Principles of Medical Device Classification in the South African context

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Intent

• Regulatory controls are intended to *safeguard the health and safety* of patients, users and others

• The level of controls depend on the *identified risks* associated with devices.

• The level of *premarket intervention* by the regulator is proportional to the level of *potential risk* and established through a *classification system*.

Risk: Combination of the probability of occurrence of harm and the severity of that harm
The classification of risk is determined from:

• The manufacturer’s intended purpose for the medical device,
• A set of classification rules.
• These rules will classify medical devices & IVDs into one of 4 classes of medical devices & IVDs.
The purpose of risk based classification

- To ensure that the regulatory controls applied to a medical device are proportionate to risk.
- To assist a manufacturer to allocate its medical device to an appropriate risk class.
- Regulatory authorities have the responsibility of ruling upon matters of interpretation for a particular medical device.
- Controls follow the market, not the manufacturing location.
Regulatory Control

• i. Regulatory control is *proportional to the level of risk* associated with a medical device or IVD.

• ii. The level of regulatory control *increases with the increasing degree of risk*, taking into account of the benefits offered by use of the device.

• iii. The classification of the device is based on the risk associated to it *at the point of usage*. 
The risk presented by a particular device depends on

- Its intended purpose,
- The effectiveness of the risk management techniques applied during design, manufacture and use,
- Its intended user(s),
- Its mode of operation,
- Technologies.
Factors Influencing Device Classification

a) The *duration* of contact of the device with the body.
b) The degree of, and site of, *invasiveness* into the body.
c) Whether the *device deliver medicines or energy* to the patient.
d) Whether the device is intended to have a *biological effect* on the body.
e) *Intended action* on the human body.
Factors Influencing Device Classification cont.

f) *Local* versus *systemic* effects.
g) Whether the device comes into *contact with injured skin*.

h) Whether for *diagnosis or treatment*,

i) The ability to be *re-used or not*, and

j) *Combination* of devices.
Note

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• 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.
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• In some cases, classification is inconclusive and more than one rule can apply. If this happens the higher classification applies.
• 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.
• **Accessories are classified separate** to the medical device they are used with.
Note

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.
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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.
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In the event of a dispute between the manufacturer and the notified body concerned, resulting from application of the classification rules, the Council shall determine the classification.
For Software

• Where it *drives, controls or influences* the use of a separate medical device, it is classified according to the intended use of the combination.

• Where intended as an *accessory* to a medical device should be classified separately from the device with which it is used.

• Where it is *independent* of any other medical device, it is classified in its own right using the classification rules for medical devices.

• *Standalone* software (to the extent it falls within the definition of a medical device) is deemed to be an *active device* since it relies on an energy source for its operation.
# 4 Risk based classes – where risk relates to the patient or to public health

<table>
<thead>
<tr>
<th>Class</th>
<th>Risk</th>
<th>Medical Device Examples</th>
<th>IVD Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Low individual risk &amp; minimal or no public health risk</td>
<td>Surgical retractors/tongue depressors</td>
<td>Reagents, instruments, specimen receptacle, microbiological culture medium</td>
</tr>
<tr>
<td>B</td>
<td>Low-moderate</td>
<td>Hypodermic needle/suction equipment</td>
<td>Pregnancy self-test kit, urine self-test strips to detect glucose; biochemistry tests for blood gases, hormones, vitamins</td>
</tr>
<tr>
<td>C</td>
<td>Moderate-high</td>
<td>Lung ventilator/orthopaedic implants</td>
<td>Malaria rapid test; Human genetic testing, STD test; Prenatal screening tests, tumour markers, self monitoring of blood glucose</td>
</tr>
<tr>
<td>D</td>
<td>High</td>
<td>Heart valves/implantable defibrillator</td>
<td>Screening for HIV / Hepatitis B; detection of Rhesus markers; testing red blood cell antigens or antibodies within ABO blood group system</td>
</tr>
</tbody>
</table>
Rules based system

The Manufacturer should:

a) Decide if the product is a medical device or IVD, based on the definition

b) Determine the intended use of the medical device or IVD.

c) Consider all the rules in order to establish the proper classification for the device (if a medical device has features that place it into more than one class, classification and conformity assessment should be based on the highest class indicated).
Classification Rules – NON IVDs

Total of 16 rules:
• 12 general rules (1 – 12),
• 4 additional rules (13 – 16).
• Rules applicable for
  • NON-INVASIVE DEVICES: 1 - 4
  • INVASIVE DEVICES: 5 – 8
  • ACTIVE DEVICES: 9 – 12
  • ADDITIONAL RULES: 13 - 16
Application of Classification Rules

1. Active device?
2. Invasive device?
3. Non-invasive device?
4. Other?
DECISION TREE

Rule 1: NON-INVASIVE DEVICES

Rule 1
In contact with injured skin and intended as a barrier or for compression, or absorption of exudate

Class A
Unless

Rule 2
Intended principally for wounds which breach the dermis

Class B
Unless

Rule 3
The wound can heal only through secondary intent

Class C

Examples
- Polymer film strips; hydrogel dressings
- Wound strips; Gauze dressing
- Dressings for burns; dressings with temp skin substitute

Examples
- Non-Invasive Devices
- Rule 1
- Rule 2
- Rule 3
- Rule 4
Examples:

A. Administration sets for gravity infusion, syringes without needles.

B. Oxygen tubing and masks; anaesthetic tubing and breathing circuits; and syringes and tubing for infusion pumps.

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.
NON-INVASIVE DEVICES

Rule 1

Examples

C. Auto transfusion systems and devices used to separate cells such as gradient medium for sperm.

B. Particulate filtration of blood in an extracorporeal circulation system, centrifugation of blood for transfusion or autotransfusion, removal of carbon dioxide from the blood and/or adding oxygen, and warming or cooling blood in the extracorporeal circulatory system.

Rule 3

Modify biological or chemical composition of blood/body liquids/other liquids intended for infusion

Unless

Class C

ACTION

Class B

Rule 4

Device or other than those where rules 1, 2, or 3 apply

A. Urine collection bottles, ostomy pouches, wound drainage collection bottles and incontinence pads, non-sterile dressings, plaster bandages, cervical collars and gravity traction devices or compression hosiery
**DECISION TREE**

**Rule 1**
- Are in contact with injured skin and intended as a barrier or for compression, or absorption of exudate
  - Class A
    - Unless
      - Intended principally for wounds which breach the dermis
    - Class B
      - Unless
        - The wound can heal only through secondary intent
      - Class C
  - Class B

**Rule 2**
- Channel or store liquids/tissues/ gases intended for eventual infusion or administration
  - Class A
    - Unless
      - May be in contact with an active medical device in Class B or higher
    - Class B

**Rule 3**
- Modify biological or chemical composition of blood/body liquids/other liquids intended for infusion
  - Class C
    - Unless
      - Action is filtration, centrifugation or exchange of gas/heat
    - Class B

**Rule 4**
- Device or other than those where rules 1, 2, or 3 apply
  - Class A
    - Non-invasive Blood bag
    - Class B

**NON-INVASIVE DEVICES**
Invasive through body orifice or stoma (not surgical)

- **Transient use**
- **Short term use**
- **Long term use**

**Rule 5**

- **Less than 60 minutes**
- **Between 60 min & 30 days**
- **More than 30 days**

Class A
Rule 5

**INVASIVE DEVICES**

- Invasive through body orifice or stoma (not surgical)

**Examples**

A. handheld dental mirrors, dental impression materials, exam gloves, prostatic balloon dilation catheters.

**Class A**

- Transient use
- Short term use
- Long term use
Rule 5

INVASIVE DEVICES

Invasive through body orifice or stoma (not surgical)

Transient use  Short term use  Long term use

Examples

B. hard contact lenses, urinary catheters, tracheal tubes, stents, vaginal pessaries, perineal reduction devices.

A. dressing for nose bleeds, dentures removable by the patient

Unless

Used in oral cavity, ear canal or nasal cavity only

Class A

Class B
Rule 5

**INVASIVE DEVICES**

Invasive through body orifice or stoma (not surgical)

- **Transient use**
- **Short term use**
- **Long term use**

**Examples**

- **B.** orthodontic wire, fixed dental prostheses, fissures sealants.
- **C.** long-term urinary catheters, artificial eyes, urethral stents, contact lenses for long-term continuous use.

**Unless**

- **B.** tracheostomy tubes connected to a ventilator, powered nasal irrigators, nasopharyngeal airways, heat and moisture exchangers, suction catheters or tubes for stomach drainage

- **Class C**
  - Used in oral cavity or nasal cavity & not liable to be absorbed by mucous membrane

- **Class C**
  - Invasive device with respect to body orifices, connected to an active medical device that is Class B or higher

- **Class B**
  - SHS
Rule 6

INVASIVE DEVICES

Surgically invasive – transient use

Class B

Unless

A reusable surgical instrument

Class A

Unless

Supplies energy as ionizing radiation

Class C

Unless

Biological effect or mainly absorbed

Class C

Unless

Administer medicinal products in a potentially hazardous manner

Class C

Unless

For use in direct contact with CNS

Class D

C. catheters containing or incorporating radioactive isotopes where the isotope is not intended to be released into the body

D. cardiovascular catheters, angioplasty balloon catheters, coronary artery probes.

Intended to diagnose, monitor, control or correct a defect of heart or CCS through direct contact

B. suture needles, hypodermic needles and syringes, suckers, surgical swabs, surgical gloves

A. scissors, artery forceps, tissue forceps, tissue clamps, excavators, osteotomes, chisels.

C. Bone wax

C. personal insulin injectors (commonly referred to as ‘pens’).

CCS – Central Circulatory System

CNS – Central Nervous System
B. clamps, infusion cannulae, skin closure devices or temporary filling materials, some surgical retractors for example, chest retractors for cardiac surgery.

B. dental adhesives used for root canal therapy.

D. cardiovascular catheters, cardiac output probes and temporary pacemaker leads, thoracic catheters intended to drain the heart, including the pericardium and a carotid artery shunt.

**Rule 7**

**INVASIVE DEVICES**

- **Surgically invasive – short term use**
  - Unless
    - Administer medicinal product
    - Unless
      - Undergoes chemical change in the body (excluding teeth)
        - Unless
          - Supplies ionizing radiation
            - Unless
              - Biological effect or mainly absorbed
                - Unless
                  - Wholly or mostly absorbed by patient’s body
                    - Unless
                      - Use in direct contact with the CNS

- **Class B**

- **Class C**
  - C. intravenous cannulae.
  - C. surgical / tissue adhesives
  - C. bradytherapy devices
  - D. haemostatic sponge.
  - D. absorbable sutures.
  - D. neurological catheters, cortical electrodes, connonoid paddles.
Rule 8

**INVASIVE DEVICES**

- **Surgically invasive long term use/implant**
  - Unless
  - Placed in teeth
  - Unless
    - Used in direct contact with the heart, CCS or CCN
    - Unless
      - Life supporting or life sustaining
      - Unless
        - Active implants & accessories
        - Unless
          - Biological effect or mainly absorbed
          - Unless
            - Administer medicines
            - Unless
              - Undergoes chemical change in the body (excluding teeth B)

- **Class C**
  - B. bridges and crowns

- **Class D**
  - D. pacemakers
  - D. electrode leads associated with pacemakers, defibrillators, nerve stimulators.
  - D. rechargeable non-active drug delivery systems.
  - Surgical adhesives.

- **Class D**
  - Breast implant

- **Class D**
  - C. prosthetic heart valves, aneurysm clips, vascular prostheses, spinal stents, vascular stents, CNS electrodes, cardiovascular sutures

- **Class D**
  - C. implantable joint replacements, shunts, stents, nails, plates and screws, intra-ocular lenses, infusion ports, peripheral vascular grafts, bone cements, maxillo-facial implants
Active devices intended to administer or exchange energy

Class B

Unless

Active devices intended to administer or exchange energy (including ionizing radiation) in a potentially hazardous way

Class C

C.
- 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.

B.
- 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.
ACTIVE DEVICES

Rule 9ii

Intended to control monitor or directly influence the performance of active therapeutic devices in Class C

Class C

Rule 10i

Active diagnostic devices or supply energy that is absorbed or intended to image in vivo radio-pharmaceuticals intended to allow direct diagnosis/monitoring of vital physiological processes

Class B

Unless

The patient is or could be in immediate danger

Class C

C. Intensive care monitoring systems, biological sensors, blood gas analysers used in open-heart surgery, cardioscopes and apnoea monitors including those in home care.

B. Magnetic resonance equipment, diagnostic ultrasound. Gamma cameras, positron emission tomography, single photon emission computer tomography. ECGs, EEGs, cardioscopes with or without pacing pulse indicators, electronic thermometers

C. External feedback systems for active therapeutic devices, after-loading control devices
Intended to control monitor or directly influence the performance of active therapeutic devices in Class C diagnostic and/or interventional radiology devices, including their controls & monitor.

C. diagnostic x-ray sources, linear accelerators.
auto exposure control systems, radiotherapy afterloading controls systems
In a potentially hazardous manner

**Rule 11**

- **Class B:** Active devices to administer or remove medicinal products & other substances from the body

**Rule 12**

- **Class A:** Active devices other than those where Rules 9, 10 or 11 apply

**Class C:** Unless

**C. infusion pumps, ventilators, anaesthesia machines, anaesthetic vaporisers, dialysis equipment,**

**A. examination lights, surgical microscopes, diagnostic devices for thermography, active devices for recording, processing or viewing of diagnostic images, dental curing lights**
Rule 13

Device incorporating medicinal product which has ancillary action

Class D

D. antibiotic bone cements, condoms with spermicide, heparin-coated catheters

Rule 14

Device manufactured from or incorporating human or animal tissues, cells or derivatives thereof

Class D

D. biological heart valves, porcine xenograft dressings, catgut sutures, implants, dressings made from collagen

Unless

Non-viable animal tissues or derivatives thereof & in contact with intact skin only

Class A

A. leather straps associated with limb prostheses.
additional rules

rule 15

device intended specifically for sterilisation of medical devices or disinfection as the end point of processing

class b

unless

used for disinfecting medical devices prior to end point sterilisation or higher level disinfection

class c

unless

specifically for disinfecting, cleansing, rinsing or hydrating of contact lenses

class c

rule 16

device used for contraception or prevention of sexually transmitted diseases

class c

unless

implantable or long-term invasive

class d

condoms, contraceptive diaphragms

class c

implantable or long-term invasive

contraceptive intrauterine devices (iuds), surgically implanted contraceptive devices

unclassified

b. disinfectants for haemodialysis devices or endoscopes, sterilisers to sterilise medical devices, washer disinfectors.

c. hard contact lens solutions, comfort solutions.
Medical Devices with Measuring Function

• A medical device is considered to have a measuring function if the device is intended by the manufacturer to measure quantitatively a physiological or anatomical parameter:
  • a quantity or a qualifiable characteristic of energy or of 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 Council, 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 Council, and
  • be accurate to enable the device to achieve its intended purpose.

• The device must meet each of the above requirements to fit the definition of measuring function.

• 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 please see Guideline 8.02 Essential Principles

• 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 Council with conformity assessment evidence to demonstrate that the relevant Essential Principles have been met.
Classification of IVD Medical Devices
Rule 1- Detection of transmissible agents posing a high public health risk

- IVD medical devices intended for the following purposes are classified as Class D:
  - Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, cells, tissues or organs in order to assess their suitability for transfusion or transplantation, or
  - Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening, often incurable, disease with a high risk of propagation

  *eg.* Tests to detect infection by HIV, HCV, HBV, HTLV. This Rule applies to first-line assays, confirmatory assays and supplemental assays.
Rule 2- Detection of Red blood cell antigens & antibodies & non red blood cell typing

• **Class C**: IVD intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation.

• **Class D**: ABO system [A (ABO1), B (ABO2), AB (ABO3)], rhesus system [RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e)], Kell system [Kel1 (K)], Kidd system [JK1 (Jka), JK2 (Jkb)] and Duffy system [FY1 (Fya), FY2 (Fyb)] determinations.
Rule 3: Detection transmissible agents or biological characteristics posing moderate public health or high personal risk

Class C

- in detecting the presence of, or exposure to, a sexually transmitted agent.
- in detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation.
- in 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 fetus being tested.
- in pre-natal screening of women in order to determine their immune status towards transmissible agents.
Rule 3: Detection transmissible agents or biological characteristics posing moderate public health or high personal risk

Class C

• in determining infective disease status or immune status, and 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.

• in screening for selection of patients for selective therapy and management, or for or for disease staging, or in the diagnosis of cancer

• in human genetic testing

• 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. Examples: Cardiac markers, Cyclosporin, Prothrombin time testing.

• In the management of patients suffering from a life-threatening infectious disease.

• In screening for congenital disorders in the foetus.
Rule 4: IVD medical device for self testing

- Class C: except those devices from which the result is not determining a medically critical status, or is preliminary and requires follow-up with the appropriate laboratory test in which case they are Class B.

- IVD medical devices intended for blood gases and blood glucose determinations for near-patient testing would be Class C.

- Other IVD medical devices that are intended for near-patient should be classified in their own right using the classification rules.
Rule 5: Non assay specific quality control material

Class A:

• Reagents or other articles which possess specific characteristics, intended by the manufacturer to make them suitable for in vitro diagnostic procedures related to a specific examination.

• Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures

• Specimen receptacles
Rule 6: IVD medical devices not covered in Rules 1 through 5

Class B:

These devices present a moderate individual risk as they are not likely to lead to an erroneous result that would cause death or severe disability, have a major negative impact on patient outcome or put the individual in immediate danger. The devices give results that are usually one of several determinants.

Blood gases, H. pylori and physiological markers such as hormones, vitamins, enzymes, metabolic markers, specific IgE assays and celiac disease markers.
Rule 7: Other IVDs

Class B

IVD medical devices that are controls without a quantitative or qualitative assigned value
RULE 1: Detection of transmissible agents posing a high public health risk

CLASS D

RULE 2: Detection of red blood cell antigens and antibodies and non red cell typing

CLASS C

RULE 3: Detection of agents posing a moderate public health risk or high personal risk

CLASS C

RULE 4: IVD for self-testing for serious condition, ailments or defect

CLASS C

RULE 5: Non assay-specific quality control material

CLASS B

RULE 6: Instruments, reagents, etc.

CLASS A

Determination of ABO, Rh, Kell, Kidd, Duffy systems

CLASS D

IVD for self-testing that is preliminary & follow-up testing is required

CLASS B

RULE 7: IVDs not covered elsewhere in the classification rules

CLASS B
In Closing

• Classification is intended to determine the level of regulatory control based on risk assessment
• There are principles and factors to be considered before assigning the classification
• There are 16 rules of classification with 12 general rules and 4 additional rules.