South African Health Products
Regulatory Authority
Building A
Loftus Park
Arcadia
Pretoria

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GUIDELINE FOR A LICENSE TO MANUFACTURE, IMPORT, EXPORT OR DISTRIBUTE MEDICAL DEVICES AND 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 South African Health Products Regulatory Authority 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 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 manufacturers, import, distributes or exports only Class A Medical devices is exempt from the medical device establishment License requirement until further notice. A separate Guideline will be published for a License to wholesale medical devices.

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

Document History

Final Version	Reason for Amendment	Effective Date
1	- First issue - Industrial comments and Typographical corrections incorporated and published for implementation	September 2016
2	Administrative update	November 2019
3	- Content structured on the new SAHPRA Guideline Template - Old Guideline no. 16.03 changed to a new document number SAHPGL-MD-06	March 2023

DR BOITUMELO SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER

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Glossary

Abbreviation/ Term	Meaning
MAH	Marketing Authorization Holder
IVD	In-Vitro Diagnostics
CEO	Chief Executive Officer
STeD	Summary Technical Documentation
CDRH	Center for Devices and Radiological Health
PMA	Premarket Approval
GMDN	Global Medical Device Nomenclature Code
TGA	Australia's Therapeutic Goods Administration
WHO	World Health Organization
Adverse event	- in relation to a medical device or IVD means possible faults or failures of the medical device or IVD, difficulties in the use of or an undesirable outcome associated with the use of the medical device or IVD that can or does result in permanent impairment, injury or death to the professional user or patient user.
Authorised representative	- means any 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 License, distributor License, wholesaler License

	and 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.
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.
Manufacture	- means all 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) the 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 behalf by a third party; or b) any other person who assembles, packages, reprocesses, fully 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.
Modification	- in relation to a medical device or IVD means a) any significant change in the medical device or IVD; b) any change in the purpose of a medical device or IVD, where significant change may include: i) the manufacturing process; ii) facility or equipment; iii) the quality control measures used to control the quality and sterility of the medical device or IVD; or iv) a change of the materials used in manufacture, the design of the medical device or IVD, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories and the intended use of the medical device or IVD; v) any new or extended use, any addition or deletion of a contra-indication of the medical device or IVD; and vi) any change to the period used to establish its expiry date.
Nomenclature	- means the common generic description as per the Global Medical Device Nomenclature for medical devices having similar features, characteristics and intended use.
Summary Technical Documentation (STeD)	- means a summary of technical documentation held or submitted for conformity assessment purposes.
Technical Documentation	- means the documented evidence, normally an output of the quality management system that demonstrates compliance of a device to the *Essential Principles of Safety and Performance of Medical Devices*.
Wholesaler	- means a dealer who purchases medical devices or IVDs from a manufacturer or distributor and sells them to a retailer.

1. INTRODUCTION

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 License is to ensure that the South African Health Products Regulatory Authority is made aware of:

a) manufacturers of medical devices in South Africa and the classification of the medical devices manufactured in South Africa.

b) persons importing and distributing medical devices in South Africa and the risk classification of those medical devices; and

c) to establish criteria for importation of medical devices into South Africa.

1.1 Purpose

To ensure that the integrity of the applications submitted are not compromised during the process of application. It is therefore important the Medical Device confirms the process of application for establishments.

1.2 Scope

The scope of this guideline is to identify the minimum requirements of the application form which a person who makes application for and holds a licence to import, manufacture, distribute or export a medical device, including an *in vitro diagnostic* (IVD) medical device.

2. LEGAL PROVISION

a) Medicines and Related Substances Act, Act 101 of 1965 as amended.

b) General Regulations relating to Medical Devices and IVDs.

3. LICENSING WITH THE SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

3.1 The manufacturer, importer, distributor or exporter of a low to moderate (Class B), medium to high risk (Class C) and a high risk (Class D) medical device or IVD must be licensed with the South African Health Products Regulatory Authority relating to the ownership of the manufacturer, importer, distributor or exporter and the Quality Management System implemented at the manufacturer,

importer, distributor or exporter.

3.2 The following information must be supplied on the prescribed form below:

- Full Name of legal person
- Company Registration Number or Individual Person's Identity Number
- Physical address
- Postal address
- Telephone Number
- Nature of business activities: manufacture; importation; distribution; wholesaler or exportation
- Authorised Representative's Name
- Authorised Representative's work telephone number and mobile telephone number
- Authorised Representative's email address

Details of medical devices and IVDs manufactured, imported or exported for distribution and sale including the following information:

- The name and or group or family of the medical device or IVD, and
- Global Medical Device Nomenclature code, and
- Risk classification i.e. Class B, C or D, and
- Name and address of manufacturer for Class C and Class D medical devices & IVDs. Medical Devices and IVDs are divided into the following classes depending on 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, user or to public health.

4. LEGAL REQUIREMENTS FOR THE MANUFACTURE, IMPORTATION, DISTRIBUTION OR EXPORTATION OF MEDICAL DEVICES OR IVDs

4.1 Ordering Medical Devices or IVDs from Abroad

No person shall order any Class B, Class C or Class D medical device or IVD from abroad for personal use unless the South African Health Products Regulatory Authority has granted the said person an authorisation to import during a specified period a specified quantity of the particular medical device or IVD, which is not registered with the Authority.

4.2 License to Manufacture, Distribute, Wholesale, Import or Export Medical Devices or IVDs

In terms of section 22C(1)(b) of the Act, The Authority 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 License to:

a) manufacture, import or export; or

b) import, distribute or export; or

c) act as a wholesaler of,

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 Authority may determine.

No manufacturer, importer or exporter shall import or export any medical device or IVD unless he or she is the holder of a License as contemplated in section 22C(1)(b) of the Act.

4.2.1 **Medical Device Manufacturer License:**

License to manufacture, import or export a Class B, Class C or Class D medical device.

A person referred to in section 22(1)(b) of the Act must apply to the Authority for a License to manufacture, import, or export a Class B, Class C or a Class D medical device or IVDs

The person must submit the following information to the CEO in an application for a License to

manufacture, import or export a medical device in the electronic format approved and provided by the Authority and available on the website www.sahpra.org.za and in a printed and signed document:

a) A list of all medical devices or IVDs imported into South Africa by product classification with the Global Medical Device Nomenclature Code (GMDN) and in the format as provided in the License Application for Medical Device Manufacture or License Application for Medical Device Import and Distribution.

b) For a medium to high risk (Class C) and high risk (Class D) medical device or IVD proof of pre-market approval or registration for the medical device or IVD from at least one of the following regulatory authorities:

- Australia's Therapeutic Goods Administration (TGA) i.e. inclusion in the Australian Register of Therapeutic Goods
- Brazil's ANVISA (National Health Surveillance Agency) approval and registration.
- Canada's Medical Device License to market;
- The European Union's CE certificate, to show conformity to all obligations for medical devices as required by the Medical Devices Directives;
- Japan's Marketing Authorization Holder (MAH) License;
- USA's FDA's Center for Devices and Radiological Health (CDRH) Premarket Approval (PMA) or Premarket Notification 510(k) clearance.
- Evidence of IVDs approved under the *World Health Organisation* (*WHO) Prequalification of In Vitro Diagnostics Programme* will also be accepted.

Such pre-market approval/s or registration/s submitted with an application for a License to import, distribute or export a Class C or Class D medical device or IVD will be referred to as the "originating approval/s".

c) For a low to moderate risk (Class B) and moderate to high risk (Class C) and high risk (Class D) medical device or IVD Certificate of Free sale from country of manufacture or final assembly;

The certificate of free sale is evidence that the medical devices are legally sold or distributed in

the open market, freely without restriction, and approved by the regulatory authorities in the country of origin.

d) For a moderate to high risk (Class C) and high risk (Class D) medical device or IVD License holders must be able to provide full technical documentation on request by The Authority.

e) Where relevant, certificate of conformance / analysis.

4.2.2 **Medical Device Distributor License**

License to import, distribute or export a Class B, Class C or Class D medical device.

A person referred to in section 22(1)(b) of the Act must apply to The Authority for a License to import, distribute or export a Class B, Class C or a Class D medical device or IVD.

The person must submit the following information to the CEO in an application for a License to distribute a medical device in the electronic format approved and provided by the Authority and available on the website www.sahpra.org.za and in a printed and signed document:

a) A list of all medical devices or IVDs imported into South Africa by product classification with the Global Medical Device Nomenclature Code (GMDN) and in the format as provided in the License Application for Medical Device Manufacture or License Application for Medical Device Import and Distribution.

b) For a medium to high risk (Class C) and high risk (Class D) medical device or IVD proof of pre-market approval or registration for the medical device or IVD from at least one of the following regulatory authorities:

- Australia's Therapeutic Goods Administration (TGA) i.e. inclusion in the Australian Register of Therapeutic Goods
- Brazil's ANVISA (National Health Surveillance Agency) approval and registration.
- Canada's Medical Device License to market;
- The European Union's CE certificate, to show conformity to all obligations for medical devices as required by the Medical Devices Directives;
- Japan's Marketing Authorization Holder (MAH) License;

- USA's FDA's Center for Devices and Radiological Health (CDRH) Premarket Approval (PMA) or Premarket Notification 510(k) clearance.
- Evidence of IVDs approved under the *World Health Organisation* (*WHO) Prequalification of In Vitro Diagnostics Programme* will also be accepted.

Such pre-market approval/s or registration/s submitted with an application for a License to import, distribute or export a Class C or Class D medical device or IVD will be referred to as the "originating approval/s".

c) For a low to moderate risk (Class B) and moderate to high risk (Class C) and high risk (Class D) medical device or IVD Certificate of Free sale from country of manufacture or final assembly;

The certificate of free sale is evidence that the medical devices are legally sold or distributed in the open market, freely without restriction, and approved by the regulatory authorities in the country of origin.

d) For a moderate to high risk (Class C) and high risk (Class D) medical device or IVD License holders must be able to provide full technical documentation on request by The Authority.

e) Where relevant, certificate of conformance / analysis.

4.2.3 **A License issued to:**

a) manufacture, import or export; or

b) import, distribute or export, as the case may be, a Class B, Class C or Class D medical device or IVD will be valid until the guideline is revised or for a period of five years, whichever occurs first.

4.2.4 **Every application for a License to:**

a) manufacture, import or export; or

b) import, distribute or export, as the case may be, a Class B, Class C or Class D medical device or IVD must have an appointed Authorised Representative with the knowledge and responsibility to ensure that the correct procedures are followed at all times, including the processes of importation, transportation, storage, distribution, marketing and sale. The owner of the manufacturer, importer, distributor or exporter of a medical device or IVD must provide and

maintain such staff, premises, equipment and facilities to enable the Authorised Representative to carry out the said functions.

4.2.5 The South African Health Products Regulatory Authority upon issuing a License and/or reviewing a License holder may add certain conditions to the License.

4.2.6 In order for a manufacturer, distributor, importer to be considered for the issue of a License the company or person should have available and implemented at least the following:

a) A Quality Management System addressing all aspects of quality assurance be in place, covering contracts (agreements); purchasing; manufacturing, Final Product handling, storage; facility installation, servicing, cleanliness; documentation controls and records; international regulatory control; internal and external audits; training; complaint handling; emergency plan and recalls; quality assurance, management review; distribution (transport, delivery, temperature control); and export documentation (proof of export);

b) If any of the activities are delegated to a competent third party it should be done in a written formal agreement.

4.2.7 In the event of any modification of a Class C or Class D medical device or IVD or change in the approval status or certification of the Class C or Class D medical device or IVD in the jurisdiction/s which was/were submitted to support the License application as the “originating approval/s”, the License holder must submit full information to The Authority within 30 days of the change.

4.2.8 In the event the medical device or IVD is recalled from the market which was submitted as the ‘originating approval” in the License application, the License holder must notify The Authority immediately and the recall procedure must be initiated immediately.

4.2.9 In the event the medical device or IVD is withdrawn from the market which was submitted as the ‘originating approval” in the License application, The Authority must be notified immediately, and a withdrawal plan of action is to be agreed with Council.

4.3 Fees

Fees payable to the CEO shall be levied as per the Regulations published by the Minister for Fees payable to the Registrar from time to time in the Government Gazette in respect of any License application, permits or any authorization for the medical device and/or IVD manufacturers, distributors, importers and exporters as applicable.

4.4 Where to send applications

Applications should be delivered for attention of the CEO to:

Mdcovid@sahpra.org.za and mdadmin@sahpra.org.za

4.5 Exportation of IVD or Non-IVD Medical Devices

4.5.1 It is the responsibility of the licensed Exporter to comply with the legal registration information approved by the relevant Ministry of Health of the importing country;

4.5.2 Class B, Class C or Class D medical devices or IVDs registered by another Health Authority however not registered by the South African Health Products Regulatory Authority of South Africa and not intended for sale or distribution in South Africa however manipulated i.e. manufactured, packed, labelled, stored in South Africa prior to export to the importing country will be subject to the requirements of a Quality Management System.

4.6 Transitional Arrangements

Persons who wish to manufacture, import, distribute or export a Class B, Class C or Class D medical device or IVD have six months from the date of implementation of the Guideline to make an application for a License to manufacture, import, distribute or export a medical device or IVD.

5. REFERENCES

The following related documents are referenced:

5.1 Medicines and Related Substances Act, Act 101 of 1965 as amended.

5.2 General Regulations relating to Medical Devices and IVDs.

6. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces the old guideline number 16.03 for License to Manufacture, Import, Export or Distribute Medical Devices & IVDs. It will be reviewed on this timeframe or as and when required.