



Overview of the regulatory developments for Medical Devices and IVDs in South Africa

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Jane Rogers
25 November 2016



Agenda

Introduction

- IVDs and Non IVDs (nIVDs)

Regulatory Framework

Ideal Regulatory Status

Medical Device Regulations

Licensing of Medical Device Establishment

- Common problems and queries

Registration - Phase 2



Regulatory Framework

Medicines & Related Substances Act 101 as amended

Hazardous Substances Act 15

- Electro-medical & Radiation devices <https://sites.google.com/site/radiationcontroldoh/>

Standards Act

Legal Metrology Act

SANAS

National Regulator for Compulsory Specifications Act (NRCS)

Foodstuffs, Cosmetics & Disinfectants (FC&D) Act

PAJA and PAIA

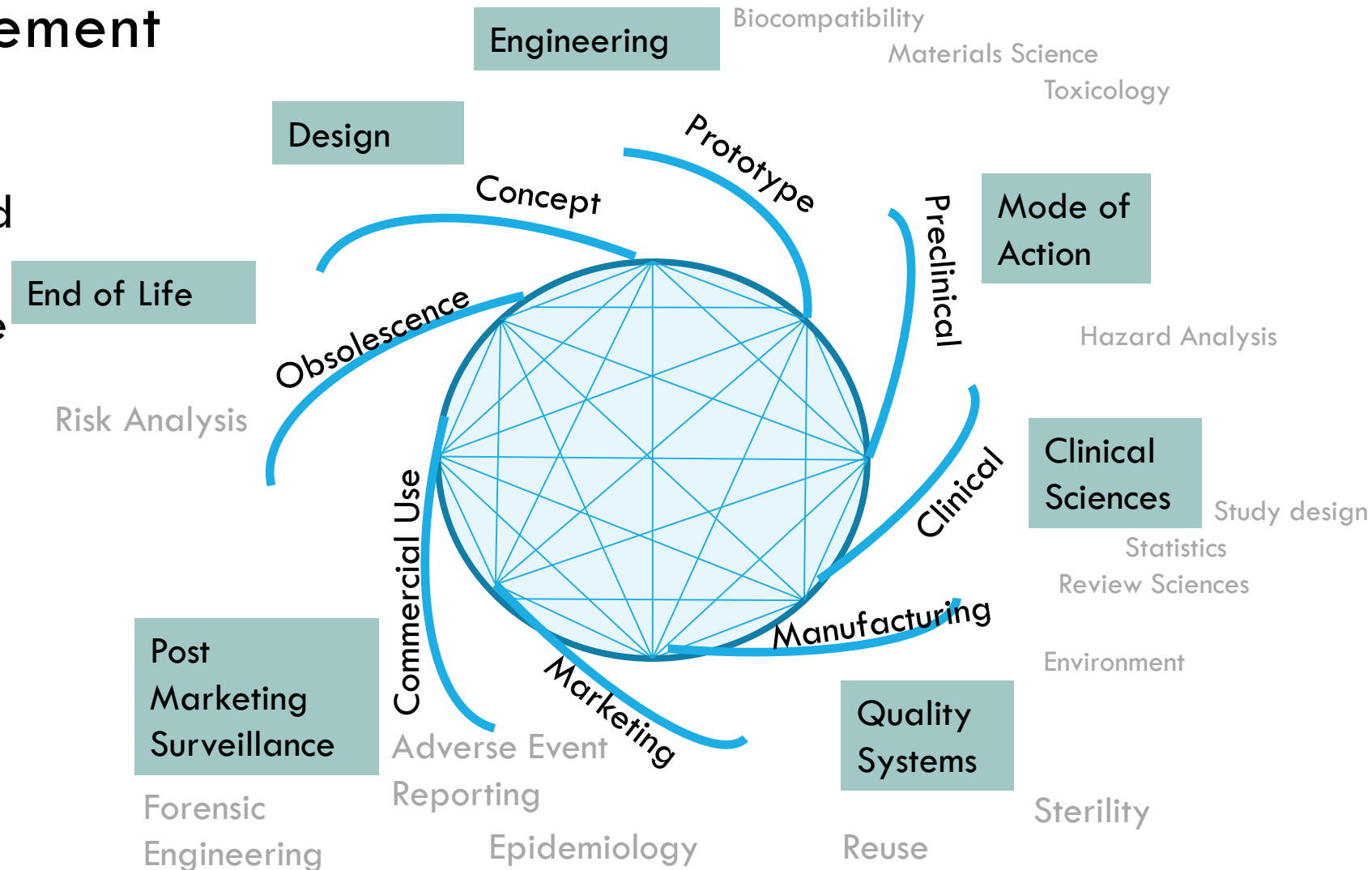
- Govern conduct with the technical law (e.g. Meds Act)



Life Cycle Management

Regulatory approach based on conformity assessment and post market surveillance

- Major control point is post market testing rather than premarketing as for medicines.
 - Mandatory manufacturer **Vigilance reporting** for serious AEs and
 - **Adverse Incident** reporting - voluntary and directed towards users.





Ideal Regulatory & Quality Status

Pre - Market Requirements			Post – Marketing Requirements		
Key Criteria	Target Standard	Status	Inspections	Reports	Change Control
Quality assurance controls Authorised Representative	Relate to the organisation				
Essential principles of Safety & Performance	Relate to the product				



Ideal Regulatory & Quality Status

Pre - Market Requirements			Post – Marketing Requirements		
Key Criteria	Target Standard	Status	Inspections	Reports	Change Control
Quality assurance controls Authorised Representative	Certified Quality Management System ISO13485:2016	SA medical device establishment licensed to import / manufacture/ distribute/ export			
Essential principles of Safety & Performance	Criteria according to risk class of product – certified by accredited inspection body	SA Declaration of Conformity -> MCC registration as a medical device / IVD			



Phase 1: Regulatory & Quality Status

Pre - Market Requirements			Post – Marketing Requirements		
Key Criteria	Target Standard	Status	Inspections	Reports	Change Control
Quality assurance controls	Certified Quality Management System ISO13485:2016	SA medical device establishment licensed to import / manufacture/ distribute/ export	Regulator – ad hoc	Class C & Class D: Link to “originating approvals” - significant changes	
Authorised Representative					
Essential principles of Safety & Performance					



Phase 2: Regulatory & Quality Status

Pre - Market Requirements			Post – Marketing Requirements		
Key Criteria	Target Standard	Status	Inspections	Reports	Change Control
Quality assurance controls	Certified Quality Management System ISO13485:2016	SA medical device establishment licensed to import / manufacture/ distribute/ export	ISO audits Regulator – ad hoc		
Authorised Representative				Adverse Event Reporting & vigilance	Risk based
Essential principles of Safety & Performance	Criteria according to risk class of product – certified by accredited inspection body	SA Declaration of Conformity -> MCC registration as a medical device / IVD		Recalls	Significant changes as per ISO13485:2016



Phase 1 - Regulatory & Quality Status

Pre - Market Requirements			Post – Marketing Requirements		
Key Criteria	Target Standard	Status	Inspections	Reports	Change Control
Quality assurance controls Authorised Representative	Certified Quality Management System ISO13485:2016	SA medical device establishment licensed to import / manufacture/ distribute/ export	Regulator – ad hoc	Class C & Class D: Link to “originating approvals” - significant changes	

Phase 2: Future Regulatory & Quality Status

Pre - Market Requirements			Post – Marketing Requirements		
Key Criteria	Target Standard	Status	Inspections	Reports	Change Control
Quality assurance controls Authorised Representative	Certified Quality Management System ISO13485:2016	SA medical device establishment licensed to import / manufacture/ distribute/ export	ISO audits Regulator – ad hoc		
Essential principles of Safety & Performance	Criteria according to risk class of product – certified by accredited inspection body	SA Declaration of Conformity -> MCC registration as a medical device / IVD		Adverse Event Reporting & vigilance Recalls	Risk based Significant changes as per ISO13485:2016

South African Regulatory Road Map - Phased Implementation

Licence to a) manufacture; b) Import & distribute or c) Wholesale

Six months notice:

Authorised Representative

Quality Management System (declaration) ---->
ISO13485 (2016)

Full list of Medical Devices by company & classification

Class C & D: Evidence of pre-market authorisation in either:

USA (FDA);	EU (CE marking);	Japan;
Canada;	Australia;	Brazil
WHO Pre-Qualification IVD		

Registration - New High Risk Medical Devices (Class D, Class C)

Technical Documentation

- including quality standard certifications – depending on risk classification

SA Authorised Rep's Declaration of Conformance

SANAS: Development of Conformity Assessment Framework for Medical Devices
ISO 13485 (2016)

Accreditation of South African Conformity Assessment Bodies



Act 101 of 1965, as amended (current)

Preamble includes

- to provide for the control of medicines and scheduled substances and **medical devices**;
-to provide for the licensing of certain persons to compound, dispense or manufacture medicines and **medical devices** and also to act as wholesalers or distributors;

Medical devices included in

Section 22C

1(b) the council may, on application in the prescribed manner and on payment of the prescribed fee, issue to a manufacturer, wholesaler or distributor of a medicine or medical device a licence to manufacture, import or export, act as a wholesaler of or distribute, as the case may be, such medicine or medical device, upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the council may determine.



MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965) REGULATIONS RELATING TO MEDICAL DEVICES AND IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDs)

1. Definitions
2. Manner and conditions for allowing international tendering
3. **Importation** of medical devices and IVDs into the Republic
4. **Transmission** of medical devices or IVDs through the Republic
5. **Licence** to manufacture, import, export, or act as a distributor or wholesaler of medical devices or IVDs
6. Period of validity of licence issued in terms of regulation 5 and renewal of licences
7. Appeal against the decision of the Council
8. Application for **registration** of a medical device or IVD
9. Information that must appear in the register for medical devices or IVDs
10. Amendment to the medical devices and IVDs register
11. **Classifications** of medical devices and IVDs
12. Registration certificate
13. **Parts and components**
14. Destruction of medical device and IVD
15. **Short title**
16. Conduct of **clinical trials and clinical investigations**
17. **Adverse event reporting & vigilance**
18. Investigation
19. Offences and penalties
20. Compliance with requirements
21. **Advertising** of medical device or IVD
22. **Labelling** of medical device or IVD
23. **Instructions for Use** of medical device
24. **Instructions for Use** of IVD
25. **Custom made medical devices**
26. **Record of implantable** medical devices and custom made medical devices
27. **Transitional arrangements - unlicensed manufacturer, distributor and wholesaler**
28. **Transitional arrangements - unregistered medical devices and IVDs**
29. Short title



5. Licence to manufacture, import, export or act as a distributor or wholesaler of medical devices or IVDs

- (1) A manufacturer, wholesaler or distributor referred to in section 22C(1)(b) of the Act must-
 - (a) prior to commencing business-
 - (i) apply to the Council for-
 - (aa) a **manufacturer licence** to manufacture, import or export medical devices or IVDs; or
 - (bb) a **distributor licence** to import, export and distribute medical devices or IVDs; or
 - (cc) a **wholesale licence** to act as wholesaler of medical devices or IVDs;
 - (ii) appoint and designate an **authorised representative** who must reside in South Africa-
 - (aa) be responsible to the Council for **compliance with the** Act; and
 - (bb) **control the manufacturing, distribution, wholesaling and the sale** of medical devices or IVDs.



Regulations relating to Medical Devices and IVDs

5. Licence to manufacture, import, export or act as a distributor or wholesaler of medical devices or IVDs cont.

- (b) submit to the Registrar an application for a licence, on a form approved and provided by the Council;
- (c) as part of the application, provide acceptable documentary proof of-
 - (i) the particulars of the owner of the business;
 - (ii) the particulars of the authorised representative; and
 - (iii) certification to a Quality Management System for medical devices and IVDs as determined by the Council;
- (d) specify, as determined by the Council, the medical devices or IVDs or group or family of medical devices or IVDs to be manufactured, imported, exported or distributed and sold; and
- (e) pay the application fee.



Regulations relating to Medical Devices and IVDs

5. Licence to manufacture, import, export or act as a distributor or wholesaler of medical devices or IVDs cont.

- (2) The Registrar may give the person referred to in sub-regulation (1) written notice to, within a reasonable time as specified in the notice, furnish the Council with such additional documentation or information as the Council may require.
- (3) The Council **may, where applicable, inspect the business premises** specified in the application.
- (4) If the Council is satisfied that-
 - (a) the person referred to in sub-regulation (1) complies with the prescribed requirements;
 - (b) the application for a licence-
 - (i) to manufacture, import or export medical devices or IVDs; or
 - (ii) to act as a distributor; or
 - (iii) to act as a wholesaler of medical devices or IVDs complies with the prescribed requirements; and

the authorised representative is able to provide certified evidence of **certification to a Quality Management System as determined by Council,**

the Council must approve, **with or without conditions,** the application and issue the person with a licence.



MEDICINES CONTROL COUNCIL



DEPARTMENT OF HEALTH
Republic of South Africa



GUIDELINE FOR A LICENCE TO MANUFACTURE, IMPORT, EXPORT OR DISTRIBUTE MEDICAL DEVICES & IVDs

This guideline is intended to provide recommendations to applicants wishing to submit applications for the manufacture, importation, distribution and exportation of Class B, Class C and Class D medical devices and *In Vitro* diagnostics (IVDs). It represents the Medicines Control Council's current thinking on the safety, quality and performance of medical devices and IVDs. It is not intended as an exclusive approach. Council 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 Council is committed to ensure that all registered medical devices and IVDs will meet the requirements of the Essential Principles relating to quality, safety and performance. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

A person who manufactures, import, distributes or exports only Class A Medical devices is exempt from the medical device establishment licence requirement until further notice. A separate Guideline will be published for a licence to wholesale medical devices.

Guidelines and application forms are available from the office of the Registrar of Medicines and the website.



Guideline for a licence to manufacture, import, export or distribute medical devices & IVDs July 2016

The manufacture, importation, exportation and distribution of Medical Devices and IVDs are subject to control in terms of the provisions of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended.

The **intent** of the Medical Device Establishment Licence is to ensure that the Medicines Control Council is **made aware** of:

- **manufacturers of medical devices** in South Africa and the **classification of the medical devices manufactured** in South Africa;
- **persons importing and distributing** medical devices in South Africa and the **risk classification** of those medical devices; and
- to establish **criteria for importation** of medical devices into South Africa.

Phased Implementation

Licence to a) manufacture; b) Import & distribute or c) Wholesale

Six months notice:

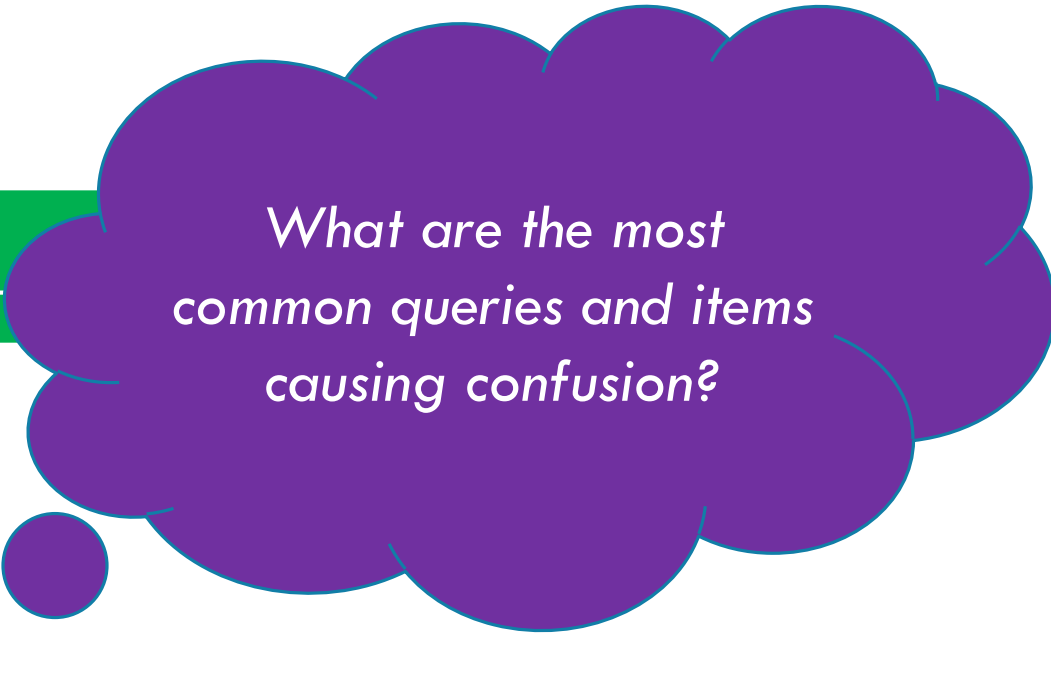
Authorised Representative

Quality Management System (declaration) ---->
ISO13485 (2016)

Full list of Medical Devices by company & classification

Class C & D: Evidence of pre-market authorisation in either:
"Originating approval"

USA (FDA);	EU (CE marking);	Japan;
Canada;	Australia;	Brazil
WHO Pre-Qualification IVD		



What are the most common queries and items causing confusion?



Definitions

"authorised representative" means a natural person, resident in the Republic of South Africa, who-

- (a) has the written mandate to represent a manufacturer, importer, distributor, wholesaler, retailer or service provider in the Republic;
- (b) acts on behalf of a manufacturer, importer, distributor, wholesaler, retailer or service provider for specified tasks with regard to the latter's obligations and in whose name the manufacturer licence, distributor licence, wholesaler licence or certificate of registration is issued; and
- (c) is responsible for all aspects of the medical device or IVD, including performance, quality, safety and compliance with conditions of registration, clinical trials or clinical investigations;



Regulation 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 with the 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 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, the Council must, after following the classification rules, place 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, taking into account its design and intended use.

"user" means a person or organisation that uses a medical device or IVD



Regulations relating to Medical Devices and IVDs

Definitions

“distributor” means a natural or legal person who-

- (a) **imports or exports** a medical device or IVD, which is **on the register** for medical devices or on the register for IVDs in its final form, wrapping and packaging, with a view to the medical device or IVD being placed on the market under the natural or legal person’s own name; and
- (b) **sells** the medical device or IVD to a healthcare professional, healthcare institution, wholesaler or the user;

"wholesaler" means a dealer who purchases medical devices or IVDs from a manufacturer or distributor and sells them to a retailer.



Definitions

"manufacture" means operations that include the design, purchasing of material, specification development, production, fabrication, assembly, processing, reprocessing, releasing, packaging, repackaging, labelling, and refurbishing of a medical device or IVD, as the case may be, and includes putting a collection of medical devices or IVDs, and possibly other products, together for a medical purpose in accordance with quality assurance and related controls;




"manufacturer" means -

(a) a natural or legal person with the responsibility for the design, manufacture, packaging and labelling of a medical device or IVD before it is placed on the market under the natural or legal person's own name, or in the name of a firm or company, regardless of whether these operations are carried out by that person by himself or on his or her behalf by a third party; or

(b) any other person who assembles, packages, reprocesses, refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a medical device or IVD, with a view to their being placed on the market under the natural or legal person's own name, except a person who assembles or adapts medical devices or IVDs already on the market to their intended purpose for patients;







LICENSING SCENARIOS

Activity	Type of Licence	Licensed to...
 Import IVD or nIVD (finished product)	Import Licence	Import only
 Manufacture IVD and or nIVD in SA	Manufacture Licence	Manufacture, sell & make application to register a IVD/ nIVD
Import IVD / nIVD (finished product) AND Manufacture in SA	Import & Manufacture Licence = Manufacturer Licence	Manufacture, sell & make application to register a IVD/ nIVD
 Export IVD / nIVDs	Export Licence	Export





LICENSING SCENARIOS

Activity	Type of Licence	Licensed to...
 Import IVD or nIVD (finished product)	Import Licence	Import only
 Import IVD / nIVD (finished product) AND Distribute finished products in SA ONLY	Import & Distribute Licence = Distributor Licence	Import, distribute, sell & make application to register a IVD/ nIVD
 Import IVD / nIVD (finished product) AND distribute medical equipment in SA AND provide technical service	Import & Manufacture (Tech service) = Manufacturer Licence	Import, distribute, sell & provide technical service & make application to register a IVD/ nIVD
 Import IVD / nIVD AND add a label (SA information) AND distribute medical equipment in SA AND	Import & Manufacture (Packing) = Manufacturer Licence	Import, label, distribute, sell & provide technical service & make application to register a IVD/ nIVD



LICENSING SCENARIOS

Activity	Type of Licence	Licensed to...
 <ul style="list-style-type: none"> i) Import & distribute IVD or nIVD (finished product) and ii) buy medical devices from another local company 	<ul style="list-style-type: none"> i) Import & Distribute = Distributor Licence ii) Wholesaling activity 	<ul style="list-style-type: none"> i) Import, distribute, sell & make application to register a IVD/ nIVD ii) Not yet addressed
 <ul style="list-style-type: none"> i) Import & distribute IVD or nIVD (finished product) and ii) Provide technical service iii) buy medical devices from another local company 	<ul style="list-style-type: none"> i) Import & ii) Manufacture = Manufacture Licence iii) Wholesaling activity 	<p>Import, distribute, sell & provide technical service & make application to register a IVD/ nIVD</p>





LICENSING SCENARIOS



Distributor						

Type of Licence



LICENSING SCENARIOS



Distributor	Manufacture	Manufacture	Manufacture			

Type of Licence



LICENSING SCENARIOS



				Manufacture	Manufacture	Manufacture

Type of Licence

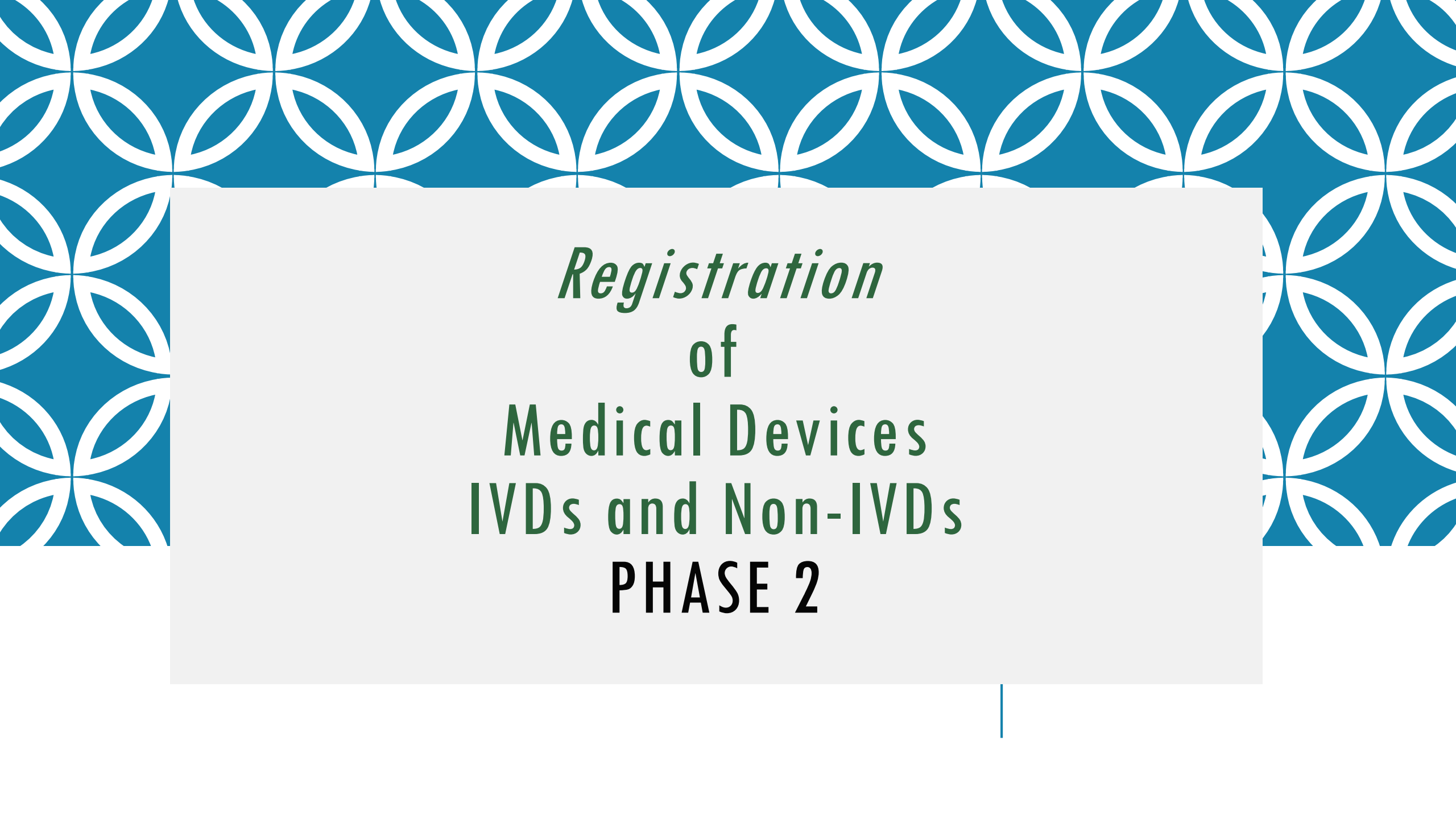


LICENSING SCENARIOS



Distributor	Manufacture	Manufacture	Manufacture	Manufacture	Manufacture	Manufacture

Type of Licence



Registration
of
Medical Devices
IVDs and Non-IVDs
PHASE 2



8. APPLICATION FOR REGISTRATION OF A MEDICAL DEVICE OR IVD

- (1) A person residing and doing business in the Republic may apply for the registration of a medical device or IVD.
- (2) An application for the registration of a medical device or IVD must include the particulars of the **authorised representative** in South Africa who is responsible for communication with the Council.
- (3) An application for the registration of a medical device or IVD must be made on the appropriate form obtainable from the Registrar and must be accompanied by -
 - (a) the completed application form;
 - (b) a proposed label for use on the medical device or IVD, if applicable;
 - (c) the instructions for use of the medical device or IVD;
 - (d) where applicable,
 - (i) a copy of the manufacturer licence or distributor licence together with a **conformity assessment certificate** of a **Quality Management System** for the **local medical device establishment**, as determined by the Council; and
 - (ii) a certified copy of the **conformity assessment certificate to a quality standard**, as determined by the Council, for the medical device or IVD to be registered, and which is issued by a **Conformity Assessment Body**;
 - (e) any other information as the Council may determine; and
 - (f) the application fee.



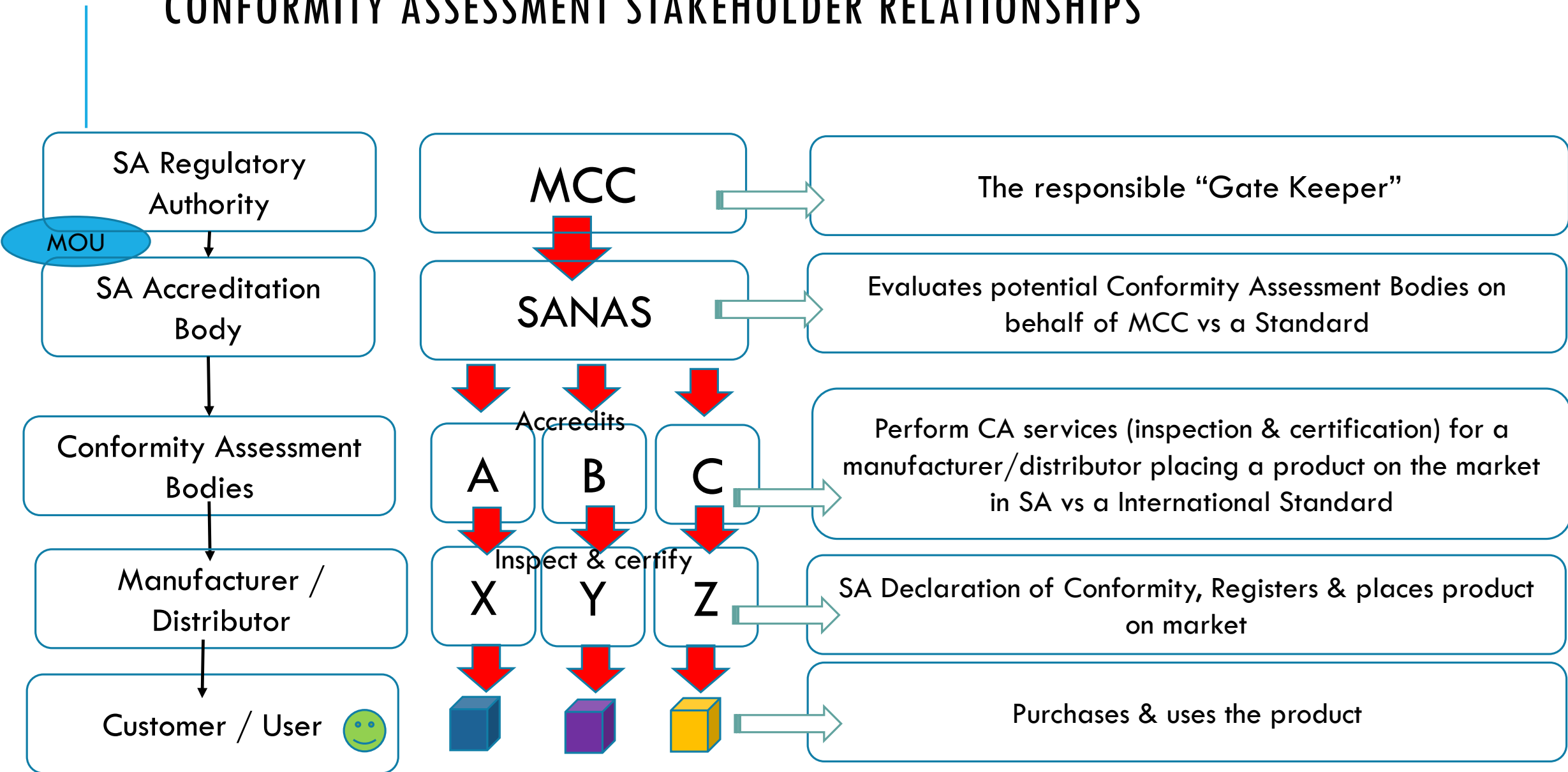
CONFORMITY ASSESSMENT?

“Auditing Organization: An organization that audits a medical device manufacturer for conformity with quality management system requirements and other medical device regulatory requirements. Auditing Organizations may be an independent organization or a Regulatory Authority which perform regulatory audits.”

IMDRF / MDSAP WG/N3 FINAL:2016 (Edition 2)

AUDITING ORGANISATION(S)	
INTERNAL to REGULATOR	EXTERNAL / INDEPENDENT (Conformity Assessment Bodies)

CONFORMITY ASSESSMENT STAKEHOLDER RELATIONSHIPS





CONFORMITY ASSESSMENT ELEMENTS

Medical device regulations specify the manner in which the manufacturer demonstrates to the RA/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,
- iv. a SA declaration of conformity, and
- v. the licence of manufacturers, importers, exporters, wholesalers and distributors and their medical devices by the Registrar

South African Regulatory Road Map - Phased Implementation

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Technical Documentation

- including quality standard certifications – depending on risk classification

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Regulations relating to Medical Devices and IVDs

Regulation 8. Application for registration of a medical device or IVD cont.

- (4) The information referred to in sub-regulation (3) must, at least, be in English.
- (5) The application form referred to in sub-regulation (3)(a) must contain at least the following information:
 - (a) Particulars of the prospective holder of the certificate of registration:
 - (i) Name;
 - (ii) Business Address;
 - (iii) Postal Address;
 - (iv) Telephone Number;
 - (v) Fax Number, where available ;
 - (vi) e-mail address; and
 - (vii) contact details of the authorised representative referred to in sub-regulation (2).
 - (b) Particulars of the medical device or IVD:
 - (i) The name and group or family name, make and model, where applicable;
 - (ii) intended purpose or use;
 - (iii) classification and registration status in recognised authorities outside the Republic, as determined by the Council, and the Republic; proposed classification in
 - (iv) nomenclature system code;
 - (v) in the case of a combination device, the name and quantity of the scheduled substances or biological substances;
 - (vi) the name and physical address of the original manufacturer; and
 - (vii) the name and physical address of the clinical investigation sites, where applicable.



REGULATION 8. APPLICATION FOR REGISTRATION OF A MEDICAL DEVICE OR IVD CONT.

- (6) A medical device or IVD, in respect of which an application for registration is made, must comply with the **Essential Principles for Safety and Performance** of Medical Devices which include requirements for quality, safety and performance, as determined by the Council.
- (7) An application for registration of a medical device or IVD must be accompanied by a **declaration of conformity** by the **authorised representative** as determined by the Council.
- (8) An application must be made in respect of each individual medical device or IVD, or medical device or IVD group or family or modification thereof, as determined by the Council.



DEFINITIONS

“**essential principles**” means the requirements relating to the safety and performance characteristics of medical devices and IVDs determined by the Council;

<http://www.mccza.com/Publications>

Medical Devices and IVDs

Essential Principles of Safety & Performance

MEDICINES CONTROL COUNCIL



DEPARTMENT OF HEALTH
Republic of South Africa



MEDICAL DEVICES and IVDs ESSENTIAL PRINCIPLES of SAFETY & PERFORMANCE

This guideline is intended to provide recommendations to applicants wishing to sell medical devices and IVDs in South Africa. It represents the Council's current thinking on the safety, quality and performance of medical devices and IVDs and the applicable essential principles relating to these products. It is not intended as an exclusive approach. The council 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 Council is committed to ensure that all 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 Registrar and the website.



REGULATION 20. COMPLIANCE WITH REQUIREMENTS

- (1) A medical device or IVD must conform to the **standards and specifications** which were furnished to the Council on the form referred to in regulation 8 and which form has been accepted by Council in respect of the medical device or IVD.
- (2) A medical device or IVD must conform to the Essential Principles furnished to the Council with a **declaration of conformity** referred to in regulation 8(7).
- (3) A proposed deviation from accepted standards and specifications referred to in sub-regulations (1) and (2), must be submitted to the Council for prior approval.



Thank you



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