PRA/LPP/GUD/072

REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDELINES FOR REGISTRATION OF MEDICAL DEVICES ESTABLISHMENTS

February 2022

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Prepared by Deputy Director, Product Evaluation and Registration

Sign.....for Warsen.....

Date.....25/2/2022.....

Reviewed by Director, Pharmacy Practice

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Date.....25/2/2022.....

Checked by Head, Quality Management

Sign.....

Date.....28/2/2022.....

Authorized by Chief Executive Officer

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Date.....27/04/2022.....

1. ACKNOWLEDGEMENTS

The Board acknowledges all the authors and contributors who contributed to the preparation of this document.

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2. ABBREVIATIONS AND ACRONYMS

CSDT	Common Submission Dossier Template
EU NB	European Union Notified Bodies
EWG	Experts Working Group
GMDN	Global Medical Devices Nomenclature
GMP	Good Manufacturing Practices
IMDRF	International Medical Devices Regulators Forum
IVD-MD	In-Vitro Diagnostics Medical Device
LAR	Local Authorized Representative
LM	Legal Manufacturer
PMA	Premarket Approval
STED	Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices
UDI	Unique Device Identification
UMDNS	Universal Medical Device Nomenclature System
US FDA	US Food and Drug Administration
WHO	World Health Organization
ISO	International Standards Organization

3. DEFINITIONS

The definitions given below apply to the terms as used in this document. They may have different meanings in other contexts.

Act: a statute or law made by a legislative body.

The Pharmacy and Poisons Board, hereinafter referred to as the 'Board' **is the national regulatory authority in Kenya** that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements.

Authorized representative: a natural or legal person established within a country or jurisdiction that has received a written mandate from the manufacturer, distributor or wholesaler to act on its behalf for specified tasks related to the latter's obligations under that country or jurisdiction's legislation.

Classification name: the term used by the Board and its classification panels to describe a device or class of devices for purposes of classifying devices.

Classification system: the classification system for medical devices, including in-vitro diagnostics (IVDs), that guides the regulatory controls to be implemented for each device class. It is widely accepted that medical devices are separable into groups or classes (typically four: A, B, C and D) by applying a set of classification rules and specifying separately the various conformity assessment procedures that should apply to each group of devices.

Commercial distribution: any distribution of a medical device intended for human use which is held or offered for sale.

Distributor: a natural or legal person in the supply chain who, on his/her own behalf, furthers the availability of a medical device to the end user.

Establishment registration: registration of the medical devices establishment that manufactures, imports and/or distributes medical devices as prescribed in these guidelines and the Pharmacy and Poisons Act

Importer: a natural or legal person in the supply chain that is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed.

In-vitro diagnostic (IVD): 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.

Manufacturer: any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his/her name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).

Note: This "natural or legal person" has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the regulatory authority within that jurisdiction.

Material change: includes any change or modification in the labelling of or advertisements that affects the identity or safety and effectiveness of the device. These changes may include, but are not limited to, changes in the common, usual or proprietary name, declared ingredients or components, intended use, contraindications, warnings or instructions for use. Changes that are not material may include graphic layout, grammar, correction of typographical errors which do not change the content of the labelling, changes in lot number and, for devices where the biological activity or

known composition differs with each lot produced, the labelling containing the actual values for each lot.

Medical device: any instrument, apparatus, implement, machine, appliance, implant, reagent for in-vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment and alleviation of or compensation for an injury;
- investigation, replacement, modification or support of the anatomy or of a physiological process;
- supporting or sustaining of life;
- control of conception;
- disinfection of medical devices;
- providing information by means of in-vitro examination of specimens derived from the human body;

and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Authorized Person: the person designated as in charge of the establishment and responsible for the following:

- Registration of the establishment;
- Market authorization and regulatory matters
- Correspondence with the Board
- Safety and performance of the products.

Owner or operator: the corporation, subsidiary, affiliated company, partnership or proprietor directly responsible for the activities of the registering establishment.

Product code: the code used by the Board to identify the generic category of a device.

Quality management system: set of interrelated or interacting elements of an organization to establish quality policies and quality objectives and to establish the processes that are needed to ensure that those policies are followed, and those objectives are achieved.

The current Good Manufacturing Practices (cGMPs) for medical device manufacturers are an interrelated set of practices that describe up-to-date manufacturing practices for medical devices required to maintain compliance with established quality standards, and ensure the quality, safety and efficacy/performance of the medical device. Compliance Good Manufacturing Practices and Quality System Regulations is imperative for medical device manufacturers.

1. INTRODUCTION

1.1 Background

Medical devices play a critical role in the diagnosis, management and prevention of disease. It is therefore critical that available medical devices should be safe and high-quality and perform as intended by the originating manufacturer throughout their life cycle. The International Organization for Standardisation (ISO) standard ISO 13485:2016 (Medical devices – quality management systems – requirements for regulatory purposes) is widely accepted by regulators as the basis of the appropriate quality management systems requirements for medical devices establishments that need to demonstrate their ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services throughout the product life-cycle.

The medical devices establishment is expected to have an established quality management system to ensure continued safety, quality and performance of all medical devices throughout the product's life cycle and within the supply chain. The registration of the establishment is one of the processes which ensures that the manufacturer, importer and/or distributor fulfils the regulatory requirements, as determined through the legislative framework informing the control of medical devices.

This Guideline provides the framework for Registration of Medical devices Establishments under the Pharmacy and Poisons Act. It should be read alongside other relevant guidance documents and other relevant legislation.

1.2 Legal Framework

In regulation of health products and technologies, the Board is empowered under section 3A and Section 3B(2)(e) of the Pharmacy and Poisons Act, Cap 244 of the Laws of Kenya, to grant, withdraw or revoke licenses to manufacturers, wholesalers, retailers, importers, exported and distributors. This empowers the Board to regulate contractors for medical devices and physical security for products including radioactive material and biological products.

Premises, facilities, establishments and companies that manufacture, distribute, import, export and trade in medical devices in Kenya will require to be licensed in accordance with the laws of Kenya. Section 3B(2)(j) of the Act mandates the Board to inspect and license all manufacturing premises, importing and exporting agents, wholesalers, distributors, pharmacies, including those in hospitals and clinics, and other retail outlets.

The personnel, premises and practices employed in the manufacture, storage, marketing, distribution and sale of medicinal substances including medical devices and IVDs comply with the defined codes of practice and other prescribed requirements in line with Section 3B(2)(c) of the Act.

Except where necessary, regulated entities such as manufacturers, establishments that are already licensed under the Pharmacy and Poisons Act do not need to apply separately to be licensed for purposes of medical devices.

1.3 Scope

This guidance is intended to provide medical device, manufacturers, importers, wholesalers, distributors and retailers in Kenya with the requirements for registration of medical devices establishments, based on implementation of quality management systems, to ensure their conformity with the requirements of ISO 13485:2016 through established processes.

The manufacture, importation, exportation and distribution of medical devices is subject to the legal provisions of the Pharmacy and Poisons Act. The intent of the medical devices' establishment registration is to ensure that the Board, is made aware of:

a) manufacturers of medical devices in Kenya and the classification of the medical devices manufactured in Kenya;

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

c) to establish criteria for importation of medical devices into Kenya

Manufacturers, importers and distributors shall ensure that the quality, safety and performance of medical devices are maintained throughout their life cycle, as specified in national regulations, by registering medical devices establishments and ensuring compliance with regulations. Other law enforcers shall collaborate with national regulatory authorities (Boards) when executing their legal mandate to ensure optimum enforcement of the Act and other relevant national laws.

Manufacturing, use and handling of medical devices is guided by risk classification established in the PPB Guideline on submission of documentation for registration of medical devices and In-Vitro Diagnostics. It is the role of the manufacturer to determine and establish the risk class of the medical device. A medical devices establishment registration certificate shall be required for all medical devices

2. REGISTRATION OF MEDICAL DEVICES ESTABLISHMENTS

Any establishment that manufactures, imports or distributes a medical device in Kenya shall be registered by the Board.

The Board may, subject to these guidelines and regulations under the Pharmacy and Poisons Act, upon application in the prescribed manner and after payment of the prescribed fee, issue to a manufacturer, wholesaler or distributor of a medical device a registration certificate to:

a) manufacture;

b) import;

c) export; or

d) act as a wholesaler of,

as the case may be, such a medical device, in such conditions and with the application of such acceptable quality assurance principles as the Board may determine.

No company or individual shall manufacture, import or export or distribute any medical device unless he or she is the holder of a registration certificate, as provided for in the Pharmacy and Poisons Act. Medical devices intended to be manufactured, imported or distributed by the applicant must be listed in the application for the registration of a medical device's establishment. Individuals importing medical devices for personal use shall not be required to make an application to the Board for the registration of a medical device's establishment. However, authorization to import medical devices for personal use must be obtained from the Board**.**

2.1 Application for registration of medical devices establishments

An application for registration of medical device establishments shall be made through the online licensing system to the Board and must be accompanied by the following documents:

a) application form, duly filled in, signed and dated (see Annex 1 for the form to be used for the initial application and Annex 2 for the form to be used for registration renewal);

b) copy of the quality manual;

c) quality management system in place

d) attestation by an Official Correspondent of the establishment that the establishment has documented procedures in place with respect to: complaints handling, including field safety corrective action; handling of substandard and falsified products; disposal; and any other procedure as required by quality management systems;

e) an attestation by an Authorized Representative or responsible establishment official that the establishment has documented procedures in place, where applicable, for handling, storage, delivery, installation, corrective action and servicing in respect of the devices.

f) electronic copy of the establishment quality management system manual and establishment procedures and processes;

g) copy of practice/certificate of registration of the Official Correspondent;

h) copy of items required for national registration of companies, such as a business licence;

i) Business registration certificate or certificate of incorporation from the Registrar of Companies

j) list of all medical devices imported into Kenya product codes, product description, brand name and group/family name, as applicable

k) evidence of payment of prescribed fees.

2.2 Processing of the application

The Board shall review the application and perform a desk review of the quality manual and the establishment procedures and processes.

In evaluating an application for registration of a medical device's establishment, the Board will consider the supporting documentation

provided and information therein including evidence of availability and implementation of at least the following:

A. quality management system addressing all aspects of quality assurance 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; complaints handling; emergency plan and recalls; quality assurance; management review; distribution (transport, delivery, temperature control); and export documentation (proof of export);
B. written formal agreement in case any of the activities are delegated to a competent third party.
C. list of all medical devices imported into Kenya product codes, product description, brand name and group/family name, as applicable;
D. for a medium-to-high-risk (Class C) or high-risk (Class D) medical device, proof of pre-market approval or registration of the device from at least one of the member regulatory authorities of the International Medical Device Regulators Forum or confirmation of WHO prequalification; such pre-market approval(s) or registration(s) submitted with an application will be referred to as the "originating approval(s)";
E. for a low-to-medium-risk (Class B), medium-to-high-risk (Class C) or high-risk (Class D) medical device, 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 and without restriction, and are approved by the regulatory authorities in the country of origin;
F. for a medium-to-high-risk (Class C) or high-risk (Class D) medical device, the holder of the medical devices establishment registration certificate must be able to provide full technical documentation on the request of the Board;
G. where relevant, certificate of conformance/analysis.

The Board will conduct onsite inspection to assess implementation of the quality management system requirements.

2.3 Issuance of a registration certificate

Upon confirmation of fulfilment of the requirements specified in section 3.1 above, the Board shall issue a registration certificate for the medical device's establishment in the prescribed format. (Annex 2). Registration certificates issued through the online licensing system shall bear an electronic signature and will not be subject to physical signing.

A medical devices establishment registration certificate shall expire on 31st December each year and it is renewable annually. The registration certificate for manufacturers will be valid for five years following a successful reinspection.

2.4 Refusal to issue a medical devices establishment registration certificate

The Board may refuse to issue a medical devices establishment registration certificate if:

a) the applicant has made false or misleading statement(s) in the application; or

b) the Board has reasonable grounds to believe that issuing the medical devices establishment registration certificate will constitute a risk to the health or safety of patients, users or other persons; or

c) the applicant has failed to meet the conditions for medical devices establishment registration as specified in section 3.1 above.

In any case where the Board does not recommend the issuing of a medical device's establishment registration certificate, the Board shall:

a) notify the applicant in writing of the reasons for not recommending/refusing the registration of the establishment; and

b) give the applicant an opportunity to respond to the Board and provide relevant documentation/evidence in support of the application.

2.5 Notification of change

After the issuance of a medical device's establishment registration certificate, if there is a change to any of the information submitted at the time of application, the holder of the registration certificate shall submit the new information to the Board within 10 working days of the change.

The Board shall be notified of any changes to the application for registration of a medical device's establishment. The applicant shall obtain written authorization from the Board prior to the implementation of any change(s) that are likely to impact the quality, safety or performance of medical devices.

Variations to an existing registration can also be notified online and shall be subject to approval

2.6 Suspension, revocation, withholding or cancellation of an establishment registration certificate

Subject to the requirement stated under section 3.4 above, the Board may suspend, revoke or cancel a medical devices establishment registration if the Board has reasonable grounds to believe that:

a) the holder of a registration certificate has contravened conditions of licensure as provided in these guidelines or regulations or in the Pharmacy and Poisons Act relating to medical devices; or

b) the holder of a medical devices establishment registration certificate has made false or misleading statement(s) in the application or notification of change; or

c) failure to suspend the medical devices establishment registration certificate would compromise the safety, performance and/or quality of the medical device, or constitute a risk to the health or safety of patients, users or other persons.

The Board shall not cancel, revoke or suspend a medical devices establishment registration certificate unless:

a) It has sent written notice of 21 working days to the holder of an establishment registration certificate, setting out the reason for the proposed suspension;

b) The period of time set out in the notice for corrective action, if required, has passed without the action having been taken; and

c) The establishment registration certificate holder has been given an opportunity to respond to the Board in respect of the suspension.

2.7 Restoration of a registration certificate

The Board may, within 30 working days of the date of receiving the response from the holder of a registration certificate and considering the supporting documentation/information provided by the holder, reinstate the medical devices establishment registration certificate.

2.8 Other general regulatory requirements for holders of establishment registration certificates for medical devices establishments

a) Holders of registration certificates are required to follow the PPB Guideline on the safety and vigilance of Medical Products and Health Technologies and WHO Guide on post-marketing surveillance and market surveillance of medical devices including in vitro diagnostics (6), including adverse event reporting and recalls, in the event of an incident or need to withdraw a medical device from the market.

b) Holders of registration certificates that are responsible for the manufacture, import, export, distribution and/or wholesale of medical devices are required to be certified under ISO 13485 within 1 year from date of issuance of registration certificate.

c) In terms of the exportation of medical devices, it is the responsibility of the holder of the registration certificate to comply with the legal registration information approved by the relevant competent authority of the importing country.

3. REFERENCES

1. Global Harmonization Task Force (GHTF)-/SG1/N12:2000 Role of Standards in the Assessment of Medical Devices.
2. GHTF/SG1/N29:2005 Information Document Concerning the Definition of the Term 'Medical Device'.
3. GHTF/SG1/N40:2006 Principles of Conformity Assessment for Medical Devices.
4. GHTF/SG1/N41:2005 Essential Principles of Safety and Performance of Medical Device.
5. The Global Harmonization Task Force (GHTF)which is now The International Medical Devices Regulatory Forum (IMDRF)
6. The Asian Harmonization Working Party (AHWP)
7. British Standard Institute
8. Health Safety Authority
9. Global Medical Devices Agency
10. ISO Standards
11. World Health Organization (WHO)

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5. ANNEXURES:

ANNEX 1. APPLICATION FOR CERTIFICATE OF REGISTRATION FOR A MEDICAL DEVICES ESTABLISHMENT

APPLICATION FOR CERTIFICATE OF REGISTRATION OF MEDICAL DEVICES ESTABLISHMENT

PHARMACY AND POISONS CAP 244 CAP
P.O Box 27663-00506
Nairobi, Kenya

I/We hereby apply for registration of my/our existing/new establishment registration certificate in accordance with PHARMACY AND POISONS CAP 244 CAP

Name of applicant.....
.....
Physical postal address.....Tel. No.....
Email.....
Full name(s) of partner(s)/director(s).....
Full name(s) of official correspondent/registered practitioner.....,

Certificate number
.....
Establishment type.....

The business will be under the direct supervision of (full name(s) of Official Correspondent and Registered Practitioner).....,
Certificate no. .....

My/our financial resources committed to this business amount to..... and my/our annual projected turnover is

If my/our establishment is registered, I/we shall keep it in hygienic condition and in a good state of repair as required under the above-mentioned PHARMACY AND POISONS CAP 244 CAP and Regulations.

I/we have not been convicted of any offence relating to any provision of PHARMACY AND POISONS CAP 244 CAP and Regulations or any other written law related to the business being applied for in the 6 months immediately preceding this Application and have not been disqualified from holding a certificate, and my/our certificate has been/has not been suspended.

NB False declaration constitutes an offence.

Date ..... Signed
.....
Fees 45,000 Kenya Shillings.....Receipt No. ..... dated
.....

FOR OFFICIAL USE ONLY
Registration granted/not granted
because.....
....
Registration No.....Approved by management meeting
No..... dated.....
Date Signature of Applicant
.....
.....

ANNEX 2. APPLICATION FOR RENEWAL OF REGISTRATION CERTIFICATE OF MEDICAL DEVICES ESTABLISHMENTS

APPLICATION FOR RENEWAL OF REGISTRATION CERTIFICATE OF MEDICAL DEVICES ESTABLISHMENTS

PHARMACY AND POISONS BOARD
PO BOX 27663-00506
Nairobi Kenya

PART I:

I/We hereby apply for renewal of certificate/for a new certificate to manufacture, sell, pack, store or distribute the following:

.....
.....

Name of Applicant .....
.....

Postal address .....Tel. No .....Fax .....

Email .....

Full name(s) of
partner(s)/director(s).....
.....

Establishment situated at..... Street/village/plot No.....

District/municipality .....
.....

Region.....
.....

Establishment registered for the business
of.....

Establishment Registration No.....

Dated.....

Existing certificate No..... Dated..... Expiry date .....

PART II: APPLICABLE TO MANUFACTURERS ONLY

PRODUCT REGISTRATION STATUS

I wish to manufacture the following item, whose registration status is shown below:

Serial No.	Common Trade Name Registration

For official use only/generic No.

Name

.....

PART III: APPLICANT DECLARATIONS

If my/our business is registered, I/we shall keep the establishment in hygienic condition and in a good state of repair as required under the above-mentioned CAP244 and Regulations.

I/we have not been convicted of any offence relating to any provision of the Pharmacy and Poisons CAP 244 and Regulations made there under or any other written law related to the business being applied for within 3 months immediately preceding this application and have not been disqualified from holding a certificate and my/our certificate is/is not suspended.

NB False declaration constitutes an offence.

Date.....
.....
Signature of Applicant and stamp

Fees 50,000 Kshs.....Receipt No.....
dated.....

FOR OFFICIAL USE ONLY

Certificate granted/not granted
because.....
Certificate No.....Approved by management meeting No.
..... dated .....

.....	.....
Date	Signature

ANNEX 3. REGISTRATION CERTIFICATE OF MEDICAL DEVICES ESTABLISHMENT

REGISTRATION CERTIFICATE OF MEDICAL DEVICES ESTABLISHMENT
PHARMACY AND POISONS BOARD

This is to certify that the establishment owned by (Name) ..... of (Postal address)..... which is located at..... Street, in.....Village/township/municipality/city, have been registered to be used as..... ..... for preparation/selling/packing/carrying/advertising/storing/manufacturing of..... ..... with establishment Registration No.....

Subject to the following conditions.

1. The establishment and the manner in which the business is to be conducted must conform to requirements of the PHARMACY AND POISONS CAP 244 or any other written law related to the establishment registration at all times failing of which this certificate shall be suspended or revoked.
2. Any change in the ownership, name and location of the registered establishment shall be approved by the Board**.**
3. This certificate is not transferable to any other establishment or person.
4. This certificate shall be displayed conspicuously in the registered establishment.

Date:

Signature of:

P. O. Box 27663 00506 Lenana Road Opposite Russian Embassy Nairobi,
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