MINISTRY OF MEDICAL SERVICES

PHARMACY AND POISONS BOARD KENYA

GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR REGISTRATION OF MEDICAL DEVICES

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EDITION

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ACKNOWLEDGEMENTS

PREFACE

Medical Device Regulation in Kenya will be supervised and directed by Kenya Pharmacy and Poisons Board (PPB). Classification, requirements and evaluation of Medical Devices will be mainly simulation of rules and regulations recognized by the international regulatory benchmarks, which are mainly:

a. The Pharmacy and Poisons Act Chapter 244 of 2002
b. Global Harmonization Task Force (GHTF) for Medical Device
c. EU Medical Device Directives 93/42/EEC, EU In Vitro Diagnostic Device Directive

(IVDD) 98/79/EC and EU Active Implantable Medical Device Directive (AIMDD) 90/385/EEC.

d. US FDA (United States Food & Drug Administration)
e. Australia TGA (Therapeutics Goods Act)

The regulation of medical devices in Kenya is aimed at maintaining balance between ensuring product safety, quality and effectiveness and providing the public with timely access to medical devices and preventing the entrance of unsafe or ineffective devices into the market.

SCOPE

These guidelines shall apply to medical devices and their accessories. For the purposes of these guidelines, accessories shall be treated as medical devices in their own right.

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 use set by the PPB.

If, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall be governed by corresponding regulations for registration of medicinal products for human use set by the PPB.

The relevant essential requirements set in Annex 1 of this guideline shall apply as far as safety and performance related device features are concerned.

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.

This guideline does not apply to:

a) Medicinal products
b) Cosmetic products
c) Active implantable devices

d) human blood, human blood products, human plasma or blood cells of Human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells;

e) Transplants or tissues or cells of human origin nor products incorporating or derived from tissues or cells of human origin.

f) Transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

g) Medical Devices not in direct contact with human beings, not used for channelling blood products or not in direct contact with open wounds.

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LIST OF ABBREVIATIONS

LAR - Local Authorized Representative

DoC - Declaration of Conformity

ER - Essential Requirements

GHTF - Global Harmonization Task Force

GMDN - Global Medical Devices Nomenclature

GMP - Good Manufacturing Practices

ISO - International Organization for Standardization

MoMS - Ministry of Medical Services

PPB - Pharmacy and Poisons Board

QMS - Quality Management System

STeD - Summary Technical Documentation

DEFINITIONS

Medical Device

Means "any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation, of, or compensation for an injury of handicap,
- Investigation, replacement or modification of the anatomy or of a Physiological process, Control of conception ,

and, which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means " (EU Medical Device Directive,93/42/EEC, and Global Harmonization Task Force).

Product or Device Family

Means devices that have similar intended use,, technical characteristics (similarity in terms of size, materials of construction, performance characteristics and basic design) similar classification, similar manufacturing facility and follow standard manufacturing processes and the evidence to support compliance with the essential requirement is similar.

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

Manufacturer

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 himself or on his behalf by a third party.

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.

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.

Intended use

Means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials;

Incident

"Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health."

Placement on the Market

Means the first making available in return for payment or free of charge of a device with a view to distribution and/or use on the market, regardless of whether it is new or fully refurbished;

Objective Evidence

Information that can be proved true based on facts obtained through observation, measurement, testing or other means.

Process Validation

It is a confirmation by objective evidence that a process consistently produces a result or product meeting its pre-determined requirements.

Quality System

It is system which consists of the organizational structure, responsibilities, procedures, processes and resources for implementing quality management and achieving the objectives.

Quality Management System

Management system to direct and control an organization with regard to quality, from establishing quality policy, quality objectives and implementing and maintaining quality system.

Recall

Any action taken by the manufacturer, importer or distributor in respect of a medical device that has been sold to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after being aware that the device may be hazardous to health, may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety or may not meet the requirements of the Act or regulations.

Recognized Standards

National or international standards deemed to offer the presumption of conformity to specific essential principles of safety and performance

GENERAL INFORMATION

ESSENTIAL REQUIREMENTS

The Medical devices must meet the essential requirements set out in Annex 1 which apply to them, taking account of the intended purpose of the devices concerned.

CLASSIFICATION

Devices shall be divided into Classes I, IIa, IIb and III. Classification shall be carried out in accordance with Annex 2. Classification will be extremely claim sensitive.

According to the class of the concerned product and the available bench mark regulatory bodies' approvals, the PPB registration will decide to approve its registration through either one or two stages registration procedure.

PAYMENT OF FEES

Every application shall be accompanied by appropriate fees as specified in these guidelines. Any application that will not be accompanied by appropriate fees will not be screened or evaluated.

(a) Application Fees for Class I (non-exempt) Medical Devices

Screening Fees per submissions - US$ 25

(b) Application Fees for Class IIa, IIb and III Medical Devices

(i) Screening Fees per submission - US$ 50

(ii) Evaluation Fees per submission is as follows

Risk Class	**Fees**
Class I	US$ 200
Class IIa	US$ 500
Class IIb	US$ 750
Class III	US$ 1000

Screening fees is payable at the time of lodging an application and evaluation fee is payable once an application has been accepted for evaluation.

Mode of Payment: Payment shall be by crossed or bankers cheque payable to PHARMACY AND POISONS BOARD.

Both screening and evaluation fees are non-refundable once paid to the Board.

For each registered device family an annual retention fees shall be paid on or before the end of January of each year for which the fees are due to maintain a medical device family on the medical device register. The registration number of the device must be quoted at the time of payment.

Risk Class	**Annual Retention Fees**
Class I	US$ 25
Class Iia	US$ 40
Class Iib	US$ 60
Class III	US$ 100

OUTLINE OF EVALUATION PROCESS

The manufacturer or its local authorized representative is required to apply for the Medical device registration at the Pharmacy and Poisons Board. Only Medical Devices

with a valid Registration certificate will be allowed to be placed in the market. The local authorized representative is explicitly designated by the manufacturer, to act and to be addressed by PPB in Kenya on their behalf, with regards to the latter's legal obligations and responsibilities.

The PPB will briefly review the Medical Device in concern and it will decide if it will be either exempted from further evaluation or otherwise to issue the applicant an official letter requesting submission of more documents.

The decision will be made according to set criteria, which in turn depends on the rules for classification of Medical Device mentioned in Annex 3 of this guidelines.

TIMELINES

Once an application has been accepted and evaluation fees paid the processing of application will take 90 calendar days. This will involve evaluation of application, request for additional data/samples and clarification of some issues where applicable.

TERMINATION OF REGISTRATION

The PPB may by giving reasons in writing suspend or revoke the registration of a device, or amend the conditions of its registration within a reasonable time.

The registrant may by giving 60 days written notice and reasons to the PPB
Terminate the registration of a device.

VALIDITY OF REGISTRATION

When the Medical Device proves its safety efficacy and compliance with all the essential requirements and gets approval of the committee on medical Devices it will be granted a Registration certificate which in turn entitles the applicant to import and freely sell the registered

medical device given that the said applicant will comply with all the post marketing requirements in article ten.

A registration certificate will be valid for 5 years unless significant changes are made to the approved application data.

PPB can cancel the registration certificate if any of the following takes place:

- Based on the request of the applicant
- Based on non-compliance with the manufacturer's obligations set in article ten
- The product proved to be not safe or harmful to health
- The quality became substandard to that in the time of the application
- They differ from the approved label
- If the intellectual property rights of other similar product is violated.

The director of PPB will notify the registration holder in writing of the cancellation.

APPEALS

Any person aggrieved by a decision of the Board in relation to any application for registration or cancellation of a medical device may make representations in writing to PPB. If after consideration of the representations, the Board is satisfied it may approve registration of a medical device and if not satisfied it shall reject the application.

VARIATIONS

For application for variation of a registered device, the Board should be informed on any significant change(s) that could reasonably be expected to affect the safety or effectiveness of a medical device. Significant change(s) may include any of the following:

(a) the manufacturing process, facility or equipment;

(b) 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;

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

(d) The intended use of the device, including any new or extend 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 approval before they can be implemented. Any other change(s) should be notified immediately to the Board and may be implemented without prior approval.

All applications for variation to a registered device shall be made in writing and shall be accompanied by variation fee as prescribed in fees and charges in force at the time of application. Fees structures and processing time are detailed in Annex IV of this guidelines

RETENTION

Applications for retention of registration shall be made at least 90 days before the expiry date of registration of the device. The application shall include submission of filled in application form and information pertaining to changes that were made to a registered device.

POST-MARKET REQUIREMENTS AND VIGILANCE SYSTEM

The purpose of a Medical Device Vigilance System is to minimize risk to the health and safety of patients, users and others by reducing the likelihood of a serious incident involving a medical

device from occurring. Close co-operation among the PPB, manufactures and practicing medical professionals is necessary to achieve an effective vigilance system.

Manufacturers and local authorized representatives must also meet post-market requirements that consist of:

a) Maintain Distribution Records

The manufacturers, local authorized representatives, importers and distributors are required to keep distribution records to facilitate the accountability and traceability of a medical device. This ensures that the device distribution channels in Kenya, including medical device exports from Kenya, are identifiable

b) Maintain Complaint Handling Procedures and records

The manufacturers and local authorized representative are required to maintain records of problem report relating to the safety of the device, including any consumer complaints and perform corrective action if necessary.

c) Maintain Adverse Incident reporting procedures and records

The manufacturers and local authorized representative are required to notify the PPB of any adverse events related to a failure of the device or a deterioration of its effectiveness, or any inadequacy in its labelling or in its directions for use, which has resulted in the death or a serious deterioration in the state of health of a patient, users or other person, or could potentially lead to such consequences due to its recurrence.

d) Have Recall procedures in place.

The manufacturers and local authorized representatives are to establish and implement documents, procedures that will enable them to carry out effective and timely investigations of reported problems and recalls; and maintaining records of incident reports and of actions taken in response to these reports. Given that

defective or potentially defective medical devices should either be removed from the market or measures are taken to correct the problem in an effective and timely fashion.

The device manufacturer or its local authorized representative must submit the documents for the following post-market procedures in applying to place the medical device on the Kenyan market.

If a particular establishment has already submitted its post-market procedures in one product application, it need not repeat this submission in subsequent applications provided:

i. Proper reference are made to the documents submitted in the earlier application and
ii. There are no additional requirements and no changes made to the procedures.

INCIDENT REPORTING

Users (patients, practicing medical professionals or procuring officers) have the primary responsibility to report to PPB and manufacturer any malfunction or deterioration in the characteristics and/or performance of a device as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state or health.

Guidance on how initial vigilance reports should be made and what information should be included in them is given in Annex 3.

If the user cannot identify the manufacturer of the medical device then a report should be made direct to the PPB.

Where a reportable adverse incident occurs which involves medical devices placed on the market by more than one manufacturer, then a report should be made by each manufacturer involved (either separately or as a combined report) unless it is clear that the incident has been caused by one component only in which case the manufacturer of that component should report.

Maximum elapsed time for making an initial report is 10 days for incidents and 30 days for near incidents. For example a joint revision is not considered to be near incident.

After the initial report has been made, the manufacturer or authorized representative carries out or continues an investigation, while the PPB monitors progress. The PPB may intervene, or initiate an independent investigation, if appropriate.

Depending on the severity of the incident, the manufacturer or its authorized representative has up to 90 days to supply a report to PPB detailing investigation carried out, the root cause of the problem and actions taken or planned to be taken to implement corrective action.

Failure by the manufacturer or its authorized representative to report within stipulated period will lead to disciplinary action being taken. The measures will vary depending on the severity of the incident reported. These include:

a) Financial penalties
b) Temporary stop to distribution of the affected product batch
c) Product Recall
d) Temporary withdrawal of operating licence
e) Loss of operating licence.

IMPLEMENTATION

The implementation of these guidelines will be effective as soon as they are gazetted

REGISTRATION DOSSIER

PART 1: ADMINISTRATIVE INFORMATION

1.1. Details of the applicant

The manufacturer or its local authorized representative is required to apply for the Medical device registration at the Pharmacy and Poisons Board. The local authorized representative is explicitly designated by the manufacturer, to act and to be addressed by PPB in Kenya on their behalf, with regards to the latter's legal obligations and responsibilities.

1.2. Product Information

This requires a description of the device, intended use and instructions of use. Product information is manifested in the form of device labelling which must accompany each device. This includes any physician's manual, pack labelling, and promoting material and product brochure containing information on indications, contraindications, warnings, potential adverse effects and alternative therapy.

1.2.1. Name of Product

Provide the proprietary name of the product

1.2.2. GMDN Code

Provide the GMDN code specific to the product

1.2.3. Device Description

Besides a general description of the device, a more detailed description of the device attributes is necessary to explain how the device functions, the basic scientific concepts that form the foundation for the device, the component materials and accessories used in its operation as well as packaging . A complete description of each functional component, material or ingredient of the device should be provided, with labelled pictorial representation of the device in the form of diagrams, photographs or drawing as, appropriate.

1.2.4. Sterilization requirement

Indicate whether the product is sterilized, requires sterilization before use, requires partial sterilization or sterilization is not required.

1.2.5. If devices contain biological materials, the devices and manufacturing processes must be designed in such ways as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. Materials of animal origin must be from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the material. Safety with regards to viruses and other transferable agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.

1.2.6. Intended Use and indication

This means the use for which the medical device is intended for which it is suited to the data supplied by the manufacturer in the instruction as well as the functional capability of the device. The indication is a general description of the disease or condition that the device will diagnose, treat, prevent cure, or mitigate includes a description of the target patient population for which the device is intended.

1.2.7. Potential Adverse Effects

These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/ user, or side effects from the use of the medical device, under normal conditions.

1.2.8. Contraindications

This is a general description of the disease or condition and the patient population, for which the device should not be used for the purpose of diagnosis, treating, curing or mitigating. Contraindications are conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit.

1.2.9. Warnings and Precautions

This is the specific hazard alert information that a user needs know before using the device. Precautions alert the user to exercise special care necessary for the safe and effective use of the device. They may include actions to be taken to avoid effects on patients/users that may not be potentially life-threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the device of the use or misuse and the care necessary to avoid such effects.

1.2.10. List of components

1.2.11. Instruction of Use

These are all necessary information from the manufacturer including the procedures, methods, frequency, duration, quantity and preparation to be followed for safe use of the medical device. Instruction needed to use the device in a safe manner shall, to the extent possible, be included on the device itself and/or on its packaging.

Refer to annex 1 under labelling requirements for details

1.2.12. Shelf life/ Storage Conditions

Indicate the shelf life and storage conditions of the device. This may be supported by stability studies provided in section 2.9

1.3. Details of the Local Authorized Representative

Any manufacturer based outside the Kenya must designate 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.

1.4. Details of the Manufacturer

Provide the details of 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 himself or on his behalf by a third party.

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.

1.5. Quality Systems Standard

Quality System consists of the organizational structure, responsibilities, procedures, processes and resources for implementing quality management and achieving the objectives.

Quality Management System directs and controls an organization with regard to quality, from establishing quality policy, quality objectives and implementing and maintaining quality system.

1.6. Details of conformity assessment

1.6.1. Indicate whether product is marketed in the country of origin

1.6.2. Indicate when the device was originally introduced in the market and write the registration number.

1.6.3. List the certification/approval held for the product indicating the agency(s) and year of approval.

1.6.4. Provide the mode of dispensing of the medical device in the country of origin

1.6.5. Provide the classification of the medical device in the country of origin

Refer to annex 3

PART 2: SUPPORT INFORMATION

2.1. Manufacturer certificates

2.1.1. Provide copies of all certificates related to ISO 9001 standards. The ISO 13485 standard attested and authenticated

2.1.2. Provide GMP certificate issued by the relevant health authorities at country of origin attested and authenticated where applicable.

2.2. Regulatory Approval

Medical devices with prior approval from recognized regulatory agencies Medical device approvals or clearance from recognized regulatory authority, for example, from FDA (USA), EU (European Union), TGA (Australia) TPP (Canada) and/or MLHW (Japan), SFDA(China), (Brazil) and CDSCO (India) can be used to abridge the evaluation process for medical devices to be marketed in Kenya.

Evidence of regular approval or clearance of the medical device in the form of certification and/or relevant documents must be provided, as original authenticated documents

2.3. Post Market Surveillance

Provide evidence of established procedures and systems for Distribution Records, complaint Handling, Adverse Incident Reporting and Recall

2.4. Product Information

2.4.1. Device Labelling

This is the description and information literature that accompanies the device any time while it is held for sale or shipped, such as any physician's manual, pack labelling, promotional material and product brochures etc.

Physician's Manual

The physician's manual is also otherwise known as the user manual, operators manual, prescriber's manual or reference manual. It contains directions under which the physician or end-user can use a device safely and for its intended purpose. This should include information on indications, contraindications, warnings, precautions, potential adverse effects, alternative therapy and the conditions that should be managed during normal use to maintain the safety and effectiveness of the device.

Pack Labelling

This is printed, written or graphic product information provided on or attached to one or more levels of packaging, including the outer packaging or the outside container wrapper. Any pack labelling which is not provided on the outer packaging must be easily legible through this outer packaging.

Promotional Material

This is any mode or medium of disseminating product information for advertising and/or labelling purpose (s) , for example all forms of printed (e.g. posters, tags, brochures, pamphlets, circulars, books, direction sheets, etc.), written, or graphic product information and description, including those transmitted by means of print, radio and television mass media.

2.4.2. Specifications of materials used in device manufacturing and packaging

The material identifications and specifications must be provided including raw materials and components. The information must include complete chemical, biological and physical characterization of all component materials.

2.5. Declaration of Conformity

A declaration of conformity is required consisting of the manufacturer's declaration that the medical device complies with the quality, safety and effectiveness requirements. The manufacturer can only prepare a declaration of conformity after appropriately performing a critical design review minimizing risk and documenting the objective evidence into a summary technical file. Certification to demonstrate this compliance should also be submitted.

Compliance with recognized standards may be used, if the manufacturer chooses, to demonstrate the relevant quality, safety and effectiveness requirement of the medical device. Documentation should include the standards itself, how it was applied, deviations, test results other outputs and the certification obtained.

Refer to Annex 1 for details.

2.6. Status of Device Distribution

A summary of marketing history of the device is requested. The manufacturer or its local authorized representative must provide a list of countries where the device is currently being introduced and sold, its date of instruction and details of the regulatory status (e.g. marketing approval, product recall, product ban, etc.). The manufacturer or its local authorized representative must also provide a summary of reported problems related to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use, and has led to the death or serious deterioration in the state of health of a patient, user or other person, or could do so were it to recur. These

incidents require ‘mandatory ‘problem reporting that the manufacturer had submitted to the relevant regulatory authorities.

2.7. Safety and Effectiveness Data

The safety and effectiveness requirements must be applied as a function of the risk inherent with a given product. This requires a summary of all studies that the manufacturer relies on to ensure that the device meets the safety and effectiveness requirements, as well as the conclusions drawn from those studies. This includes evaluation of those risks against the claimed benefits of the device and the method used to reduce risk to acceptable levels. The studies must be organized into the following sub-sections and reported as appropriate. An introductory summary should accompany each study presented.

Risk Assessment

A list of possible hazard for these devices must be prepared. Indirect risks from medical devices including IVD may result from device- associated hazards, such as instability, which lead to erroneous results, or from user-related hazards, such as infectious reagents. The evaluation of these risks against the claimed benefits of the device and the method used to reduce risk to acceptable levels must be described. The individual or organization that carries out the risk analysis must be clearly identified. The technique used to analyze risk must be specified, to ensure that it is appropriate for the device and the risk involved.

Pre-clinical and clinical studies

Details must be provided on all biocompatibility tests conducted on the materials used in a device. At a minimum, tests must be conducted on samples from the finished, sterilized device. All materials that are significantly different must be characterised. Information describing the tests, the results and the analyses of data must be presented.

Complete pre-clinical physical test data must be provided, as appropriate. The report must include the objectives, methodology, results and manufacturer’s conclusion of all physical studies of the device and its components. Physical testing must be conducted to predict the adequacy of device response to physiological stresses, undesirable conditions and forces, lone-term use and all known and possible failure modes.

Pre-clinical animal studies used to support the probability of effectiveness in human must be reported. These studies must be undertaken using good laboratory practices. The

objectives, methodology, results analysis and manufacture's conclusion must be presented. The study conclusion should address the device's interactions with animal's fluids and tissues and the functional effectiveness of the device in the experimental animal model(s). The rationale (and limitations) of selecting the particular animal model should be discussed.

Clinical evidence of effectiveness may comprise device-related investigations conducted in Kenya or other countries. It may be derived from relevant publications in peer-reviewed scientific literature .The documented evidence submitted should include the objectives, methodology and results presented in context, clearly and meaningfully. The conclusion on the outcome of the clinical studies should be preceded by a discussion in context with the published literature.

Process Validation Studies

The results of all process validation studies must be presented. When the results of a particular process cannot be verified by subsequent observation, the process must be validated to obtain objectives evidence. This applies to sterilization processes as well. The procedures for monitoring and controlling the process parameters of validated process must be fully described. For example, the type of process, details of the equipment and process parameters employed in sterilization must be specified. Process validation data must include sterility tests data and methods, culture media, time and temperature of incubation, controls, number or samples examined and frequency of testing. Pyrogen test data and methods are required , including frequency of testing , number of units tested methods of testing , data from test results or a substantial rational for not conducting this kind of testing . Toxicity test methods and data must be described. If the sterilizer is toxic or produces toxic residues, test data and methods for establishing that post-process sterilizer and/or are within acceptable limits must be presented.

Software validation studies, if applicable:

The correctness of a software product is another critical product characteristic that cannot be fully verified in a finished product. The manufacturer and/or device sponsor must provide evidence that validates the software design development process. This information should include the results of all verification, validation and testing performed

in-house and in a user's environment to final release, for all of the different hardware configurations identified in the labelling. As well as representative data generated from both testing environments

Literature Studies

Copies are required of all literature that the manufacturer is using to support safety and effectiveness. These will be a subset of the bibliography of references. General bibliographic references should be device-specific as supplied in chronological order.

Care should be taken to ensure that the references are timely and relevant to the current application.

Devices Containing Biological Material

Results of studies substances the adequacy of the measures taken with regards to the risks associated with transmissible agents must be provided. This will include viral clearance results for known hazards. Donor screening concerns must be fully addressed and methods of harvesting must also be fully described. Process validation results are required to substantiate that manufacturing procedures are in place to minimize biological risks.

2.8. Human Clinical Data

Human clinical data needs to be submitted in the evaluation of higher risks medical devices and forms a part of the application criteria. In order to demonstrate compliance with the safety and effectiveness requirements, the human clinical data provided may be in the following forms:

- A compilation of the relevant peer-reviewed scientific literature currently available on the intended purpose of the device and the techniques employed with, if appropriate, a written report containing a critical evaluation of the compilation;
- The results and conclusion of a specifically designed clinical investigation.

Scientific Literature

Critical analysis and evaluation of scientific literature are broad concepts, which include any experience gained from as establishment device already on the market used in clinical practice. This includes data on the materials or type of design used in the particular device and data on the type of medical procedures used.

Designed Clinical Investigations

A designed clinical investigation on human subjects is performed on the basis of an appropriate protocol with well-defined objectives under the guidelines of good clinical practices. It involves procedures that are appropriate to the device under examination .The clinical investigation should be performed under circumstances that are similar to the intended conditions of use. The approval of ethics review committee and patient consent must be sought before conducting a clinical investigation, in observation of the Declaration of Helsinki.

The PPB will review the device information submitted to ensure that the devices meet the safety, quality and effectiveness requirements.

Information to justify the safety, quality and effectiveness of the medical device should be provided by the manufacturer or its local authorized representative, who is responsible for the accuracy of the information submitted and for matters consequent upon supply of the devices such as reporting adverse incidents, maintaining distribution records, facilitating tracking of certain implanted devices and establishing written procedures regarding investigating incidents and devices from the market

2.9. Stability Studies

2.10. Manufacturing Information

2.10.1. Quality plan

Quality Plan sets out the quality practices, resources and sequence of activities relevant to the device including service along with type of inspection equipment record requirement.

This quality plan would outline the design and process control material characterization. The plan may be presented as a narrative or in the form a flow diagram.

2.10.2. Manufacturing Process

Manufacturing Process for the device should be provided in the form of a list of resources and activities that transform inputs into the desired output. The manufacturing process should include the appropriate equipment specifications, manufacturing methods and procedures, manufacturing environment or condition and the facilities and controls used for the manufacturing, processing packaging, labelling storage product distribution, appropriate installation, and maintenance and servicing. Sufficient details must be provided to enable a person generally familiar with quality system to judge the

appropriateness of the controls in place. The sterilization method and processing should be included if any.

If multiple facilities are involved in the manufacture of a device, the applicable information for each facility must be submitted. Firms that manufacture or process the device under contract to the manufacturer may elect to submit all or a portion of the manufacturing information applicable to their facility directly to the Authority in the form of a master file. The manufacturer should inform these contractors of the need to supply detailed information on the device.

2.11. Quality Control Lab requirements

Specifications

Analysis method

Analysis requirements

PART 3: DECLARATION

The Declaration by the applicant should be submitted and declare that:

a) all submitted documents are true

b) They will be fully responsible for the product and post market plan submitted for complain handling or recall

c) They will fully comply with the requirements of the PPB after placing the product in the market.

All documents, including certificates, should be in English or Swahili and to be according to explanation in Annex 1

ANNEX 1: ESSENTIAL REQUIREMENTS FOR MEDICAL DEVICES

1.1. General Requirements

- Mechanical Device when used under the conditions and for the purpose intended, it will not compromise the clinical condition or the safety of the patients, users and where applicable, other persons.
- The devices must achieve the performance intended by the manufacture
- The lifetime of the device as indicated by the manufacturer shouldn't be affected when the device is subjected to the stresses which can occur during normal conditions of use
- Any undesirable side effects must constitute acceptable risks when weighed against the benefits intended.

1.2. Chemical and Physical Properties

i. Non-toxic and where appropriate, non-inflammable materials should be used.

ii. Materials used should be compatible with biological tissues cells and body fluids, taking account of the intended purpose of the device.

iii. Risk posed for person involved in the transport, storage and use of the devices and to the patients by the contaminants and residues should be minimized by its design, manufacturing method and packing.

1.3. Infection and Microbial Contaminations

i. The devices and manufacturer processes must be designed in such a way as to minimize the risk of infection to the patient. The design must be of easy handling and where necessary, minimize contamination of the device by the patient or vice versa during use.

ii. Sterile device must be designed, manufactured and packed in a non- reusable pack and/or according to appropriate procedures to ensure to remain sterile under the storage and transport conditions laid down, until the protective packaging is damaged or opened.

iii. Devices labelled sterile must have been sterilized by an appropriate, validated method.

iv. Packaging system for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and

v. If the devices are to be sterilized prior to use, the risk of microbial contamination must be minimized.

vi. The packs and/or label of the device must distinguish between products sold in similar sterile packaging.

1.4. Construction and Environmental Properties

If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.

Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible:

a) Flammability or explosion ;

b) Presence of a contaminate or chemical or microbial residue; I Radiation

c) Electrical , mechanical or thermal hazards : and

d) Fluid leaking from or entering into device

e) Vibration generated by the devices, noise emitted

i. The terminal and connections to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risk

ii. Accessible parts of the devices and their surrounding must not attain potentially dangerous temperatures under normal use.

1.5. Labelling Requirements

i. Any labelling artwork should be approved during the Registration process

ii. Any deviation from the approved set of labels will lead to suspension of the registration approval.

iii. All information required be easily understood by the intended user and must be English and Swahili. For self testing IVD and Devices used by patients it is a must.

iv. Instructions for use are not required for class I and II devices if these devices can be used safely without such instruction.

Medical devices must be labelled with the following information:

- The name and address of the manufacturer
- The identifier of the device, including the identifier of any medical device that is part of a system, test kit. Medical device group , medical device family device group familywhere appropriate, the batch code, or the serial number;
- Where appropriate, an indication that the device is for single use. If the contents are not readily apparent, an indication of what the package contains expressed in

terms appropriate to the device, such as the size net weight length volume or number of units ;

- The expiry date of the device, if any, determined by the manufacturer on the basis of the component with the shortest projected useful life;Unless self-evident to the intended user, the medical conditions , purpose and uses for which the device is manufactured , sold or represented, including the performance specifications of the device if those specifications are necessary for proper use

v. The directions for use, unless directions are not required for the device to be used safely and effectively; the condition for transporting and storing the device /or handling conditions applicable to the device; any special operating instruction; any warning and/or precaution to take.

vi. A medical device that is to be sold in a sterile condition shall be manufactured and sterilized under appropriately controlled conditions, and the sterilization method used shall be validated. Declaration that the device is sterile should be in the form a label.

vii. An indication of the time limit for implanting the device safely

viii. Where appropriate, the instructions for use must contain the following particulars:

a) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;

b) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized, and any restriction on the number of reuses.

c) Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I.

d) If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used.

e) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);

The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:

a) precautions to be taken in the event of changes in the performance of the device;
b) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc;
c) Date of issue or the latest revision of the instructions for use.

ANNEX 2: CLASSIFICATION OF MEDICAL DEVICES

2.1. Risk based classification

The control of medical devices will be based on a risk assessment and risk management. The level of regulatory control applied to the medical device is proportional to the degree of perceived risk associated with the device. The requirements of the review process differ for each class, type and technology of medical device. Medical devices may be classified into 4 classes: Class I (low risk), IIa and IIb (medium risk) or III (high risk) according to the European Union classification rules.

2.2. Basic Definitions

The classification rules are based on terms related to duration of contact with the patient degree of invasiveness and the part of the body affected by use of the device.

Time (Duration):

Transient

Normally intended for continuous use for less than 60 minutes

Short term

Normally intended for continuous use for not more than 30 days

Long term

Normally intended for continuous use for more than 30 days

Concept of continuous use

Concepts of duration such as transient short term and long term are defined in terms of continuous use. Continuous must be understood as an uninterrupted actual use for the intended purpose.

Invasiveness

Invasive devices

A device which in whole or in part penetrates inside the body . either through a body orifice or through the surface of the body.

Body orifice

It's any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening such as a stoma.

Surgically invasive device.

It's 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.

For the purposes of this guideline, devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, shall be treated as surgically invasive devices.

There are two exceptions to this:

i. A surgically crested stoma used in colostomy and ileostomy or permanent tracheostomy is considered to be a natural body orifice. Therefore devices introduced into such a stoma are not surgically invasive. A surgically created opening to allow access to the circulatory system in contrast should not be considered to be such a "natural body orifice". Devices introduced into such an opening are surgically invasive.
ii. A device that administers energy to the body should not be considered as invasive if only energy penetrates the body and not the device itself. Energy as such a device and therefore it cannot be classified. Only the device generating the energy must be classified. However, if a device administers a substance, whether this substance is a medicine or a medical device, such a substance must be assessed in its own right (e.g. substances administered by a jet injector).

Any device which in whole or in part penetrates inside the body either through a natural body orifice or through the surface of the body is an invasive device. A surgically

invasive device always implies that it enters through an artificially created opening. This can be a large opening such as a surgically incision, or

it can be a pinprick opening created by a needle. Therefore surgically gloves and needles used with syringes are surgically invasive.

Implantable device

Any device which is intended:

- to be totally introduced into the human body or
- to replace an epithelial surface or the surface of the eye

By surgical intervention which is intended to remain in place after the procedure Any device intended to be partially introduced into human body through surgical intervention and intended to remain I place after the procedures for at least 30 days is also considered an implantable device.

One of the key elements in defining what an implantable device is, is the concept of "procedure". Thus as implantable device must remain in the patient after the procedures. A "procedure" must be understood in this context to include the surgical procedure during which the implant is placed into the body and the immediate post-operative care is associated with the procedures . The "procedure" does not extent to the conclusion of the therapeutic treatment, e.g. the removal of an implant must be considered to be another "procedure" thus a plate used to reduce a fracture of the bone is an implant even if it is taken out after the fracture has healed. In this case the placing of the plate and its explanation are two different surgical procedures.

Some partially implanted devices are deemed to be implants. For instance if an operation is carried out to specifically to place an infusion port into the body then such as infusion port would remain for least 30 days after the procedure and consequently be an implant.

However, a suture used for skin wound closure that is taken out prior to 30days is not an implant

2.3. Application of Rules

In terms of further interpretation of the decision rules, the following should be considered:

- It is the intended and not the accidental use of the device that determines the class of the device. If a medical practitioner uses the device in a manner not intended by the manufacturer this does not change the class of the device for purpose of conformity assessment.
- It is the intended purpose assigned by the manufacturer to the device that determines the class of the device and not the class assigned to other similar products.
- as an alternative to classifying the system as a whole the determination of the class of a particular device may be made with respect to the simplest configuration that can still be considered , in view of its proper functional features, as a device in its own right . A device that is part of a system may be classed as a device in its own right rather than classifying the system as a whole. Similarly combination devices with parts that have different functional purpose may be analysed separately with respect to each of these parts for instance a drainage device will have an invasive tube and non-invasive collections device. These components may be classified separately.
- Accessories must be classified separately from their parent device.
- If a given device can be classified according to several rules, then the highest possible class applies.
- If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use. Classification of the device will have to be determined on the basis of claims contained in the information provided with the device. The manufacturer must be sufficiently specific in that regard. If the manufacturer wants to avoid the particular higher classification, then it must clearly on the labelling the intended purpose in such a way that device falls into the lower class. The manufacturer must provide as a minimum requirement either appropriate positive or negative indications for use.
- For a device to be “specifically intended” for the purpose referenced in a particular classification rule, the manufacturer must clearly indicate that the device is intended for such a specific purpose in the information accompanying the device. Otherwise it is deemed to intend to be used principally for the purpose that is accepted in general medical practice.

- Multi-application equipment such as laser printers and identification cameras, which may be used in combination with medical devices, are not medical devices unless their manufacturer places them on the market with specific intended purpose as medical devices.
- Standalone software, e.g. software which is used for image enhancement is regards as driving or influencing the use of a device and so falls automatically into the same class. Other standalone software, which neither is nor regarded as driving or influencing the use of a device is classified in its own right

2.4. Rules Used for Classification

Non- Invasive Devices

Rule 1

All non-invasive devices are in class I, unless one of the rules set out hereinafter applies

Rule 2

All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in class II if:

- they may be connected to an active medical device in Class II or higher class,
- they are intended for use for storing or channelling blood or other liquids or for storing organs, parts of organs or body tissues.

In all other cases they are in Class I.

Rule 3

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 are in Class III unless the treatment consists of filtration, centrifugation or exchanging of gas, heat in which case they are in Class II

Rule 4

All non-invasive devices that come into contact with injured skin:

- Are in Class I if they are intended to be used a mechanical barrier, for compression or for absorption of exudates,

- Are in class III if they are to be used principally with wounds, which have breached the dermis and can only heal by secondary intent ,
- Are in Class in II in all other cases, including devices principally intended to manage the micro-environment of a wound.

Invasive Devices

Rule 5

All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to a medical device:

- Are in Class I if they are intended for transient use
- Are in class II if they are intended for short-term use expect if they used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class I,
- Are in class III if they are intended for long-term use, except if they are 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 membranes, in which case they are in Class II.

All invasive devices with respect to body orifices other than surgically invasive devices, intended for connection to an active medical device in Class II or a higher class, are in class II

Rule 6

All surgically invasive devices intended for transient use are in Class II unless they are:

- Intended specifically to diagnose, monitor or correct of the heart or the central circulatory system through direct contact with these parts of the body, in which case they are in Class IV,
- Reusable surgically instruments in which case are in class I
- Intended to supply energy effect to be wholly or mainly absorbed in which case they are in Class III,
- Intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class III,
- Intended to administer medicines by means of a delivery system, if this system, if this done in a manner that is potentially hazardous taking account of the mode of application in which they are in Class III.

Rule 7

All surgically invasive devices intended for short-term use are in Class II unless they are intended:

- Either 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, in which case they are in Class IV,
- Or specifically for use in direct contact with the central nervous system, in which they are in Class IV,
- Or to supply energy in the form of ionizing radiation in which case they are in Class III,
- Or to have a biological effect or to be wholly or mainly absorbed in which case they are in Class IV,
- Or to undergo chemical change in the body , except if the devices are placed in the teeth , or to administer medicines , in which case they are in Class III.

Rule 8

All implantable devices and long-term surgically invasive devices are in Class III unless they are intended:

- To be placed in the teeth, in which case they are in Class II,
- To be used in direct contact with the heart , the central circulatory system or the central nervous system in which case they are in Class IV,
- To have a biological effect or to be wholly or mainly absorbed in which they are in Class IV,
- Or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class IV.

Additional Rules Applicable to Active Devices

Rule 9

All active therapeutic devices, intended to administer or exchange energy are in class II unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the human nature, the density and site of application of the energy, in which case they are in Class III.

All active devices intended to control or monitor therapeutic devices in Class III, or intended to influence the performance of such devices are in Class II.

Rule 10

Active devices intended for diagnose are in Class II:

- If they are intended to supply energy which will be absorbed by the human body , except for devices used to illuminate the patient's body, in the visible spectrum
- If they are intended to image in vivo distribution of radiopharmaceuticals
- If they are intended to allow direct diagnose or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters , where the nature of variations is such that it could result immediate danger to the patient for instance variations in cardiac performance , respiration, activity of CNS; in which case they are in Class III.

Active devices intended to emit ionizing radiation and intended for diagnose and therapeutic interventional radiology including devices which control or monitor such devices or which directly influence their performance, are in Class III.

Rule 11

All active devices intended to administer and/or remove medicines; body liquids other substances to or form the body are in Class II unless this is done in a manner

This is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are in Class III.

Rule 12

All other active devices are in Class I.

Special Rules

Rule 13

All devices incorporating, as integral part, a substance that if used separately can be considered to be a medicinal product, which is liable to act on the human body with action ancillary to that of the devices, are in Class III.

Rule 14

All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class IIb, unless they are implantable or long term invasive devices in which case they are in class III.

Rule 15

All devices intended specifically to be used for disinfecting, cleaning, rising or when appropriate, hydrating contact lenses are in Class III.

All devices intended specifically to be used for disinfecting medical devices are in Class II.

This rule does not apply to products that are intended to clean medical devices other than contact lenses by means of physical action

Rule 16

Non-active devices specifically intended for recording of X-ray diagnose images are in class II.

Rule 17

All devices manufactured utilizing tissues or derivatives rendered non-viable are Class IV except where such devices are intended to come into contact with intact skin only

Rule 18

By derogation from other rules, blood bags are in Class III

ANNEX 3: Incident Vigilant Reporting Form

Submitter's Information				
Patient/Healthcare professional/Procurement Officer/Social Care worker/others				
Name of the contact Person				
Address				
City			Country	
Phone			Fax	
Email				
Medical Device Information				
Class	I	IIa	IIb	III
Nomenclature system (preferable GMDN)				
Commercial name/ brand name / make				
Catalogue number				
Serial/Lot/batch number(s) (if applicable)				
Device Manufacturing date			Expiry date	
Implant date (for implants only			Explant date (for implants only)	
Duration of implantation (to be filled is the exact implant or explant dates are unknown)				
Accessories/ associated device (if applicable)				
Notified Body (NB) ID-number				
Incident Information				
User facility report reference number, if applicable				
Date the incident occurred				
Incident description narrative				
Number of patients involved (if known			Number of medical devices involved (if known)	
Medical device current location/disposition (if				

known)		
Operator of the Medical Device at the Time of Incident (Select one)		
health care professional	patient	other
Usage of the medical device (select from list below)		
initial use	reuse of a single use medical device	
reuse of a reusable medical device	re-serviced/refurbished	
other (please specify)	problem noted prior use	
Patient Information		
Patient outcome		
Remedial action taken by the healthcare facility relevant to the care of the patient		
Age of the patient at the time of incident, if applicable		
Gender, if applicable	Female/ Male	
Healthcare Facility Information		
Name of the health care facility		
Contact person within the facility		
Address		
City	Country	
Phone	Fax	
Email		
Send one copy to PPB and the other to Manufacturer or authorized representative		

ANNEX 4: APPLICATION FORM