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REPUBLIC OF KENYA



MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDELINES FOR REGISTRATION OF MEDICAL DEVICES INCLUDING IN-VITRO DIAGNOSTICS

JANUARY,2022

Citation and address

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Prepared by Head, Medical Devices and Invitro Diagnostics

Sign.....

Date.....20th-01-2022.....

Reviewed by Deputy Director, Product Evaluation and Registration

Sign.....

Date.....20th January 2022.....

Checked by Head, Quality Management

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Date.....21/01/2022.....

Authorized by Chief Executive Officer

Sign.....

Date.....25/01/2022.....

I. ABBREVIATIONS

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

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III. GLOSSARY OF TERMS

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

Applicant: is the person applying for a medical device registration.
Intended Use: means the objective intended use or purpose, as reflected in the specifications, instructions and information provided by the medical device owner of the medical device.
Label: in relation to a health product, means any written, printed or graphic representation that appears on or is attached to the health product or active ingredient or any part of its packaging, and includes any informational sheet or leaflet that accompanies the health product or active ingredient when it is being supplied.
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:

a. diagnosis, prevention, monitoring, treatment or alleviation of disease,
b. diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
c. investigation, replacement, modification, or support of the anatomy or of a physiological process,
d. supporting or sustaining life,
e. control of conception,
f. disinfection of medical devices,
g. providing information by means of in vitro examination of specimens derived from the human body;
h. disinfection substances,
i. aids for persons with disabilities,
j. devices incorporating animal and/or human tissues,
k. Devices for in-vitro fertilization or assisted reproduction technologies.

and 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.
In-Vitro Diagnostics Medical Device (IVD-MD): 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;

a. Natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person her/himself or on her/his behalf by a third party.

b. The obligations of this guideline to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name.

Product Owner (Legal Manufacturer (LM): a person who sells a medical device under his own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for one or more of the following activities:-designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on his behalf.

Serious Deterioration in the state of Health: in relation to a person, means;

- a life-threatening illness or injury suffered by that person;
- a permanent impairment of a bodily function of that person;
- any permanent damage to any part of that person's body; or
- a condition requiring medical or surgical intervention to prevent any such permanent impairment or damage.

Accessory: An article which whilst not being a device is intended specifically by its Manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

Risk: Probability of occurrence of harm and the severity of that harm.

Universal Medical Device Nomenclature System (UMDNS)- A system used to facilitate identifying, processing, filing, storing, retrieval, transferring, and communicating data about Medical Devices. UMDNS Includes all Medical Devices and Supplies, clinical laboratory Equipment and IVD's, Generic Tests, Medical Software related to Devices, Selected Hospital Furniture, Systems and Test Equipment, as well as personal and assistive devices.

Unique Devise Identification (UDI)- A series of Numeric or alphanumeric characters that is created through a coding system. It allows the unambiguous identification of a specific product on the Market and represents the 'access Key' to Device related information stored in the UDI data. The UDI comprises the Device Identifier and Production Identifier.

Global Medical Devices Nomenclature (GMDN) – A Poly-Hierarchical system of identifying Medical Devices into collective Terms which give a Device attribute and high-Level terms allowing analysis of the Device by Product attribute or Feature.

Non-Invasive Medical Devices- A device which in whole or in part does not penetrate the body, either through a body orifice or through the surface of the body.

Invasive Medical Devices: A device, which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

Body orifice: Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy.

Surgically invasive device: An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

Active Medical Devices: any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy.

Accessory: An article which, is intended specifically by its manufacturer to:

- be used together with a parent device to enable that device achieve its intended use as an IVD Medical Device.
- or to augment or extend the capabilities of the parent device in fulfilment of its intended use as an IVD Medical Device.

IVD Medical Device for Self-testing: Any device intended by the manufacturer for use by lay persons.

Examination: Set of operations having the object of determining the value of a property.

Note: In the IVD Medical Device industry and in many laboratories that use IVD Medical Devices, examination of an analyte in a biological sample is commonly referred to as a test, assay or analysis.

Harm: Physical injury or damage to the health of people or damage to property or the environment.

Hazard: Potential source of harm.

Intended use / purpose: The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

Instrument: equipment or apparatus intended by the manufacturer to be used as IVD Medical Device.

IVD Medical Device: A 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. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

Reagent: chemical, biological or immunological components, solutions or preparations intended by the manufacturer to be used as IVD Medical Devices.

Lay person: individual that does not have formal training in a specific field or discipline

Near patient (testing): Testing performed outside a laboratory environment by a professional other than a laboratory professional, generally near to, or at the side of, the patient.

Risk: Combination of the probability of occurrence of harm and the severity of that harm.

Self-testing: Testing [examination to align with labelling standard] performed by lay persons.

Specimen receptacle: a device, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment of specimens derived from the human body.

Transmissible agent: An agent capable of being transmitted to a person, as a communicable, infectious or contagious disease.

Transmission: The conveyance of disease to a person.

Local Authorized Representative – Any manufacturer based outside the Kenya must designate a local authorized representative (LAR). The appointed LAR must provide written evidence that they are acting with the consent of a manufacturer located outside the Kenya. The responsibility of the LAR is, to assure regulatory compliance and serve as the central communication pathway with the PPB

1.0 PART ONE

1.1 INTRODUCTION

The Pharmacy and Poisons Board (PPB) is the National Regulatory Authority established under the Pharmacy and Poisons Act, Cap 244 of the Laws of Kenya, to regulate the profession of pharmacy and ensure the safety, quality and efficacy/effectiveness of health products and health technologies including medical devices and *in vitro* diagnostics.

Medical devices including *In vitro* diagnostics constitute a vital component of health products and health technologies that contribute to the attainment of the highest attainable standards of health for all citizens as envisioned in Article 43 of the Constitution of Kenya, 2010.

In 2007, the World Health Organization advised member states on the mechanism for the regulation of Medical Devices including In-Vitro Diagnostics (IVD's) through Resolutions 67.29 and Resolutions 60.27 '*regulatory system strengthening for medical products and the WHO global model regulatory framework for Medical Devices including In vitro diagnostics (IVDs).'* This recommendation was adopted by the PPB in 2012 resulting in

evaluation of applications for marketing authorization of medical devices including IVDs.

This Guideline provides a framework for Evaluation and Registration of Medical Devices Including In-Vitro Diagnostics including the evaluation pathways to be followed for different applications. It provides for the risk classification of medical devices according to the different classes and specifies the requirements applicable for each class.

This document should be read alongside other PPB Guidelines and applicable legislation such as the Nuclear Regulatory Act (Cap 243) which provides for the production and use of radiation sources and management of radioactive waste. Applicants are therefore reminded that, notwithstanding the registration of a medical device under the Pharmacy and Poisons Act, the supply and use of any medical device including *IVDs* in Kenya should also comply with the requirements under other applicable legislations and the requirements to monitor market performance of the registered medical devices including IVDs.

This Guideline should be implemented while taking into consideration Good Regulatory Practices (GRP) that guide all personnel at the PPB in making regulatory decisions that are legal, clear, transparent, consistent, impartial, proportionate, prompt, and scientifically sound.

If there are any contradictions between the guidance documents and any written law, the latter shall take precedence.

1.2 LEGAL FRAMEWORK

The PPB is empowered under Section 3A(a) of the Pharmacy and Poisons Act ("the Act") to formulate guidelines for regulating the manufacture, import and export, distribution, sale and use of medical products including medical devices and IVDs.

Further, the PPB is empowered under Section 3A of the Act grant or withdraw marketing authorization for medical devices and IVDs subject to appropriate

conditions and revise such conditions for marketing authorization as necessary.

This guideline is intended to implement the requirements of the Act stipulated under Section 3B(2)(b) to ensure that all medicinal products manufactured in, imported into or exported from the country conform to prescribed standards of quality, safety and efficacy. In doing so, Section 3B(2)(i) of the Act requires the PPB to consider applications for approval and alterations of dossiers intended for use in marketing authorization of medicinal substances.

In performing its regulatory functions, the PPB is empowered under Section 3B92) (r) of the Act to collaborate with other national, regional and international institutions on medical substances regulation. This enables the PPB to recognize and rely on registrations and certifications from notified bodies and listed reference regulatory authorities. The remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.

1.3 SCOPE:

This Guideline describes the processes and general requirements for the submission of an application for registration of medical devices and In-Vitro diagnostics.

a) These guidelines shall apply to medical devices and their accessories.

b) Where a device is intended to administer a medicinal product, that device shall be governed by this guideline, without prejudice to the corresponding regulations for registration of medicinal products for human and veterinary use set by the PPB.

c) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product and which is liable to act upon the body with action ancillary to that of the device, that device must be assessed and authorized in accordance with this guideline.

2.0 PART TWO

2.1 RISK BASED CLASSIFICATION FOR MEDICAL DEVICES

The inherent risk of a medical device depends substantially on its intended purpose and the effectiveness of the risk management techniques applied during design, manufacture and use.

Other considerations in risk classification include its intended user(s), its mode of operation and the technology used. Examples of factors influencing risk classification include the duration of medical device contact with the body, the degree of invasiveness, whether the medical device delivers medicinal products or energy to the patient, whether they are intended to have a biological effect on the patient and local versus systemic effects, etc**. *Annex: 5;*** *Risk Based Classification of Medical Devices and Examples (In-Exhaustive List)*

Table 1: Risk Based Classification of Medical Devices with Examples

CLASS	RISK LEVEL	EXAMPLES
A	Low Risk	➢ Cotton wool, bandages, urine collection bottles; compression hosiery; non-invasive electrodes, hospital beds.
B	Low-moderate	➢ Urinary catheters, tracheal tubes. ➢ Orthodontic materials, removable dental prosthesis
C	Moderate-high	➢ urethral stent; contact lenses for long-term continuous use ➢ catheter containing sealed radioisotopes
D	High Risk	➢ Pacemakers; Implantable defibrillators. ➢ prosthetic heart valves; cardiovascular stents; pacemaker leads and electrodes; deep brain stimulation electrodes; cerebrospinal catheter.

Medical devices vary greatly in complexity and application. Examples range from simple devices such as tongue depressors, medical thermometers, and disposable gloves to advanced devices such as computers which assist in the conduct of medical testing, implants including those used for contraception and prostheses. The design of medical devices constitutes a major segment of the field of biomedical engineering.

For the purpose of this guidance document, the rules applied for the risk-based classification of Medical devices are as below;

a. **Non-Invasive Medical Devices -** A device which in whole or in part does not penetrate the body, either through a body orifice or through the surface of the body.
b. **Invasive Medical Devices-** A device, which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.
    i. **Body orifice:** Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy.
    ii. **Surgically invasive device:** An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.
c. **Active Medical Devices -** any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy
d. **Exceptional Classes**
    i. Medical Devices which Incorporate Medicinal Substances
    i. Devices manufactured from or incorporate non-viable animal tissues or their derivatives
    ii. Medical Devices- used for sterilizing or Disinfecting Medical Devices
    iii. Medical Devices Incorporating Animal or Human Cells/Tissues/Derivatives

iv. Medical Devices for Ophthalmic Solutions Use
v. Medical Devices for Contraception or the prevention of Sexually Transmitted Diseases' (STD's)
vi. Implantable Medical Devices for Long-term Use

e. More than one class

a. Where a medical device has features that place it into more than one class, classification and conformity assessment should be based on the highest class indicated.
b. The actual classification of a Medical Device is determined by the Manufacturer and on its intended use.

2.1.1 Determination of Device Classification using this Rules-based System

The manufacturer should:

a. Decide if the product concerned is a medical device, using the appropriate definition.
b. Document the intended use of the medical device.
c. Take into consideration all the rules that follow in order to establish the proper classification for the device, noting that where a medical device has features that place it into more than one class, classification and conformity assessment should be based on the highest class indicated.
d. Determine if the device is subject to special national rules that apply within a particular jurisdiction**.**

Explanatory notes:

Once a rules-based system has been adopted, modifications may occasionally be required. For example, where through post-market experience, a level of risk for a type of medical device, classified using the criteria found in this guidance document is no longer appropriate, consideration should be given to re-classification of the device type by a change to the rules.

Similarly, the historical knowledge of a device may necessitate a different class than the one assigned by the initial classification. Unlike the principle of reclassification after post-market experience with a device, this principle of

historical knowledge should be applied immediately when the initial classification yields an inappropriate result.

Where special national rules are applied, resulting in a device class other than that suggested by the present rules, then a different conformity assessment procedure may be indicated. This may have an effect on the acceptability of such devices for free movement in countries where these present rules have been adopted unless other, or additional, conformity assessment procedures are carried out.

2.1.2 Level of Regulatory Requirements

The level of regulatory requirements increases as the level of the device risk class increases. These regulatory controls may include, for example:

i. Operation of a quality system (recommended for all devices);
ii. Submission of technical data;
iii. Product testing using in-house or independent resources;
iv. Documentation of clinical evidence to support the manufacturer's claims;
v. The need for and frequency of independent external audit of the manufacturer's quality system; and
vi. Independent external review of the manufacturer's technical data

2.2 REGISTRATION REQUIREMENTS OF MEDICAL DEVICES

This document aims to provide guidance on the preparation of a product registration application for general medical devices using the Common Submission Dossier Template (CSDT). In particular, this document serves to clarify the information to be submitted in each section of the CSDT and the format that this information is to be submitted in.

The CSDT document contains elements of the International Medical Devices Regulators Forum (IMDRF) guidance document titled "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)".

Product registration applications for medical devices submitted to PPB must be prepared in the format set out in the CSDT document

All medical devices including *in vitro diagnostic* medical devices must be registered with PPB prior to placing them on the Kenya market unless exempted by the Regulations.

2.2.1 The Common Submission Technical Dossier (CSTD) format of submitting an application for Medical Devices

The Common Submission Dossier Template (CSDT) will have the following components to be provided by the applicant depending on the class of the Medical device applied for, along with the list of configurations of medical devices to be registered;

I. Administrative information

Administrative information includes details of the Applicant, the details of the Local Representative Person, Physical Address for the Local Representative Person and Details of the Registered Business of the Local Representative Person and contact details domiciled in Kenya.

II. Manufacturer name and address

The application should identify the name and location of the legal manufacturer (Legal Manufacturer) who is placing the devices on the market. This should be consistent across the device labels and Declarations of Conformity.

Whereas a company is contracted to Manufacturer a Medical Device for another; Details of the Contracting company must also be provided.

a. Manufacturer Site Name
b. Site Address
c. Physical Address
d. Town
e. Postal Code
f. Street

g. Country

h. Contact Person

i. Contact Person Cell No.

j. Email address of the contact Person

k. Local Responsible Persons address

Table 2: Types of marketing clearances or approvals from each country/region

No.	Country/Region	Approval Type
1.	Australia	Australia Therapeutic Goods Administration (TGA) license
2.	Canada	Health Canada License
3.	European Union (EU)	For General Medical Devices -Annex II Section 3 or Annex V of MDD (for Class IIA) -Annex II Section 3 or Annex III coupled with Annex V of MDD (for Class IIB) -Annex II Section 3 and 4 of MDD (for Class C) -Annex II Section 3 and 4 of AIMDD (for active implantable medical devices)
4.	Japan	Ministry of Health, Labour and Welfare (MHLW) License
5.	United States of America (USA)	US FDA 510(K) clearance letter [510(K) exempted products do not qualify for abridged evaluation route.]; or • US FDA PMA approval letter
6.	Ireland	Irish Health Products Regulatory Authority
7.	Saudi Arabia	Saudi Arabia Food and Drugs Authority
8.	Switzerland	Swiss Medic

III. Local Authorized Representative and Subcontractors

The name and location of the Representative in Kenya should be identified. Details of the local Authorized Representatives, its registered Business including location should be provided.

The Pharmacy and Poisons Board will register all the Local Authorized Representative for Medical Devices in Kenya.
Only one Local Authorized Representative should be identified, and this should be consistent across the device labels, and Declarations of Conformity.
This requirement is mandatory before registration approvals are granted.

III.a The roles of a Local Authorized Representative include;

a. Acting as primary contact point with the competent authority;

b. Keeping technical file documentation ready and available for the Competent Authority;

c. Protecting documentation confidentiality because they are authorized to show them to the Competent Authorities only;

d. Notification of Adverse Event and Incident Reporting to the Competent Authorities (Sign a declaration to provide regular vigilant reports to PPB);

e. Assurance of supply chain regulatory compliance and accountability of medical devices;

f. Product Safety Vigilance reporting;

g. Field Safety Corrective Action implementation, management, coordination and reporting;

h. Assistance with technical file documentation;

i. Annual review of your technical file;

j. Notification of changes and amendments to the Medical Device regulations that affect the device(s).

III.b Responsibilities of the Local Authorized Representative

a. Any manufacturer based outside of Kenya must designate a local authorized Representative (LAR). The appointed LAR must provide written evidence that they are acting with the consent of a manufacturer located outside Kenya **(Annex 1: Letter of Authorization Template)**

b. The responsibility of the LAR is, to assure regulatory compliance and serve as the central communication pathway with the PPB.

c. The Local Authorized Representative Must obtain a letter from the Manufacturer appointing them as the Exclusive LAR, With the exclusive rights for distribution, sale, importation and registration of the medical device.

d. A Manufacturer / MAH/Innovator cannot appoint more than One LAR for the {Same product line or product portfolio} to be sold in Kenya.

e. An applicant may have more than One LAR for *all* their product portfolios'

f. Whereas there exists more than One LAR, The LAR shall control a product portfolio or product line in the Kenyan jurisdiction and Kenyan Market.

g. Local Technical Representatives will be required to apply for a license to trade in the business of Medical Devices including IVDs.

a) Device identification

A complete list of product codes should be provided. GMDN Code and Device subcategory/ Generic Device Group should be identified.

b) Device classification

Please indicate the device classification and rationale. The rationale should address each point of the selected classification rule.

If the device contains multiple components that on their own might be classed differently, please note:

i. If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the strictest rules resulting in the higher classification shall apply.

ii. If multiple classification rules apply, all should be identified. GMDN/Unique Identification Number (UIN)

c) Related previous submissions

Details of any other submissions relevant to the application, such previous submissions and all outcomes from such reviews.

d) Accessories

The following information should be provided for any accessories (including Class A) associated with the device:

i. Brief description of the accessory/ accessories and how they are used with the device(s)

ii. Classification of the accessories and rationale for classification

iii. Technical Documentation references

iv. Please note the Technical Documentation of the main machine/equipment should demonstrate compatibility of the devices with any applicable accessories.

e) Device description

The device description should enable understanding of the design, packaging, sterilization, or other characteristics of the device.

Sufficient information should be provided to distinguish different variants of the device, and the intended purpose of different design features. For example, if one variant of a device has a coating and another does not, what is the intended purpose of that coating, and why are both variants considered to meet the requirements for safety and performance?

Pictures and schematics should be provided wherever possible to enable an understanding of the device design features and intended purpose.

f) Intended use

The intended use should provide sufficient detail to explain the disease conditions the device is intended to treat or monitor, the basic principles of operation (ie intended users and environment), the intended patient population and the indications and contraindications of the device.

- indications and contraindications should be supported by objective evidence (eg, evidence provided in the risk assessment and clinical evaluation reports).
- The intended use must include use of the device as a “medical device” as defined by Article 1 of the respective Directives unless this is otherwise justified.
- Please ensure the intended use been described consistently throughout the file (eg. in the IFU, risk management documentation, clinical evaluation report, and design requirements).
- If the application includes a change to the intended use, all sections of the file should be reviewed for potential impact.
- For clarity it is suggested that this should be separate from the device description.

g) Market history

All submissions should be accompanied by a market history to enable an understanding of the context of device development.

- If the device is new and has never been marketed by the manufacturer anywhere in the world, please state this explicitly.
- For existing devices:
    i. Ensure that a market history is provided indicating the nature and timing of any changes and that any associated documents (i.e. risk analyses, labelling, clinical evaluation reports, verification/ validation data, etc.) account for these changes.

h) Sales, complaints and vigilance

Please provide sales, complaints and vigilance data for the last 5 years for your device, if available.

- Sales and complaints data should include sales outside the country of Origin/ Manufacturer. A breakdown should be provided to enable evaluation of sales and complaints by region.
- Complaints data should be evaluated rather than just listed. For example, why is the complaints rate considered acceptable? Have any trends been noted, or corrective actions taken? What is the status of these actions?
- Full details of vigilance issues should be provided, including the status of any Field Safety Corrective Actions or Notices.

i) Draft Declaration of Conformity

Ideally, the Declaration of Conformity should include:

- Manufacturer's name and address.
- EU Representative's name and address (if applicable).
- Compliance Statement with relevant Directive, indicating that the manufacturer is exclusively responsible for the Declaration of Conformity route (ISO 13485 certification)
- Product name(s), or other unambiguous reference of declaration scope (may be supplemented with an appendix with product codes and descriptions if appropriate).
- Signature line indicating appropriate responsible person and date.

j) Manufacturing process and subcontractors

- A detailed overview of the manufacturing processes should be provided. This should clearly identify any special or proprietary processes, and any subcontracted processes.
- The name and location of key manufacturing subcontractors should be provided.
- If new key subcontractors are used, provide copies of their ISO 13485 certificates.
- Validation documents for processes that can affect final product quality should be provided.

k) General labeling provisions

Name and Place of Business

- The label of a device shall contain the name and place of business of manufacturer, packer, or distributor including the Plot No, street address, city and county.
- If the firm's street address is in the local telephone directory, the street address can be omitted.
- If the firm listed on the label is not the manufacturer, the firm information must be qualified by an appropriate statement such as, "Manufactured for..." or

"Distributed by" Intended Use

- If a packer, distributor, or seller intends a device for uses other than those intended by the person from whom he received the device, these parties must furnish adequate labeling in accordance with the new intended use.
- If a manufacturer knows or has information indicating that his device is to be used for conditions or purposes other than which it was intended, he is required to provide adequate labeling in accordance with such other uses. (An example of this might be a manufacturer of dental X-ray equipment who is routinely selling his product to podiatrists.)

- **Medical devices and invitro diagnostics labeling Label requirements for the immediate container**

The label information must appear on the outside container or wrapper, or be easily legible through the outside container or wrapper.

If the presence of any label information will interfere with the test, the information may appear on the outside wrapper or container instead of the label.

If the immediate containers are too small, or otherwise unable to bear labels with sufficient space, then the required labeling as listed below annotated with an asterisk (*) may appear on the outer container labeling only.

The label for IVD's must state the following information, except in cases where it is not applicable:

- Information identifying the device, or the kind of device;
- Information explaining how to use the device safely; and
- The established and proprietary names of the product;
- The intended use or uses, e.g., diabetes screening, etc.;
- A statement of warnings or precautions for users (hazardous substances) and any other warnings appropriate to user hazards, and a statement "For In Vitro Diagnostic Use;"
- Name and place of business of the manufacturer, packer, or distributor/Authorized representative;
- Lot or control number traceable to the production history

  - Multiple unit products must have traceability of the individual units;

  - Instrument lot numbers must allow for traceability of subassemblies; and

  - **A** multiple unit product that requires use of its components as a system should have the same lot number, or other suitable form, identification, on all units.
- Other information about the device that the manufacturer considers would be useful for patients.

For Reagents

- Established (common or usual) name;
- Quantity, proportion, or concentration of all active ingredients: e.g mg., weight per unit volume, mg./dl etc., and for reagents derived from biological materials the source and measure of its activity, e.g., bovine, I.U., etc.;
- Storage instructions, i.e., temperature, humidity, etc.; Instructions for manipulation of products requiring mixing or reconstitution;
- Means to assure that the product meets appropriate standards of purity, quality, etc., at the time of use, including one or more of the following:
    a) expiration date (date beyond which the product is not to be used);
    b) statement of any visual indication of alteration;
    c) instructions for a simple check to assure product usefulness;

l) User information

- Documents may include labels, instructions for use (IFU), patient implant cards, surgical manuals, brochures, marketing literature, etc.
- Legible versions of all levels of labels should be provided (e.g. secondary pack, primary pack) and should be representative of the finished form, showing all included symbols.
- It is sufficient to show information concerning labelling in English only, but items to be translated and the plan for translation should be indicated.
- If possible, provide drawings with the packaging configuration (showing placement of all labels) and label specifications.
- The position of labels on the finished product should be clear. If any of the packaging is printed with information for the user (including pictures/ schematics of the device) this should also be provided. It should be clear how the labelling documents are controlled.

- Supporting evidence should be provided for any claims made in the labelling or marketing literature.
- Please ensure that any specific requirements of relevant harmonized standards are addressed in the labels and information for use.

m) Design verification and validation

Product design specifications should be adequately documented, outlining the key functional characteristics and technical performance specifications for each device, along with verification/ validation tests to substantiate that they have been achieved.

Overall, manufacturers should demonstrate that design requirements have been identified in accordance with the intended use, safety and performance requirements, risk assessments, and relevant harmonized and other key standards.

To this end, the source of design requirements should be indicated. Although compliance to harmonized and other key standards is expected, please be aware that testing beyond that required by the standards may be necessary to demonstrate compliance of your device to the relevant Essential Requirements. Design requirements should be mapped to the intended use, performance and risks identified for the device.

A design verification/ validation strategy document and/ or summary of the outcomes should be provided. Verification/ validation results should be provided for each design requirement. If compliance has been demonstrated without testing, an appropriate rationale should be provided.

Test reports should document objectives, acceptance criteria, materials & methods, results, protocol deviations, and conclusions.

a. If test results are considered representative for a group of devices (i.e. worst-case devices or comparative devices), then a justification for leveraging protocol(s) and report(s) should be provided.
b. Similarly, if testing has been undertaken on prototypes or devices that otherwise do not represent the finished goods, a justification for the adequacy of this testing should be provided.

c. If multiple design verification / validation studies were conducted please provide a flow chart or table that shows how the studies were conducted and highlight which study ultimately demonstrates that the design meets the product performance specifications.
d. For line extensions or devices based on "existing" devices, it may be possible to leverage data from testing undertaken on the existing devices. In this case, a rationale for the use of existing data must be provided, including:
e. Evidence of equivalence to the comparative devices – a table showing the similarities and differences greatly speeds the review process. Key things to consider include (but may not be limited to):
    i. materials of construction
    ii. indications for use
    iii. methods of manufacturing
    iv. key design features

An evaluation of the impact of any differences on clinical safety, performance, and testing undertaken. The evaluation should support the conclusion that the new devices do not represent a worst case in terms of testing as compared to the devices tested.

n) Risk management

A thorough design, clinical and process Risk Management assessment should be conducted for the entire life-cycle of the device (from initial design concept up to and including device disposal). This should be updated (as appropriate) with data from PMS.

a. The risk management documentation should provide a template for preparedness, indicating whether controls (i.e. process validations, biocompatibility, sterilization, clinical, shelf-life or other key verification / validation tests) have reduced all risks as low as possible (vs. as low as reasonably practicable) to acceptable levels in light of state-of-the-art for the product(s) under review.

b. The assessment must demonstrate that the benefits outweigh all the residual risks when the device is used as intended.
c. The analysis must demonstrate that appropriate controls (design out then protective measures) have been applied to all risks.
d. Information for use may reduce occurrence of some risks, but it cannot reduce the occurrence of residual risks. Please ensure appropriate use and quantification of risk control measures in the risk assessment.
e. A copy of Risk Management Procedure(s) that include the definition of any rating systems used for risk analysis and risk acceptability should be provided.

For line extensions and devices based upon existing devices, the manufacturer may conclude that pre-existing risk management documentation is applicable. However, there are always risks associated with even small changes, and a summary to demonstrate that these risks have been considered (and have been adequately mitigated) should be provided.

o) Clinical evaluation

Clinical evaluations are required for all medical devices.

a. It is useful to provide a copy of the procedure for conducting Clinical Evaluation.
b. If a pre-market clinical investigation has been conducted, please ensure:
    i. appropriate documentation (CIP, letter of "no objection" from the Competent Authority, evidence of Ethics approval, final report, etc.) is provided;
    ii. the final clinical trial protocol agrees with that submitted to the Competent Authority, and evidence that any deviations have been agreed with the CA has been provided;
    iii. the final report demonstrates that requirements for all safety and performance endpoints have been met;
    iv. there are no open clinical investigations relevant to your devices with endpoints related to safety or performance claims.

c. Representative clinical data must be provided for all indications and variants. Justifications for why one group of data is representative of another must be clearly substantiated.
d. If no clinical investigation data is available for the subject device and the Clinical Evaluation relies on a justification of equivalence of comparative devices, the justification must identify and discuss the potential clinical impact of all differences between the subject and comparable devices relative to intended use, technical, or biological factors.
e. A justification should be provided (with appropriate evidence) to substantiate the qualifications of individual(s) conducting/ approving the clinical evaluation.
f. Some indications or specific clinical benefit claims may require the Notified Body to consult with an external expert (a surgeon or similar). Contracting a confidential source that is mutually agreed with the Manufacturer may be time consuming.

p) PMS and PMCF

A Post-Marketing Surveillance Plan (PMS Plan)/risk management plan commensurate with the product risk, lifetime, and available clinical data should be provided for each device/ device family.

a. Ensure that the PMS plan/Risk Management Plan adequately justifies the monitoring of the safety and intended performance of the device.
b. If Post-Market Clinical Follow-up (PMCF) is not part of the PMS Plan, please ensure that adequate justification is provided, based on the risk and clinical data available for the device.
c. A copy of the Post Market Surveillance procedure should also be provided. Please note that the procedure is not the same as the Plan – the former refers to the manufacturer's quality system
a. requirements and is generic to all devices marketed by a manufacturer, whereas the latter is specific to the subject device, and can only be generated in light of data from the clinical evaluation and risk evaluation for that device.

q) Biological safety

Biological safety assessments should be undertaken in accordance with ISO 10993-1. See Clause 7 of this standard for guidance with respect to appropriate report content. Link to ISO 10993-1 https://www.iso.org/standard/44908.html

Biocompatibility assessments should include evidence of compliance for the finished device (including consideration of all materials and all manufacturing steps). It is not sufficient to simply state that devices have been manufactured.

r) Sterilization validation

Sterilization validation is reviewed separately by laboratories pre-qualified by PPB;

i. Appropriate rationales are required if sterilization validation is by adoption into an existing family or sterilization validation.

ii. Devices for End-User-Sterilization also require review of cleaning and sterilization validation/ adoption with respect to parameters recommended in the IFU.

iii. Documents should describe:

- use of "State of the art" process validation methods;
- the bio-burden controls and monitoring;
- the product qualification (Dose verification, BI suitability testing, SAL calculations);
- the process qualification (Performance qualification, Dose Map, BI Inactivation's).

Additional guidance relating to specific document types is provided below:

s) Shelf-Life Validation should include:

a. Protocol (with acceptance criteria for each test performed) and appropriate test references;
b. A clear statement of the intended shelf life;
c. A clear statement defining the sterilization status of the test samples (1X, 2X sterilized);
d. A summary of the accelerated aging parameters (temperature and humidity) and how the aging times were calculated;

e. A statement covering Real Time Aging plans;
f. A clear delineation of statistically significant sample quantities;
g. Actual physical/microbiological test data reports supporting the expiration date, or post aging, claim (peel testing, burst testing, dye testing, etc.);
h. A summary of the ship testing/ transit simulation testing conducted and applicable test reports.

t) Sterilization Validation – Radiation should include:

a. Protocol;
b. Dosimetry mapping data (typically from the sterilization contractor);
c. Validation of bio-burden testing method & test report;
d. Bio-burden determination & test reports;
e. Calculation or determination of verification dose and full dose;
f. Validation of product sterility testing method & test report;
g. Sterility testing of verification dose samples & test report.

u) Software

Appropriate documentation is required if the medical devices are either stand-alone software or rely upon software.

If medical device is stand-alone software, guidance for the qualification and classification of the software should be provided with a report of the same.

There should be a rationale for why the software is a medical device and for its classification. If applicable, the software should be broken down into modules, some that have a medical purpose and some that do not. The modules with a medical purpose must comply with the requirements of the Medical Device requirements and must carry own jurisdiction marking. The non-medical device modules are not subject to the requirements for medical devices.

Ensure all relevant harmonized and non-harmonised software standards have been considered. Ensure the software systems/ modules/ items have been assigned safety classifications based on standards.

Include documentation on the medical device software life-cycle processes implemented (e.g., software design/ development, maintenance/ change

management, risk management, configuration management, problem resolution, verification, and validation processes).

Include software development process documentation (e.g., software development plan, software requirements specification, software architecture, software detailed design, software unit testing procedures/ reports, software integration testing procedures/reports, and software system testing) and maintenance process documentation (e.g. software maintenance plan). Note: Some documentation may or may not be required per the standards based on software system/ module/ item risk classification.

Include software risk assessment documentation (e.g. software hazard analysis, software failure mode and effects analysis, fault tree analysis, traceability). Note: Some documentation may or may not be required per the standards based on software system/ module/ item risk classification.

Instructions for use that detail the validated sterilization and cleaning parameters. Please be aware that reference to "standard hospital practice" is insufficient;

v) Packaging

Packaging testing should address requirements for both transit endurance and shelf-life stability, and be undertaken in accordance with relevant standards.

A complete packaging Bill of Material (BoM) and diagrams should be provided to illustrate how each device is packaged.

If all packaging/device combinations have not been tested, a rationale based on worst case (ie heaviest and lightest devices, sharp or pointy edges, etc) should be provided.

Any change to packaging is considered a significant change. For Class C devices, these must be reported to the PPB for review and certificate re-issue.

w) Shelf life and stability testing

Shelf life is normally considered to be the time the device can be kept in the packaging prior to use. This is not the same as "Lifetime".

Shelf-life testing is not restricted to the packaging. The device itself should be subject to shelf-life testing, or a rationale provided to demonstrate why its characteristics are not expected to degrade over the claimed shelf life.

If shelf-life testing is based on accelerated age testing, this should be accompanied by a plan for real time testing. Real time testing should be underway by the time documentation is submitted for review.

x) Product lifetime

The lifetime of the device should be defined, and considered relative to other parts of the dossier (e.g. risk management, clinical evaluation, PMS). Product lifetime is normally considered as the time from manufacture until the device ceases to fulfill its intended use. This is not the same as "Shelf Life".

Medicinal substances/Human blood derivative & recombinant protein/peptides. The submission should clearly indicate whether or not the device contains any medicinal substances and /or human blood derivatives and/ or recombinant peptides/proteins. Full justification on the primary mode of action of the device and evidence that the above components are ancillary should be provided.

Devices which incorporate, as an integral part, an ancillary medicinal substance or an ancillary human blood derivative or ancillary recombinant protein/ peptide are subject to requirements of additional Regulations.

y) Animal derived substances

The submission should clearly indicate whether or not the device utilizes, or is used in conjunction with, any materials of animal origin.

Manufacturing subcontractors should be consulted if appropriate to establish if any such substances are used during manufacture, even if they do not feature in the final device (e.g. lubricants or mould release agents which may use animal derived substances). If in doubt, speak with your Scheme Manager before submitting a dossier.

Evidence demonstrating compliance with the relevant clauses of EN ISO 22442 (parts 1-3) should be provided.

Link: https://www.iso.org/standard/68553.html

Devices which incorporate materials from TSE-susceptible species will be subject to conformity assessment.

z) Grouping Requirements for Product Registration

Each submitted application shall contain only one of the following:

- a SINGLE medical device;
- one medical device FAMILY;
- one medical device SYSTEM;
- one medical device GROUP;
- one dental grouping term (DGT).

Table 3: Summary of Application Process To Be Followed For All Medical Devices

Step 1	Step 2	Step 3	Step 4
Submission Of Application To The Online Portal	Verification Of Submitted Application	Reviewing of the application	Regulatory outcome and or issuance of registration certificate

2.3 REGISTRATION OF CLASS A MEDICAL DEVICES

2.3.1 Submission Requirements

Upon submission via the *Online Portal of the Pharmacy and Poisons Board*, prims.pharmacyboardkenya.org the product application fee will be charged immediately. Review of the application by PPB is based on the data set submitted by the applicant. An input request will be issued to the applicant if clarification or additional information is required. A regulatory decision is made based on the outcome of PPB's review of the submitted application. Only applications which satisfy the registration requirements will be registered and listed.

The stop-clock starts whenever PPB issues an input request and ends when PPB receives a complete and satisfactory response from the applicant.

Table 4: Summary of Submission Requirements for listing of Class A

No.	Document Required
1.	Letter of Authorization
2.	Proposed Device Labelling (Actual Artworks, Packaging material in contact with the product and or the Secondary packaging to be provided)
3.	Pre-Verification certificate for a Notified Body in liaison with KEBS. Certificate of Conformity also acceptable in place of PVOC

4.	IFU, patient information leaflet and promotional material (including brochures and catalogues)
5.	Certificate of analysis (COA) for of all materials of animal, human, microbial and/or recombinant origin used and manufacturing process (Where applicable)
6.	For Personal protective equipment, i.e Face Masks, Surgical face masks, Gloves; a certificate of analysis for conformity through a PPB recognized Laboratory must be obtained.
7.	Information on sterilization method(s) and validation standard(s) used (where applicable)
8.	Regulatory approval from the country of origin of the product.
9.	Proof of Quality Management System (QMS) – E.g. ISO 13485 certificate, conformity to US FDA Quality System Regulations (Certificate of free sale), Japan MHLW Ordinance 169 or attestation stating adequate QMS, CE Certificate from the EU/UK IRELAND

2.4 REGISTRATION OF CLASS B MEDICAL DEVICES

2.4.1 Evaluation Routes

There are four evaluation routes for Class B medical devices:

a) **Full Evaluation Route**

b) **Abridged Evaluation Route**

c) **Expedited Class B Registration (EBR) Evaluation Route**

d) **Immediate Class B Registration (IBR) Evaluation Route**

Abridged, expedited and immediate evaluation routes are set out according to a confidence-based approach, leveraging on the approvals by listed medical device reference regulatory agencies (8) and/or prior safe marketing history of the Class B devices. The types of approvals that qualify for the abridged, expedited and immediate evaluation routes are:

i. Australia Therapeutic Goods Administration (TGA) Device Registration License

ii. Health Canada (HC) Device Registration License

iii. Japan Ministry of Health, Labor and Welfare (MHLW)

- Pre-Market Certification from a Japanese Registered Certification Body
- -Pre-Market Approval from MHLW

iv. US Food and Drug Administration (US FDA)

a. 510K clearance
b. Premarket Approval (PMA)

v. European Union Notified Bodies (EU NB) via EC certificates issued according to

a) Directive 93/42/EEC Annex II section 3 or Annex V for Class IIA devices

b) Directive 98/79/EC Annex IV or Annex V with Annex VII for List B and self-testing IVDs

vi. Irish Health Products Regulatory Authority

vii. Swiss Medic

viii. Saudi Arabia Food and Drugs Authority

2.4.1.1 Full Evaluation Route

a) Eligibility Criteria

A medical device that has not **obtained any prior approval** from any Reference Regulatory Agencies at the point of application will be subject to the **full evaluation route**.

b) Submission Requirements

- Letter of Authorization
- List of configurations of medical devices to be registered
- Common Submission Dossier Template (CSDT)
- Executive Summary
- Essential Principles Checklist and Declaration of Conformity
- Device Description
- Detailed Information of Design Verification and Validation Documents
- Full reports of Preclinical Studies including the detailed sterilization validation, if applicable

- Clinical Evidence, including publications and full reports of the studies referenced in the clinical evaluation report Proposed Device Labelling
- Risk Analysis
- Manufacturer Information
- Name and address of the manufacturing site(s)
- Proof of Quality Management System – e.g. ISO13485 Certificate, Conformity to US FDA Quality System Regulations or Japan MHLW Ordinance 169
- Manufacturing Process – Flow Chart

For medical device with labelled use beyond the inherent performance of the device, additional clinical data may be requested to substantiate the proposed label use.

Table 5: Summary of Submission Requirements (Class B/C/D)

No.	**Document Required**
1.	Letter of Authorization
2.	List of configurations of medical devices to be registered to be provided
3.	Executive Summary
4.	Essential Principles Checklist and Declaration of Conformity
5.	Device Description
6.	Detailed Information of Design Verification and Validation Documents
7.	Full reports of Preclinical Studies including the detailed sterilization validation, if applicable
8.	Risk Analysis
9.	Manufacturer Information (Including details of Manufacturing Site(s))

10.	Manufacturing Flow Process
11.	Clinical Evidence, including publications and full reports of the studies referenced in the clinical evaluation report Proposed Device Labelling
12.	Proof of Quality Management System (QMS) – E.g. ISO 13485 certificate, conformity to US FDA Quality System Regulations (Certificate of free sale), Japan MHLW Ordinance 169 or attestation stating adequate QMS, CE Certificate from the EU/UK IRELAND

2.4.1.2 Abridged Evaluation Route

a) Eligibility Criteria

A medical device that has obtained **at least two** reference regulatory agency approval for a labelled use identical to that intended for marketing in Kenya at the time of submission will qualify for the **abridged evaluation route**.

2.4.1.3 Expedited Class B Registration (EBR) Evaluation Route

a) Eligibility Criteria

A Class B medical device may qualify for registration via the EBR route if it complies with the following conditions;

- obtained approval from at least Two of PPB's independent reference regulatory agencies for a labelled use identical to that intended for marketing in Kenya;
- marketed for at least three years in the above independent reference regulatory agency's jurisdiction;
- no safety issues globally associated with the use of the medical device(s) when used as intended by the Product Owner, in the last three years, defined as
  a) no reported deaths;
  b) no reported serious deterioration in the state of health[3] of any person; and
  c) no open field safety corrective actions (including recalls) at the point of submission.

OR

Obtained approvals from at least Three of PPB's independent reference regulatory agencies for a labelled use identical to that intended for marketing in Kenya.

b) Submission Requirements

a. Letter of Authorization

b. List of configurations of medical devices to be registered

c. Proof of approval from independent reference regulatory agencies –

d. Proof of marketing history in the same independent reference regulatory agency's jurisdictions i.e. Invoice with date, proof of sale or a declaration on marketing history

e. Declaration of no safety issues globally

f. Common Submission Dossier Template (CSDT) dossier approvals from the independent reference regulatory agencies

2.4.1.4 Immediate Class B Registration (IBR) Evaluation Route

a) Eligibility Criteria

A Class B medical device may qualify for registration via the IBR route if it complies with the following conditions:

(i) approvals by at least **three** of PPB's <u>independent</u> reference regulatory agencies for intended use identical to that submitting for registration in Kenya;

(ii) marketed for at least four years in two of the independent reference regulatory agencies' jurisdictions; no safety issues globally associated with the use of the medical device(s) when used as intended by the Product Owner, in the last three years, defined as

- no reported deaths;
- no reported serious deterioration in the state of health[3] of any person; and
- no open field safety corrective actions (including recalls) at the point of submission; and
- no rejection/withdrawal of the medical device by/from any reference regulatory agency/that foreign jurisdiction(s) or Kenya due to quality, performance/efficacy or safety issues.

(iii) For medical device with labelled use beyond the inherent performance of the device, additional clinical data may be requested post-registration to substantiate the proposed label use.

PPB's independent reference regulatory agencies are HC, MHLW, USFDA, TGA, EU-NB, SWISSMEDIC, HPRA.

b) Submission Requirements

Upon submission via PPB online Portal *(portal.pharmacyboardkenya.org*, the medical device will be registered immediately and will be listed on the PPB Online registry within an hour. An email notification regarding the successful registration of the device will be sent within 48 hours of submission in PPB online Portal. The total fees will also be charged immediately upon successful submission for this route. As devices are registered immediately upon successful submission, applicants are reminded to ensure the application fulfills **ALL** the eligibility criteria and that all the required information is entered correctly and accurately.

PPB will verify the documents submitted in PPB online Portal after successful submission. Based on the intended use of the device by the Product Owner, additional registration conditions may be imposed post-registration.

The IBR evaluation route facilitates immediate market access for the medical devices. Any IBR application which fails to fulfill the **ALL** the registration criteria specified under **Section 5.1.4.1** for the IBR evaluation route or a non-Class B medical device submitted via the IBR evaluation route would result in *cancellation of the registration* and the registration fee will NOT be refunded.

*2.*5 REGISTRATION OF CLASS C AND D MEDICAL DEVICES MODULE -

2.5.1 Evaluation Routes

There are three evaluation routes for Class C and D and IVD medical devices:

(i) Full Evaluation Route
(ii) Abridged Evaluation Route
(iii) Expedited Evaluation Route
    a. Expedited Class C Registration (ECR)
    b. Expedited Class D Registration (EDR)

Approvals from EU and TGA will qualify as independent reference regulatory agency's approval only if the devices have been reviewed and approved by the respective agencies and the devices are not registered based on the Mutual Recognition Agreement (MRA).

The abridged and expedited evaluation routes are set out according to a confidence-based approach, leveraging on the approvals by PPB's medical device reference regulatory agencies and/or prior safe marketing history. The types of approvals that qualify for abridged and expedited Class C and D evaluation routes are listed below;

1. Full Evaluation Routes

a) Eligibility Criteria

A medical device that has **not obtained any prior approval** from any of PPB's reference regulatory agencies at the point of application will be subject to the **full evaluation** route.

2. Abridged Evaluation Route

a) Eligibility Criteria

A medical device that has obtained **at least three** reference regulatory agency approval for a labelled use identical to that intended for marketing in Kenya at the time of submission will qualify for the **abridged evaluation route**.

3. Expedited Class C Registration (ECR) Evaluation Route

a) Eligibility Criteria

A Class C medical device may qualify for registration via the following routes if it complies with the following conditions:

I. **ECR**:

a) obtained approval from at least **three** of PPB's independent reference regulatory agencies for a labelled use identical to that intend for marketing in Kenya; [PPB's medical device independent reference regulatory.

b) marketed for at least five years in the above independent reference regulatory agency's jurisdiction; and

c) no safety issues globally associated with the use of the medical device(s) when used as intended by the Product Owner, in the last three years, defined as

- no reported deaths;

- no reported serious deterioration in the state of health3 of any person; and
- no open field safety corrective actions (including recalls) at the point of submission **OR**

II. ECR:

a) Obtained approvals from at least **five** of PPB's independent reference regulatory agencies for a labelled use identical to that intended for marketing in Kenya.

Approvals from EU and TGA will qualify as independent reference regulatory agency approvals only if the devices have been reviewed and approved by the respective agencies and not registered based on the Mutual Recognition Agreement (MRA).

Or the medical device has been marketed in the jurisdiction of the reference regulatory agency for at least 5 years as stated in the proof of marketing history. For devices that are part of a test kit or a system, an invoice or declaration containing the kit name or system will be sufficient.

The following Class C devices are **excluded** from submission via the ECR evaluation route:

(i) Hip, knee and shoulder joint replacement non-bio-active implants (e.g. non-bioactive metal/polymer implants).

These devices will have to be registered via Full or Abridged routes only

Procedure for handling of applications

Upon submission via PPB Online Portal, an application fee will be charged immediately. The application will be verified for eligibility for ECR and the dossier will be verified for completeness. Once confirmed, the application will be accepted for evaluation. The evaluation fees will be charged at this point. In the event that the application does not qualify for ECR, the application will be required to be re-routed to the abridged or full evaluation route and the respective evaluation fees shall apply.

Evaluation of the technical data/application by PPB is based on the data set submitted by the applicant. An input request will be issued to the applicant if

clarification or additional information is required. A regulatory decision is made based on the outcome of PPB's evaluation of the submitted dossier. Only applications which satisfy the registration requirements will be registered and listed on the PPB Online Registry.

The stop-clock starts whenever PPB issues an input request and ends when PPB receives a complete and satisfactory response from the applicant.

4. Expedited Class D Registration (EDR) Evaluation Route

a) Eligibility Criteria

A Class D medical device may qualify for registration via the EDR route if it complies with the following condition:

(i) obtained approvals from at least **two** of PPB's independent reference regulatory agencies for a labelled use identical to that intended for marketing in Kenya.

The following Class D devices are **excluded** from being registered via EDR route:

(i) Active implantable devices (e.g., pacemakers, neuro stimulators)

(ii) Implantable devices in direct contact with the central circulatory system or central nervous system

(iii) Hip, knee and shoulder joint replacement (e.g., bioactive implants)

(iv) Devices incorporating a registrable drug in an ancillary role

These devices will have to be registered via Full or Abridged evaluation routes only.

2.6. MEDICAL DEVICES INCORPORATING MEDICINAL PRODUCT

By the design and intent of the product owner, a medical device may be incorporated with a medicinal product in an ancillary role (chemical drug or biologic), to achieve its intended purpose. The regulatory controls applicable (i.e., medical device or medicinal product) to such products including both medical device and medicinal product components is determined based on their primary mode of action (PMOA).

"Primary mode of action (PMOA)" means the mode of action that makes the greatest contribution to the overall intended therapeutic purpose of the combined product.

A product that does not achieves its PMOA in or on the human body by pharmacological, immunological or metabolic means will be regulated as a medical device under the *Act*.

Examples of medical devices incorporating a medicinal product that are regulated as medical device include:

- Drug eluting stents
- Dermal filler incorporating analgesic
- Antimicrobial silver dressings.

Medical devices incorporating registrable medicinal products are classified as Class D medical devices. The product registration applications for such devices will be jointly evaluated by the Medical Device Unit together with the Unit of Biologicals and the medical products Human Medicines Unit of the Pharmacy and Poisons Board. Such devices would qualify for the abridged evaluation route if the product is approved as a medical device in at least one of PPB's medical device reference regulatory agencies **and** the chemical or biological component has been evaluated and approved by at least one competent drug regulatory agency, as defined by the World Health Organisation (WHO). The product registration applications for such product should be submitted via the full evaluation route if they **do not** qualify for the abridged route.

Where such medical devices incorporate medicinal products exempted from medicinal product registration, the risk classification would follow the medical device risk class.

The applicant can enquire with PPB about the product classification for such products to determine the applicable regulatory controls.

2.7 TURN-AROUND-TIME (TAT) FOR PRODUCT REGISTRATION

PPB shall Endeavour to meet the target processing timelines for all submitted applications. Applicants should ensure that the dossiers are complete before submission. Incomplete submissions and untimely responses to queries will

result in unnecessary delays to the registration process and thus, will have a negative impact on the target processing timelines.

The target turn-around-time (TAT) for product registration applications commences from the date of receipt of the application and does not include 'stop-clock time' due to input requests for clarifications and additional information.

In the event that the medical device is a subject of a Field Safety Corrective Action (FSCA), the application will be placed on stop-clock until resolution of the FSCA.

N.B It remain the prerogative of the regulatory authority on time line for regulatory approval to be granted. The above is a guide to inform stakeholders.

FAST TRACKINNG

Classes B, C/D applications qualify for fast tracking processes. Reference is made to the Guideline for Fast Track Review of Application for Health Products (*HPT/PER/GUD/041***)**

2.8 PRODUCT REGISTRATION FEES

The fees herewith listed are per product by an applicant seeking registration with the Pharmacy and Poisons Board.

The application fee is payable at the time of submission in PPB Online Portal.

Evaluation fees are payable upon acceptance of the application for evaluation.

The application fees are **non-refundable** once the application has been successfully submitted via PPB Online Portal. The applicant should ensure that the product registration application is compiled according to the prevailing required format.

The evaluation fees are **non-refundable** once the application is accepted for evaluation, regardless of the final decision by HSA. Withdrawal of the application after the application is accepted will result in **forfeiture** of the evaluation fees. Rejection of the application by PPB will also result in the **forfeiture** of the evaluation fees.

The registration fees are payable per class per manufacturer per product as illustrated below.

Table 6: Registration, retention and variations fees for Medical Devices

FEE STRUCTURE	IMPORTED PRODUCTS	LOCAL MANUFACTURED
REGISTRATION OF MEDICAL DEVICES	CLASS A USD 100	USD 50
	CLASS B USD 200	USD 50
	CLASS C & D USD 1000	CLASS C & D USD 100
VARIATION OF REGISTERED MEDICAL DEVICE	USD 200	USD 50
ANNUAL RETENTION OF MEDICAL DEVICES	CLASS A & B: USD 50	USD 50
	CLASS C & D: USD 300	USD 50

2.9 Guidance on Change Notification of Medical Devices including IVDs

Medical devices undergo changes as part of their product life cycle. This guidance document is intended to aid Applicants in determining whether a Change Notification has to be submitted for a registered medical device. Applicants are required to notify changes concerning registered medical devices to the Authority.

This guidance document is also applicable to situations when a registered device undergoes any changes or proposed changes, including labelling changes, as a result of a reportable Adverse Event (AE) or an on-going Field Safety Corrective Action (FSCA).

When several simultaneous changes are being implemented on a registered device or its accessories, this guidance document should be used to assess each change separately. If a Change Notification is required, the Registrant shall describe how the modified device differs from the previously registered device (or device type).

Some changes that will **NOT** qualify for Change Notification and require the submission of a NEW **Common Submission Technical Dossier (CSTD) Format of Submitting an application for Medical Devices** include:

- Change to the intended purpose of a registered medical device;

- Change to the risk classification of a registered medical device;
- Guidance on Grouping of Medical Devices for Product Registration;
- Change to the medicinal substance in a device that incorporates a medicinal product in an ancillary role;
- An addition of medical devices with different device proprietary names into a single-family listing even when they satisfy the FAMILY grouping requirements

The applicant is requested to complete "**Changes notification to a Registered Medical Devices including IVDs'** ***reference annex 4*** for the types of changes and required documents to be provided for a Change/variations Notification submission.

- Copy of Pharmacy and Poisons Board Initial registration certificate of the device
- Copy of Pharmacy and Poisons Retention certificate of the device
- Letter of no objection from the existing LTR

a) Categories of changes

Changes to registered medical devices that require the submission of a Change Notification are classified into four categories as summarized in Table 1: Table 1 - Categories of Change Notification for Class A, B, C and D Medical Devices namely;

i. Technical Changes for Class C and D medical devices affect the safety, quality or efficacy of these medical devices. These require PPB's approval prior to implementation of the change(s) in Kenya.

ii. Review Changes for Class A and B medical devices affect the safety, quality or efficacy of these medical devices. These require PPB approval prior to implementation of the change(s) in Kenya and are as follows:

- Change(s) to indications for use of the registered medical device (except reduction of indications for use not arising due to device safety, quality or efficacy concerns);
- Addition of new model(s) (except Class A accessories) to a registered medical device listing;
- Removal and/or revision of warnings, precautions and contraindications;
- Modification of approved method of use, including change from "Professional use only" to "Home use".

a) Administrative Changes include changes to the administrative documents and information submitted at the point of registration of the medical device. These require PPB's approval prior to implementation of the change(s) in Kenya.

b) Notification Changes may be implemented immediately upon receipt of the acknowledgement email from PPB after submission via online portal, unless the change is in the context of, or is a consequence of a reportable Adverse Events (AEs) or Field Safety Corrective Actions (FSCAs).

NOTE: 'Notification' changes which are incorrectly classified will be rejected upon review and further supply of the affected device will be prohibited. Subsequent supply will be subject to approval of the change in the correct change notification category.

Table 7 - Categories of Change Notification for Class A, B, C and D Medical Devices

Risk Classification	**Technical Changes**	**Review Changes**	**Administrative Changes**	**Notifications**
Class A		√*	√	√
Class B		√*	√	√
Class C	√		√	√
Class D	√		√	√

2.10. AMENDMENT OF DEVICE LISTING/REGISTRATION

In cases of any typographical errors incurred in the device listing information on the PPB Online Portal, the Registrant may submit a written request to PPB for the necessary amendments

2.11. ANNUAL RETENTION

It is a requirement for all medical devices and IVDs to annually be retained in the PPB Database to maintain the market authorization status in Kenya. This procedure should be done three months before the end of the year.

An annual retention fee is payable in order to retain the registration of the medical device on the PPB Online Registry.

The payment of the retention fee should be submitted via PPB Online Portal. Submission via the system will be available 60 days before the due date of the annual retention fee. It is the responsibility of the registrant to keep track of the annual retention due date. Failure to make the necessary payment may lead to suspension and cancellation of the registration of the medical device.

The retention of a product is per calendar year and the annual registration retention fees are **non-refundable**.

2.12 Certificate of registration

a. Issuance

i. Certificate of registration is issued upon providing satisfactory documentation in accordance to the dossier and satisfying regulatory process

b. The certificate of registration is valid for 5 years.

ii. In an emergency situation or in the public interest, PPB can at its discretion issue certificate of registration valid for 2 years.

iii. A certificate of registration can be suspended, withdrawn, withheld or revoked is the conditions

stipulated in the guideline for suspension, withdrawal, withholding and revocation (HPT/PER/GUD/042)

2.13. SUSPENSION AND CANCELLATION OF REGISTRATION

Pursuant to section the Cap 244 Laws of Kenya, when a regulatory decision has been made on reasonable grounds to suspend or cancel a registered product, the Registrant will be given written notice. The Registrant will also be given an opportunity to be heard prior to the suspension or cancellation.

Once the registration is suspended or cancelled, the Registrant and all dealers are required to immediately cease all activities related to the importation and supply of the affected medical devices including IVD Medical Devices.

2.14. EXEMPTION FROM REGISTRATION OF MEDICAL DEVICES

The requirements for registration of medical devices including IVDs may be exempted in the following circumstances;

I. The purpose of demonstration for marketing
II. The purpose of education
III. The purpose of clinical research or performance evaluation of medical device
IV. A Custom-Made Medical Device; or
V. Exemption of Medical Device & IVDs from registration requirements

An applicant who imports or manufactures the above medical device also exempted from the requirement of an establishment license. However, prior to importation and supplying a device potentially eligible for exemption, manufacturer or importer of the device must submit a notification to Pharmacy and Poisons Board, together with supporting documents

Exemption Type	Examples of exemptions

Demonstrations	1. Medical Device for Demonstration for Marketing
	2. Disposed of or Destroyed; or Exported out of Kenya' of Unregistered Medical Device
Education	Medical Device for the Purpose of Education
Clinical Iinvestigations	1. Import and/or Supply Medical Devices for Clinical Investigational Use
	2. Import Medical Devices for Clinical Research Use
	3. Serious Adverse Device Events (SADE)
	4. Export /Disposal of Devices Upon Completion /Termination of Clinical Investigation /Drug Study
	5. Investigational Device (IDE) Progress Report
	6. Change on Clinical Trial for Medical Devices Use
Custom made	Unregistered Medical Device for Custom Made
Special Access	Unregistered Medical Device for Special Access

2.14.1 Payment and Review of the notification

Upon receipt of notification, the authority will issue a payment advice to the applicant as per the PPB import and export control requirements.

2.15 GUIDANCE ON THE PRINCIPLE OF RISK BASED CLASSIFICATION OF IN-VITRO DIAGNOSTIC (IVD) MEDICAL DEVICES

2.15.1 Risk based classification of IVD medical devices

The Classification of an IVD Medical Device is based on the following criteria:

1. The intended use and indications for use as specified by the manufacturer (specific disorder, condition or risk factor for which the test is intended)
2. The technical/scientific/medical expertise of the intended user (lay person or professional)

3. The importance of the information to the diagnosis (sole determinant or one of several), taking into consideration the natural history of the disease or disorder including presenting signs and symptoms which may guide a physician the impact of the result (true or false) to the individual and/or to public health

Table 8: Risk classification of IVD's and Examples.

CLASS	RISK LEVEL	DEVICE EXAMPLES
A	Low Individual Risk and Low Public Health Risk	Clinical Chemistry Analyser, prepared selective culture media
B	Moderate Individual Risk and/or Low Public Health Risk	Vitamin B12, Pregnancy self-testing, Anti-Nuclear Antibody, Urine test strips
C	High Individual Risk and/or Moderate Public Health Risk	Blood glucose self-testing, HLA typing, PSA screening, Rubella
D	High Individual Risk and High Public Health Risk	HIV Blood donor screening, HIV Blood diagnostic

2.15.2 In-country assessment for performance and evaluation for In-vitro diagnostic and condoms

a. It is a requirement for in-country assessment of In-vitro Diagnostics for medical Devices. This procedure will include submission of samples with defined samples sizes to the Quality control Laboratory department for Performance and Validation Testing.

b. The Report from the Laboratory, forms part of the Assessment documents for consideration before issuance of a registration certificate or Emergency Use Authorization.

c. An IVD that fails to meet the set criteria for the performance testing will not be approved for registration.

d. Additionally, other medical devices which includes Male Latex Condoms must also under laboratory testing.

2.15.3 Classification Rules

Rule 1: IVD Medical Devices intended for the following purposes are classified as Class D:

1. Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, cells, tissues or organs in order to assess their suitability for transfusion or transplantation, or
2. Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening often incurable disease with a high risk of propagation.

Rationale: Devices in this Class are intended to be used to ensure the safety of blood and blood components for transfusion and/or cells, tissues and organs for transplantation. In most cases, the result of the test is the major determinant as to whether the donation/product will be used. Serious diseases are those that result in death or long-term disability, that are often incurable or require major therapeutic interventions and where an accurate diagnosis is vital to mitigate the public health impact of the condition.

Examples: Tests to detect infection by HIV, HCV, HBV, HTLV. Pyrogenicity tests (Endotoxin Activity Assay) marketed for detection of bacterial contamination of blood components. This Rule applies to all types of assays, such as first-line assays, confirmatory assays and supplemental assays.

Rule 2: IVD Medical Devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation, are classified as Class C, except for ABO, rhesus (C,c,D,E, e) and anti-Kell determination which are classified as Class D.

Rationale: A high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation. The rule divides blood grouping into two subsets depending on the nature of the blood group antigen the IVD Medical Device is designed to detect, and its importance in a transfusion setting.

Examples: HLA, Anti-Duffy, Anti-Kidd

Rule 3: IVD Medical Devices are classified as Class C if they are intended for use:

1. In detecting the presence of, or exposure to, a serious sexually transmitted agent. Examples: Sexually transmitted diseases, such as *Chlamydia trachomatis*, *Neisseria gonorrhoeae*.
2. In detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation. Examples: *Neisseria meningitidis* or *Cryptococcus neoformans*.
3. In detecting the presence of an infectious agent where there is a significant risk that an erroneous result would cause death or severe disability to the individual or fetus being tested. Examples: CMV, *Chlamydia pneumoniae*.
4. In screening pre-natal women in order to determine their immune status towards transmissible agents. Examples: Rubella or *Toxoplasma gondii*.
5. In determining infective disease status or immune status, and where there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient. Example: *Legionella pneumophila*.
6. in screening for selection of patients for selective therapy, or in the diagnosis of, cancer,

   NOTE: those IVD Medical Devices where the therapy decision would usually be made only after further investigation and those used for monitoring and cancer staging would fall into class B under rule 6.
7. in predictive genetic screening, when the outcome of the test would ordinarily result in a substantial impact on the life of the individual. Examples: Guthrie test for phenylketonuria, Huntington's Disease, Cystic Fibrosis.
8. to monitor levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient. Example: Cardiac markers, Cyclosporin, Prothrombin time testing.

9. In the management of patients suffering from a life-threatening infectious disease. Example: HIV Viral Load

Rationale: Devices in this Class present a moderate public health risk, or a high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation, or would have a major negative impact on outcome. The devices provide the critical, or sole, determinant for the correct diagnosis. They may also present a high individual risk because of the stress and anxiety resulting from the information and the nature of the possible follow-up measures.

Rule 4: IVD Medical Devices intended for near-patient testing and self-testing are classified as Class C, except those devices from which the result is not determining a medically critical status, or is preliminary and requires follow-up with the appropriate laboratory test in which case they are Class B.

Rationale: In general, these devices are used by individuals with no technical expertise and thus the labelling and instructions for use are critical to the proper outcome of the test.

Examples for class C: Blood glucose monitoring, near-patient test for *Streptococcus B*, occult blood test, near-patient devices for blood gases.

Examples for class B: Pregnancy self-test, Fertility testing, Urine test-strips.

Rule 5: The following IVD Medical Devices are classified as Class A:

1. Reagents which possess specific characteristics, intended by the manufacturer to make them suitable for in vitro diagnostic procedures related to a specific examination.
2. Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures
3. Specimen receptacles

Note: Any product for general laboratory use not manufactured, sold or represented for use in specified in vitro diagnostic applications are not deemed to be IVD Medical Devices. However, in certain jurisdictions products for general laboratory use are considered to be IVD Medical Devices.

Rationale: These devices present a low individual risk and no or minimal public health risk.

Examples: Selective/differential microbiological media, identification kits for cultured microorganisms, wash solutions, instruments and plain urine cup.

Note 1: In certain jurisdictions there might be differences to whether a device classified in this rule is considered an IVD Medical Device.

Note 2: Performance of software or instrument that is specifically required to perform a particular test will be assessed at the same time as the test kit.

Note 3: The interdependence of the instrument and test methodology prevents the instrument from being assessed separately, even though the instrument itself is still classified as Class A.

Rule 6: IVD Medical Devices not covered in Rules 1 through 5 are classified as Class B.

Rationale: These devices present a moderate individual risk as they are not likely to lead to an erroneous result that would cause death or severe disability, have a major negative impact on the outcome or put the individual in immediate danger. The devices are usually one of several determinants. If it is the sole determinant however other information is available, such as presenting signs and symptoms or other clinical information which may guide a physician, the risk classification may be justified. Other appropriate controls may also be in place to validate the results. This Class also includes those devices that present a low public health risk because they detect infectious agents that are not easily propagated in a population.

Examples: Blood gases, *H. pylori* and physiological markers such as hormones, vitamins, enzymes, metabolic markers.

Table 9: Description of Common Test Purposes for IVD Medical Devices

Test Purpose	Description	Examples
Diagnosis	Diagnostic tests are used to determine, verify or confirm a patient's clinical condition as a	· genetic test for the diagnosis of Tay-Sachs

	sole determinant. This type of testing also includes sole confirmatory assays (to verify results of previous testing) and sole exclusion assays (to rule out a particular condition). These tests are designed to evaluate a patient's current state.	· HBs antigen confirmatory assay to verify positive screening results · D-dimer assay for exclusion of deep vein thrombosis · karyotype testing for the diagnosis of Trisomy 18 (Edward's syndrome)
Aid to Diagnosis	Aid to Diagnosis tests are used to provide additional information to assist in the determination or verification of a patient's clinical status. The test is not the sole determinant. These tests are designed to evaluate a patient's current state.	· troponin test as an aid in myocardial infarction diagnosis · genetic testing to aid in the diagnosis of familial hypercholesterolaemia (FH) · thyroid-stimulating hormone test to evaluate thyroid function · toxoplasma IgG avidity assay to determine likelihood of active infection · ANA test for autoimmune disease determination · test for genotyping of the Factor V Leiden mutation as an aid to diagnosis of thrombophilia
Screening	Screening tests are used to determine the status of a disease, disorder or other	· test to detect hepatitis B surface antigen in donated blood

	physiological state in an asymptomatic individual. These types of tests include genetic screening assays, tests for physiological typing, and tests used to reduce the risk of infectious disease transmission, such as assays for prenatal screening and donor screening (transfusion or transplantation). Depending on the nature of the condition and the targeted patient population, screening tests may be used routinely or may be restricted to 'at risk' patients. These tests are designed to evaluate an individual's current state.	· prenatal rubella IgG screening in pregnant women ·Prenatal genetic testing for trisomy 21 (Down syndrome) ·Newborn genetic testing for phenylketonuria · tests for the determination of HLA, blood groups and blood group factors for donor matching.
Monitoring	Monitoring tests are used for the measurement of analyte levels for the purpose of adjusting treatments/interventions as required. Monitoring tests include the following: Assays which are used to ensure that an analyte remains within physiological levels or	· intraoperative iPTH monitoring during parathyroidectomy surgery to confirm removal of abnormal tissue · self-test glucose monitoring to allow for quick responses to hyperglycemia or hypoglycemia

	within an established therapeutic drug range. These types of monitoring tests are designed to evaluate an individual's current state. Assays which are used for serial measurement, whereby multiple determinations are taken over time. These types of monitoring tests are typically used for the detection/assessment of disease progression/ regression, disease recurrence, minimum residual disease, response/resistance to therapy, and/or adverse effects due to therapy. These types of monitoring tests are designed to evaluate changes in an individual's state	· therapeutic drug monitoring of immunosuppressants to prevent rejection of transplanted organs · viral load testing of patients known to be infected with HIV to determine treatment response and adjust therapy if necessary · monitoring of CA 15-3 levels in breast cancer patients in remission to detect recurrence · test for the detection of BCR-ABL transcripts to monitor response/resistance in patients undergoing treatment for acute lymphoblastic leukemia (ALL) or chronic myeloid leukemia (CML) ·Test for immunoglobulin and T-cell receptor gene rearrangements for the detection of minimal residual disease in cancer patients.
Predisposition	Predisposition assays are used to determine the likelihood of disease onset (i.e., assessing the risk of developing the disease in future) in PR symptomatic patients. For patients at sufficient risk (as determined by test results),	· Genetic test for apolipoprotein E to assess the risk of developing Alzheimer's disease · BRCA1/BRCA2 mutation status testing to assess the risk of developing breast cancer (patient may choose to have prophylactic

	preventive interventions may be taken. These tests are designed to evaluate a patient's future state.	mastectomy if they are at sufficient risk)
Prognosis	Prognostic tests are used to measure factors linked to clinical outcome irrespective of treatment. Such tests may be used to estimate the natural progression of a disease (i.e., outcome in the absence of treatment), or to determine the likelihood of a clinical outcome irrespective of therapeutic intervention. These tests are designed to evaluate a patient's future state.	·Highly sensitive C- reactive protein measurement for the risk stratification of patients with acute coronary syndromes to determine the likelihood of future cardiac events ·Measurement of baseline HIV-1 RNA level to assess patient prognosis Cancer Gene Expression profile testing for metastasis risk to tailor treatment aggressiveness.
Prediction (of Treatment Response or Reaction)	Predictive tests are used to measure factors that determine the likelihood of patient responses or adverse reactions to a specific therapy. Predictive tests designed specifically for use with a targeted therapy are sometimes termed 'companion diagnostics' or 'personalized medicine'.	·HER-2/neu testing in breast cancer patients to assess likelihood of response to hormone therapy ·Identification of variations in cytochrome P450 genes (i.e., metabolizer status) to determine potential therapeutic benefits and/or adverse reactions to antiplatelet treatment

	These tests are designed to evaluate a patient's future state.	
Determination of Physiological Status	Physiological status determination tests are used to evaluate the physiological state of an individual for the purpose of identifying a human condition or characteristic. These tests are designed to evaluate a patient's current state.	·hCG test for the determination of pregnancy

3.0 References Regulatory Authorities

1. Australia Therapeutic Goods Administration (TGA) Device Registration License
2. Health Canada (HC) Device Registration License
3. Japan Ministry of Health, Labour and Welfare (MHLW)
    i. Pre-Market Certification from a Japanese Registered Certification Body
    ii. Pre-Market Approval from MHLW
4. US Food and Drug Administration (US FDA)
    i. 510K clearance
    ii. Premarket Approval (PMA)
5. European Union Notified Bodies (EU NB) via EC certificates issued according to
    i. Directive 93/42/EEC Annex II section 3 or Annex V for Class IIA devices
    ii. Directive 98/79/EC Annex IV or Annex V with Annex VII for List B and self-testing IVDs
6 Irish Health Products Regulatory Authority
7 Swiss Medic

4.0 Revision History

Section	Section(S) Modified	Description Of Change
Header	- PPB/PER/MDV/GDL/003 Revision 000 **2017** August 2017	- PPB/PER/MDV/GDL/005 REVISION 001 **2021** August 2021
Main Title	GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR REGISTRATION OF MEDICAL DEVICES	GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR REGISTRATION OF MEDICAL DEVICES INCLUDING IN-VITRO DIAGNOSTICS
Introduction	Section Referring To Gazette Notice No 35 2014	Suggested Update To GAZETTE NOTICE No. 1879; Gazette Notice No 37 2014
Pre-Introduction	Nil	To Include The Adoption Page Signed And Dated By The Author And QAO
LTR	Local Authorized Representative a. Any Manufacturer Based Outside Kenya Must Designate A Local Authorized Representative (LAR). The Appointed LAR Must Provide Written Evidence That They Are Acting With The Consent Of A Manufacturer Located Outside The Kenya **(Annex 1: Letter Of**	Local Authorized Representative a. Any Manufacturer/ MAH/Innovator Based Outside Kenya Must Designate A Local Authorized Representative (LAR). The Appointed LAR Must Provide Written Evidence That They Are Acting With The Consent Of A Manufacturer Located Outside The Kenya **(Annex 1: Letter Of Authorization Template)** The Local Authorized Representative Must Obtain A Letter From The Manufacturer Appointing

	Authorization Template)	Them As The Exclusive LAR, With The Exclusive Rights For Distribution, Sale, Importation And Registration Of The Medical Device. A Manufacturer / MAH/Innovator Cannot Appoint Two LAR For The Same Products To Be Sold In Kenya. Propose To Give A License To LAR Indicating Their Practice In Medical Device
1.5.3	Local Authorized Representative And Subcontractors Only One Local Representative Person Should Be Identified, And This Should Be Consistent Across The Device Labels, And Declarations Of Conformity.	Local Authorized Representative And Subcontractors Only One Local Representative Person Should Be Identified, And This Should Be Consistent Across The Device Labels, And Declarations Of Conformity. This Requirement Is Mandatory Before Registration Approvals Are Granted.
MODULE 1	- LISTING OF CLASS A MEDICAL DEVICES Certificate Of Analysis (COA) For Of All Materials Of Animal, Human, Microbial And/Or Recombinant Origin Used And Manufacturing Process (Where Applicable)	Registration OF CLASS A MEDICAL DEVICES Certificate Of Analysis (COA) For Of All Materials Of Animal, Human, Microbial And/Or Recombinant Origin Used And Manufacturing Process (Where Applicable) For Personal Protective Equipments, I.E Face Masks, Surgical Face Masks, Gloves; A Certificate Of Analysis For Conformity Through The PPBQC Laboratory

Section 1.3	Table 6: Summary Of Submission Requirements (Class B/C/D) **1.3.*Abridged Evaluation Route***	Propose To Remove This From Guideline As Its Not Being Used.
1.4	**1.4.*Expedited Class B Registration (EBR) Evaluation Route***	Propose To Remove This From Guideline As Its Not Being Used.
Section 1.5	**1.5.*Immediate Class B Registration (IBR) Evaluation Route*** **1.5.1.*Eligibility Criteria***	Propose To Remove This From Guideline As Its Not Being Used.
Section 8	TURN-AROUND-TIME (TAT) FOR PRODUCT REGISTRATION	Remove The Immediate, Expedited And Abridged Regulatory Pathways Revision On Time Times For The Turnaround Time Consider Removing This Table. Include A Footnote On The Regulatory Flexibility
Section 11	***Guidance On Change Notification Of Medical Devices Including Ivds***	For This To Be Implemented By The IT Team. Proposed Training To The Staff On Change Notifications
Section 17	***Addendum 1: Guidance On The Principle Of Risk Based Classification Of In-Vitro Diagnostic (IVD) Medical Devices***	Inclusion For The Requirements For In-Country Assessment By A Ppb Recognized Laboratory For Performance And Validation As A Mandatory Requirement Pre-Registration.
Annex 1	***Annex 1:* Letter Of Authorization Template**	We, *[Name Of Product Owner]*, As The Product Owner, Hereby Authorise *[Name Of Registrant (Company Name)]*, As The Registrant

	We, *[Name Of Product Owner]*, As The Product Owner, Hereby Authorise *[Name Of Registrant (Company Name)]*, As The Registrant To Prepare And Submit Applications For The Evaluation And Registration Of Medical Devices To The Pharmacy And Poisons Board On Our Behalf.	To Prepare And Submit Applications For The Evaluation And Registration Of Medical Devices To The Pharmacy And Poisons Board On Our Behalf. We Give Exclusive Rights To The LAR For Importation, Registration And Distribution Of Our Product In Kenya.
Prepared By	**Paulyne Wairimu** Head Medical Devices& Ivds	

5.0 Contributors and Reviewers

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13. Mr. Henry Chweya, Assistant Principal Regulatory Officer, Border line Products Department, Directorate of Health Products and Technologies
14. Mr. Peter Mugala, Senior Information and Communication Technology Officer; Drug Product Evaluation and Registration (DPER) Department, Directorate of Health Products and Technologies
15. Mr. Anthony Kemboi, Information and Communication Technology Officer; Drug Product Evaluation and Registration (DPER) Department, Directorate of Health Products and Technologies
16. Mr. Victor Kipchumba, Information and Communication Technology Officer Medical Devices Department Directorate of Health Products and Technologies

6.0 ANNEXURES:

Annex 1: Letter of Authorization Template

[To be printed on Company Letterhead of Product Owner]
Medical Device Department
Pharmacy and Poisons Board
Lenana Road Offices
P.o Box 27663-00508
Nairobi,Kenya.
[Date]
Dear Sir/Madam,
Subject: Letter of Authorization for *[name of Registrant (Company Name)]*
We, *[name of Product Owner],* as the Product Owner, hereby authorise *[name of Registrant (Company Name)],* as the Registrant to prepare and submit applications for the evaluation and registration of medical devices to the Pharmacy and Poisons Board on our behalf.
This authorisation shall apply to the following medical devices:
[List containing product names of medical devices]
We also authorise *[name of Registrant (Company Name)]* to make declarations and to submit documents on our behalf, regarding the above medical devices, in support of this application. These declarations and submissions are made pursuant to the requirements of the Health Act 2017, which includes the Health Products and Technologies and any other applicable laws that may also be in force.
This authorisation shall remain in effect until our notification to the Pharmacy and Poisons Board in writing (either by postal mail or facsimile transmission) that the authorisation is revoked.
We undertake to provide post-market support and assistance to the Registrant as may be required in relation to any matter involving the above medical devices.
We acknowledge that any non-compliance with any registration condition issued by the Pharmacy and Poisons Board in relation to medical devices registered in Kenya may result in the suspension or cancellation of the medical device registration.
We give exclusive rights to the LAR for importation, registration and distribution of our product in Kenya we give exclusive rights for the importation, registration and distribution has been given to the LAR

We agree to assist the Pharmacy and Poisons Board with any request for information on the above medical devices.
Yours Sincerely,
[Signature]
[Full Name and Title of Senior Company Official]
[Company stamp]

Annex 2: Marketing History Declaration Template

[To be printed on Company Letterhead of Applicant]

Medical Device Department
Pharmacy and Poisons Board
Lenana Road Offices
P.o Box 27663-00508
Nairobi,Kenya.

[Date]

Dear Sir/Madam,

I, *[name of Company]*, the Applicant for registration of the medical device(s) stated below, hereby declare that the medical devices have been marketed in the reference regulatory agency's jurisdiction for at least three years. The first date of market introduction in [jurisdiction/country] was *[mm/yyyy] (for ECR 1).*

OR reference stringent authority for at least three years. *[mm/yyyy] (for ECR 1.)*This declaration is made with respect to the following medical device(s):

[List containing product names of medical devices]

I, the Applicant, am aware that making a declaration which I know to be false is an offence under the Health Act 2017 (Cap. 244 Laws of Kenya) and may result in the cancellation of registration of the above medical devices.

Yours Sincerely,

[Signature]

[Full Name and Title of Senior Company Official]

[Company stamp]

Annex 3: Safety Declaration Template

[To be printed on Company Letterhead of Applicant]

Medical Device Department
Pharmacy and Poisons Board
Lenana Road Offices
P.o Box 27663-00506, Nairobi, Kenya.

[Date]

Dear Sir/Madam,

I, *[name of Company],* the Applicant for registration of the medical device(s) stated below, hereby declare that there are no safety issues globally associated with the use of the medical device(s) when used as intended by the Product Owner, in the last three years from *[dd/mm/yyyy] to [dd/mm/yyyy]*:

No reported deaths;

No reported serious deterioration in the state of health[1] of any person; **and**

No open field safety corrective actions (including recalls) at the point of submission of this application.

This declaration is made with respect to the following medical device(s):

[List containing product names of medical devices]

I, the Applicant, am aware that making a declaration which I know to be false is an offence under the Health Act 2017 (Cap. 244 Laws of Kenya) and may result in the cancellation of registration of the above medical devices.

Yours Sincerely,

[Signature]

[Full Name and Title of Senior Company Official]

[Company Stamp

Annex 4 Change Notification

(Medical Device is not a subject of an on-going FSCA and conforms to Essential Principles for Safety and Performance)

[To be printed on Company Letterhead of Registrant]

Medical Device Branch
Pre-Marketing Division
Health Products Regulation Group
Health Sciences Authority
[Date]

Dear Sir/Madam,

I, *[name of Company]*, the Registrant of the medical device(s) stated below, hereby declare that the medical device(s) in this Change Notification application,

☐ Is/are not a subject of an open reportable adverse event and/or an on-going field safety corrective action

☐ Conform(s) to the Essential Principles for Safety and Performance as laid out in the guidance for submission of medical devices

This declaration shall apply to the following medical device(s):

[List containing product names of medical devices]

I, the Registrant, am aware that a false declaration is an offence under the Health Products Act (Cap. 122D) and may result in the cancellation of registration of the above medical devices under Section 37(1) of the Act.

Yours Sincerely,

[Signature]
[Full Name and Title of Senior Company Official]
[Company stamp]

Annex 5: MEDICAL DEVICES PROCESS FLOW & INTERACTIONS

The Department of Product Evaluation and Registration under the Directorate of Medical Products and Health Technologies oversees the function of Marketing Authorization and Registration of all Medical products and health technologies.

The Division of Medical Products Evaluation and Registration is tasked with the Marketing Authorization function on Medicines, Biologics, Vaccines, Cosmetics, Food Supplements and Borderline products.

The following is the regulatory process flow with the other regulatory functions: -

1. Quality control (QC)

   The Product Evaluation and Registration Department provides QC access to Product Specifications and Analytical procedures, registration and retention databases. The Product Evaluation and Registration utilizes Certificates of analysis for registration of products. The QC is involved in screening and testing of Post marketing Surveillance Samples and Samples resulting from Inspections and enforcement activities. Some of these tests are outsourced to external laboratories such as the National Quality Control Laboratory(NQCL), Mission for Essential drugs (MEDS), Kenya Medical Research Institute (KEMRI) These results are shared with the Marketing control and Surveillance, Inspectorate, Surveillance and Enforcement and Product Evaluation and Registration (Division of Health Products Evaluation and Registration and division of Health Technologies Evaluation and Registration)
2. Marketing Control & Surveillance

   The Function carries out Post marketing Surveillance, it is engaged investigation of product related market complaints and poor-quality reports of HPTs, decisions on regulatory actions which include decisions on quarantine, recalls , withdrawals, which are enforced by inspectorate department and product evaluation and registration department. Conduct post-marketing quality surveys which include sampling and testing, MC coordinates protocol development and actual implementation of protocol for sampling and testing in collaboration with quality control laboratory

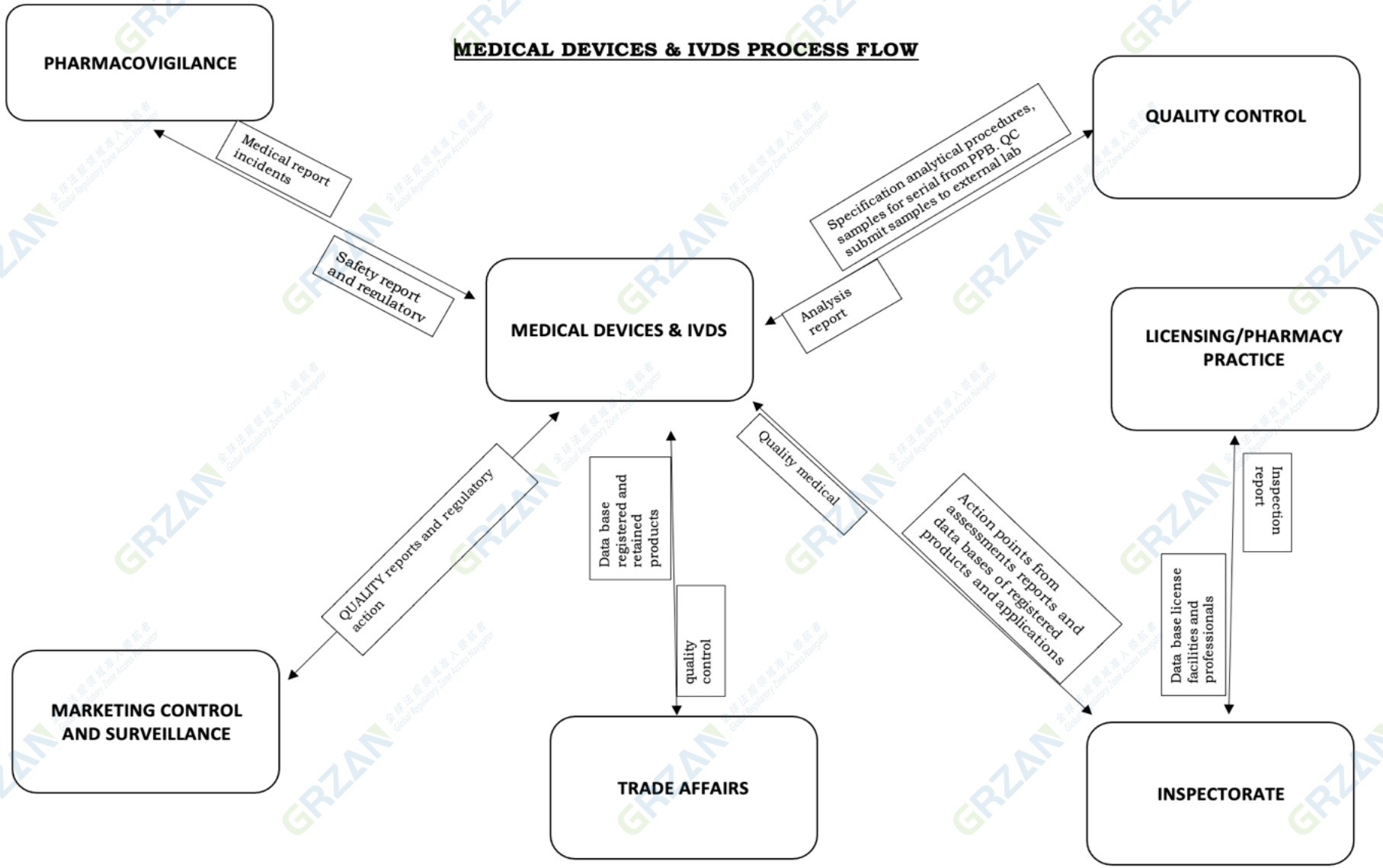
3. Inspectorate, Surveillance and Enforcement

The Inspectorate, Surveillance and Enforcement function is engaged in Regulatory inspections i.e. the GDP, GMP and GCP. Further, the Department is involved in investigations of complaints, investigation of pharma crimes, supervision of disposal of pharmaceutical waste, audit of court cases, management and storage of exhibits

4. National Pharmacovigilance Centre
   Pharmacovigilance unit monitors safety of health products and technologies in the market. This is through both active and passive surveillance. There is a system for receiving reports on safety and incidences following use of medical devices. There is also a procedure for receiving, investigation and review of field safety action reports. Regulatory actions undertaken after review of this reports includes issuing of safety alerts and recommendations on use of health products and technologies.

5. Trade Affairs
   Control of import and export of HPTs as well as health technologies assessment (HTAs) for HPTs include taxation regimes and facilitation of access of HPTs, work with product evaluation and registration department, inspectorate (port of entries), product safety department and quality control department and licensing department

6. Licensing
   Licensing of establishments that handle medical products and health technologies. These include wholesale dealers, distributors, retail/community pharmacies, hospitals, importers and exporters, manufacturers etc. Product registration, inspectorate, trade affairs closely interact with licensing function in executing their functions


MEDICAL DEVICES & IVDS PROCESS FLOW
PHARMACOVIGILANCE
Medical report incidents
Safety report and regulatory
MEDICAL DEVICES & IVDS
Specification analytical procedures, samples for serial from PPB. QC submit samples to external lab
QUALITY CONTROL
Analysis report
LICENSING/PHARMACY PRACTICE
QUALITY reports and regulatory action
MARKETING CONTROL AND SURVEILLANCE
Data base registered and retained products
quality control
TRADE AFFAIRS
Quality medical
Action points from assessments reports and data bases of registered products and applications
Data base license facilities and professionals
Inspection report
INSPECTORATE

Annex 6: Risk Based Classification of Medical Devices with Examples

	Category	**Classification**	**Examples**
1	**Non-Invasive Medical Devices** All Non-Invasive devices which come into contact with injured skin -if they are intended for channeling or storing liquids, or gases for the purpose of *eventual infusion,* administration or introduction into the body (Such devices are 'indirectly invasive' in that they channel or store liquids that will eventually be delivered into the body)	Class A- if they are intended to be used as a mechanical barrier, for Compression or for absorption of exudates only (they heal by primary intent) where the devices either do not touch the patient or contact intact skin only.	Cotton wool, bandages Administration sets for gravity infusion; syringes without needles. Urine collection bottles; compression hosiery; non-invasive electrodes, hospital beds.

		Class B- if they are intended to be used principally with wounds which have breached the dermis • Including devices principally intended to manage the micro-environment of a wound. • If they may be connected to an active medical device in Class B or a higher class .*N.B "Connection" to an active device covers those circumstances where the safety and performance of the active device is influenced by the non-active device and vice versa.* • if they are intended to be used for - channeling blood, or storing or channeling other body liquids, or storing organs, parts of organs or body tissues, for the purpose of eventual infusion, administration or introduction into the body • where the Medical device is used for the treatment consists of filtration, centrifuging or exchanges of gas or of heat.	• Non-medicated impregnated gauze dressing • syringes and administration sets for infusion pumps; anaesthesia breathing circuits • Tubes used for blood transfusion, organ storage containers devices to remove carbon dioxide; particulate filters in an extracorporial circulation system

		Class C- if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent • If they are Blood Bags that do not incorporate an anti-coagulant • All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids, or other liquids, intended for infusion into the body(N.B Such devices are 'indirectly invasive' in that they treat or modify substances that will eventually be delivered into the body. They are normally used in conjunction with an active device within the scope of either Rule 9 or 11)	• Dressings for chronic ulcerated wounds; dressings for severe burns • Blood Bags that do not incorporate an anti-coagulant • haemodializers; devices to remove white blood cells from whole blood.

	Invasive Medical Devices	1. Class A- All invasive devices with respect to body orifices (other than those which are surgically invasive) and which: ➢ -Are not intended for connection to an active medical device, or ➢ Are intended for connection to a Class A medical device only. ➢ If they are intended for transient use N.B Such devices are invasive in body orifices and are not surgically invasive .Devices tend to be diagnostic and therapeutic instruments used in ENT, ophthalmology, dentistry, proctology, urology and gynecology. Classification depends on the duration of use and the sensitivity (or vulnerability) of the orifice to such invasion. 2. if they are intended for short-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, 3. All surgically invasive devices that are reusable surgical instruments	• Examination gloves; enema devices • dressings for nose bleeds • Manually operated surgical drill bits and saws.

		Class B- if they are intended for short-term use. they are intended for long-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear-drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane All invasive devices with respect to body orifices (other than those which are surgically invasive) that are intended to be connected to an active medical device in Class B or a higher class. **2.** All surgically invasive devices intended for **transient use** All implantable devices, and **long-term surgically invasive** devices that are intended to be placed into the teeth or on prepared tooth structure.	• urinary catheters, tracheal tubes. • Orthodontic materials, removable dental prosthesis • *Example*-tracheal tubes connected to a ventilator; suction catheters for stomach drainage; dental aspirator tips. • A majority of such devices fall into several major groups: those that create a conduit through the skin (e.g. syringe needles; lancets), surgical instruments (e.g. single-use scalpels; surgical staplers; single-use aortic punch); surgical gloves; and various types of catheter/sucker • materials for inlays, crowns, and bridges; dental filling materials.

		• Class C- if they are intended for long-term use; • if they are reusable surgical instruments intended to supply energy in the form of ionizing radiation • intended to have a biological effect or be wholly or mainly absorbed(**NOTES**: (a) The 'biological effect' referred to is an intended one rather than unintentional. The term 'absorption' refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body. (b) This part of the rule does not apply to those substances that are excreted without modification from the body). ➢ intended to administer medicinal products by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application. (: The term 'administration of medicines' implies storage and/or influencing the rate/volume of medicine delivered not just channeling. The term 'potentially hazardous manner' refers to the characteristics of the device and not the competence of the user)	➢ urethral stent; contact lenses for long-term continuous use ➢ catheter containing sealed radioisotopes ➢ *Example*-Insufflation gases for the abdominal cavity. ➢ insulin pen for self-administration ➢ infusion cannulae; temporary filling materials; non-absorbable skin closure devices; tissue stabilizers used in cardiac surgery. ➢ surgical adhesive ➢ brachytherapy device ➢ Maxilla-facial implants; bone plates and screws; bone cement; non-absorbable internal sutures; posts to secure teeth to the mandibular bone(without a bioactive coating)

		➢ All surgically invasive devices intended for **short-term use(Includes devices that are used during cardiac surgery but do not monitor or correct a defect)** ➢ They are intended to undergo chemical change in the body ➢ **C-**they are intended to supply energy in the form of ionizing radiation ➢ All implantable devices, and **long-term surgically invasive** ➢ implants used in the orthopaedic, dental, ophthalmic, and cardiovascular fields.	
		• Class D- they are intended specifically for use in direct contact with the central nervous system • If they are -intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body • they are intended to have a biological effect or to be wholly or mainly absorbed.	• spinal needle • angioplasty balloon catheters and related guide wires; dedicated disposable cardiovascular surgical instruments • absorbable suture; biological adhesive • Neurological catheter.

		• they are intended specifically for use in direct contact with the central nervous system • they are intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body • They are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system. • **D-** if they are intended to be life supporting or life sustaining • they are intended to have a biological effect or to be wholly or mainly absorbed • **if** they are intended to administer medicinal products • if they are intended to undergo chemical change in the body (except if the devices are placed in the teeth) • *if they are Breast Implants*	• cardiovascular catheters; temporary pacemaker leads; carotid artery shunts • Prosthetic heart valves; cardiovascular stents; pacemaker leads and electrodes; deep brain stimulation electrodes; cerebrospinal catheter. • -pacemakers; implantable defibrillators. • Examples- implants claimed to be bioactive(Hydroxy-apatite-Hydroxy-apatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer). *-subcutaneous infusion ports for long-term use.* • *Breast Implants*

	Active Medical Devices	• Class A- If they are devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum.	Examination lamps; surgical microscopes; powered hospital beds & wheelchairs; powered equipment for the recording, processing, viewing of diagnostic images; dental curing lights.
		Class B- All active therapeutic devices intended to administer or exchange energy (Such devices are mostly electrically powered equipment used in surgery; devices for specialized treatment and some stimulators.) ➢ If they are active devices intended for diagnosis ➢ If they are active devices intended to supply energy which will be absorbed by the human body ➢ if they are intended to image *in vivo* distribution of radiopharmaceuticals ➢ If they are active devices that are intended to allow direct diagnosis or monitoring of vital physiological processes ➢ All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body	• Muscle stimulators; powered dental hand pieces; hearing aids; neonatal phototherapy equipment; ultrasound equipment for physiotherapy. • Equipment for ultrasonic diagnosis/imaging, capture of physiological signals. • magnetic resonance equipment; diagnostic ultrasound in non-critical applications; evoked response stimulators • gamma/nuclear cameras. ➢ Examples-electronic thermometers, stethoscopes and blood pressure monitors; electrocardiographs • Examples-suction equipment; feeding pumps; jet injectors for vaccination; nebuliser to be used on conscious and spontaneously breathing patients where failure to deliver the appropriate dosage

			characteristics is not potentially hazardous.
		Class C- their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionizing radiation, taking account of the nature, the density and site of application of the energy -All active devices intended to control or monitor the performance of active therapeutic devices in Class C, or intended directly to influence the performance of such devices -if they are intended they are specifically intended for: a) monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of central nervous system. b)diagnosing in clinical situations where the patient is in immediate danger, - Active devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology, including devices	➢ lung ventilators; baby incubators; electrosurgical generators; external pacemakers and defibrillators; surgical lasers; lithotriptors; therapeutic X-ray and other sources of ionizing radiation • external feedback systems for active therapeutic devices. • monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnoea monitors. • ultrasound equipment for use in interventional cardiac procedures • devices for the control, monitoring or influencing of the emission of ionizing radiation. • Infusion pumps; anaesthesia equipment; dialysis equipment; hyperbaric chambers; nebulizer where the failure to deliver the appropriate dosage characteristics could be hazardous.

		which control or monitor such devices, or those which directly influence their performance. -if-this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode and route of administration	
	Exceptional Classes		
	Medical Devices which Incorporate Medicinal Substances	• Class D- All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the devices • This medical devices incorporate Medicinal substances in an ancillary role	Examples antibiotic bone cements; heparin-coated catheters; wound dressings incorporating antimicrobial agents to provide ancillary action on the wound; blood bags incorporating an anti-coagulant
	Devices manufactured from or incorporate non-viable animal tissues or their derivatives	• Class A- A-such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only	leather components of orthopedic appliances
	Medical Devices-used for sterilizing or	Class A- they are intended to clean medical devices by means of physical action only	

	Disinfecting Medical Devices	Class B: All devices intended specifically to be used for sterilizing or disinfecting medical devices	Desk-top sterilizers for use with dental instruments.
		• **Class C**- they are disinfectant solutions or washer-disinfectors intended specifically for invasive medical devices, as the end point of processing, washer-disinfector equipment specifically for disinfecting an endoscope or another invasive device	solutions intended to be used for the disinfection of medical devices without further processing (for example in a steriliser) including those where the infective agent is a prion;
	Medical Devices Incorporating Animal or Human Cells/Tissues/Derivatives	**Class D:** All devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable	porcine heart valves
	Medical Devices for Ophthalmic Solutions Use	Are in **Class C**-All devices that are intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses	Contact cleaning solutions
	Medical Devices for Contraception or the prevention of STD's	**Class C**- All devices used for contraception or the prevention of the transmission of sexually transmitted diseases	Condoms; Contraceptive diaphragms

	Implantable Medical Devices for Long-term Use	**Class D-** they are implantable or long-term invasive devices	intrauterine contraceptive device

Annex 6: Example of an Essential Principles Conformity Checklist

A Sample of the Completed Essential Principles Conformity Checklist is herewith attached for illustrative purposes to the applicant.

For a medical device to be listed, the Local Responsible Person, with support from the manufacturer, is responsible for demonstrating that the device conforms to the Essential Principles of Safety and Performance of Medical Devices, as well as the Medical Device Labelling Requirements.

EP Checklist control number:

Product Owner Name:

Product Name:

No.	**Essential Principles – General requirements**	**Applicable to the device?**	**Method of Conformity**	**Identity of Specific Documents**

2	Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	*Yes*	*1.The devices are designed and manufactured under a full quality management system in accordance with ISO 13485 and presently certified* *2.The implantable cardiac pacemaker is tested to comply with ISO 5841-1 standard* 3. *Risk analysis has been performed in accordance with ISO 14971. Together with the proactive surveillance studies, it shows that any risks which may be associated with the devices are acceptable when weighed against the benefits to the patient and are compatible with a high level of*	*1. ISO 13485 Certificate No. 012345* *2. Type Test Certificate No. 123456 compliant with ISO 5841-1 standard.* *3. Proactive Surveillance Report PSR-001* *4. Risk Analysis Report RAR-001*

			protection of health and safety	

3	The solutions adopted by the product owner for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the product owner should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. The product owner should apply the following principles in the priority order listed: • identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse, • eliminate risks as far as reasonably practicable through inherently safe design and manufacture, • reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms, • inform users of any residual risks.	*Yes*	-DITTA-	-DITTA-
4	Devices should achieve the performance intended by the product owner and be designed, manufactured and packaged in such a way	YES	-DITTA-	-DITTA-

	that they are suitable for one or more of the functions within the scope of the definition of a medical device.			
5	The characteristics and performances referred to in Clauses 1, 2 and 3 should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the product owner, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the product owner's instructions.		-DITTA-	-DITTA-
6	The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the product owner.		-DITTA-	-DITTA-

7	The benefits must be determined to outweigh any undesirable side effects for the performances intended.		-DITTA-	-DITTA-
8	Every medical device requires clinical evidence, appropriate for the use and classification of the device, demonstrating that the device complies with the applicable provisions of the essential principles. A clinical evaluation should be conducted.		-DITTA-	-DITTA-
Essential Principles – Design and Manufacturing Requirements				
8.1	The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Clauses 1 to 6 of the 'General Requirements'. Particular attention should be paid to: • the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, • the compatibility between the materials used and biological tissues, cells, body fluids, and specimens, taking account of the intended purpose of the device,	YES	*The materials used to manufacture the device have been subject to biological evaluation in accordance with ISO 10993 standards.*	Biological Evaluation Test Report No. 012345

	• the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.			
8.2	The devices should be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the product. Particular attention should be paid to tissues exposed and to the duration and frequency of exposure.	Yes	*1.The devices are packaged in accordance with a system in compliance with ISO 11607.* *2.The materials used to manufacture the device have been subject to biological evaluation in accordance with ISO 10993 standards.*	*Biological Evaluation Test Report No. 012345*

8.3	The devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.	YES	1.Risk analysis has been performed accordance with ISO 14971 2.The materials used to manufacture the device have been subject to biological evaluation in accordance with ISO 10993 standards	*1.Biological evaluation Test Report No. 012345* *2. Risk Analysis Report RAR-001*

8.4	Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product/drug as defined in the relevant legislation that applies and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance should be verified, taking account of the intended purpose of the device.	no	not applicable	not applicable
8.5	The devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the device.	Yes	*1.The materials used to manufacture the device have been subject to biological evaluation in accordance with ISO 10993 standards.* *2.Risk analysis has been performed in accordance with ISO 14971.*	*1.Biological evaluation Test Report No. 012345* *2. Risk Analysis Report RAR-001*
8.6	Devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the	Yes	*Risk analysis has been performed in accordance with ISO 14971.*	*Risk Analysis Report RAR-001*

	device taking into account the device and the nature of the environment in which it is intended to be used.			
9	Infection and microbial contamination			
9.1	The devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons. The design should: • allow easy handling, and, where necessary: • reduce as far as reasonably practicable and appropriate any microbial leakage from the device and/or microbial exposure during use, • prevent microbial contamination of the device, or specimen where applicable, by the patient, user or other person.	yes	*The devices are produced under strictly controlled conditions to minimize contamination. The devices are sterilized using EtO. The methods of sterilization and process control of sterilization are in conformance with ISO 11135* *2.Risk analysis has been performed in accordance with ISO 14971.* 3. *The devices are packaged in*	Risk Analysis Report RAR-001

			accordance with a system in compliance with ISO 11607.	
9.2	Where a device incorporates substances of biological origin, the risk of infection must be reduced as far as reasonably practicable and appropriate by selecting appropriate sources, donors and substances and by using, as appropriate, validated inactivation, conservation, test and control procedures.	NO	Not applicable	not applicable

9.3	Products incorporating non-viable tissues, cells and substances of animal origin falling within the definition of a medical device, should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. The product owner is required to retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.	YES	Not applicable	Not applicable
9.4	For products incorporating cells, tissues and derivatives of microbial or recombinant origin falling within the definition of a medical device, the selection of sources/donors, the processing, preservation, testing and handling of cells, tissues and derivatives of such origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods	YES	Not applicable	Not applicable

	of elimination or inactivation in the course of the manufacturing process.			
9.5	For products incorporating non-viable human tissues, cells and substances falling within the definition of a medical device, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.	YES	Not applicable	Not applicable

9.6	Devices labelled as having a special microbiological state should be designed, manufactured and packed to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the product owner.	yes	-DITTA-	Risk Analysis Report RAR-001
9.7	Devices delivered in a sterile state should be designed, manufactured and packed in a non-reusable pack, and/or according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the product owner, until the protective packaging is damaged or opened.	yes	*The devices are sterilized using EtO. The methods of sterilization and process control of sterilization are in conformance with ISO 11135.*	Risk Analysis Report RAR-001
9.8	Devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.	yes	*The devices are sterilized in conditions tightly controlled under the Quality Management System that governs the entire manufacturing process. The environments are in compliance with ISO 14644 standard*	*Clean Room Certificate No. 012345*

9.9	Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.	NO	Not applicable	N?A
9.10	Packaging systems for non-sterile devices should keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilization indicated by the product owner.	NO	Not applicable	N/A
9.11	The packaging and/or label of the device should distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.	NO	Not applicable	Not applicable
10.1	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should be safe and should not impair the specified performance of the devices. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use.	NO	Not applicable	Not applicable

10.2	Devices should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate: • the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; • risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure and acceleration; • the risks connected to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use; • the risks of accidental penetration of substances into the device; • the risk of incorrect identification of specimens; • the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;	YES	*1.The device is tested to comply with ISO 5841-1.* *2.Risk analysis has been performed in accordance with ISO 14971.*	*1.Type Test Certificate No. 123456 compliant with ISO 5841-1.* *2.Risk Analysis Report RAR-001*

	• risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.			

10.3	Devices should be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.	YES	DITTA	DITTA
10.4	Devices must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.	NO	Not applicable	N/A
11.1	Devices with a measuring function, where inaccuracy could have a significant adverse effect on the patient, should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the device. The limits of accuracy should be indicated by the product owner.	no	Not applicable	Not applicable

11.2	Diagnostic devices should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended use, based on appropriate scientific and technical methods. In particular the design should address sensitivity, specificity, trueness, repeatability, reproducibility, control of known relevant interference and limits of detection, as appropriate.		Not applicable	N/A
11.3	Where the performance of devices depends on the use of calibrators and/or control materials, the traceability of values assigned to such calibrators and/or control materials should be assured through a quality management system.		Not applicable	N/A
11.4	Any measurement, monitoring or display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device.		Not applicable	N/A
11.5	Wherever possible values expressed numerically should be in commonly accepted, standardized units, and understood by the users of the device.		Not applicable	N/A

12.1.1	General Devices should be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation should be reduced as far as practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.		Not applicable	N/A
12.2.1	Intended radiation Where devices are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it should be possible for the user to control the emissions. Such devices should be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.		Not applicable	Not applicable

12.2.2	Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where practicable, with visual displays and/or audible warnings of such emissions.		Not applicable	Not applicable
12.3.1	Unintended radiation Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as practicable and appropriate.		Not applicable	N/A
12.4.1	Instructions for use The operating instructions for devices emitting radiation should give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.		Not applicable	Not applicable

12.5.1	Ionizing radiation Devices intended to emit ionising radiation should be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.		Not applicable	N/A
12.5.2	Ionizing Radiation Devices emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.		Not applicable	N/A
12.5.3	Ionizing radiation Devices emitting ionizing radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the		Not applicable	N/A

	beam type and energy and where appropriate the energy distribution of the radiation beam.			
13	Requirements for medical devices connected to or equipped with an energy source			
13.1	Devices incorporating electronic programmable systems, including software, should be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition in the system, appropriate means should be adopted to eliminate or reduce as far as practicable and appropriate consequent risks.		*The device is tested to comply with ISO 5841-1 standard.* *2. Type Test Certificate No. 123456 compliant with ISO 5841-1 standard.* 3. *Risk analysis has been performed accordance with ISO 14971.*	*1.3485 Certificate No. 012345* *2. The device is tested to comply with ISO 5841-1 standard.* 3.. *Type Test Certificate No. 123456 compliant with ISO 5841-1 standard.*

13.2	Devices where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.		*1.The devices are designed and manufactured under a full quality management system in accordance with ISO 13485 and presently certified*	*Type Test Certificate No. 123456 compliant with ISO 5841-1 standard.*
13.3	Devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.		Not applicable	Not applicable
13.4	Devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.		Not applicable	Not applicable
13.5	Devices should be designed and manufactured in such a way as to reduce as far as practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the usual environment.		N/A	N/A

13.6	Devices should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.		Not applicable	N/A
13.7.1	Protection against electrical risks Devices should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed and maintained as indicated by the product owner.		Not applicable	Not applicable
14.1	Protection against mechanical risks Devices should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.		Not applicable	Not applicable

14.2	Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.		Not applicable	Not applicable
14.3	Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.		Not applicable	Not applicable
14.4	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.		Not applicable	Not applicable
14.5	Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings		Not applicable	Not applicable

	should not attain potentially dangerous temperatures under normal use.			
15.1	protection against the risks posed to the patient by supplied energy or substances Devices for supplying the patient with energy or substances should be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.		Not applicable	Not applicable
15.2	Devices should be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Devices should incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.		Not applicable	Not applicable

15.3	The function of the controls and indicators should be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.		Not applicable	Not applicable
16.1	Such devices should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in user's technique and environment. The information and instructions provided by the product owner should be easy for the user to understand and apply.		Not applicable	Not applicable
16.2	Such devices should be designed and manufactured in such a way as to reduce as far as practicable the risk of use error in the handling of the device and, if applicable, the specimen, and also in the interpretation of results.		Not applicable	Not applicable

16.3	Such devices should, where reasonably possible, include a procedure by which the user can verify that, at the time of use, that the product will perform as intended by the product owner.		Not applicable	Not applicable
17	Information supplied by the manufacturer			
17.1	Users should be provided with the information needed to identify the product owner, to use the device safely and to ensure the intended performance, taking account of their training and knowledge. This information should be easily understood.	yes	*The information supplied with the device Labels and instructions complies with the labelling requirements for use enclosed under specified under guidance document oo1.*	labels and instructions for use enclosed under section 2 of the submission folder.
17.2	Clinical investigations on human subjects should be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.	no	Not applicable	not applicable

Annex 7: Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices (STED)

Essential Principles Checklist					
Identity of IVD medical device:					
	Essential Principle Identify of IVD Medical Device	Applicable to the device?	Method Used to Demonstrate Conformity	Method Reference	Reference to Supporting Controlled Documents
	General Requirements				
	5.1 Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.				

	5.2 The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed: ▪ identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse, ▪ eliminate risks as far as reasonably practicable through inherently safe design and manufacture, ▪ reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms, ▪ inform users of any residual risks.				
	5.3 Devices should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device applicable in each jurisdiction.				

	5.4 The characteristics and performances referred to in Clauses 5.1, 5.2 and 5.3 should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.				
	5.5 The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.				
	5.6 The benefits must be determined to outweigh any undesirable side effects for the performances intended.				
	Design and Manufacturing Requirements				
	5.7 Chemical, physical and biological properties				

	5.7.1 The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Clauses 5.1 to 5.6 of the 'General Requirements'. Particular attention should be paid to: ▪ the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, ▪ the compatibility between the materials used and biological tissues, cells, body fluids, and specimens, taking account of the intended purpose of the device, ▪ the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.				
	5.7.2 The devices should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the product. Particular attention should be paid to tissues exposed and to the duration and frequency of exposure.				
	5.7.3 ---------- etc. ----------				
	5.7.4 ---------- etc. ----------				

	5.7.5				
	5.7.6				

Declaration

I confirm that I have neither amended the wording in this form, nor otherwise altered the form in any material manner, apart from filling in the blanks. I declare that the information provided in this form is accurate and correct and the device conforms to all the applicable requirements stipulated above.

Name:

Position:

The Applicant (Local Authorized Representative):

Signature:

……

…..Date:……

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. *Singapore Health Safety Authority (HSA)*
9. *Global Medical Devices Agency*
10. *Medical Devices -ISO 13485 Standards-Quality Management Systems-Requirements for Regulatory purposes 2016*
1. *WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices (WHO Medical device technical series 2017*

ANNEXES

Addendum 1-Guidance on the principle of Risk Based Classification of In-Vitro Diagnostic (IVD) Medical Devices

Annexes

Annex 1: Letter of Authorization Template
Annex 2: Marketing History Declaration Template (Class B)
Annex 3: Safety Declaration Template
Annex 4. Guidance on Change Notification of Medical Devices including IVDs
Annex 5: MEDICAL DEVICES PROCESS FLOW & INTERACTIONS
Annex 6: Risk-Based Classification of Medical Devices with Examples
Annex 7: Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)
Annex 8: Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices (STED)

Tables

Table 1: Risk Based Classification of Medical Devices and Examples
Table 2: Types of marketing clearances or approvals from each country/region
Table 3: Summary of Application Process to be followed for All Medical Devices.
Table 4: Summary of Submission Requirements for listing of Class A
Table 5: Summary of Submission Requirements for Class B
Table 6: Summary of Submission Requirements for Class C and D
Table 7: Turn-around-time (TAT) for medical devices registration
Table 8: Registration, retention and variations fees for Medical Devices

Table 9: Categories of Change Notification for Class A, B, C and D Medical Devices

Table 10: Risk classification of In-Vitro Diagnostics and Examples.

Table 11: Description of Common Test Purposes for IVD Medical Devices

Revision History

Revision No	Date	Author/Reviewer	Sections amended	Reason for change
000	August 2021	Paulyne	Header	PPB/PER/MDV/GDL/003 revision 000 2017 August 2017
			Main title	GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR

				REGISTRATION OF MEDICAL DEVICES
			Introduction	Section referring to gazette notice no 35 2014
			LTR	Local Authorized Representative h. Any manufacturer based outside Kenya must designate a local authorized Representative (LAR). The appointed LAR must provide written evidence that they are acting with the consent of a manufacturer located outside the Kenya (Annex 1: Letter of Authorization Template)
			1.5.3	Local Authorized Representative and Subcontractors Only one Local Representative Person should be identified, and this should be consistent across the device labels, and Declarations of Conformity.
2.0	January 2022	Paulyne	Citation Page	Addition of opening and closing citations
			format	Glossary and Abbreviations added
			Back page	Aligment with control of document SOP.

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