GUIDELINES FOR THE SUBMISSION OF DOCUMENTS FOR THE REGISTRATION OF VETERINARY MEDICAL DEVICES

Document Number:	Effective Date:	Review Date
Revision Number:	Revision Date:	

TABLE OF CONTENTS

LIST OF ACRONYMS

EEC	European Economic Community
FIFO	First In First Out
GHTF	Global Harmonization Task Force
IVDD	In Vitro Diagnostic Device Directive
LTR	Local Technical Representative
TGA	Therapeutic Good Administration
US FDA	United States Food and Drugs Administration
VMD	Veterinary Medicines Directorate

DEFINITION OF TERMS

Veterinary Medical Device: Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent, software, material or other similar or related article intended for use, alone or in combination in animals for one or more of the following specific purpose;

i. Diagnosis, prevention, monitoring, treatment or alleviation of disease;
ii. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury
iii. Investigation, replacement, modification, or support of the anatomy or of a physiological process;
iv. Supporting or sustaining life;
v. Control of conception;
vi. Disinfection of medical devices;
vii. Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the animal body;

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

Active Device: Any active medical device, together with any accessories for its proper functioning, which is intended to be totally or partially introduced, surgically or medically, into the animal body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

In-Vitro Diagnostic Device (IVD): medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the animal body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

Manufacturer: A natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person her/himself or on her/his behalf by a third party. 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 Technical Representative: Any manufacturer based outside the Kenya must designate a local technical representative (LTR). The appointed LTR must provide written evidence that they are acting with the consent of a manufacturer located outside the Kenya. The responsibility of the LTR is, to assure regulatory compliance and serve as the central communication pathway with the Authority.

Local Technical Representative roles 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 the only ones 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 regulations that affect the device(s)

User: The institution, professional using or maintaining a medical device

Intended use: 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.

Adverse Event: 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 an animal, or user or of other persons or to a serious deterioration in their state of health.

Device Label: Any written, printed or graphic representation affixed to a veterinary medical device or any part of its packaging, or accompanying a device, when the medical device is being supplied.

Placement on the Market: 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: Confirmation by objective evidence that a process consistently produces a result or product meeting its pre-determined requirements.

Quality System: System consisting 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.

Field Corrective Action: Any action taken by the manufacturer, importer or distributor in respect of a medical device that has been sold to field safety corrective action 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. Recognised, National or international standards deemed to offer the presumption of conformity to specific essential principles performance.

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

Hazard: Potential source of harm.

Immediate danger: A situation where the animal is at risk of either losing life or an important physiological function if no immediate preventative measure is taken.

Implantable device: Any device, including those that are partially or wholly absorbed, which is intended:

i. To be totally introduced into the animal body or,
ii. 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 the animal body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

Life supporting or life sustaining: A device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of animal life.

Reusable surgical instrument: Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or other surgical procedures, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures for cleaning and/or sterilisation have been carried out.

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

Specimen: The discrete portion of a body fluid or tissue or other sample associated with the body taken for examination, study, or analysis of one or more quantity or characteristic to determine the character of the whole.

Continuous use: The entire duration of use of the device without regard to temporary interruption of use during a procedure or, temporary removal for purposes such as cleaning or disinfection of the device. OR The accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.

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. Devices which produce penetration other than through an established body orifice, should be treated as surgically invasive devices

Device Family Name

The device family name is the name assigned by the manufacturer to a group of one or more devices manufactured by, or for, the same manufacturer. In order to belong to a device family, the device must have the same basic design and performance characteristics related to device safety and effectiveness; intended use and function; device classification and product code.

Devices that function in exactly the same way, have the same electrical and mechanical design and performance characteristics, have the same intended uses, and differ only cosmetically or in minor ways not related to device safety or effectiveness may be grouped as a family.

Brand name, common name and whether the devices were introduced into commercial distribution under the same approval may be used as factors when grouping devices into families.

INTRODUCTION

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

The relevant essential principles set in these guidelines shall apply as far as safety and performance related device features are concerned.

The guidelines should help the applicant to decide if the product concerned is a medical device, using the appropriate definitions. Applicants should take into consideration information given in Annex 1 in order to establish the proper classification for the device, noting that where a veterinary medical device has features that place it into more than one class, classification and conformity assessment will be based on the highest class indicated.

Submission of Application

An application for registration for either locally manufactured or imported veterinary medical device online through the registration portal hosted in www.vmd.go.ke . If the application is from a foreign company, the applicant shall appoint a local technical representative through whom an application shall be submitted. The local agent shall be a registered wholesale dealer.

Types of applications

For the purposes of submission to the Authority, applications are classified into four categories as follows:

New applications for registration

This is an application for registration of a veterinary medical device that is intended to be placed on the Kenyan market for the first time.

Applications for Renewal of Registration

An application for renewal of veterinary medical device shall be made to the Authority at least ninety (90) calendar days before expiration of the last registration by completion of the prescribed application form. If an application for renewal is not made within 90-day period following the expiration of the registration validity, it shall be considered as a new application for registration.

Applications for renewal of registration shall be made according to the guidelines for renewal of registration in place at the time of submission.

Retention of a veterinary medical device

Every marketing authorization holder shall retain registered products in the register every year. This shall be done by completing the application form for retention of a veterinary medicine and pay annual retention fees as stipulated in the regulations (LN. No. 209 of 2015). Applications for retention of a registered product for a particular year shall be made by 31st of December of the preceding year. Application received beyond this date will be penalized.

Timelines for Registration

Applications for registration shall be scheduled for assessment according to the First in First out (FIFO) basis upon compliance of the requirements. A response to a new application shall be given within six (6) months of receipt of the application.

For Post Approval Variation and Renewal of registration complete applications will be processed within three (3) months of receiving the application including evaluation of documentation and consideration by a committee on product registration.

The applicant will be required to provide any requested additional data in the shortest time possible. The registration process is stopped and resumes once response from applicants are received.

Application for Variation of a registered veterinary medical device

The holder of registration of a veterinary device should notify the Authority, where a change that may affect the safety or effectiveness of a registered medical device is made. These changes may be categorized according to whether they are technical or administrative
changes. A summary of all these changes is tabulated in Annex 2.

All change notification to a registered device shall be made in writing and shall be accompanied by supporting information and appropriate fee.

Multiple changes (both administrative and technical changes) will be considered in one
change notification application if they are submitted together.

Payment of Fees

Fees are charged each time for registration, notification, update or change of the registration details held with the Directorate. The payment schedule is indicated in Table 1.

Initial registration fees and re-registration fee shall be based on a family of related devices, intended for the same purposes(s) and offered by the same manufacturer or importer.

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

Class	**Registration Fees ($)**	**Retention Fees ($)**	**Variation Fees ($)**	**Renewal Fees ($)**
Class A	25	10	10	25
Class B	350	100	20	350
Class C	450	150	50	450
Class D	550	200	70	550

ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF VETERINARY MEDICAL DEVICES

1 Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of animals, 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 animal and are compatible with a high level of protection of health and safety.

2. The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed:

    i. Identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse,

ii. Eliminate risks as far as reasonably practicable through inherently safe design and manufacture,

iii. Reduce as far as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms,

iv. Inform users of any residual risks.

3 Devices should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device according to these guidelines.

4 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 animal or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

5 The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.

6 The benefits must be determined to outweigh any undesirable side effects for the performances intended.

Design and Manufacturing Requirements

7) Chemical, physical and biological properties

7.1) 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 (above) of the Essential Principles of Safety and Performance '. Particular attention should be paid to:

i. The choice of materials used, particularly as regards toxicity and, where appropriate, flammability

ii. The compatibility between the materials used and biological tissues, cells, body fluids, and specimens, taking account of the intended purpose of the device;

iii. The choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.

7.2) The devices should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to animals, 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.

7.3) 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.

7.4) 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 within that jurisdiction 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.

7.5) 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.

7.6) 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.

8) Infection and microbial contamination

8.1) 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 animals, users and, where applicable, other persons. The design should:

i. Allow easy handling and, where necessary

ii. Reduce as far as reasonably practicable and appropriate any microbial leakage from the device and/or microbial exposure during use

iii. Prevent microbial contamination of the device, or specimen where applicable, by the animal, user or other person.

8.2) 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, and test and control procedures.

8.3) 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 manufacturer.

8.4) 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 manufacturer, until the protective packaging is damaged or opened.

8.5) Devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.

8.6) Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.

8.7) Packaging systems for non-sterile devices should keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilization indicated by the manufacturer.

8.8) 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.

9. Manufacturing and environmental properties

9.1) 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.

9.2) Devices should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate:

i. The risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;
ii. 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;
iii. 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;
iv. The risks of accidental penetration of substances into the device;
v. The risk of incorrect identification of specimens;
vi. The risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;
vii. 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.

9.3) Devices should be designed and manufactured in such a way as to minimize 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.

9.4) Devices must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substance.

10. Device with a diagnostic or measuring function

10.1) Devices with a measuring function, where inaccuracy could have a significant adverse effect on the animal, 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 manufacturer

10.2) 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.

10.3) 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.

10.4) Any measurement, monitoring or display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device.

10.5) Wherever possible values expressed numerically should be in commonly accepted, standardised units, and understood by the users of the device.

10.6) Note: While SG1 generally supports convergence on the global use of internationally standardised measurement units, considerations of safety, user familiarity, and established clinical practice may justify the use of other recognised measurement

11. Protection against radiation

11.1) General

11.1.1) Devices should be designed and manufactured and packaged in such a way that exposure of animals, 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.

11.2) Intended radiation

11.2.1) 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.

11.2.2) 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.

11.3) Unintended radiation

11.3.1) Where devices are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation

11.3.2) Devices should be designed and manufactured in such a way that exposure of animals, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as practicable and appropriate.

11.4) Instructions for use

11.4.1) The operating instructions for devices emitting radiation should give detailed information as to the nature of the emitted radiation, means of protecting the animal and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.

11.5) Ionizing radiation

11.5.1) Devices intended to emit ionizing 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.

11.5.2) Devices emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the animal and user.

11.5.3) Devices emitting ionizing radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam

12. Requirements for medical devices connected to or equipped with an energy source

12.1) 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.

12.2) Devices where the safety of the animals depends on an internal power supply should be equipped with a means of determining the state of the power supply.

12.3) Devices where the safety of the animals depends on an external power supply should include an alarm system to signal any power failure.

12.4) Devices intended to monitor one or more clinical parameters of a animal should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the animal's state of health

12.5) 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.
12.6) 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.
12.7) Protection against electrical risks
12.7.1) 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 manufacturer.

13. Protection against mechanical risks

13.1) Devices should be designed and manufactured in such a way as to protect the animal and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.
13.2) 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. 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.
13.3) Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.
13.4) 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.

14. Protection against the risks posed to the animal by supplied energy or substances

14.1) Devices for supplying the animal 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 animal and of the user.

14.2) 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.

14.3) 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 animal.

15. Protection against the risks posed to the animal for devices which do not require professional skills to operate

15.1) 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 manufacturer should be easy for the user to understand and apply

15.2) 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.

15.3) 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 manufacturer.

16. Information supplied by the manufacturer

16.1) Users should be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the intended performance, taking account of their training and knowledge. This information should be easily understood.

17. Performance evaluation including, where appropriate, clinical evaluation

17.1) All data generated in support of performance evaluation should be obtained in accordance with the relevant requirements applicable in each jurisdiction.

17.2) Clinical investigations on animal 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. In addition, some countries may have specific regulatory requirements for pre-study protocol review or informed consent.

TECHNICAL INFORMATION REQUIRED FOR SUBMISSION OF APPLICATIONS

The manufacturer or its local technical representative is required to apply for the registration of Veterinary Medical device. The information required is in three parts

2.1) Administrative Information

2.2) Supporting Documents

2.3) Declaration

Part 1: Administrative Information

The following information is required;

Description	**Details of the manufacturer, if is also the applicant**	**Local Technical Representative (if applicable**
Contact Person submitting the Application		
Company Name		
City		
P O Box		
Tel		
Fax		
Email		

Part 2: Registration Dossier Information

Executive Summary

An executive summary shall include the following information:

i. An overview, e.g., introductory descriptive information on the medical device and any novel features;
ii. Commercial marketing history;
iii. Intended uses and indications in labelling;
iv. List of regulatory approval or marketing clearance obtained;
v. Status of any pending request for market clearance and;
vi. Important safety/performance related information.

Relevant Essential Principles and Method Used to Demonstrate Conformity

The applicant should identify the Essential Principles of Safety and Performance of Medical Devices that is applicable to the device. The applicant should identify the general method used to demonstrate conformity to each applicable Essential Principle. The methods that may be used include compliance with recognized or other standards, state of the art or internal industry methods, comparisons to other similar marketed devices, etc. The applicant should identify the specific documents related to the method used to demonstrate conformity to the Essential Principles.

The evidence of conformity can be provided in tabular form with supporting documentation available for review as required. For example, a completed Essential Principles conformity checklist can be used to demonstrate that a recognized test standard was used as part of the method to demonstrate conformity to one Essential Principle. As such, applicant would then include a declaration of conformity to the standard or other certification permitted by the Regulatory Authority, and a summary of the test data, if the standard does not include performance requirements. When the manufacturer uses international or other standards to demonstrate conformity with the Essential Principles, the applicant should identify the full title of the standard, identifying numbers, date of the standard, and the organization that created the standard. When the manufacturer uses other means, such as internal standards, the applicant should describe the means.

Not all the essential principles will apply to all devices and it is for the manufacturer of the device to assess which are appropriate for his particular device product. In determining this, account must be taken of the intended purpose of the device.

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 fundamentals for the device, the component materials and accessories used in its principles of 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 drawings, as appropriate.

Intended use: - This means the use for which the medical device is intended, for which it is suited according to the data supplied by the manufacturer in the instructions as well as the functional capability of the device.

Instructions 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. Instructions needed to use the device in a safe manner should, to the extent possible, be included on the device itself and/or on its packaging by other formats /forms.

Limitations - This is a general description of the disease or condition and the animal population for which the device should not be used for the purpose of diagnosing, treating, curing or mitigating.

Warnings: - This is the specific hazard alert information that a user needs to know before using the device.

Precautions: - This alerts 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 animals/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 use or misuse and the care necessary to avoid such effects.

Materials: - This section must include complete chemical, biological and physical characterization of materials that have direct or indirect contact with the animal body.

i. If applicable, process validation results to be provided to substantiate that manufacturing procedures are in place to minimise biological risks;
ii. If applicable, information to be provided on irradiating components, non-ionising or ionising.

The functional characteristics and technical performance specifications for the device including, as relevant, accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability and other factors; and other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging to the extent necessary to demonstrate conformity with the relevant Essential Principles

Product Verification and Validation Documents

This section includes data from pre-clinical and clinical studies. The data required is to the extent appropriate to the complexity and risk classification of the device.

Pre-clinical Studies

Information on preclinical studies to establish the safety and performance of the medical device for its intended use must be provided. The pre-clinical studies provided should include information on study design, complete test or study protocols, and methods of data analysis, data summaries and study conclusions.

Clinical Evidence

This section should indicate how any applicable requirements of the essential principles for clinical evaluation of the device have been met. Where applicable, this evaluation may take the form of a systematic review of existing bibliography, clinical experience with the same or similar medical devices, or by clinical investigation. Clinical investigation is most likely to be needed for higher risk class medical devices or for medical devices where there is little or no clinical experience.

i. Use of Existing Bibliography: - Copies are required of all literature studies, or existing bibliography, 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 medical device-specific as supplied in chronological order. Care should be taken to ensure that the references are timely and relevant to the current application.

ii. Clinical evidence of effectiveness may comprise device-related investigations conducted domestically or other countries. It may be derived from relevant publications in a peer reviewed scientific literature. The documented evidence submitted should include the objectives, methodology and results presented in context, clearly and meaningfully.

The conclusions on the outcome of the clinical studies should be preceded by a discussion in context with the published literature.

Device Labelling

This section should summarize or reference or contain the following labelling data to the extent appropriate to the complexity and risk class of the device, which is generally considered as "labeling":

i. Labels on the device and its packaging
ii. Instructions for use;
iii. User manual
iv. Any information and instructions given to the animal, including instructions for
v. any procedure the animal is expected to perform (if applicable).
vi. Samples of Labels on the Medical device and its Packaging

Device is the 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.

If it is physically impossible to include samples of labels (e.g. large warning labels affixed onto an X-ray machine), alternative submission methods (e.g. photographs or technical drawings), to the extent appropriate, will suffice to meet the requirements of this section.

Operative Technique: The operative technique for use is commonly referred to as the veterinarnary professional's manual, user manual, operator's manual, prescriber's manual or reference manual. It contains directions under which the veterinarnary professional or end-user can use a device safely and for its intended purpose. This should include information on indications, contra-indications, 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 medical device.

Risk Analysis: This section should summarize or reference or contain the results of the risk analysis. This risk analysis should be based upon international or other recognized standards, and be appropriate to the complexity and risk class of the device.

Results of Risk Analysis: A list of possible hazards for these devices must be prepared. Indirect risks from medical devices may result from device-associated hazards, such as moving parts, which lead to sustained injury, or from user-related hazards, such as ionizing radiation from an X-ray machine. The evaluation of these risks against use to maintain the safety and effectiveness of the medical device, the claimed benefits of the device and the method(s) 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 medical device and the risk involved.

Manufacturer Information

This section should summarize or reference or contain documentation related to the manufacturing processes, including quality assurance measures, which is appropriate to the complexity and risk class of the medical device.

Manufacturing process for the medical device should be provided in the form of a list of resources and activities that transform inputs into the desired output. Example: The manufacturing process should include the appropriate manufacturing methods and procedures, manufacturing environment or condition, and the facilities and controls used for the manufacturing, processing, packaging, labelling, storage of the medical device. Sufficient detail must be provided to enable a person generally familiar with quality systems to judge the appropriateness of the controls in place. A brief summary of the sterilization method and processing should be included, if any.

If multiple facilities are involved in the manufacture of medical device, the applicable information (e.g. quality assurance certificates issued by an accredited third party inspection body) for each facility must be submitted. Firms that manufacture or process the medical 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 Regulatory Authority in the form of a

master file. The manufacturer should inform these contractors of the need to supply detailed information on the medical device.

However, it is not the intent of this section to capture information relating to the supply of sub-components (i.e. unfinished medical device) that contributes towards the manufacture of the finished medical device itself

PART 3: Declaration

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

i. All submitted documents are true;
ii. They will be fully responsible for the product and post market plan submitted for complain handling or field safety corrective action;
iii. They will fully comply with the requirements of the Authority after placing the product in the market.

REFERENCES

i. Laws of Kenya-Veterinary Medicines Directorate Regulation LN No. 209 of 2015
ii. Global Harmonization Task Force (GHTF) for Medical Device
iii. European Union Directives (on Medical Device Directives 93/42/EEC
iv. In Vitro Diagnostic Device Directive (IVDD) 98/79/EC
v. Active Implantable Medical Device Directive (AIMDD) 90/385/EEC)
vi. US FDA (United States Food & Drug Administration)
vii. Australia TGA (Therapeutics Goods Act).
viii. ISO/IEC Guide 51:1999

ANNEX 1: CLASSIFICATION OF VETERINARY MEDICAL DEVICES

The classification is based on terms related to duration of contact with the animal, degree of invasiveness and the part of the body affected by use of the device. Duration of use can be transient (continuous use for less than 60 minute), short term (continuous use for between 60 minutes and 30 days) long term (continuous use for more than 30 days).

These guidelines classify veterinary medical devices into 4 classes; A (Low Risk), B (Low to Moderate Risk), C (Moderate to High Risk) and D (High Risk). The devices are categorized into 4; Non Invasive Devices, Invasive Devices-Non Surgical, Invasive Devices-Surgical. The examples given are for illustration only and the applicant must apply the classification to each medical device according to its intended purposes.

NON INVASIVE DEVICES

Class	Risk Level	Description of Device	Illustrative Examples
A	Low	All non-invasive devices which come into contact with injured skin, intended to be used as a mechanical barrier, for compression or for absorption of exudates only, i.e. they heal by primary intent	Simple wound dressings; cotton wool
		All non-invasive devices intended for channelling or storing, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the animal	Intramammary infusion tube, administration sets for gravity infusion, syringes without needles, slip syringes, Vaccinators, automatic syringes, teat cannula
		All other non-invasive devices that either do not touch the animal or contact intact skin only	urine collection bottles, non-invasive electrodes, animal hospital beds, animal weight tapes, Animal marking crayons, applicators (metallic or plastic), eye hook, percussion hammer, Stethoscope,
B	Low –Moderate	All non-invasive devices which come into contact with injured skin, intended to be used principally with wounds which have breached the dermis, including devices principally intended to manage the microenvironment of a wound.	Non-medicated impregnated gauze dressings

Class	Risk Level	Description of Device	Illustrative Examples
		All non-invasive devices intended for channelling or storing, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the animal connected to an active medical device	Intramammary infusion tubes, administration sets for gravity infusion, Vaccinators, automatic syringes syringes without needles
		All non-invasive devices intended for use of channeling blood, or storing or channeling other body liquids, or for storing organs, parts of organs or body tissues	Organ storage containers and tubes used for blood transfusion
C	Moderate – High	All non-invasive devices which come into contact with injured skin, intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent	Dressings for chronic ulcerated wounds; dressings for severe burns
		All non-invasive devices intended for use of storing blood	Blood bags
		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	Haemodializers

INVASIVE DEVICES-NON SURGICAL

Class	Risk Level	Description of Device	Illustrative Examples
A	Low	Not intended for connection to an active medical device, or intended for connection to a Class A medical device only. Devices are invasive in body orifices and tend to be diagnostic and therapeutic instruments	Bull Ring, Teat plug, calving chain, calving ropes, Ear tags and tag applicators
		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	dentures intended to be removed by the animal; dressings for nose bleeds.
		Intended for transient use	Examination gloves; enema devices
B	Low –Moderate	Intended for short-term use	urinary catheters, tracheal tubes
		Intended for long-term use in the oral cavity as far as the pharynx, in an ear canal up to the eardrum or in a nasal cavity and are not liable to be absorbed by the mucous membrane	orthodontic wire, fixed dental prosthesis, mouth gag, oral canula, teeth plier,

Class	Risk Level	Description of Device	Illustrative Examples
		Intended to be connected to an active device	Automatic drench, Tracheal tubes connected to a ventilator; suction catheters for stomach drainage; dental aspirator tips
C	Moderate – High	Intended for long-term use;	Thermometers

INVASIVE DEVICES-SURGICAL

Class	Risk Level	Description of Device	Illustrative Examples
A	Low	Intended for transient use	
		Re-usable surgical instrument	Manually operated surgical drill bits and saws, Artery forceps, Burdizzo, castration rings, de-beaker, dog nail cutter, dehorner, hoof treamer, teat cannula
B	Low –Moderate	Surgical instruments supplied sterile and intended for single use	Hypodermic needles, scapel blades,
		Intended for short-term use mostly used in the context of surgery or post-operative care, or are infusion devices, or are catheters of various types.	infusion cannulae, non-absorbable skin closure devices, non disposable syringe
		All implantable devices intended to be placed into the teeth	Dental filling materials
C	Moderate – High	All implantable devices, and long-term surgically invasive devices	Maxilla-facial implants; prosthetic joint replacements; bone cement; non-absorbable internal sutures; posts to secure teeth to the mandibula bone (without a bioactive coating), plaster of paris
D	High	Intended specifically for use in direct contact with the central nervous system	neurological catheter, Dental filling materials
		Intended 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	Angioplasty balloon catheters and related guide wires dedicated disposable cardiovascular surgical instruments.
		Intended to have a biological effect or to be wholly or mainly absorbed	Absorbable sutures

ACTIVE DEVICES

Class	Risk Level	Description of Device	Illustrative Examples
A	Low	Intended for diagnosis and supply energy which will be absorbed by the animal body	Magnetic resonance equipment
		All other active devices	Electric sheep shearing, foreign body detector, Examination lamps; surgical microscopes; powered hospital beds, powered equipment for the recording, processing, viewing of diagnostic images
B	Low –Moderate	Intended for diagnosis	Ultrasonic diagnosis/imaging, capture of physiological signals, interventional radiology and diagnostic radiology
		Intended to allow direct diagnosis or monitoring of vital physiological processes	Electronic thermometers, stethoscopes, blood pressure monitors and electrocardiographs
		Intended to administer and/or remove medicinal products, body liquids or other substances to or from the body. Such devices are mostly drug delivery systems or anaesthesia equipment.	Suction equipment, feeding pumps, jet injectors for vaccination, nebulizer, automated stomach tubes

CROSS CUTTING CLASSIFICATION

Class	Risk Level	Description of Device	Illustrative Examples
A	Low	Manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable in contact with intact skin only	Muzzles (leather)
B	Low –Moderate	Manufactured from other materials in contact with intact skin only	Elizabethan collar (non medicated)
C	Moderate – High	All devices used for contraception and Artificial Insemination	Intra-uterine devices, AI gloves, AI guns, AI sock, AI sheath, Rumen magnets, traceability microchips bolus
D	High	All devices containing reagents and other items necessary to conduct a test to detect the presence of or to measure a given Biomarker in a given specimen	Diagnostic kits, CMT solution,
		All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is	Antibiotic bone cements; heparin-coated catheters; wound dressings incorporating

Class	Risk Level	Description of Device	Illustrative Examples
		liable to act on the animal body with action ancillary to that of the devices	antimicrobial agents to provide ancillary action on the wound; blood bags incorporating an anticoagulant
		Manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable	Catgut sutures

ANNEX 2: DOCUMENTATION REQUIRED FOR VARIATION

Administrative Changes

	Type of Change	Required Documents
1	**Management System, Manufacturing Facility, Process and Quality**	
1a.	Manufacturing facility (including sterilisation facility)	1) Quality Management System certificate(s)Device labelling, if applicable 2) Validation studies from new site 3) Summary of new manufacturing process (Please provide a Declaration if there is no change in manufacturing process)
2	**Labelling**	
2a.	Reduction in approved indications for use	1) Reasons for the reduction of approved indications 2) Revised device labelling
2b.	Other labelling changes: 1) Layout 2) Colours 3) Font sizes and design; 4) Addition and removal of language(s) not required by the Authority. 5) Changes to software version number that are not due to changes affecting safety, quality or efficacy of the medical device.	1) Revised device labelling 2) Reasons for change of software version number (For software only) 3) Software validation report (For software only)
3	**Other Changes**	
3a.	Addition of new Package size(s)	1) Justification for addition of product(s) to be grouped within the registered product 2) List of Configurations of Medical 3) Devices to be Registered

		4) Regulatory approval documents from the reference agencies 5) Device Information 6) Device labelling for new product(s) 7) Declaration of conformity document 8) Letter of Authorisation
3b.	Deletion of Package size(s)	1) Reason for deletion of products
3c.	Change of Product Name only	1) Device labelling 2) Declaration of Conformity document 3) Letter of Authorisation
3d.	Change of Product Owner	1) Device labelling 2) Declaration of Conformity document 3) Letter of Authorisation 4) Quality Management System certificate(s) 5) Regulatory approval certificate(s)
3e.	Regulatory status on rejection or withdrawal (in any reference agencies)	1) Documents from relevant regulatory authorities citing the reason for the change in regulatory status
3f.	Update of regulatory approval certificates (from reference agencies)	1) Regulatory approval documents from the reference agencies

Technical Changes

	Type of Change	**Required Documents**
1	**Management System, Manufacturing Facility, Process and Quality**	
1a.	Sterilisation method and process	1) Sterilisation technique 2) Sterility assurance level achieved 3) Sterilisation protocol 4) Sterilisation validation results 5) Evidence of on-going revalidation of sterilisation process 6) Post-Sterilisation functional tests 7) Device labelling, if applicable
2	**Design or Performance Specifications**	
2a.	Control mechanism	1) Pre-clinical studies 2) Device labelling 3) Software validation report (For software only)
2b.	Operating principles	1) Pre-clinical studies 2) Clinical studies 3) Device labelling

		4) Software validation report (For software only)
2c.	Design Characteristics	1) Pre-clinical studies 2) Clinical studies 3) Device labelling 4) Software validation report (For software only)
2d.	Performance Specifications	1) Pre-clinical studies 2) Clinical studies 3) Device labelling 4) Software validation report (For software only)
3	**Materials (General Medical Device)**	
3a.	Biological materials	1) Biological safety data 2) Process validation results 3) Traceability from sources to the finished medical device
3b.	Direct and/or indirect contact with body tissues and fluids	1) Complete chemical, biological and physical characterisation of the material 2) Biocompatibility studies 3) Pre-clinical animal studies
3c.	Medical devices emitting ionising radiation	1) Information on radiation source 2) Information on materials for shielding of radiation
4	**Materials (In Vitro Diagnostic Device)**	
4a.	Materials affecting performance specification	1) Pre-clinical performance evaluation data 2) Clinical performance evaluation data
4b.	Biological materials (including supplier of materials)	1) Source of material 2) Process validation result for inactivation of infectious agents
4c.	IVD devices emitting ionising radiation	1) Information on radiation source 2) Information on materials for shielding of radiation
5	**Labelling**	
5a.	Indications for use 1) Revision 2) Addition	1) Regulatory approval documents from the reference agencies 2) Device Information 3) Device labelling for new product(s) 4) Declaration of conformity document 5) Pre-clinical studies 6) Clinical studies 7) Risk analysis 8) Software validation report (For software only)

		9) Manufacturing information
5b.	Addition and removal of Contraindications, Warnings and Precautions (include any editing)	1) Reasons for addition or removal of contraindications, warnings and precautions 2) Device labelling 3) Pre-clinical studies 4) Clinical studies
5c.	Expiry duration, shelf life and storage condition	1) Shelf life / stability data 2) Device labelling
6	**Other Changes**	
6a.	Addition of a new product to a device listing	1) Justification for addition of product(s) to be grouped within the registered product 2) List of Configurations of Medical Devices to be Registered 3) Regulatory approval documents from the reference agencies 4) Device Information 5) Device labelling for new product(s) 6) Declaration of conformity document 7) Letter of Authorisation 8) Pre-clinical studies 9) Clinical studies 10) Risk analysis 11) Software validation report (For software only) 12) Manufacturing information