Medical Device Regulatory Framework

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FUNDISA CONFERENCE
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Key Topics

- Definitions
- Essential Principles
- Classification
- Conformity Assessment Framework
- License to Manufacture, Import, Export, Distribute or Wholesale
- Medical Device Registration Pathway
- SA Declaration of Conformity
- Status Quo & Road Map
<table>
<thead>
<tr>
<th>Current Act 101 Amended</th>
<th>Act 72 of 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>“Medical device”</strong></td>
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</tr>
<tr>
<td>means any instrument, appliance, material, machine, apparatus, implant or diagnostic reagent-</td>
<td>means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article</td>
</tr>
<tr>
<td>(a) used or purporting to be suitable for use or manufactured or sold for use in</td>
<td>(a) intended by the manufacturer to be used, alone or in combination, for human beings for-</td>
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<tr>
<td>the diagnosis, treatment, mitigation, modification, monitoring or prevention of</td>
<td>(i) diagnosis, prevention, monitoring, treatment or alleviation of disease</td>
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<tr>
<td>disease, abnormal physical or mental states or the symptoms thereof;</td>
<td>(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury</td>
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<td>(ii) restoring, correcting or modifying any somatic or psychic or organic function;</td>
<td>(iii) investigation, replacement, modification or support of the anatomy or of a physiological process;</td>
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<tr>
<td>(iii) the diagnosis or prevention of pregnancy,</td>
<td>(iv) supporting or sustaining life;</td>
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<td>and which does not achieve its purpose through chemical, pharmacological, immunological or metabolic means in or on the human body but which may be assisted in its function by such means; or</td>
<td>(v) control of conception;</td>
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<tr>
<td>(b) declared by the Minister by notice in the Gazette to be a medical device, and includes any part or an accessory of a medical device;</td>
<td>(vi) disinfection of medical devices; or</td>
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<tr>
<td></td>
<td>(vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and</td>
</tr>
<tr>
<td></td>
<td>(b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means;</td>
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</table>
"'IVD' (in vitro diagnostic medical device) means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes;
Guiding Principles

The optimum assurance of medical device safety has several essential elements ¹:

- Absolute safety cannot be guaranteed
- It is a risk management issue
- It is closely aligned with device effectiveness/performance
- It must be considered throughout the life span of the device
- It requires shared responsibility among the stakeholders

Ref: 1. WHO Medical Device Regulations. Overview & guiding principles
http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf
Essential Principles of Safety & Performance

The Essential Principles set out the requirements relating to the safety and performance characteristics of medical devices

**GENERAL PRINCIPLES (6)**

1. Use of medical devices not to compromise health and safety
2. Design and construction of medical devices to conform to safety principles
3. Medical devices to be suitable for intended purpose
4. Long-term safety
5. Medical devices not to be adversely affected by transport or storage
6. Benefits of medical devices to outweigh any side effects
Essential Principles of Safety & Performance

PRINCIPLES ABOUT DESIGN AND CONSTRUCTION (9)

7. Chemical, physical and biological properties
8. Infection and microbial contamination
9. Construction and environmental properties
10. Medical devices with a measuring function
11. Protection against radiation
12. Medical devices connected to or equipped with an energy source
13. Information to be provided with medical devices.
14. Clinical evidence
15. Principles applying to IVD medical devices only
Demonstration of Essential Principles of Safety & Performance

Examples include:

- a documented and detailed risk analysis
- the results of testing of the medical device
- literature searches
- copies of the label, packaging and *Instructions for Use* to demonstrate that information requirements have been met
- expert opinion
- the design dossier, if applicable depending on class of the product.
Demonstration of Essential Principles of Safety & Performance

Which standards to apply to each device?
Manufacturers take into consideration:
- intended purpose of the device
- environment in which it is likely to be used
- likely users of the device
- generally acknowledged state-of-the-art
- Standards that are commonly used by medical device manufacturers are:
  - ISO 14971—Application of risk management to medical devices
  - ISO 13485—Quality management systems: Requirements for regulatory purposes
  - ISO 10993—Biological evaluation of medical devices
  - ISO 60601—Medical electrical equipment
  - ISO 10282—Single-use sterile rubber surgical gloves
Risk assessment is based on:
- the experience of health care professionals &
- on safety design engineering.

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- Risk Analysis & Evaluation
  - Severity & overall impact?
  - Hazards? / Potential for AE? / Source of danger?
  - Likelihood of occurrence of AE?

- Is the device intended to have contact with the patient or other persons?
- What materials and/or components are incorporated in the device or are used with, or are in contact with the device?
- Is energy delivered to and/or extracted from the patient?
- Are substances delivered to and/or extracted from the patient?
- Are biological materials processed by the device for subsequent re-use?
- Is the device supplied sterile or intended to be sterilised by the user or are other microbiological controls applicable?
- Is the device intended to be routinely cleaned and disinfected by the user?
- Is the device intended to modify the patient environment?
- Are measurements taken?
- Is the device interpretative?
- Is the device intended to control or to interact with other devices or drugs?
- Are there any unwanted outputs of energy or substances?
- Is the device susceptible to environmental influences?
- Does the device influence the environment?
- Are there essential consumables or accessories associated with the device?
- Are maintenance and/or calibration necessary?
- Does the device have a restricted shelf life?
- Are there any possible delayed and/or long-term use effects?
- To what mechanical forces will the device be subjected?
- What determines the lifetime of the device?
- Is the device intended for single use?
- Is safe decommissioning or disposal of the device necessary?
- Does installation of the device require special training?
- Will new manufacturing processes need to be established or introduced?
- Is successful application of the device critically dependent on human factors such as the user interface?
  - Connecting parts and accessories; Control interface; Display information; Controlled by a menu
  - Is the device intended to be mobile or portable?
Classification

Determining the classification of a medical device or IVD is done using a set of classification rules based on the:

- manufacturer’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.

Identical medical devices may be classified differently if they are to be used in different parts of the body. i.e. reason why the manufacturer’s intended use of the device is critical to determine the appropriate classification. The intended use can be obtained from the:

- instructions for use (IFU)
- label
- manufacturer’s advertising materials
- technical documentation.

Controls follow the market, not the manufacturing location.
Reg 12. (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 or to public health.

2) All medical devices, except custom made devices, and all IVDs shall be registered with the Council in terms of such call up notices before they may be sold or used in the Republic.  

(3) The classification of medical devices and IVDs shall be as determined by Council in accordance with the classification rules.  

(4) Where the classification of a medical device or IVD is inconclusive and places it in more than one class or between classes after following the classification rules the Council will place it in the higher of the risk classes.  

(5) The Council shall consider the classification of a medical device or IVD individually taking into account its design and intended use.
Medical Device Classification

- Risk based classification “rules”

**NON-IVDs** – rules address
- Non-invasive?
- Invasive?
- Active?
- Implants?
- Special?

**IVDs** rules address
- Use
- Indications for use

Examples of Non-IVD Medical Devices:
- Class A: Non-invasive
- Class B: Invasive, blood pressure monitors
- Class C: Lasers
- Class D: Implants; cardiac pacemakers

Examples of IVDs
- Class A: Microbiology tests
- Class B: Patient management, moderate level diagnostics
- Class C: Sexually transmitted diseases, moderate to high level
- Class D: Death or serious injury diseases, detecting high level diagnostics
Assessment of Conformity to the Essential Principles of Safety & Performance

- Different conformity assessment procedures are used to demonstrate compliance with the Essential Principles depending on product risk (Class)

- Conformity assessment intends to provide objective evidence of safety, performance, and benefits & risks to maintain public & professional confidence
Product Conformity Assessment

Classification of a device determines conformity assessment procedures/paths a manufacturer may use to demonstrate compliance with the Essential Principles.

Most commonly used conformity assessment procedures for each medical device classification and relevant clause (below) - describe which South African Declaration of Conformity is appropriate for each conformity assessment procedure.

<table>
<thead>
<tr>
<th>Class of Medical Device</th>
<th>Most commonly used conformity assessment procedures</th>
<th>Declaration of Conformity reference</th>
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<tbody>
<tr>
<td>Class A</td>
<td>Part 6 (Declaration of Conformity Procedures Not Requiring Assessment )</td>
<td>Part 6, clause 6.6</td>
</tr>
<tr>
<td>Class A (measuring) &amp; Class B (non-sterile)</td>
<td>Part 6 (Declaration of Conformity Procedures Not Requiring Assessment ) + Part 5 (Product Quality Assurance Procedures)</td>
<td>Part 6, clause 6.6</td>
</tr>
<tr>
<td>Class A (sterile) &amp; Class B (sterile)</td>
<td>Part 6 (Declaration of Conformity Procedures Not Requiring Assessment ) + Part 4 (Production Quality Assurance Procedures)</td>
<td>Part 6, clause 6.6</td>
</tr>
<tr>
<td>Class C</td>
<td>Part 1 excluding Clause 1.6 (Full Quality Assurance Procedures)</td>
<td>Part 1 clause 1.8</td>
</tr>
<tr>
<td>Class D</td>
<td>Part 1 (Full Quality Assurance Procedures) + Clause 1.6 (Examination of Design)</td>
<td>Part 1 clause 1.8</td>
</tr>
<tr>
<td>Systems or Procedure Packs</td>
<td>Part 7 (Procedures for Medical Devices Used for a Special Purpose)</td>
<td>Part 7, clause 7.2</td>
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Conformity Assessment Framework

Conformity Assessment of the QMS and products is conducted by accredited third parties.

The third parties are Conformity Assessment Bodies (CABs)

The CABs are accredited by SANAS

(see next slide for relationships)
Conformity Assessment stakeholder relationships

SA Regulatory Authority

MOU

SA Accreditation Body

Conformity Assessment Bodies

Manufacturer / Distributor

Customer / User

MCC

SANAS

A

B

C

Accredits

Inspect & certify

X

Y

Z

The responsible “Gate Keeper”

Evaluates potential Conformity Assessment Bodies on behalf of MCC vs a Standard

Perform CA services (inspection & certification) for a manufacturer/distributor placing a product on the market in SA vs a International Standard

SA Declaration of Conformity, Registers & places product on market

Purchases & uses the product

Manufacturer / Distributor

SA Declaration of Conformity, Registers & places product on market

Customer / User

Purchases & uses the product
Conformity Assessment Infrastructure

- The Conformity Assessment Infrastructure for Medical Devices & IVDs is to be established in SA.
- SANAS….to develop Conformity Assessment programme aligned to IMDRF

- A lengthy process

IAF accredits SANAS
SANAS establishes (ISO) requirements for CABs to be inspection & certification bodies for ISO standards relevant for medical devices & IVDs
CABs set up & apply to SANAS for accreditation
License to Manufacture, Import, Export, Distribute or Wholesale a Medical Device (Section 22C)

- To ensure that Council has details of
  - Importers and or distributors of medical devices into or in SA;
  - The identity of the manufacturers of the devices sold in SA;
  - The identity & contact details of Authorised Representatives;
  - The nature of the medical devices sold in SA;

- To require licence holders to provide evidence that they have the required Quality Management System in place i.e. ISO 13485 Certificate

The Certificate is issued after inspection and assessment by an accredited Conformity Assessment Body (CAB)
License to Manufacture, Import, Export, Distribute or Wholesale a Medical Device (Section 22C)

Local SA manufacturer or appointed legal representative of international manufacturer (Distributor) makes application for a License

Council may inspect the business premises for compliance with a Quality Management System as prescribed by Council.

Manufacture Licence applicant details included in Licence Register & Council notifies applicant & issues Manufacture / Import / Export Licence

Ongoing monitoring & correction of Quality Management System while business continues

Licence applicant appoints a natural person to be the Authorised Representative who is responsible for compliance with the Act, pays fees & lodges application to Council for a licence to manufacture, import or export.
“Authorised Representative”

means

any **natural person, resident** in the Republic of South Africa, who has the **written mandate** to **represent** a manufacturer, importer, distributor, wholesaler, retailer or service provider in the Republic and to **act on his or her behalf** for specified tasks with regard to the latter’s obligations and who has submitted **an application for the registration of a medical device or IVD** and in whose name the **manufacturer licence, distributor licence, wholesaler licence and or certificate of registration** is issued.

The authorised representative is **responsible for all aspects** of the medical device or IVD, **including quality, safety and compliance with conditions of registration**
Medical Device Registration Pathway

Class B, Class C, Class D Medical Device or IVD

Manufacturer determines classification of device as per technical rules

Manufacturer decides the procedures to be used to demonstrate device meets relevant Essential Principles and prepares necessary documentation

SA Authorised Representative or Manufacturer applies to SA Accredited Conformity Assessment Body or Approved International Notified Body for Conformity Assessment Certificate with supporting evidence

Application successful?

No

Revised application

Yes

Some applications may be selected for detailed audit by Council

Revised application

SA Accredited Conformity Assessment Body or Approved International Notified Body audits & certifies product vs standard as determined by Council. SA Authorised Representative prepares South African Declaration of Conformity

SA Authorised Representative prepares application for registration of medical device or IVD

If necessary:
- amendments made
- further information is provided, or
- application is withdrawn

Application successful?

No

Some applications may be selected for detailed application audit by Council

Yes

Some establishments may be selected for detailed audit by Council

Medical device included in Medical device or IVD register

Ongoing monitoring of device while device is on the market
Declaration of Conformance – Key Elements

Medical device regulations specify the manner in which the manufacturer demonstrates to the CAB that its medical devices comply with the legislation.

The necessary conformity assessment elements are:

- i. a quality management system (QMS),
- ii. a system for post-market surveillance,
- iii. technical documentation to support compliance with the Essential Principles of Safety and Performance,
- iv. SA Declaration of conformity by the Authorised Representative, and
- v. the SA licence to manufacture, import, export, distribute or wholesale.
Thank You