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
### Current Act 101 Amended

<table>
<thead>
<tr>
<th>“Medical device”</th>
<th>Act 72 of 2008</th>
</tr>
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<tbody>
<tr>
<td>means any instrument, appliance, material, machine, apparatus, implant or</td>
<td>“Medical device”</td>
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<tr>
<td>diagnostic reagent-</td>
<td>means any instrument, apparatus, implement, machine, appliance, implant,</td>
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<tr>
<td></td>
<td>in vitro reagent or calibrator, software, material or other similar or related</td>
</tr>
<tr>
<td>(a) used or purporting to be suitable for use or manufactured or sold for use in</td>
<td>article</td>
</tr>
<tr>
<td>(i) the diagnosis, treatment, mitigation, modification, monitoring or prevention</td>
<td>(a) intended by the manufacturer to be used, alone or in combination, for</td>
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<td>of disease, abnormal physical or mental states or the symptoms thereof;</td>
<td>human beings for-</td>
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<tr>
<td>(ii) restoring, correcting or modifying any somatic or psychic or organic function;</td>
<td>(i) diagnosis, prevention, monitoring, treatment or alleviation of disease</td>
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<tr>
<td>(iii) the diagnosis or prevention of pregnancy,</td>
<td>(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an</td>
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<td></td>
<td>injury</td>
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<td>(iii) investigation, replacement, modification or support of the anatomy or of</td>
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<tr>
<td></td>
<td>a physiological process;</td>
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<td></td>
<td>(iv) supporting or sustaining life;</td>
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<td></td>
<td>(v) control of conception;</td>
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<td></td>
<td>(vi) disinfection of medical devices; or</td>
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<tr>
<td>and which does not achieve its purpose through chemical, pharmacological,</td>
<td>(vii) providing information for medical or diagnostic purposes by means of in</td>
</tr>
<tr>
<td>immunological or metabolic means in or on the human body but which may be</td>
<td>vitro examination of specimens derived from the human body; and</td>
</tr>
<tr>
<td>assisted in its function by such means; or</td>
<td>(b) which does not achieve its primary intended action in or on the human body</td>
</tr>
</tbody>
</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 of class of 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
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
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.
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>
</tr>
</tbody>
</table>
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

MOU
SA Regulatory Authority
SA Accreditation Body
Conformity Assessment Bodies
Manufacturer / Distributor
Customer / User

MCC
SANAS

A
B
C
Inspect & certify
Accredits

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

Purchase & uses the product
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
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)

Ongoing monitoring & correction of Quality Management System while business continues

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

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?

Yes

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

Some applications may be selected for detailed audit by Council

No

Revised application

Revised application

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

Application successful?

Yes

Medical device included in Medical device or IVD register

Ongoing monitoring of device while device is on the market

No

Some applications may be selected for detailed application audit by Council

Some establishments may be selected for detailed audit by Council
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

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