any additional information to establish the safety, quality, and performance of a medical device or IVD in keeping with the knowledge current at the time of evaluation. Alternative approaches may be used but these should be scientifically and technically justified.

The Authority is committed to ensure that all registered medical devices and IVDs will be of the required quality, safety and performance. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications. Guidelines and application forms are available from the office of the Chief Executive Officer and the website.

Document History

Final Version	Reason for Amendment	Effective Date
1	First issue, published for implementation as part of 8.01 General Guideline Medical Devices and IVDs	August 2016
2	Approved administrative updates	November 2019
3	- Content structured on the new SAHPRA Guideline Template - Old Guideline no. 8.05 changed to a new document number SAHPGL-MD-04	March 2023

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Abbreviation/ Term	Meaning
IVD	In Vitro Diagnostic
SAL	Sterility Assurance Level

1. INTRODUCTION

The registration of medical devices and IVDs in South Africa is governed by the provisions and requirements of the Medicines and Related Substances Control Act No. 101 of 1965, (hereafter 'the Act') and the Regulations and Guidelines published in terms thereof.

Copies of the legislation can be obtained from the SAHPRA website www.sahpra.org.za

This guideline provides the classification rules for the classification of medical devices (Non-IVDs) and IVDs in South Africa.

The aim of this Guideline is to assist manufacturers, importers, distributors, and wholesalers of medical devices and IVDs in the classification of medical devices and IVDs required for the licensing of manufacturers, distributors and wholesalers and registration of medical devices or IVDs. The types of medical devices or IVDs include all products classified as per the different Classes based on a risk assessment and intended use.

The Guideline is meant to provide guidance in meeting the requirements of the Act. It is acknowledged, however, that in some instances scientific developments may dictate alternative approaches. When a deviation from a guideline is decided on, a detailed motivation giving the reason(s) for the deviation and justification for the alternative approach should be included in the expert report submitted with the application.

Whenever there is doubt, applicants are advised to consult The Authority (SAHPRA) for confirmation and/or clarification before completing and submitting the application form; refer to the website for contact details. Applicants should always refer to the **current** version of the relevant ***Classification Rules for Medical Devices and IVDs*** and the Addenda thereto.

Guidelines are constantly evolving as a result of scientific developments and harmonization of the requirements of regional and international regulatory authorities. The Authority (SAHPRA) endeavors to regularly update the guidelines to reflect current thinking and keep its technical requirements and evaluation policies in line with “best international medical device and IVD regulatory practice”.

1.1 Purpose

The purpose of this guideline is to assist manufacturers, importers, distributors and wholesalers of medical devices and IVDs in identifying the classes of the products which they manufacture, import, export and distribute in accordance with Act 101 of 1965.

1.2 Scope

This guideline is applicable to IVD and non-IVD devices.

1.3 Legal Provision

Refer to the General Regulations relating to Medical Devices and IVDs and to the Medicines and Related Substances Act, 101 of 1965.

2. CLASSIFICATION OF MEDICAL DEVICES (Non- IVDs)

2.1 Overview

The medical devices regulatory framework has a classification system for medical devices and IVDs, as per the medical device Regulations of Act 101 of 1965.

A medical device (non-IVD), other than an IVD medical device, has the medical device classification applying under the classification rules set out in the Classification Rules for Medical Devices.

An IVD medical device has the medical device classification applying under the classification rules set out in the Classification Rules for IVDs.

The classification levels for medical devices are:

Classification	Level of risk
Class A	Low risk
Class B	Low–moderate risk
Class C	Moderate – high risk
Class D	High risk – where risk relates to the patient or to public health

Identical medical devices may be classified differently if they are to be used in different parts of the body. This is why the original manufacturer's intended use of the device is critical to determining the appropriate classification. The intended use can be obtained from the:

- instructions for use
- label
- original manufacturer's advertising materials
- technical documentation

NOTE: There may be medical devices or IVDs where the classification in South Africa is different to the classification in other countries. The applicant should take into account the South African requirements when determining the classification of a device that is to be supplied in South Africa.

2.2 Principles for applying the classification rules

The classification rules are outlined in technical rules for medical devices and technical rules for IVDs. The classification process is based on the manufacturer's intended purpose, taking into account the design and how the medical device or IVD works. In some cases, classification is inconclusive, and more than one rule can apply. If this happens the higher classification applies.

All the classification rules must be considered to determine the classification of the medical device or IVD. If the device is to be used in combination with another medical device, the classification rules must be applied separately to each device. Accessories are classified separate to the medical device they are used with.

If the device is to be used in combination with another medical device, the classification rules must be applied separately to each device.

For groups, systems and procedure packs, the classification for the entire group, system or pack is the highest classification of any individual device in the group, system or pack. The presence of a registered medicine in a procedure pack does not affect the classification. For example, if there is a device in the pack that is classified as Class C, then the entire pack is classified as Class C.

Manufacturers & Distributors should pay particular attention to *Rules 13, 14, 15 & 16—Additional rules*, as these rules may not be applied consistently internationally.

Software:

- that fits the definition of a medical device is also an active medical device since it relies on an energy source for its operation.
- that is intended to make a device operate, control a device, or influence the functions of a device generally falls in the same classification as the device.
- intended as an accessory to a medical device should be classified separately from the device with which it is used; and
- is considered an accessory when it is not essential to the operation of the device.

If the intended purpose of the medical device or IVD is not clear, The Authority will request further clarification from the original manufacturer or Authorised Representative. If the documentation requested is not provided within the required period or is unclear, then The Authority will assume an intended purpose consistent with the purpose generally accepted in current clinical practice.

If a medical device is intended to be used in more than one part of a patient's body, the medical device is classified on the assumption that it will be used in the part of the body that poses the highest risk. For invasive devices, this may be the central circulatory or central nervous systems.

In the event of a dispute resulting from application of the classification rules, The Authority shall determine the classification.

2.3 Medical Devices with a measuring function

A medical device is considered to have a measuring function if the device is intended by the manufacturer to

a) measure quantitatively a physiological or anatomical parameter, or

b) measure a quantity or a qualifiable characteristic of energy, or

c) measure substances delivered to or removed from the human body. The measurements given by a medical device must:

- display in South African legal units of measurement or other units of measurement acceptable to
- The Authority, or
- be compared to at least one point of reference indicated in South African legal units of measurement or other units of measurement acceptable to The Authority, and be accurate to enable the device to achieve its intended purpose.

The medical device with a measuring function must meet each of the above requirements.

Manufacturers of medical devices that have a measuring function must prepare evidence that the device complies with the relevant Essential Principles, particularly Essential Principle 10. For more information, see Guideline 8.02 Essential Principles of Safety and Performance.

For manufacturers of Class A devices that have a measuring function, in addition to preparing a South African Declaration of Conformity, they must supply The Authority with conformity assessment evidence to

demonstrate that the relevant Essential Principles have been met.

2.4 Examples of Medical Devices and whether they have a measuring function

Device	Requirements to fit the definition of measuring function			Result
	Measurement of physiological/ clinical	Absolute measurement units/reference	Measurement critical to intended purpose	
Clinical thermometer that displays patient temperature in ºC	Yes	Yes	Yes	Measuring function
Forehead patch that indicates temperature via colour change	Yes	No	Yes	Does not have a measuring function
Time-of-day clock (HH:MM)	No	Yes	Yes	Does not have a measuring function
Medicine measuring cup with ml or defined Units marked	Yes	Yes	Yes	Measuring function
Medicine cup with no scale	Yes	No	No	Does not have a measuring function
"Biofeedback" electromyography (relative scale)	Yes	No	Yes	Does not have a measuring function
Diagnostic electromyography	Yes	Yes	Yes	Measuring function

2.5 Medical Devices required to be sterile

Some medical devices are required to be sterile when used to minimize the risk of infection. Such medical devices should be terminally sterilized to a Sterility Assurance Level (SAL) of at least 10-6, unless this is not possible due to device material incompatibility with the proposed sterilization process.

It is the responsibility of the manufacturer to determine the most appropriate method for achieving the required SAL for a particular device after due consideration of the design and construction of the device. Some common sterilization methods are:

- moist heat or steam
- dry heat
- ionizing radiation

- ethylene oxide
- liquid chemical sterilization

Devices that are required to be sterile, but cannot be subjected to terminal sterilization, can be manufactured aseptically, for example by sterile filtration. Devices manufactured in this manner have a lower SAL than those subjected to terminal sterilization.

Manufacturers of medical devices that are required to be sterile must prepare evidence that the device complies with:

- Essential Principle 8.3 for devices that are supplied sterile
- Essential Principle 8.1 for devices that are able to be reprocessed

For more information, please see *Guideline 8.02 Essential Principles of Safety and Performance.*

For manufacturers of Class A devices that are required to be sterile, in addition to preparing a South African Declaration of Conformity, they must supply The Authority with conformity assessment evidence to demonstrate that the relevant Essential Principles have been met.

2.6 Classification rules for medical devices and IVDs

NOTE: This guideline presents the classification rules for a Medical Device or IVD, and should be read in conjunction with the Medicines and Related Substances Act, 1965 (Act 101 of 1965), and the Regulations to this Act.

Additional standards to consider for sterilization of Medical Devices are the most recent version of:

Standard	Title
ISO 11135	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 11137-1	Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11137-2	Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose
ISO 11137-3	Sterilization of health care products—Radiation—Part 3: Guidance on dosimetric aspects of development, validation and routine control
ISO 17665-1	Sterilization of health care products—Moist heat—Part 1: Requirements for the

	development, validation and routine control of a sterilization process for medical devices
ISO 14160	Sterilization of health care products -- Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives -- Requirements for characterization, development, validation and routine control of a sterilization process for medical devices
ISO 11737-1	Sterilization of medical devices—Microbiological methods—Part 1: Determination of a population of micro-organisms on products
ISO 11737-2	Sterilization of medical devices—Microbiological methods—Part 2: Tests of sterility performed in the validation of a sterilization process
ISO 13408-1	Aseptic processing of health care products—Part 1: General requirements
ISO 13408-2	Aseptic processing of health care products—Part 2: Filtration
ISO 13408-3	Aseptic processing of health care products—Part 3: Lyophilization
ISO 13408-4	Aseptic processing of health care products—Part 4: Clean-in-place technologies
ISO 13408-5	Aseptic processing of health care products—Part 5: Sterilization in place
ISO 13408-6	Aseptic processing of health care products—Part 6: Isolator systems
ISO 14937	Sterilization of health care products General requirements for characterization of a sterilizing agent and the development of routine control of a sterilization process for medical devices
ISO 17664	Sterilization of medical devices—Information to be provided by the manufacturer for the processing of re sterilisable medical devices

2.7 Application of classification rules

Manufacturers should consider all the Classification Rules when determining the appropriate classification for a device as more than one rule may apply, and the higher classification applies.

A high-level summary of the classification rules is noted in Diagram 1, below.

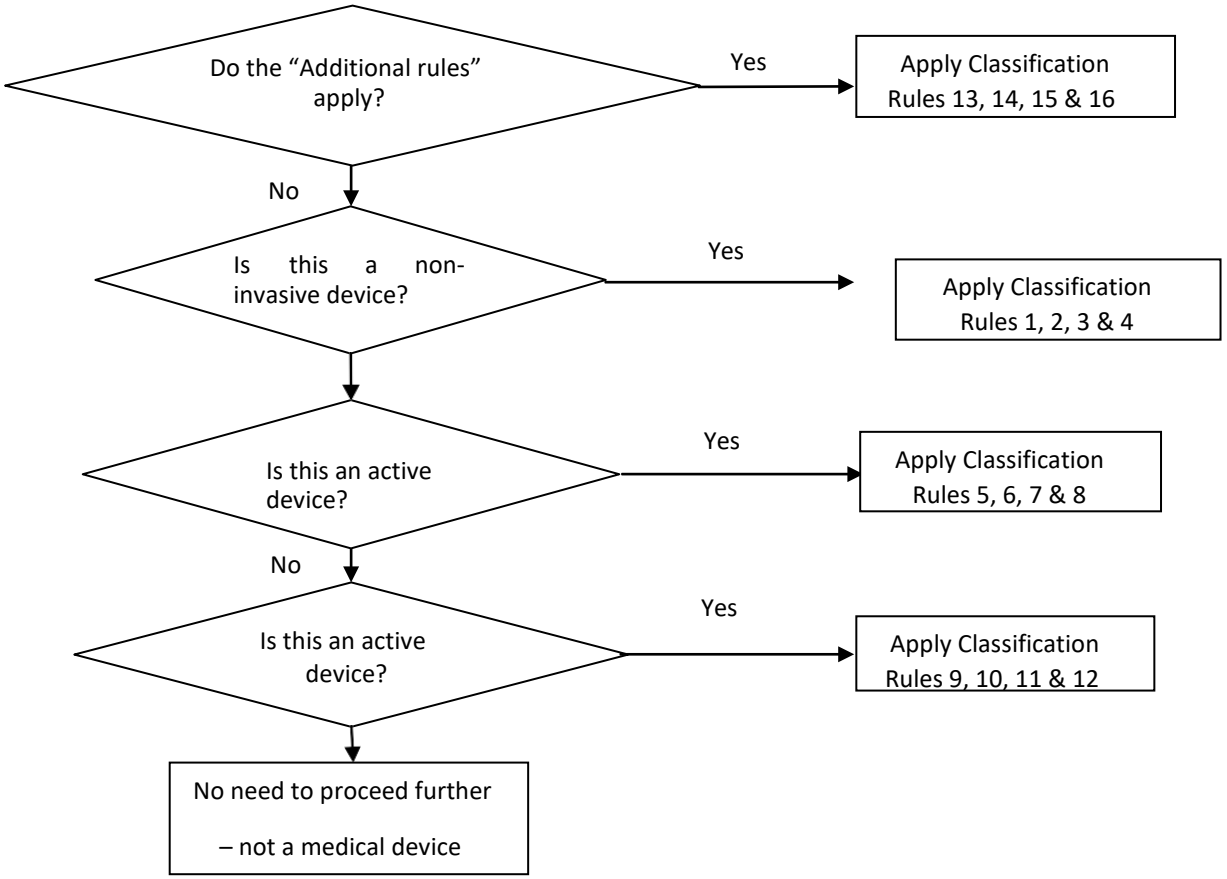


Diagram 1. Summary of Classification rules

A summary of the classification process is noted in Table 1 below.

If the device	then apply Classification Rule/s	Some examples are:
is invasive—that is, the device penetrates the body through a body orifice or is inserted into the body during surgery	5, 6, 7 & 8 - classifications vary depending on intended purpose	surgical eye probe, ophthalmic knife, eye cannula, ear/nose/throat forceps, internal tympanostomy tube, tongue depressor, intraoral x-ray sensor, oral gag, oral suction unit, thermometer, vaginal speculum, urethral bougie, anoscope, proctoscope, colonoscope, stomal peg, tracheostomy tube.
is active—that is, the device depends on a source of energy for its operation and converts energy	9, 10, 11 & 12 - classifications vary depending on intended purpose	diagnostic x-ray sources, MRI, air driven surgical drills and saws, patient monitors, electronic blood pressure measuring devices, diagnostic ultrasound, electronic stethoscopes/thermometers, software, gas regulators, radioactive seeds, mechanical infusion systems.

contains a medicine	13 - these devices are Class D	antibiotic bone cements, condoms with spermicide, heparin coated catheters, dressings incorporating an antimicrobial agent.
is for contraception or preventing sexually transmitted diseases	16 - classifications vary depending on intended purpose	condoms, contraceptive diaphragms, contraceptive intra- uterine devices (IUDs), surgically implanted contraceptive devices.
is for disinfecting, cleaning, rinsing or hydrating	15- classifications vary depending on intended purpose	contact lens solutions, comfort solutions, disinfectants for hemodialysis devices and endoscopes, sterilizers to sterilize medical devices, washer disinfectors.
not active and is intended to record x-ray diagnostic images	10(I)—these devices are Class B	x-ray films, photo-stimulable phosphor plates.
Contains viable OR non-viable animal tissues or derivatives	14 - these devices are Class D	biological heart valves, porcine xenograft dressings, catgut sutures, implants and dressings made from collagen, intra-ocular fluids, meniscul joint fluid replacement, anti-adhesion barriers, tissue fillers based on hyaluronic acid derived from bacterial fermentation processes.
is a blood bag	2—these devices are Class C	blood bags (including those containing or coated with an anticoagulant).
is an active implantable medical device	8 - these devices are Class D	implantable pacemakers, defibrillators and nerve stimulators,
is an active device to control, monitor, or directly influence the performance of an active implantable medical device	9(ii) - these devices are Class D	clinician's programming devices for pacemakers, patient control devices for nerve stimulation devices.
is a mammary implant	8 - these devices are Class D	Mammary / breast implants.
is not covered by any of the previous rules in this table	1, 2, 3 & 4 - classifications vary depending on intended purpose	devices intended to: - collect body liquid where a return flow is unlikely - immobilise body parts and/or to apply force or compression - channel or store substances that will eventually be delivered into the body - treat or modify substances that will be delivered into the body - dress wounds.

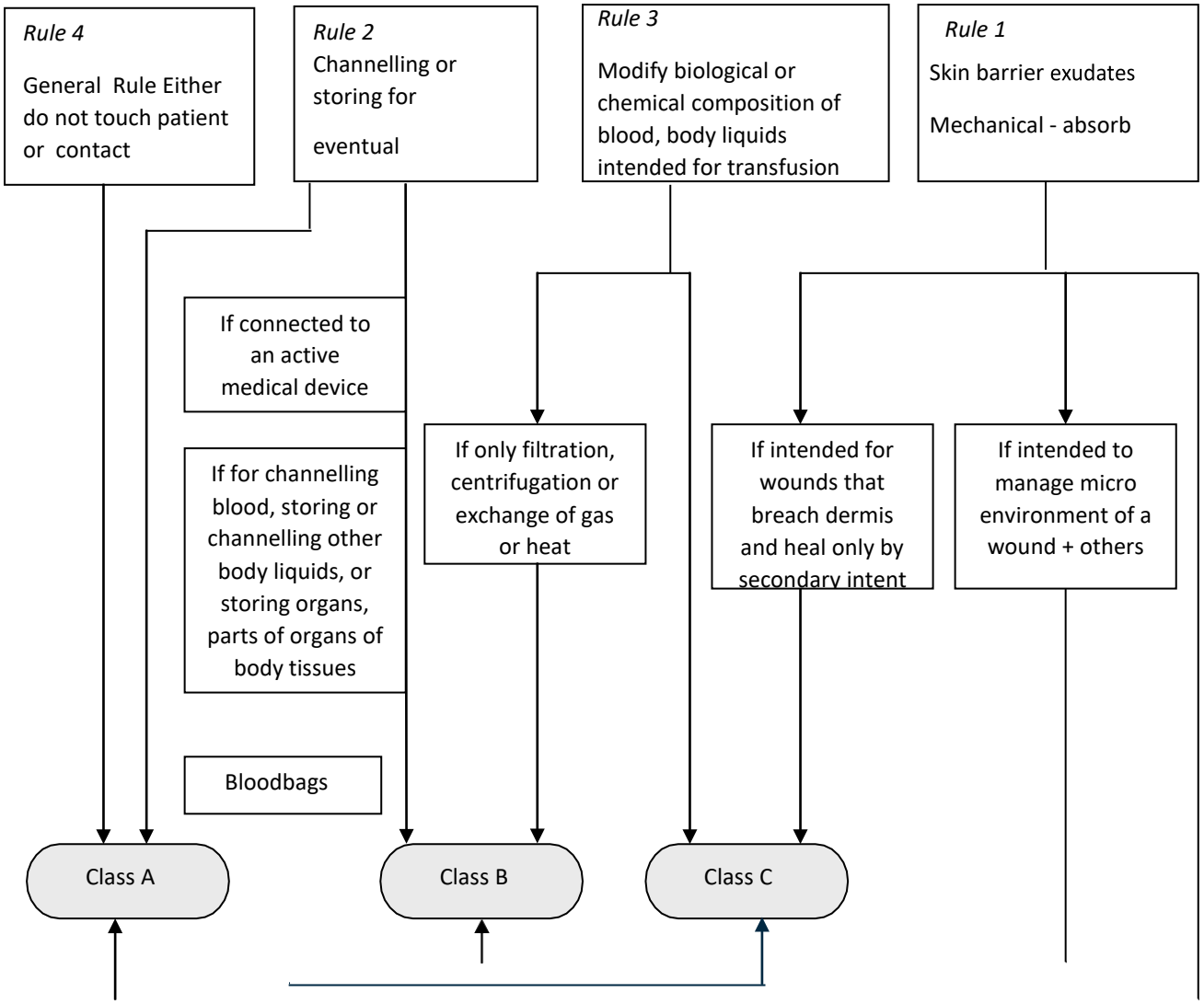
2.8 Duration of use classification: transient, short-term, and long-term use

The manufacturer or distributor in determining the classification, must take into account the duration of use:

Period of continuous use	Description
less than 60 minutes	transient
at least 60 minutes but not more than 30 days	short-
more than 30 days	long-term

2.9 Classification of non-invasive medical devices

This flowchart is a summary of the technical rules for classification of non-invasive Medical Devices.



2.9.1 Non-invasive medical devices

RULE 1: Non-invasive devices intended to have contact with injured skin

This rule covers wound dressings without consideration of the wound depth. The technology associated with these devices is well understood and they are not considered potentially hazardous to the patient.

Rule 1	Description
1(a) A non-invasive device to be used as a mechanical barrier or for compression or for absorption of exudates—Class A.	Examples: absorbent pads, island dressings, cotton wool, wound strips and gauze dressings to act as a barrier or absorb exudates from the wound. *Note: if the device is sterile, conformity evidence is required*.
1(b) A non-invasive device to be used in contact with injured skin (including a device the principal intention of which is to manage the microenvironment of a wound)—Class B.	Assists healing by controlling the level of moisture and regulating the humidity, temperature, levels of oxygen, other gases and pH values of the wound environment, or by influencing the process by other physical means. Examples: adhesives for topical use, polymer film dressings, hydrogel dressings and non-medicated impregnated gauze dressings.
1(c) A non-invasive device to be used for wounds that have breached the dermis and where the wounds can only heal by secondary intent—Class C.	Intended for severe wounds that have extensively breached the dermis, and healing is by secondary intent (by granulation from the base of the wound). Examples: dressings for chronic extensive ulcerated wounds, severe burn, severe decubitus wounds, or dressings providing a temporary skin substitute.

RULE 2: Non-invasive devices intended to channel or store body liquids or tissues, liquids or gases

Devices covered under this rule may include those that channel or store substances that will be eventually delivered into the body.

Rule 2	Description
2(a) A non-invasive device used to channel or store body liquids or tissues, liquids or gases that are to be infused, administered or introduced into a patient—Class A.	Intended to be used to channel or store liquids. Examples: administration sets for gravity infusion, syringes without needles.

2(b) A non-invasive device to channel or store a liquid or gas that is to be infused, administered or introduced into a patient and may be connected to an active medical device classified as Class B or higher—Class B.	Examples: oxygen tubing and masks; anesthetic tubing and breathing circuits; and syringes and tubing for infusion pumps.
2(c) A non-invasive device to channel blood, to store or channel other body liquids, or to store an organ, parts of an organ or body tissue that is to be later introduced into a patient—Class B.	Examples: Tubes for blood transfusion, devices to temporarily store and transport of organs for transplant or for long-term storage of biological substances and tissues such as corneas, sperm and human embryos.
2(d) A non-invasive device to store blood – i.e. blood bags -Class C. *Note: if the blood bags have a function greater than storing purposes and include systems for preservation other than anti-coagulants then other rules may apply.*	Examples: Blood bags which do not incorporate an anticoagulant

RULE 3: Noninvasive devices intended to modify the biological or chemical composition of blood, other body liquids or other liquids

Devices covered under this rule may include those that modify the biological or chemical composition of substances that will be delivered into the body.

Rule 3	Description
3(a) A non-invasive device to modify the biological or chemical composition of blood, other body liquids, or other liquids to be infused in the patient—Class C.	Devices intended to remove undesirable substances out of the blood by exchange of solutes such as hemodyalizers. Examples: Auto transfusion systems and devices used to separate cells such as gradient medium for sperm.
3(b) A non-invasive device to be used in treatment consisting of filtration, centrifugation or exchanges of gas or heat—Class B.	Examples: particulate filtration of blood in an extracorporeal circulation system, centrifugation of blood for transfusion or auto transfusion, removal of carbon dioxide from the blood and/or adding oxygen, and warming or cooling blood in the extracorporeal circulatory system.

RULE 4: Other non-invasive devices

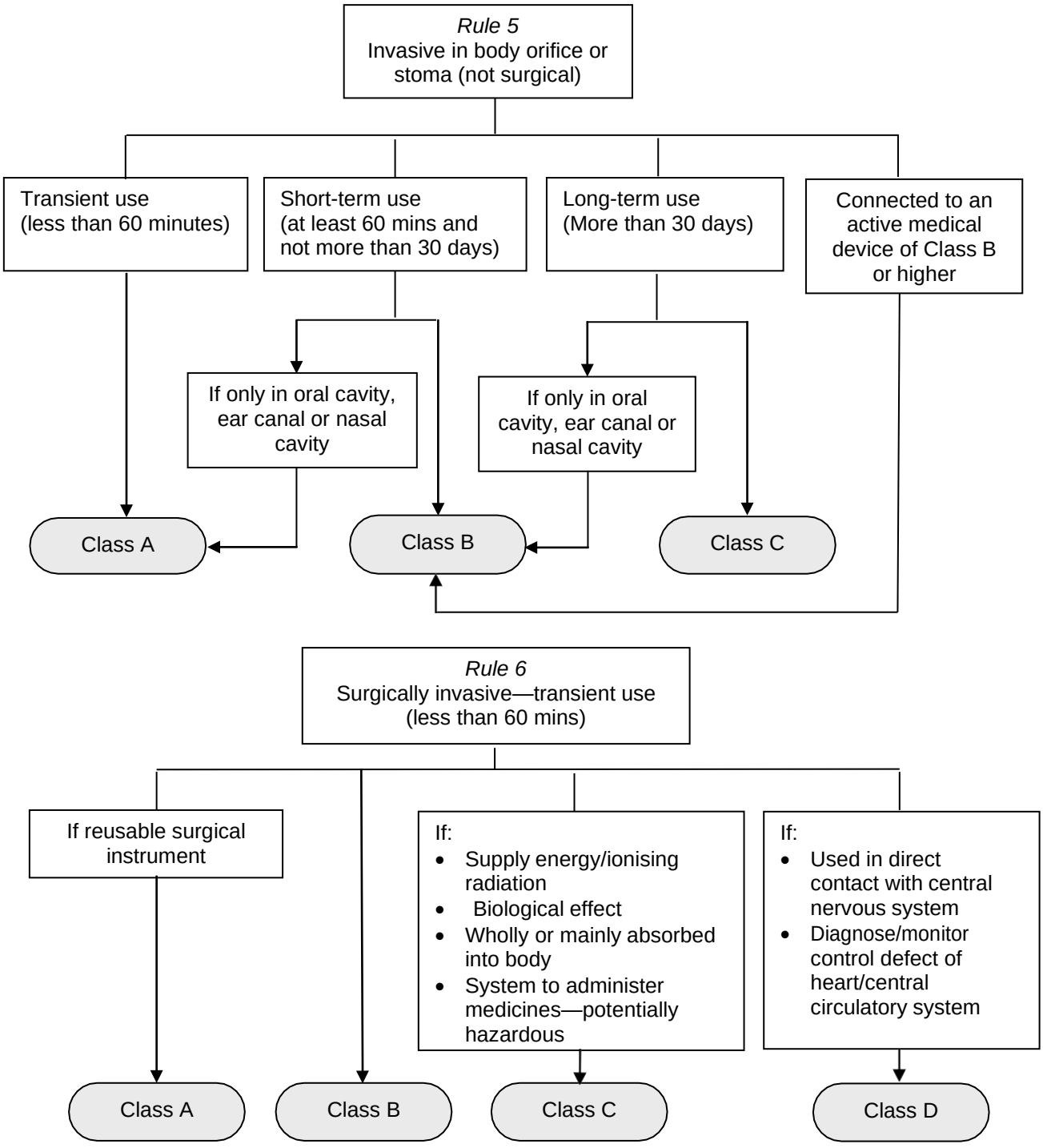
This rule applies to all medical devices that are not covered by a specific rule, devices that contact intact skin and devices that do not touch the patient.

Rule 4	Description
A non-invasive device is Class A, unless the device is classified at a higher level under another rule.	Devices used to collect body liquid where a return flow is unlikely. Examples: urine collection bottles, ostomy pouches, wound drainage collection bottles and incontinence pads. Devices used to immobilise body parts and/or to apply force or compression. Examples: non-sterile dressings, plaster bandages, cervical collars and gravity traction devices or compression hosiery.

2.9.2 Invasive Medical Devices

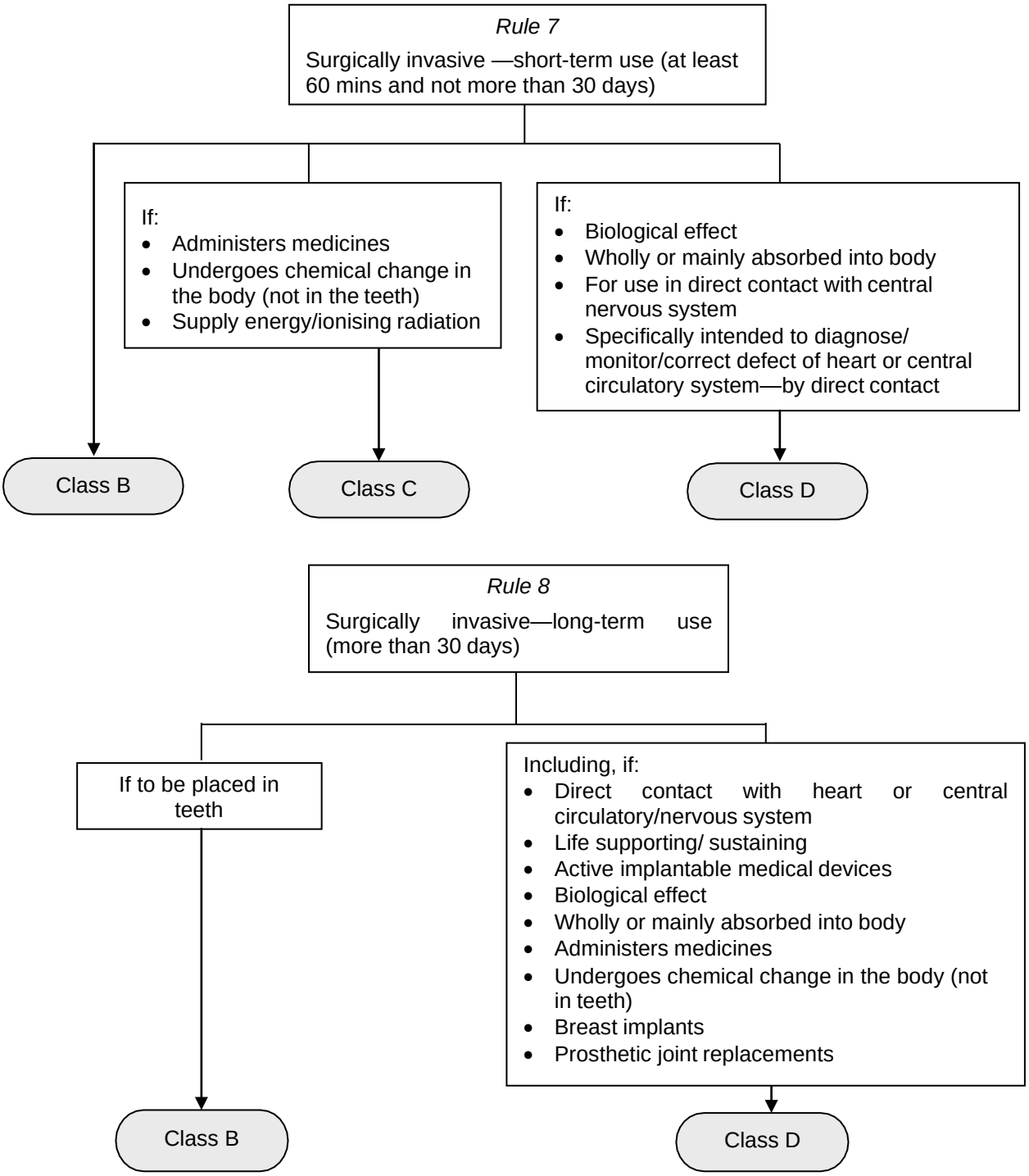
RULES 5 and 6: INVASIVE MEDICAL DEVICES - FLOWCHART

This flowchart is one of two summaries of the classification rules for invasive Medical Devices



RULES 7 AND 8: Invasive medical devices - Flowchart

This flowchart is one of two summaries of the classification rules for invasive Medical Devices.



RULE 5: Invasive devices intended to be used to penetrate body orifices

This rule covers devices that enter the body through existing body orifices (for example, ear, mouth, nose, eye) and surgically created stomas. Devices covered by this rule tend to be for diagnostic and therapeutic use in particular specialties (ear, nose, and throat; ophthalmology; dentistry; proctology; urology; and gynecology).

Rule 5	Description
5(a) Invasive devices that are not connected to an active medical device, or are intended for connection to a Class A medical device only and are for transient use—Class A.	Examples: handheld dental mirrors, dental impression materials, exam gloves, prostatic balloon dilation catheters.
5(b) Invasive devices that are not connected to an active medical device, or are intended for connection to a Class A medical device only and are for short- term use—Class B.	Examples: hard contact lenses, urinary catheters, tracheal tubes, stents, vaginal pessaries, perineal reduction devices.
5(c) Invasive devices that are for short-term use in the oral cavity as far as the pharynx, in an ear canal to the ear drum, or in a nasal cavity—Class A.	Examples: dressing for nose bleeds, dentures removable by the patient.
5(d) Invasive devices that are not connected to an active medical device, or are intended for connection to a Class A medical device only and are for long- term use—Class C.	Examples: long-term urinary catheters, artificial eyes, urethral stents, contact lenses for long-term continuous use.
5(e) Invasive devices for long-term use in the oral cavity as far as the pharynx or in an ear canal to the ear drum, or in a nasal cavity and are not liable to be absorbed by the mucous membrane—Class B.	Examples: orthodontic wire, fixed dental prostheses, fissures sealants.
5(f) Invasive device with respect to body orifices, to be connected to an active medical device that is classified as Class B or higher—Class B.	Examples: tracheostomy tubes connected to a ventilator, powered nasal irrigators, nasopharyngeal airways, heat and moisture exchangers, suction catheters or tubes for stomach drainage. (Independent of the time for which they are invasive)

RULE 6: Surgically invasive devices intended for transient use

This rule covers devices that are to be used continuously for less than 60 minutes and are used to create a conduit through the skin (needles, cannulae), surgical instruments (scalpels, saws) and various types of catheters, suckers.

Rule 6	Description
6(a) Surgically invasive device for transient use— Class B.	Examples: suture needles, hypodermic needles and syringes, suckers, surgical swabs, surgical gloves.
6(b) A reusable surgical instrument—Class A.	Examples: scissors, artery forceps, tissue forceps, tissue clamps, excavators, osteotomes, chisels.
6(c) A surgically invasive device for transient use to supply energy in form of ionizing radiation— Class C.	Examples: catheters containing or incorporating radioactive isotopes where the isotope is not intended to be released into the body.
6(d) A surgically invasive device for transient use to have a biological effect or be wholly or mainly absorbed—Class C.	Where the biological effect is an intended one rather than unintentional. e.g. bone wax "Absorption" refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body This rule does not apply for substances that are excreted without modification from the body *i.e.* insufflation gases for the abdominal cavity
6(e) A surgically invasive device for transient use to administer medicine via a delivery system, and where the administration is potentially hazardous to the patient—Class C.	Devices for repeated self-application where the dose and the medicine are critical. Examples: personal insulin injectors (commonly referred to as 'pens').
6(f) Surgically invasive device intended for use in direct contact with the central nervous system – Class D	
6(g) Surgically invasive device for transient use to diagnose, monitor, control or correct a defect of the heart, or central circulatory system through direct contact—Class D.	Examples: cardiovascular catheters, angioplasty balloon catheters, coronary artery probes.

RULE 7: Surgically invasive devices intended for short-term use

This rule covers devices to be used continuously for at least 60 minutes but not more than 30 days and are used in the context of surgery or post-operative care (for example, clamps and drains), infusion devices (cannulae and needles) and catheters of various types.

Rule 7	Description
7(a) Surgically invasive device for short-term use— Class B.	Examples: clamps, infusion cannulae, skin closure devices or temporary filling materials, some surgical retractors for example, chest retractors for cardiac surgery.
7(b) A surgically invasive device for short-term use to administer medicine - Class C.	Examples: intravenous cannulae.
7(c) A surgically invasive device for short-term use to undergo a chemical change in a patient's body (except a device intended to be placed in the teeth) - Class C.	Examples: surgical / tissue adhesives.
7(d) A surgically invasive device for short-term use to supply energy in the form of ionizing radiation - Class C.	Examples: bradytherapy devices.
7(e) A surgically invasive device for short-term use to have biological effect—Class D.	Examples: haemostatic sponge.
7(f) A surgically invasive device for short-term use to be wholly, or mostly, absorbed by a patient's body—Class D.	Examples: absorbable sutures.
7(g) A surgically invasive device for short-term use to be used in direct contact with the central nervous system—Class D.	Examples: neurological catheters, cortical electrodes, connonoid paddles.
7(h) A surgically invasive device for short-term use to be specifically used to diagnose, monitor, control or correct a defect of the heart, or central circulatory system, through direct contact with these parts of the body—Class D.	Examples: cardiovascular catheters, cardiac output probes and temporary pacemaker leads, thoracic catheters intended to drain the heart, including the pericardium and a carotid artery shunt.
7(i) A surgically invasive device for short-term use that is intended by the manufacturer to be placed in the teeth and to undergo a chemical change in the body—Class B. *Note: for this clause, a medical device to be placed in the teeth includes a device that is intended to penetrate a tooth but that does not enter the gum or bone beyond the tooth.*	Examples: dental adhesives used for root canal therapy.

RULE 8: Surgically invasive devices for long-term use and implantable devices

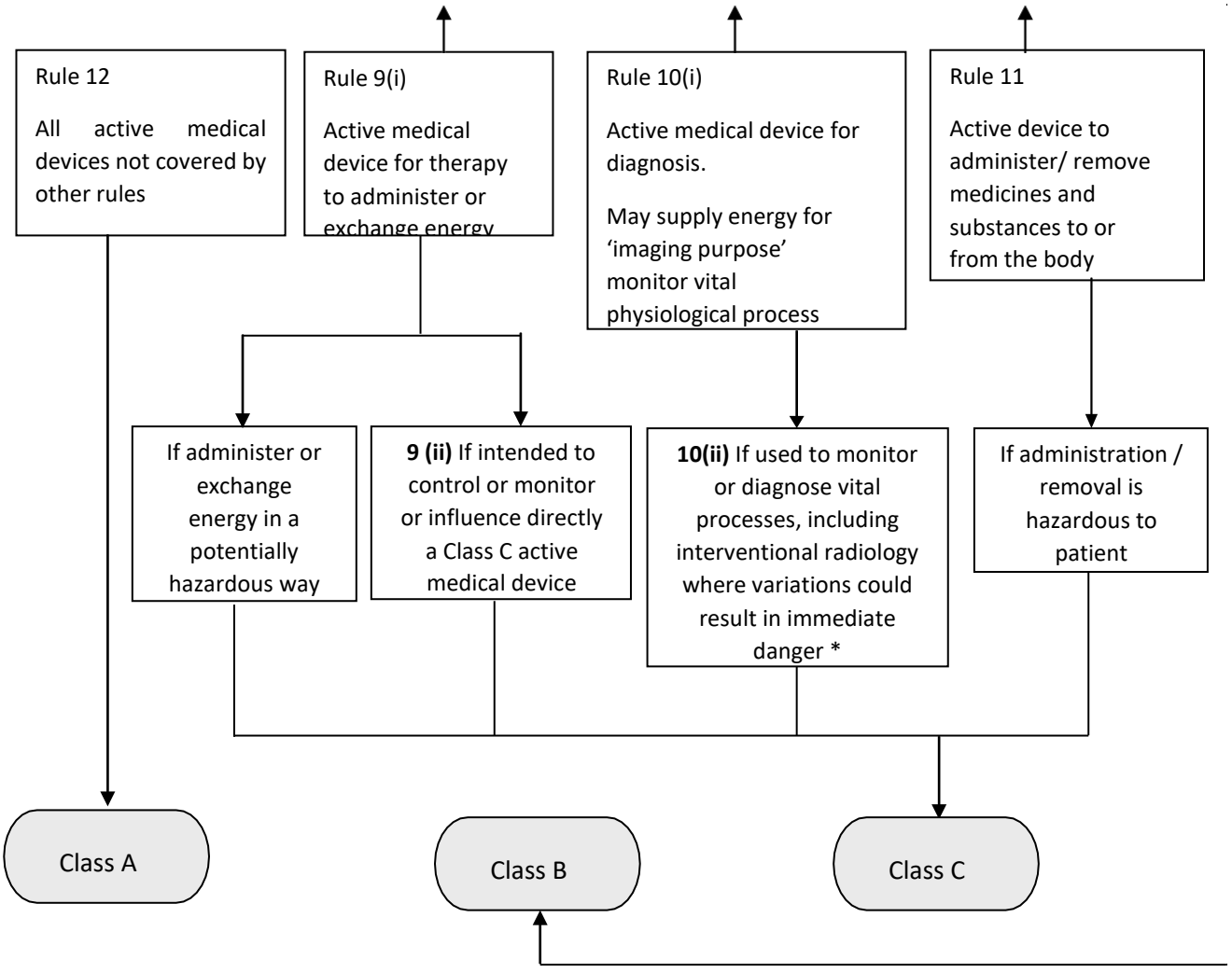
Devices covered by this rule **include** implants used in orthopaedic, dental, ophthalmic and cardiovascular fields. In addition, soft tissue implants used in plastic surgery are covered by this rule.

Rule 8	Description
8(a) All implantable devices and surgically invasive devices for long-term use and implantable devices— Class D.	Examples: implantable joint replacements, shunts, stents, nails, plates and screws, intra-ocular lenses, infusion ports, peripheral vascular grafts, bone cements, maxillo-facial implants.
8(b) A surgically invasive device for long-term use to be placed in the teeth—Class B.	Examples: bridges and crowns.
8(c) A surgically invasive device for long-term use to be used in direct contact with the heart, the central circulatory system or the central nervous system—Class D.	Examples: prosthetic heart valves, aneurysm clips, vascular prostheses, spinal stents, vascular stents, CNS electrodes, cardiovascular sutures.
8(d) A surgically invasive device intended to be life supporting or life sustaining—Class D	Example: pacemakers
8(e) A surgically invasive device intended to be active implantable medical device—Class D	
8(f) An *implantable* accessory to an active implantable medical device—Class D.	Example: electrode leads associated with pacemakers, defibrillators, nerve stimulators.
8(g) An active device to control, monitor or directly influence the performance of an active implantable medical device—Class D.	Example: clinician's programming device for pacemakers, patient control device for nerve stimulation devices.
8(h) A surgically invasive device for long-term use intended by the manufacturer to have a biological effect—Class D.	Implants claimed to be bioactive (Hydroxyapatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer)
8(i) A surgically invasive device for long-term use to be wholly, or mostly, absorbed by a patient's body— Class D.	Examples: absorbable sutures, bioactive adhesives and implants through the attachment of surface coatings such as phosphorylcholine.
8(j) A surgically invasive device for long-term use to administer medicine—Class D.	Examples: rechargeable non-active drug delivery systems.
8(k) A surgically invasive device for long-term use to undergo a chemical change in the patient's body (except a device that is to be placed in the teeth) - Class D.	Examples: surgical adhesive.
8(l) Breast Implants – Class D	
8(m) A surgically invasive device for long-term use that is intended by the manufacturer to be placed	Examples: dentine adhesives.

in the teeth and to undergo a chemical change in the body is Class B. *Note: for this rule a medical device to be placed in the teeth includes a device that is intended to penetrate a tooth but does not enter the gum or bone beyond the tooth.*	

2.9.3 Active medical devices

This flowchart is a summary of the classification rules for active Medical Devices



***NOTE:** Rule 10(i) also includes a device that is intended to emit ionising radiation and to be used for diagnostic or therapeutic interventional radiology; or a device that is intended to be used to control or monitor, or directly influence, the performance of a device that emits ionising radiation and used for diagnostic or therapeutic interventional radiology.*

"Active medical device" means any medical device of which the operation 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 to energy but excluding medical devices intended to transmit energy, substances or other elements between an active medical device and the user, without any significant change in the energy, substance or other element being transmitted;

RULE 9: Active medical devices for therapy

Active medical device for therapy means an active medical device that is intended by the manufacturer to be used either alone or in combination with another medical device, to support, modify, replace or restore biological functions or structures for the purpose of treating or alleviating an illness, injury or disability.

This rule covers devices that are electrical equipment used in surgery, devices used in specialized treatments and stimulation devices.

Rule 9	Description
9 (i)(a) An active medical device for therapy to administer energy to a patient, or exchange energy to or from a patient—Class B.	Examples: electrical—magnetic and electromagnetic energy muscle stimulators, external bone growth stimulators, TENS devices, electrical acupuncture; thermal energy—cryosurgery equipment, heat exchangers; mechanical energy—powered dermatomes, drills and dental hand pieces; light—phototherapy for skin treatment and for neonatal care; sound—hearing aids.
9 (i)(b) An active device to administer or exchange energy in a potentially hazardous way, having regard to the nature, density and site of application of the energy—Class C. (*The term "potentially hazardous" refers to the type of technology involved and the intended application)*	Examples: kinetic energy—lung ventilators; thermal energy—infant incubators, warming blankets for unconscious patients, blood warmers, heat exchangers used in intensive care; electrical energy—high-frequency electrosurgical generators, electrocautery, external defibrillators, electroconvulsive therapy equipment; coherent light—surgical lasers; ultrasound—lithotriptors, physiotherapy ultrasound devices;

	ionising radiation—radioactive sources for after-loading therapy, therapeutic cyclotrons, linear accelerators, therapeutic X-ray sources.
9(ii) An active device to control or monitor, or directly influence the performance of an active medical device for therapy of the kind in the previous entry—Class C.	Examples: external feedback systems for active therapeutic devices, after-loading control devices.

RULE 10: Active medical devices for diagnosis

Active medical device for diagnosis means an active medical device that is intended by the manufacturer to be used on a human, either alone or in combination with another medical device, to supply information for the purpose of detecting, diagnosing, monitoring or treating physiological conditions, states of health, illness or congenital deformities.

This rule covers devices that are used in ultrasound diagnosis and capture of physiological signals and devices used in diagnostic radiology.

NOTE: *Active devices for diagnosis are classified as Class A, in accordance with Rule 12, unless they are specifically covered by any of the clauses in Rules 9, 10 or 11.*

Rule 10	Description
10(i)(a) A device to supply energy that will be absorbed by a patient's body (except a device that illuminates the patient's body in the visible spectrum)—Class B.	Examples: magnetic resonance equipment, pulp testers, evoked response stimulators, diagnostic ultrasound.
10(i)(b) A device to be used to image in vivo distribution of radiopharmaceuticals in patients—Class B.	Examples: gamma cameras, positron emission tomography, single photon emission computer tomography.
10(i)(c) A device used for direct diagnosis or monitoring of vital physiological processes of a patient, excluding devices mentioned in the previous entry—Class B.	Examples: electrocardiographs, electroencephalographs, cardioscopes with or without pacing pulse indicators, electronic thermometers.
10(i)(d) A device to diagnose and or monitor vital physiological parameters of a patient, and the nature of variations monitored could result in immediate danger to the patient—Class C. *Note: For this clause 'variations monitored', is taken to mean that the result of monitoring could lead to immediate danger to the patient. This is typically,*	Examples: intensive care monitoring systems, biological sensors, blood gas analysers used in open- heart surgery, cardioscopes and apnoea monitors including those in home care.

but not always, accompanied by an alarm.	
10(ii)(a) A device to emit ionising radiation and to be used for diagnostic or therapeutic interventional radiology—Class C.	Examples: diagnostic x-ray sources, linear accelerators.
10(ii)(b) A device to control, monitor or directly influence the performance of a device in the previous entry—Class C.	Examples: auto exposure control systems, radiotherapy afterloading controls systems.

RULE 11: Active medical devices intended to administer or remove medicines, body liquids or other substances from a patient's body

This rule covers drug delivery systems and anaesthesia equipment.

Rule 11	Description
11 (a) An active device to administer or remove medicine, body liquids or other substances—Class B.	Examples: suction equipment, feeding pumps, jet injectors for vaccination.
11 (b) An active device to administer or remove medicine, body liquids or other substances in a way that is potentially hazardous to the patient, having regard to the substances, the part of the body concerned, and the characteristics of the device—Class C.	Examples: infusion pumps, ventilators, anaesthesia machines, anaesthetic vaporisers, dialysis equipment, blood pumps for heart-lung machines, hyperbaric chambers, pressure regulators for medical gases, medical gas mixers, moisture exchangers in breathing circuits, nebulisers where the failure to deliver the appropriate dosage form could be hazardous.

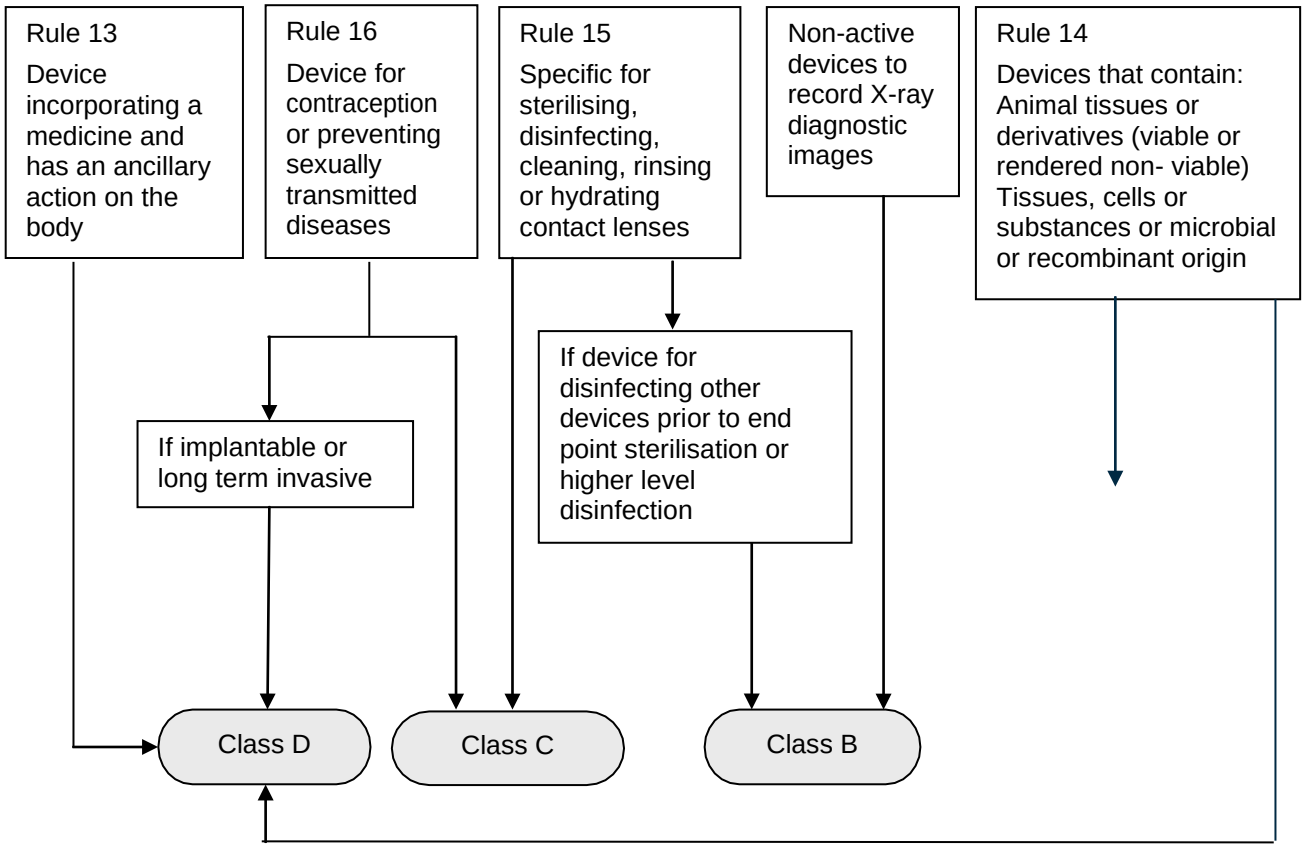
RULE 12: Active medical devices – General

This rule applies to active medical devices that are not covered by a specific rule.

Rule 12	Description
An active device is Class A, unless the device is classified at a higher level under another rule.	Examples: examination lights, surgical microscopes, diagnostic devices for thermography, active devices for recording, processing or viewing of diagnostic images, devices intended in general for external patient support (e.g. hospital beds, patient hoists, wheelchairs, dental patient chairs); Active diagnostic devices intended for thermography - Dental curing lights

2.9.4 Additional Classification Rules 13, 14, 15 & 16

This flowchart is a summary of the additional classification rules for Medical Devices



RULE 13: Devices incorporating a medicine

This rule covers medical devices that incorporate a medicinal substance including stable derivatives of human blood and blood plasma that assists the function of the device.

Rule 13	Description
13 A device incorporating a substance that if used separately would be a medicine and has an ancillary action on the body—Class D.	Examples: antibiotic bone cements, condoms with spermicide, heparin-coated catheters, dressings incorporating an antimicrobial agent where the purpose of such an agent is to provide ancillary action on the wound. Endodontic materials with antibiotics - Ophthalmic irrigation solutions principally intended for irrigation, which contain components which support the metabolism of the endothelial cells of the cornea - Dressings incorporating an antimicrobial agent where the purpose of such an agent is to provide ancillary action on the wound - Contraceptive intrauterine devices (IUDs) containing copper or silver - Drug

	eluting stents, e.g. coronary, pulmonary

RULE 14: Devices containing animal or human cells / tissues or derivatives, or microbial or recombinant tissues, cells or substances

This rule covers devices that contain or are made of animal tissues that have been rendered non-viable or derivatives from such tissues also being non-viable, or microbial or recombinant tissues, cells or substances.

Rule 14	Description
14(a) Devices that contain animal or human cells or tissues or derivatives, whether viable or that have been rendered non-viable, are Class D. Devices that contain tissues, cells or substances of microbial or recombinant origin are Class D, even if the device is only intended to come into contact with intact skin.	Examples: biological heart valves, porcine xenograft dressings, catgut sutures, implants, dressings made from collagen. Devices utilising hyaluronic acid of animal origin Examples: intra-ocular fluids, meniscule joint fluid replacement, anti-adhesion barriers, tissue fillers based on hyaluronic acid derived from bacterial fermentation processes.
14(b) Devices that only contains animal tissues that have been rendered non-viable and the device is only intended by the manufacturer to come into contact with intact skin – Class A	Examples: leather straps associated with limb prostheses.

RULE 15: Devices intended for sterilising, disinfecting, cleaning, rinsing etc

This rule covers various contact lens fluids and substances or equipment to disinfect another medical device. It does not cover devices that clean by a physical action only.

Rule 15	Description
15(a) A device specifically for sterilising medical devices, or disinfecting as the end point of processing - Class C.	Examples: hard contact lens solutions, comfort solutions.
15(b) A device intended for disinfecting medical devices prior to end point sterilization or higher level disinfection – Class B	Disinfectants specifically intended for non-invasive medical devices and equipment such as sterilizers specifically intended to sterilize medical devices in a medical environment and washer disinfectors; Washers-disinfectors intended specifically for

	disinfecting non-invasive medical devices.
15(c) A device specifically for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses - Class C. *Note: this clause does not apply to a medical device that is intended only to clean another medical device (other than contact lenses) by means of physical action—these devices are Class A.*	Denture disinfecting products; Washers-disinfectors for endoscopes; Disinfectants for the fluid pathways of haemodialysis equipment; Disinfectants for ocular prosthesis, intraosseous transcutaneous amputation prosthesis, surgical equipment and invasive dental equipment

RULE 16: Devices for contraception or prevention of sexually transmitted diseases

Some devices covered by this technical rule may perform both functions, for example, condoms.

Rule 16	Description
16 (a) A device for contraception or the prevention of sexually transmitted diseases—Class C.	Examples: condoms, contraceptive diaphragms.
16 (b) An implantable or invasive device for long-term use—Class D.	Examples: contraceptive intrauterine devices (IUDs), surgically implanted contraceptive devices.

2.9.5 Classification examples

The following examples are provided to demonstrate the importance of considering all the classification rules for a medical device to ensure that the medical device is appropriately classified. The examples will not include all the possible medical devices that may be on the market - they are intended to demonstrate how different variables affect the classification of a medical device. There may be several classification rules that apply to a medical device - if this happens the higher classification applies.

Warming Blanket

Intended purpose: To re-warm patients who are cold (hypothermic or recovering post-surgery). These patients may be unconscious.

Description	Variable/comments	Classification Rule	Classification
A large piece of fabric material blanket specially designed to keep a person warm and/or to prevent the further loss of body	Not powered	Rule 1	Class A

heat, often in an emergency situation			
Blanket used to blow warm air onto patient in hypothermia, post-surgery, (person unable to regulate own body temperature)	Electrically powered Potentially hazardous as patient may get burned or overheated; may have peripheral neuropathy (so not able to feel the intensity of the heat), may not be able to indicate if the blanket is too hot (e.g. neonates, unconscious patients). If a patient's blood pressure is critically low when the therapy is first applied, the applied heat may be detrimental to maintaining adequate blood pressure, as resulting vasodilation reduces blood pressure	Rule 9 (i) (b)	Class C

Nebuliser

Intended purpose: To deliver particles of medication/moisture (typically bronchodilators such as salbutamol) **to the airways and lungs.**

Description	Variable/ Comments	Classification Rule	Classification
A compressor that pumps compressed air through the fluid to be nebulised, thus forming droplets/vapour and carrying this into the airways during inspiration	Electrically powered	Rule 9(i)(a)	Class B
A fast-track nebuliser is able to nebulise more fluid per minute, and with finer droplets that reach more deeply into the lungs	Electrically powered—delivers medication in a more potent form than a standard nebuliser and the administration of medicine at an incorrect rate can be life threatening	Rule 9(i)(b)	Class C

Dressings

Intended purpose: To be applied to a wound in order to promote healing and/or prevent further harm.

Description	Variable/ Comments	Classification Rule	Classification
Adhesive dressing strip—not sterile	Not sterile	Rule 1(a)	Class A
Adhesive dressing strip—sterile	Sterile	Rule 1(b)	Class B

Adhesive dressing strip—with silver	Has silver (microbial agent) to assist in healing. The silver is a medicine	Rule 13	Class D
Compression bandage used for sprains	Used for compression to assist in injury management	Rule 1(a)	Class A
A wound dressing for deep wounds and ulcers that have breached the dermis containing alginate to absorb exudate	Contains alginate of microbial origin	Rule 14	Class D
A wound dressing for deep wounds and ulcers that have breached the dermis containing alginate to absorb exudate	Contains alginate of non- microbial origin. Heals by secondary intent	Rule 1 (c)	Class C
A wound dressing including materials of biological origin, such as collagen, sodium hyaluronate, chondroitin sulphate	Contains materials of biological origin	Rule 14	Class D
A non-sterile, trauma covering used to maintain the stability of a burn patient *en route* to a hospital. Dressing is coated in a gel containing anaesthetic	Contains medicine	Rule 13	Class D
A non-sterile, trauma covering used to maintain the stability of a full thickness burn patient *en route* to a hospital. Dressing is coated in a gel that does not contain any active medicine ingredients	Breached the dermis. Does not contain medicine	Rule 1(c)	Class C

Fixation Screws

Intended purpose: To hold plates or nails to bone, fasten soft tissue to bone or provide interfragmentary stabilisation for bone.

Description	Variable/ Comments	Classification Rule	Classification
Metal fixation screw; permanent implant	Permanently implanted	Rule 8	Class D
Metal fixation screw—used to hold bone together for up to 30 days (for example, to support healing of a fracture)	Short-term use	Rule 7	Class B

Metal fixation screw—used to hold bone together temporarily during surgery	Transient use	Rule 6	Class B
Absorbable fixation screw; permanent implant, absorbed into body	Will be absorbed into body	Rule 8	Class D
Fixation screw that has direct contact with central circulatory or central nervous systems	Location in body - direct contact with high-risk areas (central circulatory or central nervous systems).	Rule 8	Class D

2.10 Classification of IVD Medical Devices

2.10.1 OVERVIEW

The medical devices regulatory framework has a classification system for medical devices and IVDs, as per the regulations of Act 101 of 1965.

A medical device, other than an IVD medical device, has the medical device classification applying under the classification rules set out in the Technical Rules for Classification of Medical Devices.

An IVD medical device has the medical device classification applying under the classification rules set out in the Technical Rules for Classification of IVDs.

The classification levels for IVDs are:

Classification	Level of risk
Class A	no public health risk or low personal risk
Class B	low public health risk or moderate personal risk
Class C	moderate public health risk or high personal risk
Class D	high public health risk

The same classification rules apply to both commercial IVDs and in-house IVDs.

The manufacturer or distributor is responsible for determining the class of an IVD using the classification rules and having regard to:

- the manufacturer's intended use of the device; and
- the level of risk to the patient and the public (taking into account the likelihood of harm and the severity of that harm).

Identical devices may be classified differently if they are to be used for different diagnostic purposes. This is why the manufacturer's intended use of the device is critical to determining the appropriate class. The intended use can be obtained from the:

- Information provided with the IVD (including Instructions for Use and labelling)
- Advertising materials
- Design dossier (if applicable).

NOTE: *There may be medical devices or IVDs where the classification in South Africa is different to the classification in other countries. The manufacturer or distributor should take into account the South African requirements when determining the classification of a device that is to be supplied in South Africa.*

2.11 Principles for application of the classification rules

The classification rules are based on the manufacturer's intended purpose, taking into account the degree of risk involved to the patient and the public. The classification must be consistent with the information accompanying the IVD including the labels, Instructions for Use, brochures and operating manuals. If the intended purpose of the device is not clear, The Authority will request further clarification from the manufacturer and may also consider the purpose generally accepted in clinical and laboratory practice.

All the classification rules must be considered to determine the classification of the IVD. In some cases, more than one classification rule may be applicable to an IVD, but if this occurs the higher risk classification applies. There are exceptions to this principle, whereby a number of the classification rules state that despite certain other rules, a particular risk classification should always apply to a type of IVD. These include for example, Rule 1.5 which specifies that IVDs that are non assay-specific quality control material are Class B IVDs.

A number of IVDs are supplied with, or are required to be used in combination with other IVDs, non-IVD medical devices or accessories to medical devices. The classification rules must be applied separately to each device. An accessory to an IVD is described as an item that its manufacturer specifically intends to be used together with an IVD, to enable that IVD to be used as intended. Accessories are classified independently of the IVD that they are to be used with.

Materials that are intended to be used for the calibration or quality control of a particular named assay are considered to be part of a single assay with a common intended purpose. Therefore, they have the same risk classification as each of the other assay components based on the common intended purpose of the assay,

even if these materials are sold separately.

If one or more IVDs are supplied as part of a system or a procedure pack, the class for the entire pack is the highest class of any individual IVD in the pack. For example, if a procedure pack contains a selection of Class A, B and C IVDs, then the entire pack is classified as a Class C IVD.

If a procedure pack contains a mixture of IVDs and non-IVD medical devices, the individual component of the highest Class will determine the overall classification of the procedure pack. The individual device of the highest Class will also determine if the procedure pack is to be included in the IVD Register as an IVD medical device or a non-IVD medical device. For example, a procedure pack contains a portable prothrombin time meter (Class A IVD), test strips or cartridges for prothrombin time self-testing (Class C IVD), and a lancet (Class B medical device) for obtaining a blood specimen. The procedure pack would take on the highest classification assigned to any individual component, namely Class C IVD, and is required to be included in the IVD Register as an IVD medical device. When an IVD and a medical device within a procedure pack are of the same classification level (equivalent risk class) the primary intended purpose of the device is to be considered to determine whether the pack is included on the Register as an IVD or a medical device. Where components of a procedure pack are also supplied separately, they need to be separately included in the Register E.g. Medical devices such as lancets.

In the event of a dispute resulting from application of the classification rules, The Authority shall determine the classification

Software:

- that fits the definition of a medical device is also an active medical device since it relies on an energy source for its operation
- that is intended to make a device operate, control a device, or influence the functions of a device generally falls in the same classification as the device
- intended as an accessory to a medical device should be classified separately from the device with which it is used
- is considered an accessory when it is not essential to the operation of the device.

2.12 Classification rules for IVDs

2.12.1 Classification Rule 1 - Detection of transmissible agents posing a high public health risk

An IVD medical device intended to be used for any of the following purposes is classified as a Class D IVD medical device:

a) to detect the presence of, or exposure to, transmissible agents in blood, blood components, blood products, cells, tissues or organs or any derivatives of these products of human or animal origin, in order to assess their suitability for transfusion or transplantation;

b) to detect the presence of, or exposure to, a transmissible agent that causes a serious disease with a high risk of propagation.

2.12.2 Classification Rule 2 - Detection of red blood cell antigens and antibodies and non-red cell typing

(1) An IVD medical device is classified as a Class C IVD medical device if:

a) The device is intended to be used for detection of biological markers in order to assess the immunological compatibility of blood, blood components, blood products, cells, tissues or organs that are intended for transfusion or transplantation; and

b) The device is not one of the devices mentioned in subclause (2).

(2) An IVD medical device intended to detect the following markers is classified as a Class D IVD medical device:

a) ABO system - ABO1 (A), ABO2 (B), ABO3 (AB);

b) Rhesus system - RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e);

c) Kell system - KEL1 (K);

d) Kidd system - JK1 (Jka), JK2 (Jkb); and

e) Duffy system - FY1 (Fya), FY2 (Fyb).

2.12.3 Classification Rule 3 - Detection of transmissible agents or biological characteristics posing a moderate public health risk or a high personal risk

(1) An IVD is classified as Class C IVD medical devices if it is intended for any of the following uses:

a) detecting the presence of, or exposure to, a sexually transmitted agent;

b) detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation;

c) detecting the presence of an infectious agent where there is a significant risk that an erroneous result would cause death or severe disability to the individual or foetus being tested;

d) pre-natal screening of women in order to determine their immune status towards transmissible agents;

e) determining infective disease status or immune status where there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient;

f) the selection of patients;

i. for selective therapy and management; or

ii. for disease staging; or

iii. in the diagnosis of cancer;

g) human genetic testing;

h) to monitor levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient;

i) the management of patients suffering from a life-threatening infectious disease;

j) screening for congenital disorders in the foetus.

NOTE: For paragraph (f) an IVD medical device would fall into Class B under clause 3.3.5 if:

k) a therapy decision would usually be made only after further investigation; or

l) the device is used for monitoring.

(2) Despite subsection (1) an IVD is classified as a Class C IVD medical device if it is used to test for

transmissible agents included in the list of Notifiable conditions as published from time to time.

2.12.4 Classification Rule 4 - IVD medical devices for self-testing

An IVD medical device for self-testing is classified as a Class C IVD medical device unless:

a) the result of the examination is not determining a serious condition, ailment, or defect; or

b) the examination is preliminary and follow-up additional testing is required.

2.12.5 Classification Rule 5 - Non assay-specific quality control material

Despite rules 1 to 4, an IVD medical device that is intended to be used as non assay-specific quality control material is classified as a Class B IVD medical device.

2.12.6 Classification Rule 6 - Reagents, instruments etc.

(1) A reagent or other article that possesses specific characteristics, intended by the manufacturer, to make it suitable for in vitro diagnostic procedures related to a specific examination is classified as a Class A IVD medical devices.

(2) Despite rules 1 to 5, the following IVD medical devices are classified as Class A IVD medical devices

a) an instrument, intended by the manufacturer, specifically to be used for in vitro diagnostic procedures;

b) a specimen receptacle;

c) a microbiological culture medium.

In this clause:

"examination" means a set of operations having the object of determining the value or characteristics of a property.

Note 1. In some disciplines (for example, microbiology) an examination is the combination of a number of tests, observations or measurements.

specimen receptacle" means a device, whether vacuum-type or not, specifically intended by its manufacturer for the primary containment and preservation of a specimen derived from the human body for the purpose

of in vitro diagnostic examination.

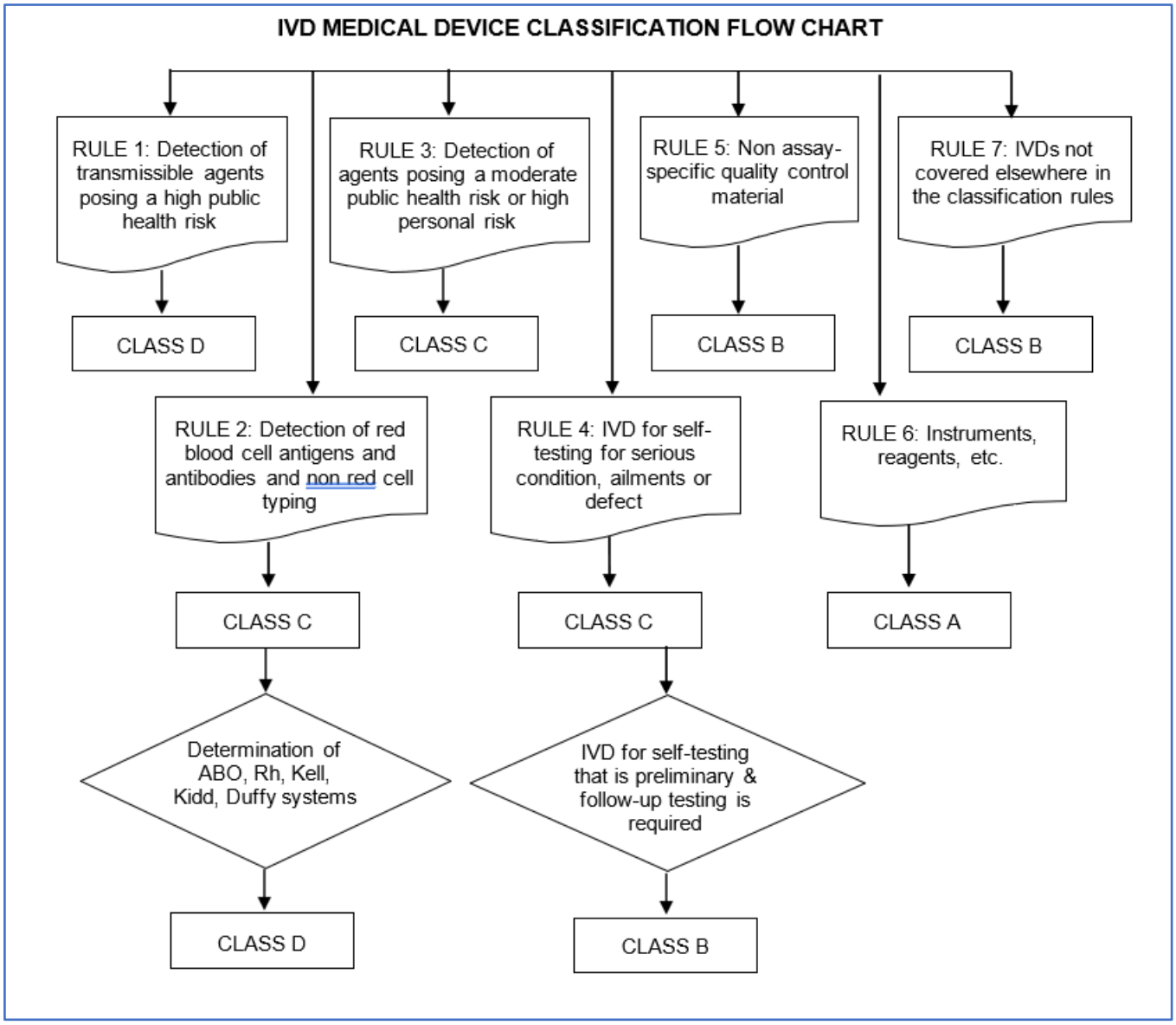
NOTE 1. A specimen receptacle is considered to be an in vitro diagnostic device.

NOTE 2. A product for general laboratory use is not an in vitro diagnostic medical device unless the product, in view of its characteristics, is specifically intended by its manufacturer to be used for in vitro diagnostic examination.

2.12.7 Classification Rule 7 - Other IVDs are Class B IVD medical devices

An IVD medical device not mentioned in rules 1 to 7 is classified as a Class B IVD medical device.

2.12.8 IVD Classification Flow Chart



2.13 Rationale and examples for classification rules for IVDSs

2.13.1 Classification Rule 1 - Detection of transmissible agents posing a high public health risk

An IVD medical device intended to be used for any of the following purposes is classified as a Class D IVD medical device:

a) to detect the presence of, or exposure to, transmissible agents in blood, blood components, blood products, cells, tissues or organs or any derivatives of these products of human or animal origin, in order to assess their suitability for transfusion or transplantation;

b) to detect the presence of, or exposure to, a transmissible agent that causes a serious disease with a high risk of propagation.

Rationale:

Devices captured by this rule pose a high public health risk.

Rule 1 is presented in two parts - paragraph 1 (a) describes IVDs that are used to establish the safety of blood and blood components for transfusion, or cells, tissues and organs for transplantation. In most cases, the result of the test is a major determinant as to whether the donation or product will be used.

Paragraph 1 (b) describes IVDs that are used to diagnose clinical infections that cause serious diseases with a high risk of transmission from person to person in the population.

Serious diseases are those:

- that may result in death or long-term disability; and
- that are often incurable or require major therapeutic interventions; and
- where an accurate diagnosis is of vital importance to mitigate the public health impact of the condition.

Rule 1 applies to all assays used to determine suitability for transfusion or transplantation as part of the laboratory's infectious disease testing algorithm, and includes front-line or screening assays, confirmatory assays, supplemental assays, and IVDs that detect structural components or surrogate markers of transmissible agents that cause serious disease.

Some IVDs are intended only to be used in a diagnostic setting but are identical to those intended to be used

for screening blood and tissue donations. These IVDs may be classified according to other rules if Rule 1 (b) does not also apply, provided the Sponsor can provide assurance that the IVD is marketed in accordance with the alternate classification. For example, a syphilis assay can be classified as a Class D IVD if it is intended to screen blood and tissue donations, but is a Class C IVD as per rule 3 (1) (a) if it is intended for diagnostic purposes only.

Examples:

All tests used by the Blood Service for testing of the blood supply are Class D IVDs, including screening and confirmatory assays for human immunodeficiency virus (HIV), Hepatitis C virus (HCV), Hepatitis B virus, HTLV I/II and syphilis. Any additional assays that are performed on a supplementary basis, such as those use to determine Cytomegalovirus status or suitability for Zoster immunoglobulin production, are also Class D IVDs.

All tests used by hospital-based laboratories that screen for infectious disease markers to determine suitability for organ or tissue transplantation under the requirements of their licence are Class D IVDs, including screening and confirmatory assays for HIV, HCV, Hepatitis B virus, HTLV I/II and syphilis.

Pyrogenicity tests (endotoxin activity assays) marketed for detection of bacterial contamination of blood components are Class D IVDs if the result of the test is a determinant as to whether or not the product will be used. By contrast, if the test is used for quality control purposes to measure the rate of contamination in a sample of products as part of the manufacturing process, then the test would be considered a manufacturing step and not an IVD.

All assays for the clinical diagnosis of infection by HIV 1 & 2, Hepatitis C virus, Hepatitis B virus and HTLV I/II are Class D IVDs. Assays for the clinical diagnosis of Hepatitis B virus are taken to include the following infectious disease markers: Hepatitis B surface antigen (HBsAg), Hepatitis B core IgM antibodies (anti-HBcore IgM), Hepatitis B core total antibodies (anti-HBcore tot) and Hepatitis B virus nucleic acid detection (HBV NAT).

Tests for detection of severe acute respiratory syndrome-associated coronavirus (SARS-CoV), highly virulent pandemic influenza, Variola virus (Smallpox virus) and viral haemorrhagic fevers such as Ebola virus or Marburg virus are Class D IVDs.

2.13.2 Classification Rule 2 - Detection of red blood cell antigens and antibodies and non-red cell typing

(1) An IVD medical device is classified as a Class C IVD medical device if:

a) The device is intended to be used for detection of biological markers in order to assess the immunological compatibility of blood, blood components, blood products, cells, tissues or organs that are intended for transfusion or transplantation; and

b) The device is not one of the devices mentioned in subclause (2).

(2) An IVD medical device intended to detect the following markers is classified as a Class D IVD medical device:

a) ABO system - ABO1 (A), ABO2 (B), ABO3 (AB);

b) Rhesus system - RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e);

c) Kell system - KEL1 (K);

d) Kidd system - JK1 (Jka), JK2 (Jkb); and

e) Duffy system - FY1 (Fya), FY2 (Fyb).

Rationale:

Devices captured by this rule present a high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation.

Classification rule 2 divides blood grouping IVDs into two subsets depending on the nature of the blood group antigen the IVD is designed to detect, and its importance in a transfusion setting. Essentially, all IVDs for testing for antigens or antibodies for any of the red blood cell markers not specifically mentioned in Rule 2 (2), and all IVDs used in tissue typing to test for human leukocyte antigens and antibodies, are Class C IVDs. The red blood cell markers captured by rule 2 (2) are critical to ensuring safe transfusion of blood and blood components, or transplantation of cells, tissues and organs, and are Class D IVDs.

Examples:

IVDs for testing for red blood cell antigens or antibodies from Blood Group A, Blood Group B, or Blood Group AB, within the ABO blood group system are Class D IVDs.

IVDs for testing for red blood cell antigens or antibodies for Cw or V from the Rhesus system; Cellano

(k) from the Kell blood group system; or any markers from MNS or Cartwright blood group systems are Class

C IVDs.

All IVDs used in tissue typing, to detect antigens and antibodies for any human leukocyte antigens are Class C IVDs.

2.13.3 Classification Rule 3 - Detection of transmissible agents or biological characteristics posing a moderate public health risk or a high personal risk

(1) An IVD is classified as Class C IVD medical devices if it is intended for any of the following uses:

a) detecting the presence of, or exposure to, a sexually transmitted agent;

b) detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation;

c) detecting the presence of an infectious agent where there is a significant risk that an erroneous result would cause death or severe disability to the individual or foetus being tested;

d) pre-natal screening of women in order to determine their immune status towards transmissible agents;

e) determining infective disease status or immune status where there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient;

f) the selection of patients;

i. for selective therapy and management; or

ii. for disease staging; or

iii. in the diagnosis of cancer;

g) human genetic testing;

h) to monitor levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient;

i) the management of patients suffering from a life-threatening infectious disease;

j) screening for congenital disorders in the foetus.

NOTE: For paragraph (f) an IVD medical device would fall into Class B under clause 3.4.5 if:

k) a therapy decision would usually be made only after further investigation; or

l) the device is used for monitoring.

(2) Despite subsection (1) an IVD is classified as a Class C IVD medical device if it is used to test for transmissible agents included in the list of Notifiable conditions as published from time to time.

Rationale:

IVDs captured by this rule present a moderate public health risk or a high individual risk, where an erroneous result could lead to a patient management decision resulting in a significant impact on patient outcome. These IVDs usually provide the critical or sole determinant for correct diagnosis.

The Department of Health publishes a list of diseases that are required to be notified nationally. A case definition is provided for each disease or disease group and a number of the case definitions rely on laboratory definitive evidence, laboratory suggestive evidence, clinical evidence (probable cases), or a combination of various markers to be present to require their notification. Contribution to the diagnosis of a particular disease through the results of testing for any of the markers mentioned as either suggestive or definitive evidence, are taken to be Class C IVDs. Where information presented in the Instructions for Use for a particular assay represents that an additional marker (beyond those specified in the case definitions) may also be used to diagnose a notifiable disease, these too are taken to be Class C IVDs.

IVDs that are used to detect the presence of, or exposure to, sexually transmitted agents are Class C IVDs. Tests for HIV, HCV and Hepatitis B virus and Tuberculosis, which are regarded as serious diseases (and are therefore Class D IVDs),

Examples:

Tests to detect the presence or exposure to a sexually transmitted agent such as *C. trachomatis* or

N. gonorrhoea are Class C3 IVDs. Antibodies to *C. trachomatis* may be used to indicate either current or previous infection and therefore are also regarded as a Class C IVD under Rule 3 (1) (a). Tests for the detection

of *Chlamydia* species to the genus level and for *Chlamydia pneumoniae* only are not captured by this rule, and would be regarded as Class B IVDs.

IVDs used to detect in cerebrospinal fluid or blood, the presence of an infectious agent that has a risk of limited propagation include the following as Class C IVDs: tests for the direct detection of

N. gonorrhoea or *Cryptococcus neoformans* antigens; tests for the detection of *Haemophilus influenza*

type B (Hib) antigen; tests for the detection of IgM antibodies to malaria parasites.

Tests that are used to detect the presence of an infectious agent, whereby an erroneous result would cause death or severe disability to the individual or foetus being tested are Class C IVDs. This includes tests for emerging serious diseases such as Hendra virus, or tests to confirm the presence or identity of methicillin-resistant *Staphylococcus aureus* (MRSA), either directly from a clinical specimen or from a cultured isolate (note that microbiological culture media is a Class A IVD under Rule 7). This rule also applies to other serious infectious diseases such as prion diseases or malaria.

Prenatal screening tests include a number of different analytes which together generate a testing profile for infections that may cause illness in pregnant women, and birth defects or serious infections in newborns. These tests are sometimes collectively referred to as a TORCH screen and are regarded as Class C IVDs. Tests usually include detection of antibodies to *Toxoplasma gondii*, *Rubella virus*, *Cytomegalovirus* (CMV), *Herpes simplex virus 1 & 2*, *Measles virus* and *Treponema pallidum*.

Tests that are used to select patients for selective therapy and management are Class C IVDs and include viral genotyping assays to establish a suitable course of therapy, or Her2/neu testing to select patients with breast cancer for treatment using the drug Herceptin.

Tests for tumour markers such as free prostate specific antigen (free PSA), or tests where results are expressed as a percentage or ratio against total PSA for use in differentiating between benign or malignant tumours are Class C IVDs.

Rule 3 (f) includes a note which describes tests where a therapy decision is only made after further investigation, or that are used for monitoring. Tests intended to be used for initial screening, such as a faecal occult blood screening test (FOBT) for bowel cancer, require further investigation if a positive result is obtained; and tests used only for monitoring disease status, such as a total PSA which may aid in the management of a prostate cancer patient are regarded as Class B IVDs under Rule 7.

Pharmacogenetic tests to predict metabolism of warfarin, or tests for other cytochrome P450 oxidative enzymes which may be used to gauge the metabolism rate of drugs are Class C IVDs.

All tests used for human genetic testing are Class C IVDs, for example tests for detecting the Philadelphia chromosome, Huntington's disease or cystic fibrosis.

Tests for therapeutic monitoring of immunosuppressive medicines such as cyclosporin and tacrolimus are Class CIVDs, due to the impact of an erroneous result on a patient and the potential for adverse transplantation outcome. Other tests for monitoring substances or biological components that are regarded as Class C IVDs include acute cardiac markers such as Troponin I, Troponin T and CKMB.

Class C IVDs used for the management of life-threatening infectious disease include viral load and genotyping assays for HIV and Hepatitis C virus.

Class C IVDs used for screening for congenital disorders include pre- and post-natal tests for trisomy 13, trisomy 18, trisomy 21 or Klinefelter's syndrome; tests for alpha-fetoprotein (AFP) when used in the detection of foetal open neural tube defects.

Software that is supplied as a "stand-alone" IVD, for use in the interpretation of a series of results obtained as part of a first trimester screening assessment, in order to determine foetal risk of trisomy 21 is a Class C IVD.

Software that is supplied as a "stand-alone" IVD, for use in staging or predicting severity of disease by means of an algorithm based on a combination of anthropometric measures and non-invasive biomarkers is a Class C IVD.

2.13.4 Classification Rule 4 - IVD medical devices for self-testing

An IVD medical device for self-testing is classified as a Class C IVD medical device unless:

a) the result of the examination is not determining a serious condition, ailment, or defect; or

b) the examination is preliminary and follow-up additional testing is required.

Rationale:

Self-testing IVDs are intended to be used by individuals with no scientific or technical expertise, or formal training in a medical field or discipline to which the test relates. Self-test devices can pose a low, moderate or

high personal risk and can therefore fall into Class A, Class B or Class C IVD.

The definition of ***IVD medical device for self-testing*** includes IVDs intended for use in the collection of a sample by a lay person and, if the sample is tested by another person (e.g. a laboratory) the results are returned directly to the person from whom the sample was taken without the direct supervision of a health professional who has formal training in a medical field or discipline to which the test relates. The Authority interprets 'direct supervision' to mean written or verbal communication from a health professional who is personally treating the person and therefore has already established a professional relationship with their client, or verbal communication with the person by a health professional who is able to explain the significance of the test and answer questions that the person may have regarding the interpretation of the result. This applies regardless of the nature of the result,

e.g. positive, negative, quantitative value.

Rule 4 classifies IVDs for self-testing as Class C IVDs if the condition, ailment or defect to which the test relates is generally considered to be:

- inappropriate to be diagnosed or treated without consulting a health professional
- beyond the ability of the average person to evaluate accurately, or be treated for safely without adequate supervision.

In situations where use of the self-test does not determine a serious condition or the result is purely preliminary, other classification rules apply. For example, a positive result from a pregnancy self-test kit will generally be followed up with a visit to the user's medical practitioner therefore a pregnancy self- test kit is not regarded as a Class C IVD, rather it is classified as a Class B IVD using rule 7.

Examples:

- System for self-monitoring of blood glucose - Class C IVD. Each of the individual components of a self-testing blood glucose monitoring system is classified individually, with the highest overall class applying to the system. So a glucose meter, as an instrument for in vitro diagnostic procedures, is classified as a Class A IVD as per rule 6, the glucose reagent test strips for use in self-testing are classified as Class C IVDs since an erroneous result obtained when self-testing for blood glucose may lead to a life-threatening situation and the lancet for obtaining a blood sample is classified as a Class B medical device. As a system intended for self-testing, a glucose meter, glucose reagent test strips and lancet would be classified as a Class C IVD.

- Urine self-test strips to detect glucose and other general urine chemistry analytes - Class B IVD.
- Pregnancy and fertility self-testing kits - Class B IVD.

2.13.5 Classification Rule 5 - Non-assay specific quality control material

Despite rules 1 to 4, an IVD medical device that is intended to be used as non-assay specific quality control material is classified as a Class B IVD medical device.

Rationale:

Devices in this class pose a low public health risk or moderate personal risk.

Quality control material is taken to be controls, calibrators and standards, and as a subset of this, non assay-specific quality control materials are those that are not assigned for use with a specific assay.

This rule does not apply to quality control materials that are assigned for use with a specific assay, or where the manufacturer of the quality control material has provided detailed information (e.g. references ranges) relating to a particular assay - these are taken to be the same risk class as the parent assay based on the common intended purpose, even if they are sold separately.

Examples:

- Non-assay specific control plasmas for use in coagulation studies.
- Non-assay specific control serum containing multiple biochemical analytes.
- Non-assay specific control serum, for use as an independent control for HCV antibody assays.
- A DNA or RNA probe supplied for use as a non-assay specific control for in situ hybridisation of targeted gene polymorphisms. Although an ISH probe is intended for use in human genetic testing and could therefore be regarded as a Class C IVD, under rule 5 despite any other classification rule, non-assay specific quality control material is a Class B IVD.

2.13.6 Classification Rule 6 - Reagents, instruments etc.

(1) A reagent or other article that possesses specific characteristics, intended by the manufacturer, to make it suitable for *in vitro* diagnostic procedures related to a specific examination is classified as a Class A IVD medical devices.

(2) Despite rules 1 to 5, the following IVD medical devices are classified as Class A IVD medical devices

a) an instrument, intended by the manufacturer, specifically to be used for in vitro diagnostic procedures;

b) a specimen receptacle;

c) a microbiological culture medium. In this clause:

"examination" means a set of operations having the object of determining the value or characteristics of a property.

Note 1. In some disciplines (for example, microbiology) an examination is the combination of a number of tests, observations or measurements.

"specimen receptacle" means a device, whether vacuum-type or not, specifically intended by its manufacturer for the primary containment and preservation of a specimen derived from the human body for the purpose of in vitro diagnostic examination.

NOTE 1. A specimen receptacle is considered to be an in vitro diagnostic device.

NOTE 2. A product for general laboratory use is not an in vitro diagnostic medical device unless the product, in view of its characteristics, is specifically intended by its manufacturer to be used for in vitro diagnostic examination.

Rationale:

Devices captured by this rule present a low individual risk and minimal or no public health risk.

Products for general laboratory use are not IVD medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination. For example, pipettes, test tubes and general consumables which are not specifically intended by the manufacturer to be used to perform a particular test are not considered IVD medical devices.

Stains are generally considered to be IVDs if they are intended by the manufacturer to be for a diagnostic purpose. Single staining solutions for diagnostic use are classified as Class A IVDs under rule 6 (1) only if they are supplied separately and without instructions on how to perform a particular staining procedure, because

they are regarded as general purpose reagents. If staining solutions are supplied either individually or as a kit, together with instructions linking that stain to a particular staining process, the staining solution or kit must be classified according to the overall intended purpose of the stain.

Stain powders or base ingredients used to prepare stains for use in a diagnostic setting are not considered to be IVDs because they are not finished products. However, once a powder or base ingredients have been made into a stain by a laboratory, the finished staining solution/s would be regarded as an IVD and an appropriate risk classification applied according to the overall intended purpose of the stain.

Due to their interdependence, an instrument or software that is specifically required to be used to perform a particular test will be assessed at the same time as the test kit even though the instrument itself is classified as Class A IVD.

Examples:

- Grams iodine solution which is individually supplied by a manufacturer without specific instructions for use in a Gram staining procedure is a Class A IVD because it may be used in multiple disciplines (e.g. clinical microbiology, histology, cytology).

  Conversely, a foetal cell staining kit, supplied with instructions for performing a Kleihauer stain to identify candidates required to receive more than one dose of anti-D immunoglobulin is a Class B IVD under rule 7. A ready-to-use Romanowski staining kit supplied for use in haematology for staining peripheral blood sme-rs to perform white cell differentiation and evaluation of red cell morphology is also a Class B IVD under rule 7.

- A separately supplied reagent labelled as intended for use with a specific microbial identification testing kit, in order to determine the biochemical identification of a clinical isolate is a Class B IVD, in line with the classification of the microbial identification IVD, e.g. 3 % hydrogen peroxide for use in a catalase test or tetra methyl-p-phenylenediamine (TMPD) for use in an oxidase test. Conversely, a general reagent labelled simply as 3 % hydrogen peroxide or TMPD, which is not manufactured and supplied specifically for in vitro diagnostic use, is not considered to be an IVD.

- Microscope counting chambers such as haemocytometers and chambered urinalysis slides labelled as being intended for the microscopic examination of urine and other body fluids are Class A IVDs because they are suitable for use across multiple disciplines or in several different diagnostic applications.

- Plain ground-glass microscope slides, although intended for an application related to microscopic analysis, are not generally intended to be used expressly as an IVD medical device.

- Except for specimen containers intended for use in self testing, evacuated or non-evacuated blood collection tubes, and specimen containers intended for the collection of urine, faeces, cell or tissue specimens for subsequent *in vitro* examination are Class A IVDs. General laboratory tubes that are used to contain reactions or to contain and store processed specimens are not considered to be specimen receptacles.

- Manual, automated or semi-automated instruments such as an enzyme immunoassay analyzer, an ESR analyzer, or a thermal cycler for performing nucleic acid amplification in a clinical specimen are Class A IVDs.

- General laboratory equipment such as water baths, centrifuges, balances and automatic pipettes are not considered to be IVDs unless they are specifically intended by the manufacturer (in product labelling or accompanying literature) to be used for an *in vitro* diagnostic examination e.g. blood bank tube centrifuge for spinning of blood grouping reactions.

- Prepared (ready to use) microbiological culture media, including agar containing selecting agents, antimicrobials, chromogenic agents or chemical indicators for colony differentiation are Class A IVDs. Dehydrated powders and agar bases are not considered to be IVDs.

- Class A IVD General Laboratory reagents are those that are suitable for use across multiple disciplines or a broad range of different purposes. Standard buffers (e.g. PBS) and saline solutions are not considered to be an IVD unless supplied specifically for use as an IVD.

- Non-assay specific instrument consumable reagents are considered to be Class A IVDs. For example a wash solution for use on instrument XYZ. The wash solution is not specific to a particular analyte, however is specified for use on instrument XYZ.

- When a separately supplied reagent is intended for use in determining a specific analyte or parameter, or it is for use with a particular IVD, or it has a clearly defined purpose relating to its use with a group of similar or closely related tests, the reagent will be classified according to the class of the analyte or parameter it is intended to be used with. For example, a diluent or lyse solution intended for use when performing a full blood count (FBC) will be classified according to the class of the FBC assay, that is, a Class B IVD; a kit or individually supplied reagents intended to

be used for the in-situ hybridisation of targeted gene polymorphisms, are classified under rule 3 as Class CIVDs for human genetic testing.

- A non-assay specific bacterial or viral RNA nucleic acid extraction kit intended for the extraction of pathogenic nucleic acid from a clinical specimen is a Class B IVD; a kit with a similar intended purpose of non-assay specific bacterial or viral RNA extraction, but which is dedicated for use on a specific instrument would be a Class A IVD.

2.13.7 Classification Rule 7 - Other IVDs are Class B IVD medical devices

An IVD medical device not mentioned in rules 1 to 7 is classified as a Class B IVD medical device Rationale

Devices captured by this rule present a moderate individual risk or a low public health risk.An erroneous result is unlikely to have a significant negative impact on patient outcome. The devices captured by this rule rarely provide the sole determinant for the correct diagnosis. If it is the sole determinant other information is available such as presenting signs and symptoms or clinical information, which may guide the physician.

This class also includes IVDs that detect infectious agents that are not easily propagated in a population.

Examples:

- Most biochemistry tests for blood gases, hormones, vitamins, enzymes, metabolic markers and substrates are Class B IVDs.

- IVDs for performing coagulation testing are generally regarded as Class B IVDs, including activated partial thromboplastin time (APTT), factor assays and prothrombin time testing (other than prothrombin time for self-testing, which is captured as a Class C IVD by rule 4).

- Biochemical tests for establishing the presumptive identification of microbiological culture isolates, or for determining antimicrobial susceptibility of microbiological culture isolates, are Class B IVDs; however, confirmatory identification or serotyping reagents for microbiological culture isolates are classified according to the analyte being detected, e.g. Salmonella poly-O antisera or Haemophilus influenza serotype b typing reagent are Class C IVDs

- Cell culture lines for the culture of viruses present in clinical specimens are Class B IVDs.

- Tests to detect infection by *Helicobacter pylori*, *Clostridium difficile*, Adenovirus, Rotavirus and *Giardia lamblia* are Class B IVDs.

- Pregnancy tests for self-testing are Class B IVDs.

3. REFERENCES

The following related documents are referenced:

a) SAHPGL-MD-06 Guideline for a licence to manufacture, import, export or distribute medical devices and IVDs

b) SAHPGL-MD-01 MEDICAL DEVICES and IVDs ESSENTIAL PRINCIPLES of SAFETY & PERFORMANCE

c) GHTF/SG1/N044:2008 Role of Standards in the Assessment of Medical Devices.

d) IMDRF/GRRP WG/N47: Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

e) WHO Global Model Regulatory Framework for Devices including in vitro Diagnostic Medical Devices – WHO Medical Device Technical series

f) ISO 14971 Medical Devices – Application of Risk Management to Medical Devices

g) ISO 13485 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

4. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces the old guideline for Classification of Medical Devices and IVDs, document number 8.05. It will be reviewed on this timeframe or as and when required.