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Medical Device Regulatory Convergence Project (MDRC)
Good Regulatory Practices & Technical Competencies

South African Risk Classification of Medical Devices and IVDs

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Background

Medical devices play a major role in health systems, they are needed to address the burden of disease, economic challenges, and infrastructure of many countries. The regulation of medical products has become increasingly complex with the globalization of product development, production and supply and the rapid pace of technological and social change in the context of limited financial and human resources.

SAHPRA aims to utilize reliance to make best use of available resources and expertise, avoid duplication and concentrate regulatory efforts and resources where most needed. Promote a more efficient approach to regulatory oversight, thereby improving access to quality-assured, effective and safe medical products over the entire life-cycle

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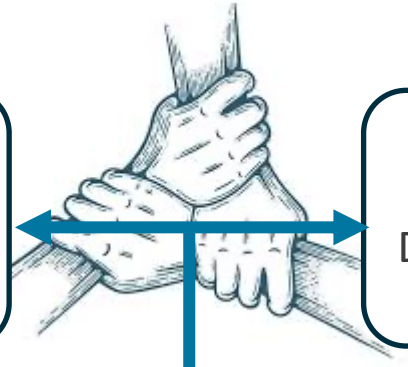
Background

Global harmonization task force (GHTF)



International Medical Device Regulatory Forum

South African Health Products Regulatory Authority

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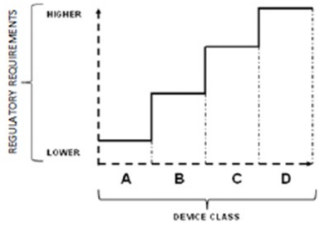
Background: GHTF/IMDRF

GHTF was established in 1993 with the purpose of harmonizing medical device laws globally. The GHTF was disbanded in 2011 and the IMDRF was conceived "as a forum to discuss future directions in medical device regulatory harmonization

Risk-based classification

GHTF/SG1/N77 Principles of Medical Devices Classification

CLASS	LEVEL	DEVICE EXAMPLES
A	Low hazard	Bandages / tongue depressors
B	Low-moderate hazard	Hypodermic needles / suction equipment
C	Moderate-high hazard	Lung ventilator / bone fixation plate
D	High hazard	Heart valves / implantable defibrillator



https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n15-2006-guidance-classification-060627.pdf

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11. Classification of medical devices and IVDs

(1) The following are the classes of medical devices and IVDs:

(a) Class A - Low Risk;

(b) Class B - Low-moderate Risk;

(c) Class C - Moderate-high Risk;

(d) Class D - High Risk,

where risk relates to the patient, user or to public health.

(2) Medical devices, except custom made medical devices, and IVDs must be registered v Council in terms of call up notices before they may be sold or used in the Republic.

(3) The Council must determine the classification of medical devices and IVDs in accc with the classification rules.

(4) Where the classification of a medical device or IVD is inconclusive and places it in mc one class, or between classes, the Council must, after following the classification rule: the medical device or IVD in the higher of the risk classes.

(5) The Council must consider the classification of a medical device or IVD individually into account its design and intended use.

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South African Health Products
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Building A
Loftus Park
Arcadia
Pretoria

8 March 2023

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

Legal Provision: Medical device Regulations and Classification guideline

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SA Risk Classification Guideline review

https://www.sahpra.org.za/document/guideline-for-classification-of-medical-devices-and-ivds/

Classification rules (NON-IVDS)

The manufacturer or distributor is responsible for determining the classification of a medical device using a set of classification rules supplied by The Authority, based on the:

- manufacturer's or distributor's intended use of the device or IVD
- level of risk to patients, users and other persons (the probability of occurrence of harm and the severity of that harm)
- degree of invasiveness in the human body
- duration of use and exposure.

NOTE: .

Once a rules-based system has been adopted, modifications may occasionally be required. For example, where through post-market experience, a level of risk for a type of medical device, classified using the criteria no longer appropriate, consideration should be given to re-classification of the device type by a change to the rules.

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

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Understanding Classification rules (NON-IVD) contd

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

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Application of Classification rules (NON-IVD) contd

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**.

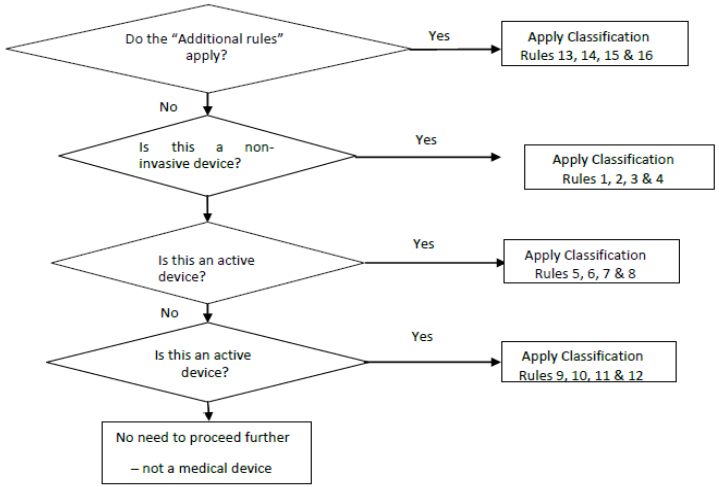

Diagram 1. Summary of Classification rules

Rules separated into the following :

- ❑ Non-invasive and Invasive MD
- ❑ Sterile and non-sterile MD
- ❑ Active and Non-Active MD
- ❑ Additional rules:
  - Devices incorporating a medicine
  - Device for contraception or preventing sexually transmitted diseases
  - Specific for sterilising, disinfecting, cleaning, rinsing or hydrating contact lenses
  - Devices that contain: Animal tissues or derivatives (viable or rendered non-viable) Tissues, cells or substances or microbial or recombinant origin
  - Non-active devices to record X-ray diagnostic images

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Understanding Classification rules (IVD's)

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).

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.

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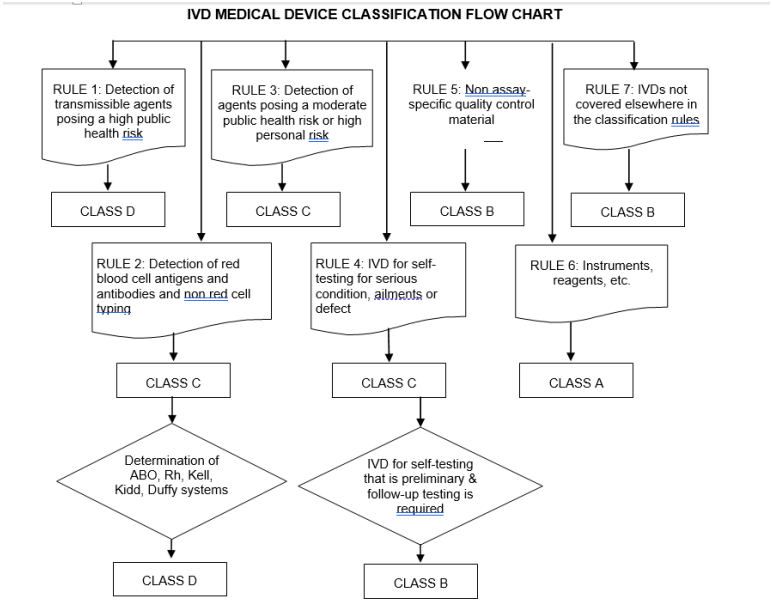
Application of Classification rules (IVD)

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 .**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.



Rules separated into the following :

- ❑ Detection of transmissible agents posing a high public health risk
- ❑ Detection of red blood cell antigens and antibodies and non red cell typing
- ❑ Detection of transmissible agents or biological characteristics posing a moderate public health risk or a high personal risk
- ❑ IVD medical devices for self-testing
- ❑ Non assay-specific quality control material
- ❑ Reagents, instruments etc.
- ❑ Other IVDs are Class B IVD medical devices

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Products Case study review

Class A- Low risk medical devices

Rule description	Example
1(a) A non-invasive device to be used as a mechanical barrier or for compression or for absorption of exudates	absorbent pads , gauze dressings
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	syringes without needles.
4 A non-invasive device is Class A, unless the device is classified at a higher level under another rule.	non-sterile dressings, plaster bandages, cervical collars
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	dental impression materials, exam gloves, prostatic balloon dilation catheters.
6(b)A reusable surgical instrument	scissors, artery forceps, tissue forceps,
12 An active device is Class A, unless the device is classified at a higher level under another rule.	processing or viewing of diagnostic images, devices intended in general for external patient support (e.g. hospital beds, patient hoists, wheelchairs, dental patient chairs);
Classification Rule 6 - Reagents, instruments etc. 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	Reagents

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Class B- Low-Moderate risk medical devices

Rule description	Example
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	oxygen tubing and masks;
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	hard contact lenses, urinary catheters, menstrual cup , vaginal pessaries
6(a)Surgically invasive device for transient use	suture needles, hypodermic needles and syringes, suckers, surgical swabs, surgical gloves.
8(b)A surgically invasive device for long-term use to be placed in the teeth	bridges and crowns.
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	electrocardiographs, electroencephalographs, cardioscopes with or without pacing pulse indicators, electronic thermometers
Rule 7 IVD :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.	Urine self-test strips to detect glucose and other general urine chemistry analytes ,Pregnancy and fertility self-testing kits

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Class C- Moderate to high risk medical devices

Rule description	Example
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	infusion pumps, ventilators, anaesthesia machines, anaesthetic vaporisers, dialysis equipment, blood pumps for heart-lung machines, hyperbaric chambers
15(a) A device specifically for sterilising medical devices, or disinfecting as the end point of processing	hard contact lens solutions, comfort solutions.
16 (a) A device for contraception or the prevention of sexually transmitted diseases	condoms, contraceptive diaphragms.
2(d) A non-invasive device to store blood – i.e. blood bags	Blood bags which do not incorporate an anticoagulant
IVD Classification Rule 2 - Detection of red blood cell antigens and antibodies and non red cell typing	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,
IVD 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

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Class D- High risk medical devices

Rule description	Example
IVD Classification Rule 2 - Detection of red blood cell antigens and antibodies and non red cell typing	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);
IVD Classification Rule 3 - Detection of transmissible agents or biological characteristics posing a moderate public health risk or a high personal risk	Tests for HIV, HCV and Hepatitis B virus and Tuberculosis, which are regarded as serious diseases (and are therefore Class D IVDs),
16 (b) An implantable or invasive device for long- term use	contraceptive intrauterine devices (IUDs), surgically implanted contraceptive devices.
14(a) Devices that contain animal or human cells or tissues or derivatives, whether viable or that have been rendered non-viable	biological heart valves, porcine xenograft dressings, catgut sutures, implants, dressings made from collagen. Devices utilising hyaluronic acid of animal origin
13 A device incorporating a substance that if used separately would be a medicine and has an ancillary action on the body	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

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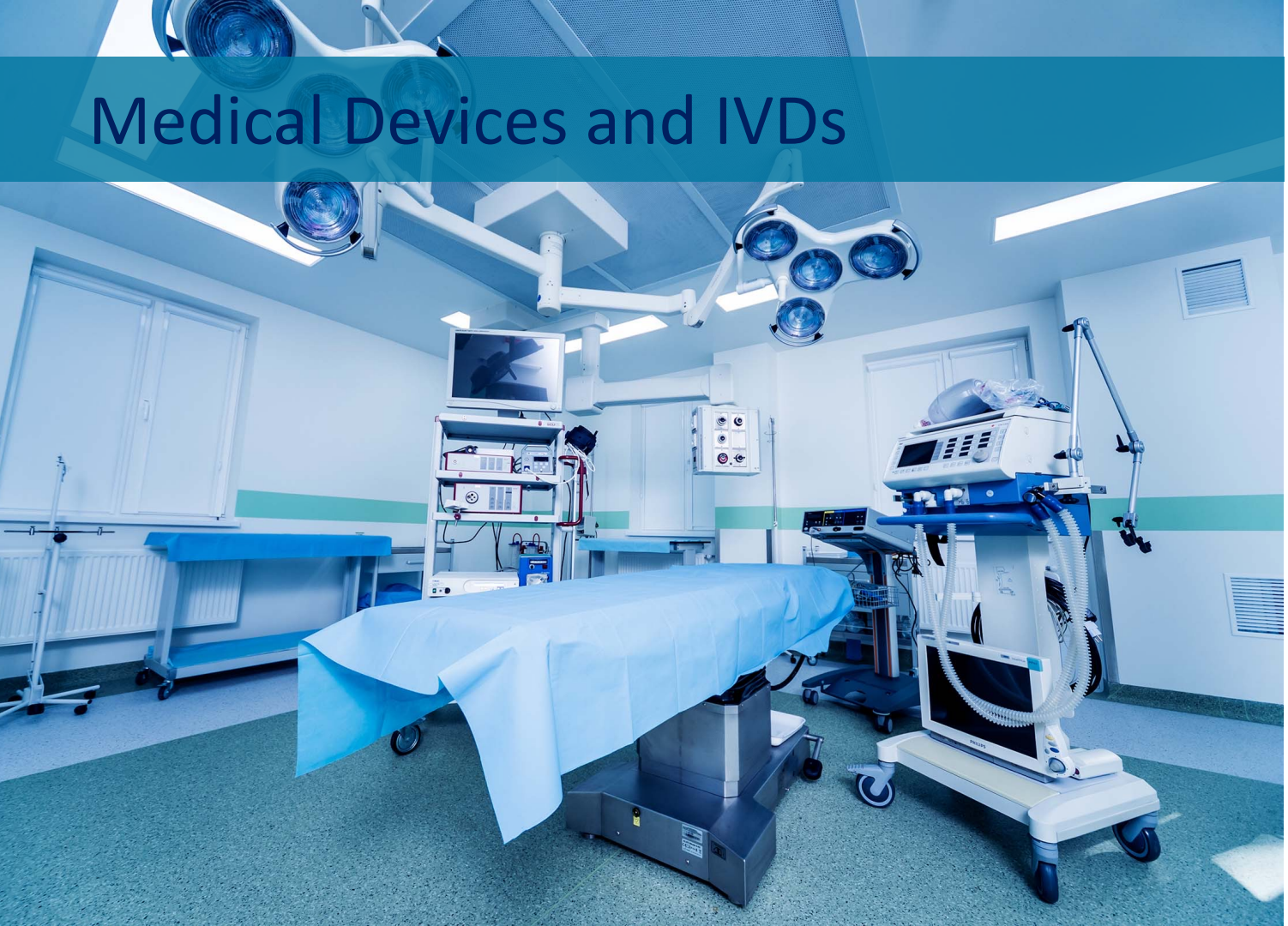
Medical Devices and IVDs



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Products Case study review

Classification review :

Which classes do the following medical devices fall under?

- Blood bags
- hard contact lens solutions
- Fertility Temperature monitor

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Answer :Blood bags with an anticoagulant medical devices

According to the SAHPRA classification guidance, blood bags with an anticoagulant are Class C.

Also of interest, the EU classification guidance captures these blood bags at the highest class (Class III medical device). There is more than one rule that applies:

Rule 2: In the EU MDCG Classification guidance it gives the following example for “Blood bags without a substance which, if used separately, can be considered to be a medicinal product”

Rule 14: In the EU MDCG Classification guidance it gives the following example for “Blood bags incorporating heparin or other substances as anticoagulant agents which, if used separately, can be considered to be a medicinal product”

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Answer :hard contact lens solutions

According to the SAHPRA classification guidance, hard contact lens are classified as Class C

To note :

When considering the claim made for a product, it is important to note whether more than one property can contribute to the overall effect of the product when used for this indication. For example, if a therapeutic substance is shown to modify an organic function as well as a physiological process (body function) or anatomy, then both medicine and medical device definitions can be satisfied. To make the necessary distinction, a comparative risk assessment should be made. Specifically, if it is determined that the greater risk is associated with the modification of an organic function, then the safety, quality and efficacy of the product would be more appropriately assessed under the medicine framework.The reverse will also apply. Ultimately, the intended purpose of the product takes precedence in the classification decision

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https://www.sahpra.org.za/wp-content/uploads/2022/08/SAHPGL-CRO-01_v1-Guideline-for-Borderline-Products.pdf

Answer :Fertility temperature monitor

According to the SAHPRA classification guidance, Temperature Fertility monitors are Class B

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.

Fertility monitors are an effective way to measure your temperature and hormone levels to predict ovulation and peak fertility. (MEASURING FUNCTION : Note does not only pertain to display of information)

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Case study 1:

A manufacturer has produced a **rapid screening test for human immunodeficiency virus (HIV)** using a whole capillary blood sample. The manufacturer intends for the device to be used by **professional users** for testing high risk and suspected individuals and by **lay persons** for self-testing.

Is it a Medical Device, IVD or neither?

- Medical Device
- In Vitro Diagnostic Medical Device (IVD)
- Neither a medical device nor an IVD

What is the risk class?

- Class A
- Class B
- Class C
- Class D

Class D

According to Rule 1… the device is a high public health risk

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- Class D

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Case study 2

A commercial testing laboratory produces an **in-house genetic testing service** that provides individuals with an understanding of their ancestry. Customers **self collect and send a saliva sample that is laboratory analysed**, using single nucleotide polymorphism genotyping, to generate reports relating to their ancestry. In addition to **providing reports on their likely ethnicity and geographical origins**, the reports also provide information on their **physical appearance and preferences to taste and smell**.

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- Class A
- Class B
- Class C
- Class D

Neither a medical device nor an IVD

The collection kit and testing services have no medical purpose

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Take Home message

- Use SAHPRA's risk classification guideline
- Request the Manufacturer to assist with classifying
- Confirm with the Regulatory

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SA vs EU

	European Union	South Africa
Definition	'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: — diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, — diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, — investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, — providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means	"medical device" means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973)— intended by the manufacturer to be used, alone or in combination, for humans or animals, for one or more of the following: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury; investigation, replacement, modification or support of the anatomy or of a physiological process; (iv) supporting or sustaining life; control of conception; disinfection of medical devices; or providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means;

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Classification comparison with EU

SA Classification	Examples	EU Classification	Examples
Class A	absorbent pads, island dressings, cotton wool and wound strips	Class I	Sterile dressing , fertility test and gloves
Class B	suction equipment and Disinfectants specifically intended for non-invasive medical devices, Fertility test	Class IIa	Surgical blade and suction equipment
Class C	Ventilator and long-term urinary catheters	Class IIb	Ventilator and implant
Class D	implantable pacemakers, defibrillators and nerve stimulators	Class III	Pacemaker , drug-eluting cardiac stent

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THANK YOU