REPUBLIC OF KENYA

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MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR REGISTRATION OF MEDICAL DEVICES

August 2017

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1. **INTRODUCTION**

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

The Health Act 2017 and Health Products and Technologies (Medical Devices including IVD Medical Devices) Regulations (*Gazette Notice 35 2014)* requires evaluation and registration of medical devices, including In-Vitro Medical Devices, prior marketing in Kenya.

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).'*

The Pharmacy and Poisons Board in 2012, and following the presidential order for streamlining business processes for the Manufacturers/Importers and Exporters, adopted the WHO recommendation by constituting a department under the Directorate of Registration and Evaluation to evaluate applications for marketing authorizations of medical devices including IVDs. Since then, milestones in the areas of reviewing of all applications coming into the country, control of imports and exports, Pre-Verification of pre-shipments and the online submission of application have created both order and restored confidence.

Applications for marketing authorization for medical devices should follow requirements outlined in this guidance and the other relevant guidance documents. 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**.** Applications with the incorrect risk classification of devices may result in rejection and re-submission of the applications according to the appropriate risk class.

Applicants are reminded that, notwithstanding the registration of a medical device under the Health Act, the supply and use of any medical device including In-Vitro Diagnostic Medical Devices in Kenya should also comply with the requirements under other applicable legislations (e.g. Radiation Protection Act) and the requirements to monitor market performance of the registered medical devices including IVDs.

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

1.Scope

This guidance document describes the processes and general requirements for the submission of an application for a new medical devices and In-Vitro diagnostics Registration.

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.Definitions

Definitions that do not indicate they are set out in the health *Act 2017* or *Regulations* are intended as guidance in this document. These definitions are not taken verbatim from the above-mentioned legislation and should not be used in any legal context. These definitions are meant to provide guidance in layman terms.

Applicant: for the purposes of this guidance document, an Applicant is the person applying for a medical device registration.

Intended Use: for the purposes of this guidance document, 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' means 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) means a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

Manufacturer

a. Means the 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 (Market Authorization Holder (MAH)): for the purposes of this guidance document, means 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

Means 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.

Local Authorized Representative

a. 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 **(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.

Risk: Combination of the 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- The Definition for Which refers to;

- **Invasive device:** 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.

Reference Regulatory Authority (Annex)

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

b. Health Canada (HC) Device Registration License

c. Japan Ministry of Health, Labour and Welfare (MHLW)

   i. Pre-MarketCertification from a Japanese Registered Certification Body

   ii. Pre-Market Approval from MHLW

d. US Food and Drug Administration (US FDA)

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

e. 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

f. Irish Health Products Regulatory Authority
g. Swiss Medic
h. Saudi Arabia Food and Drug Authority (SFDA)

2. 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**.** ***Ref to Annex: 1;*** *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
    ii. Devices manufactured from or incorporate non-viable animal tissues or their derivatives
    iii. Medical Devices- used for sterilizing or Disinfecting Medical Devices
    iv. Medical Devices Incorporating Animal or Human Cells/Tissues/Derivatives

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

2.1.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.

2.2.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**.**

2.3.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.

2.4. 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

3. 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.

3.1.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;

3.1.1.Administrative information

Administrative information include 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.

3.1.2. Manufacturer name and address

The application should identify the name and location of the legal manufacturer (Market Authorization Holder) 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 Resposible Persons address

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

Country/Region	**Approval Type**
Australia	Australia Therapeutic Goods Administration (TGA) license
Canada	Health Canada License
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 III) -Annex II Section 3 and 4 of AIMDD (for active implantable medical devices)
Japan	Ministry of Health, Labour and Welfare (MHLW) License
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

3.1.3.Local Authorized Representative and Subcontractors

The name and location of the Representative in Kenya should be identified. Details of the registered Business domiciled in Kenya of the Local Representative Person should be provided.

The Pharmacy and Poisons Board will register all the Local Representative Persons for Medical Devices in Kenya.

Only one Local Representative Person should be identified, and this should be consistent across the device labels, and Declarations of Conformity.

3.1.4.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

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;

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).

3.1.5.Device identification

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

3.1.6.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:

a. 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.

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

3.1.2.Related previous submissions

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

3.1.3.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.

3.1.4. 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.

3.1.5.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.

i. Indications and contraindications should be supported by objective evidence (eg, evidence provided in the risk assessment and clinical evaluation reports).

ii. 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.

iii. Please ensure the intended use been described consistently throughout the file (eg. in the IFU, risk management documentation, clinical evaluation report, and design requirements).

iv. If the application includes a change to the intended use, all sections of the file should be reviewed for potential impact.

v. For clarity it is suggested that this should be separate from the device description.

3.2.Market history

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

a. If the device is new and has never been marketed by the manufacturer anywhere in the world, please state this explicitly.
b. 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.

3.2.1.Sales, complaints and vigilance

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

a.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.
b.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?
c.Full details of vigilance issues should be provided, including the status of any Field Safety Corrective Actions or Notices.

3.2.2.Draft Declaration of Conformity

Ideally, the Declaration of Conformity should include:

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

3.2.3.Manufacturing process and subcontractors

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

3.2.4.User information

a. Documents may include labels, instructions for use (IFU), patient implant cards, surgical manuals, brochures, marketing literature, etc
b. 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.
c. It is sufficient to show information concerning labelling in English only, but items to be translated and the plan for translation should be indicated.
d. If possible, provide drawings with the packaging configuration (showing placement of all labels) and label specifications.
e. 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.
f. Supporting evidence should be provided for any claims made in the labelling or marketing literature.
g. Please ensure that any specific requirements of relevant harmonized standards are addressed in the labels and information for use.

3.2.5.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.

3.2.6.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, sterilisation, 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.

3.2.7. 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.

3.2.8.PMS and PMCF

A Post-marketing Surveillance Plan (PMS 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 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,
c. please ensure that adequate justification is provided, based on the risk and clinical data available for the device.
d. 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
e. 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.

3.2.9.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.

3.2.9.1.Sterilization validation

Sterilisation validation is reviewed separately by KEMRI Microbiology experts.

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

b. Devices for End-User-Sterilisation also require review of cleaning and sterilisation validation/ adoption with respect to parameters recommended in the IFU.
c. Documents should describe:
    i. use of "State of the art" process validation methods;
    ii. the bio-burden controls and monitoring;
    iii. the product qualification (Dose verification, BI suitability testing, SAL calculations);
    iv. the process qualification (Performance qualification, Dose Map, BI Inactivations).

Additional guidance relating to specific document types is provided below:

3.2.9.2.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.

3.2.9.1.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.

3.2.10.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 Directives and must carry the CE marking. The non-medical device modules are not subject to the requirements for medical devices.

Ensure all relevant harmonised 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;

Validation report for the sterilization parameters listed in the IFU;

Validation report for the cleaning parameters listing in the IFU.

3.2.11.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 configurations/ 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 III devices, these must be reported to the PPB for review and certificate re-issue.

3.2.12.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.

3.2.13.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.

3.2.14.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 (eg 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.

3.2.15.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

4. MODULE 1 - LISTING OF CLASS A MEDICAL DEVICES

4.1.Submission Requirements

Upon submission via the *Online Portal of the Pharmacy and Poisons Board*, 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**
	Letter of Authorization
	Proposed Device Labelling (Actual Artworks, Packaging material in contact with the product and or the Secondary packaging to be provided)
	Pre-Verification certificate for a Notified Body in liasons with KEBS. Certificate of Conformity also acceptable in place of PVOC
	IFU, patient information leaflet and promotional material (including brochures and catalogues)
	Certificate of analysis (COA) for of all materials of animal, human, microbial and/or recombinant origin used and manufacturing process(Where applicable)

	Certificate of Analysis of all materials of animal, human, microbial and/or recombinant origin used and manufacturing process (where applicable)
	Information on sterilization method(s) and validation standard(s) used(where applicable)
	Regulatory approval from the country of origin of the product.
	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

5. MODULE 2 - REGISTRATION OF CLASS B MEDICAL DEVICES

5.1. Evaluation Routes

There are four evaluation routes for Class B medical devices:

1. **Full Evaluation Route**
2. **Abridged Evaluation Route**
3. **Expedited Class B Registration (EBR) Evaluation Route**
4. **Immediate Class B Registration (IBR) Evaluation Route**

The 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 Licence

ii. Health Canada (HC) Device Registration Licence

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

a. Pre-Market Certification from a Japanese Registered Certification Body

b. 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

5.2.Full Evaluation Route

5.2.1.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**.

5.2.2.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 6: Summary of Submission Requirements (Class B FER/AER/EBR/IBR)

No.	**Document Required**
	Letter of Authorisation
	List of configurations of medical devices to be registered packaging to be provided
	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 sterilisation validation, if applicable
	Risk Analysis
	Manufacturer Information (Including details of Manufacturing Site(s))
	Manufacturing Flow Process
	Clinical Evidence, including publications and full reports of the studies referenced in the clinical evaluation report Proposed Device Labelling
	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

5.3.Abridged Evaluation Route

5.3.1.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**.

5.4.Expedited Class B Registration (EBR) Evaluation Route

5.4.1.Eligibility Criteria

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

(i) 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;

(ii) marketed for at least three years in the above independent reference regulatory agency's jurisdiction;

(iii) 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**

(B)

(i) 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.

5.4.2.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

5.5.Immediate Class B Registration (IBR) Evaluation Route

5.5.1.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

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; and

(iv) 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.

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,SAFDA.

5.6. 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.

6. MODULE 3 - REGISTRATION OF CLASS C AND D MEDICAL DEVICES

6.1.Evaluation Routes

There are three evaluation routes for Class C and D 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;

6.1.1.Full Evaluation Routes

1. 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.

3. Processing times

2.Abridged Evaluation Route

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

Eligibility Criteria

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

(A) ECR:

(i) 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.

(ii) marketed for at least five years in the above independent reference regulatory agency's jurisdiction[2]; and

(iii) 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**

(B) ECR:

(i) 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.

6.2.Processing Times

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 dossier by PPBis 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.

6.3.Expedited Class D Registration (EDR) Evaluation Route

6.3.1.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 <u>independent</u> 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, neurostimulators)
(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.

Table 6: Summary of Submission Requirements (Class C/D FER/AER/EBR/)

No.	**Document Required**
	Letter of Authorization

	List of configurations of medical devices to be registered packaging to be provided
	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 sterilisation validation, if applicable
	Risk Analysis
	Manufacturer Information (Including details of Manufacturing Site(s))
	Manufacturing Flow Process
	Clinical Evidence, including publications and full reports of the studies referenced in the clinical evaluation report Proposed Device Labelling
	Clinical Evidence, including publications and full reports of the studies referenced in the clinical evaluation report Proposed Device Labelling
	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

7. 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.

8. 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.

Table 7: Turn-around-time (TAT) for medical devices registration

Risk classification	**TAT for Registration (in working days)**			
Class A	30			
Risk Classificatio n	**TAT for Registration (in working days)**			
	Immediate	**Expedited**	**Abridged**	**Full**
Class B	Immediate registration upon submission	60	100	160
Class C		120	160	220
Class D		180	220	310

Class D Devices incorporating registrable medicinal products			200	310

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9. 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.

Table 8: 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 10
		CLASS C & D: USD 300	USD 50

10. NOTIFICATION FOR CHANGES/VARIATIONS TO A REGISTERED MEDICAL DEVICES

The applicant are required to submit a "**Notification of Changes/Variations to a Registered Medical Devices Including Form attached as Annex 3: VI**" application, if there are any changes or proposed changes to particulars provided in relation to the registration of the medical device, and/or if there are any changes or proposed changes that may affect the safety, quality or efficacy of a registered medical device. Significant change(s) may include the following:

The manufacturing process, facility or equipment;

The manufacturing quality control procedures including the methods, tests or procedures used to control the quality, purity and sterility of the device or of the materials used in its manufacture;

The design of the device, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories;

The intended use of the device, including any new or extended use, any addition or deletion of a contraindication for the device and any change to the period used to establish its expiry date.

These changes will require PPB's approval before being effective.

The applicant is requested to complete **Notification of Changes/Variations to a Registered Medical Devices Including Form attached as Annex 3:** for the types of changes and required documents to be provided for a Change/variations Notification submission.

i. Copy of Pharmacy and Poisons Board Initial registration certificate of the device

ii. Copy of Pharmacy and Poisons Retention certificate of the device

iii. Letter of no objection from the existing LTR

11. 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

12. ANNUAL RETENTION FEE

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**.

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.

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 Authorisation 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 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: 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 gynaecology. 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 channelling. The term 'potentially hazardous manner' refers to the characteristics of the device and not the competence of the user) ➢ 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	➢ 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 stabilisers used in cardiac surgery. ➢ surgical adhesive ➢ brachytherapy device ➢ Maxilla-facial implants; bone plates and screws; bone cement; non-absorbable internal sutures; posts

		➢ **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.	to secure teeth to the mandibula bone(without a bioactive coating)

		• 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. • 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*	• spinal needle • angioplasty balloon catheters and related guide wires; dedicated disposable cardiovascular surgical instruments • absorbable suture; biological adhesive • Neurological catheter. • 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(Hydrox

			y-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 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	➢ 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.

	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 Disinfecting Medical Devices	Class A- they are intended to clean medical devices by means of physical action only	
		Class B: All devices intended specifically to be used for sterilising 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 5: 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 protection of health and safety*	*1. ISO 13485 Certificate No. 012345* *2. Type Test Certificate No. 123456 complian with ISO 5841-1 standard.* *3. Proactive Surveillance Repo PSR-001* *4. Risk Analysis Report RAR-001*

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 that they are suitable for one or more of the functions within the scope of the definition of a medical device.	YES	-DITTA-	-DITTA-

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, • the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.	YES	*The materials used to manufacture the device have been subject to biological evaluation in accordance with ISO 10993 standards.*	Biological Evaluation Test Rep No. 01234

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. 01234*
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 device taking into account the device and the nature of the environment in which it is intended to be used.	Yes	*Risk analysis has been performed in accordance with ISO 14971.*	*Risk Analysis Report RAR-001*
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 accordance with a system in compliance with ISO 11607.*	Risk Analy Report RA 001
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 of elimination or inactivation in the course of the manufacturing process.	YES	Not applicable	Not applicable

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 Analy Report RA 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 Analy Report RA 001

9.8	Devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilised 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 sterilised should be manufactured in appropriately controlled (e.g. environmental) conditions.	NO	Not applicable	Not applicable
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 sterilised prior to use, minimise the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilisation indicated by the product owner.	NO	Not applicable	Not applicable
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; • 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.	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 complian with ISO 5841-1.* *2.Risk Analysis Report RAR-001*

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	Not applicable
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	Not applicable

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	Not applicable
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	Not applicable
11.5	Wherever possible values expressed numerically should be in commonly accepted, standardised units, and understood by the users of the device.		Not applicable	Not applicable
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	Not applicable

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	Not applicable
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	Not applicable
12.5.2	Ionizing Radiation Devices emitting ionising 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 minimising radiation exposure of the patient and user.		Not applicable	Not applicable
12.5.3	Ionizing radiation Devices emitting ionising 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 beam type and energy and where appropriate the energy distribution of the radiation beam.		Not applicable	Not applicable
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 complian 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 Certific No. 123456 compliant with IS 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 applicabl
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 applicabl

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.		Not applicable	Not applicable
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	Not applicable
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 minimise 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 should not attain potentially dangerous temperatures under normal use.		Not applicable	Not applicable

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 a instructio for enclosed under section 2 the submissio 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

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.

Signature:

Name:

Position:

The Applicant (Local Authorized Representative):

Date:

Annex 6: Notification of Changes/Variations to a Registered Medical Devices Including IVDs

REPUBLIC OF KENYA

PHARMACY AND POISONS BOARD

NOTIFICATION OF CHANGES/VARIATIONS TO A REGISTERED MEDICAL DEVICES INCLUDING IVDS

(Please complete each section of this application form electronically as a word document AND as a scanned signed PDF file. To be submitted as one original hard-copy and one electronic copy (in Ms –Word and PDF version on a CD-Rom)

CONFIDENTIAL
(Effective from 8th January 2018)

THE REGISTRAR
PPB OFFICES,
LENANA ROAD,
DIRECTORATE OF PRODUCT EVALUATION AND REGISTRATION
MEDICAL DEVICES UNIT
P.O. BOX 27663-00506,
NAIROBI.
Fax: 2713431
Telephone: Nairobi 2716905/6; 3562107
Mobile: 0720 608811; 0733 884411
WEBSITE: www.pharmacyboardkenya.org
For Inquiries email: drugreg@pharmacyboardkenya.org,
info@pharmacyboardkenya.org

1. Application details (FOR OFFICIAL USE ONLY)

Application Number (VAR No.)	
Date of submission of the dossier/application	
CONCLUSION OF THE ASSESSMENT **APPROVED** *(no outstanding issues)* **QUERY RAISED** *(Indicate the sections where query is raised)* **REJECTED** *(indicate the sec(s) that led to the rejection)* ***(Please delete which does not apply)***	

2.
2.

2. Applicant details

Information required(Particulars of the applicant)	**Information to be filled by the Applicant**
a) Name and Business Address of the Marketing Authorization Holder(MAH)	Company) Name: Address: Country: Telephone: Telefax: E-Mail:
b)Name and complete address of the Local Technical Representative of Manufacturer(if Applicable or different from section (a) above)	Company name: Address: **PPB File Number:** Telephone: Telefax: E-Mail:

2.1.Product Details

Information required(Product Details)	**Information to be filled by the Applicant**
a) Device identification number	

b) Device retention number	
c) Device Name	
d) Group Name	
e) GMDN code	
f) Risk Class	

3. Changes/Variation title and Summary of the proposed changes

3.1.Changes/Variation title(s) and Variation type Number (s):

Indicate the variation title, for multiple changes/ variations (grouped variations), indicate all the titles of the variation as per PPB Variation guideline.

3.1.1.Changes/Variation type: (tick all applicable options)

☐ Notification

☐ Minor variation ☐ Major variation

3.1.2.Grouping of changes/variations

☐ Single variation ☐ Grouped variations

3.2.Summary of the proposed changes/variations

Provide a summary of the proposed changes as indicated in the table below. For Multiple variations(Grouped Variations), reproduce this section
Indicate background for change and justification for consequential change(s) if applicable.

Current Details	**Proposed Details (change)**	Reasons for change(s)

4. Documentation required to be provided

In the case of changes to the device detail, package leaflet, IFU or catalogue; applicants should enclose a working model clearly showing the differences between the current text and the proposed new version.

The following documentation ***SHALL be*** *provided for each changes/variation requested*

Name of the Document to be Submitted	**Applicant to tick all applicable options, if the document is provided**
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	

5. Declaration by the applicant:

I hereby submit an application for the above marketing authorization to be varied in accordance with the proposals given above.

I declare that:

1. *I, the undersigned certify that all the information in this application form and accompanying documentation is correct, complete and true to the best of my knowledge.*
2. *I also agree that the undersigned will continue to carry out pharmacovigelance to monitor the safety of the product in the market and provide safety update reports in accordance with PPB requirements*
3. *I also agree that I am obliged to follow the requirements of the Pharmacy and Poisons Act, which are related to pharmaceutical products.*
4. *I hereby confirm that fees will be paid/ have been paid as provided for in the Pharmacy and Poisons Board Drug Guidelines for Regulation of Medical Devices including IVDs.*

Name: ……

Position in the company (Title/ Designation):……

Signature:
……Date:……
…

Official stamp:

References

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