RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR REGISTRATION OF VETERINARY MEDICAL DEVICES AND IN-VITRO DIAGNOSTICS

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FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by the Law N° 003/2018 of 09/02/2018. One of the functions of Rwanda FDA is to regulate matters related to quality, safety, and performance of Veterinary medical devices and In-vitro diagnostics devices (IVDDs) to protect public health by increasing access and availability.

Considering the provisions of the technical regulations Nº DFAR/HMDAR/TRG/002 Rev_2 governing the registration of Medical Device including In-vitro diagnostics devices especially in its articles 6, 7, 13, 14, 16, and 35, the Authority has issued Guidelines Nº DFAR/VMDAR/GDL/006 on submission of documentation for Registration of Veterinary Medical devices and IVDDs.

These guidelines were developed in reference to the Regulation on Harmonization in East African Community (EAC) and the International Medical Devices Regulators Forum (IMDRF) formerly known as Global Harmonization Task Force (GHTF).

The purpose of these guidelines is to provide guidance to all stakeholders intending to market veterinary medical devices and IVDDs in Rwanda on the documentation required by the Authority to assess the conformity of such products to the essential principles of safety and performance before market authorization can be issued. These guidelines are hereby promulgated for information, guidance, and strict compliance by all concerned.

Adherence to the guidelines by the manufacturers/applicants will facilitate timely assessments and approvals of veterinary medical devices and IVDDs application dossiers for marketing authorization.

We wish to express our gratitude to all individuals who actively participated in the development of the guidelines.

The Authority acknowledges all the efforts of key stakeholders who participated in the development and validation of these guidelines.

Digitally signed by Rwanda FDA (Director General)
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Director General

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TABLE OF CONTENTS

ACCRONYMES AND ABBREVIATIONS

PRC	Peer Review Committee
Rwanda FDA	Rwanda Food and Drugs Authority
FIFO	First In First Out
IVDD	In-Vitro Diagnostics Device
LTR	Local Technical Representative
EU	European Union
EEC	European Economic Community
EC	European Commission
CE	Conformité Européenne (French for "European Conformity")
CAB	Conformity Assessment Body
IMDRF	International Medical Devices Regulators Forum
GHTF	Global Harmonization Task Force
EAC	East Africa Community
QCL	Quality Control Laboratory
QMS	Quality Management System
GMP	Good Manufacturing Practice
CoC	Certificate of Conformity
IFU	Instructions for Use
ISO	International Organization for Standardization
GMDN	Global Medical Device Nomenclature

GLOSSARY / DEFINITIONS

For the purpose of these guidelines, the following definitions shall apply:

1. "**Authority**" means Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established under Law N^0. 003/2018 of 09/02/2018.

2. **"Applicant"** means the person by, or on whose behalf, an application for, an update or amendment to an existing registration, is made. After the product is registered, the applicant shall be the "Marketing Authorization Holder".

3. **"Conformity Assessment Body (CAB)"** means a body, other than a regulatory authority, engaged in determining whether the relevant requirements in technical regulations or standards are fulfilled.

4. **"Conformity Assessment"** The systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Authority, to determine that veterinary medical devices including an IVDD is safe and performs as intended by the manufacturer and, therefore, conforms to the Essential Principles of Safety and Performance of Medical Devices.

5. **"Law"** means Law N^0 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning.

6. **"Local Technical Representative (LTR)"** means any corporate body registered in Rwanda and authorized by Rwanda FDA to deal with Veterinary Medical Devices and IVDDs that has received a mandate from the Applicant to act on his/her behalf with regard to matters pertaining to the registration of veterinary medical devices and IVDDs.

7. **"Active medical device"** means any medical device which depends on a source of electrical energy or any source of power other than that directly generated by the animal/human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances, or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices. Standalone software is considered to be an active medical device.

8. **"Medical device family"** means a group of medical devices that are made by the same manufacturer, that differ only in shape, colour, flavor, or size, that have the same design and manufacturing process and that have the same intended use.

9. **"Medical device group"** means a group of devices comprising a collection of medical devices, such as a procedure pack or tray, that is sold under a single name.

10. **"Medical device group family"** means a collection of medical device groups that are made by the same manufacturer, that have the same generic name specifying their intended use and that differ only in the number and combination of products that comprise each group.

11. **"Medical Device System"** A medical device comprising a number of components or parts intended to be used together to fulfill some or the entire device's intended functions and that is sold under a single name.

12. **"Implantable device"** means any device which is intended: to be totally introduced into the animal 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 the animal/human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

13. **"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 means 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.

14. **"In-vitro diagnostic device (IVDD)"** A 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. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.
    Note: IVD devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.

15. "**Accessory to IVDD**" means an article intended specifically by its manufacturer to be used together with a particular IVD device to enable or assist that device to be used in accordance with its intended use.

16. "**Label**" means any tag, brand, mark, pictorial or other descriptive matter, written, printed stenciled, marked, embossed or impressed on or attached to a container of any medical devices or IVDDs and includes an informational sheet or leaflet that accompanies the medical devices or IVDD when its being supplied.

17. **"Labelling"** is all label and other written, printed, or graphic matter (l) upon any article or any of its containers or wrappers, or (2) accompanying such article" at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce (This excludes shipping documents).

18. **"The term "accompanying"** is interpreted liberally to mean more than physical association with the product. It extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, fillers (where applicable).

19. "**Manufacture**" means all operations that involve preparation, processing, filling transforming, packaging, repackaging and labelling of medical devices and/or IVDD.

20. **"Manufacturer"** means a person or a firm that is engaged in the manufacture of medical devices or IVDDs.

21. "**Fee**" means the fee prescribed in relevant regulation governing service tariff/fees and charges at the time of dossier submission**.**

22. **"Medical device"** means any instrument, apparatus, implement, machine, appliance, implant, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings or animals, for one or more of the specific medical purpose(s) of diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury; investigation, replacement, modification or support of the anatomy or a physiological process; supporting or sustaining life; control of conception; disinfection of medical devices; providing information by means of in vitro examination of specimens derived from the human or animal bodies, and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means.

23. **"Documentation"** a compilation of required information for registration including samples and any other additional information requested for registration.

24. **"Certificate of Registration (Market Authorization)"** means a certificate issued by the authority after its approval to market and sell the device in Rwanda; applicable to medical devices and IVD devices that are specifically intended by the manufacturer to be used in **only animal healthcare** and must be labeled on device label (s), Mock-ups and manual **"Veterinary use only/ for animal use only".**

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

26. **"Batch number (or lot number)"** a distinctive combination of numbers and/or letters which specifically identifies a batch on the labels, the batch records etc.

27. **"Packaging"** means all operations, including filling and labelling, that a medical device has to undergo.

28. **"Packaging material"** means any material, including printed material, employed in the packaging of a medical device or IVDD, excluding any outer packaging used for transportation or shipment.

29. **"IVD test kit"** an IVD test kit is an in vitro diagnostic Device (IVDD) that consists of reagents or articles that are from the same manufacturer; intended to be used in combination to complete a specific intended purpose; sold under a single test kit name or the labelling, instructions for use (IFU), brochures or catalogues for each reagent or article states that the component is intended for use with the IVD test kit; and compatible when used as a test kit.
    Note: An IVD test kit does not include the instruments, such as analyzers needed to perform the test.

30. **"Quality Management System**" means a management system to direct and control an organization with regard to quality, from establishing quality policy, quality objectives and implementing and maintaining a quality system.

31. **"Registered Veterinary medical device or IVDD"** means veterinary medical device or in - vitro diagnostic device that has been granted market authorization.

32. **"Reagent"** any chemical, biological or immunological component, solution, or preparation intended by the manufacturer to be used as a medical device or IVDD.

33. **"Specimen receptacles" m**eans devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from other animals / human body for the purpose of IVDD examination.

34. **"Technical Documentation"** means documented evidence, normally an output of the Quality Management System that demonstrates compliance of a device to the Essential Principles of Safety and Performance of medical devices including IVDDs.

35. **"Quality Audit":** The process of systematic examination of a quality system of medical device or IVDDs manufacturing facilities carried out by the Authority to demonstrate conformity for regulatory purposes.

36. **"A certificate of conformity (CoC)**" is issued by an authorized party (sometimes the manufacturer, sometimes an independent laboratory) and states that the device/product meets the required standards or specification.

37. **"Standards:** are documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines or definitions of characteristics, to ensure that materials, products/devices, process, and services are fit for their purpose.

1. INTRODUCTION

1.1 Background

Rwanda Food and Drugs Authority (Rwanda FDA) is established by Law N° 003/2018 of 09/02/2018, especially in its articles 8 and 9.

Considering the provisions of the technical regulations Nº DFAR/HMDAR/TRG/002 Rev_2 Governing Registration of Medical Devices including In-Vitro Diagnostics, especially in its articles 6, 7, 13, 14, 16, and 35, the Authority has issued Guidelines Nº DFAR/VMDAR/GDL/006 on submission of documentation for Registration of Veterinary medical devices and In-Vitro Diagnostics Devices.

All veterinary medical devices including IVDDs shall be given a market authorization by the Authority before they are placed on the Rwandan market. A person who intends to market, a single medical device, in-vitro diagnostic, a medical device group, medical device family, medical device group family, or a medical device system shall apply to the Authority for Market Authorization (MA).

There are four (4) classes of medical devices and IVDDs (**Appendix III)** as provided in the device classification rules (**Appendix IV and V**) depending on their levels of risk as follows:

Classification for Medical Devices and/or IVDDs

Device Class	Risk levels
A	Low-Risk class
B	Low to Moderate-Risk class
C	Moderate to High-Risk class
D	High-Risk class

Manufacturers of all classes of veterinary medical devices including IVDDs are expected to demonstrate conformity to the Essential Principles of Safety and Performance, through the preparation and holding of technical documentation that shows how each veterinary medical device or IVDD was developed, designed, and manufactured together with the descriptions and explanations necessary to understand the manufacturer's determination with respect to such conformity. The medical devices and IVDDs must be manufactured by facilities that comply with the requirements of the latest ISO 13485 Quality management systems and/or Good Manufacturing Practices (GMP) for regulatory purposes.

1.2 Scope

These guidelines shall only apply to medical devices and IVD devices which are specifically intended by the manufacturer to be used in **animal health care** and that are intended to be marketed in Rwanda.

1.3 Main Topics

Guidelines for registration of veterinary medical devices and IVD devices only.

1.4 General Principles

For the purpose of conformity assessment, the manufacturer should assemble information from existing technical documentation to provide evidence that the subject veterinary medical devices and/or IVDD is in conformity with the Essential Principles adopted from International Medical Devices Regulators Forum (IMDRF) formerly known as Global Harmonization Task Force (GHTF). The information submitted shall reflect the status of the veterinary medical device or IVDD at a particular moment in time (e.g. at the moment of pre-market submission or when requested) and is prepared in order to meet regulatory requirements.

Medical devices and IVDDs which are not specifically intended by the manufacturer to be used only in animal health care, and not labelled on device label (s), Mock-ups and manual **"Veterinary use only/ for animal use only"** shall comply with regulatory requirements prescribed under relevant/separate devices registration guidelines.

1.5 Submission of application

An application for veterinary medical devices and/or In-Vitro Diagnostics Devices registration for either locally manufactured or imported medical device and/or IVDD shall be made in writing via a cover letter addressed to the Rwanda FDA Director General and an application form dated and signed by the applicant. If the applicant is a foreign company, the applicant shall appoint a local technical representative (LTR) through whom an application shall be submitted. The LTR shall be any corporate body registered in Rwanda and authorized by Rwanda FDA to deal with medical devices including In-Vitro Diagnostics that has received a mandate from the applicant to act on his/her behalf with regard to matters in the relevant area.

The application should be submitted to Rwanda FDA through the authorized the LTR via Rwanda FDA Clients online portal Integrated Regulatory Information Management System (IRIMS CLIENTS) available on Rwanda FDA website.

1.6 Types of Product/devices Registration Applications

For the purposes of submission of veterinary medical device and IVDD application dossier to Rwanda FDA, applications are classified into three categories as follows:

i. **New applications for Market Authorization**: a new application for market Authorization of veterinary medical devices including In-Vitro Diagnostics Devices.

ii. **Renewal of Market Authorization**: Applications for renewal of Market Authorization Veterinary medical device and or In-Vitro Diagnostic Device. The application shall be made at least 3 months before the expiry of existing market authorization certificate.

iii. **Variation of registered Veterinary Medical device and/or IVDD**: an application for any change in the registered veterinary medical device and/or IVDD. All applications for variation to registered device shall be made according to requirements stipulated in the Rwanda FDA Guidelines for variation of registered veterinary medical devices and/or IVDDs.

1.7 Receiving of new applications for veterinary medical devices and IVDDs registration

An application submission is done LTR via Rwanda FDA Clients online portal Integrated Regulatory Information Management System (IRIMS CLIENTS) available on Rwanda FDA website. The application for assessment and registration of veterinary medical devices and/or IVDDs is only received by the Authority when the payment of prescribed fees is effectuated. After receiving a device's application dossier for market authorization (Registration), a reference number is assigned to the application and it will be used in all subsequent correspondences related to the application.

1.8 Rwanda FDA Market Authorization (Registration) Procedure

1.8.1 Assessment of the application dossier

After receiving an application requesting for market Authorization, the Authority shall proceed with screening of the submitted application dossier to confirm completeness of the submission based on the First in First out (FIFO) rules. A veterinary medical device and/or IVDD application dossier is reviewed by one assessor to verify the completeness of requirements.

During the review, additional data and/or samples may be requested. Once a query or a request for additional data has been issued to the applicant, the assessment process stops until the Authority receives a written response to the raised queries.

Further processing of the application may only be undertaken if responses to queries issued in IRIMS CLIENTS contain all outstanding information requested in one submission. Failure to comply with this condition or if the queries have been reissued for a **fourth time** and the applicant provides unsatisfactory responses, the application will be rejected.

In the event that the responses to the queries are not submitted within ninety **(90)** days from the date they were issued, it will be considered that the applicant has withdrawn the application unless the applicant has requested an extension of the deadline to the Authority.

Thereafter, application for MA of veterinary medical device and/or IVDD may only be considered upon submission of a new application.
In case the dossier is complete, the application will be scheduled for peer review.

1.8.2 Authority's Peer Review Committee for Veterinary medical device and/ or In-Vitro Diagnostics Devices Market Authorization (MA)

After a thorough dossier assessment, the final dossier assessment report shall be presented to the Authority's Peer Review Committee (PRC) before making final decisions for granting or rejecting market authorization of the veterinary medical device and or IVDD.

In the event, that there is safety, quality, or performance issues to be resolved as per the decision of the PRC, the application shall remain pending until the resolution of the raised issues. If the applicant fails to provide the required data within ninety (**90)** days from the date of issue**,** the product application shall be considered as withdrawn.

The Authority will register the veterinary medical device and/or IVDD in the event that data on safety, quality, and performance or other requirements are considered satisfactory. Thereafter, the application will be recommended for market authorization approval by the competent authority.

1.8.3 Registration Certificate Approval

Application dossier that was recommended for approval by the peer review committee will be granted a certificate of registration of Veterinary medical device and/ or IVDD **(Appendix VI)** within one hundred eighty (**180)** calendar days. The certificate of registration shall be valid for a period of five (5) years.

In the event that the Authority suspends or cancels the registration certificate validity, a written official communication shall be issued to the applicant.

1.8.4 Timelines for market authorization of veterinary medical device and/or In-Vitro Diagnostics

Veterinary medical device and/or IVDDs application dossiers for market authorization shall be scheduled for assessment according to the FIFO basis upon compliance with the requirements.

A new application: for Veterinary Medical device and/or IVDD Market Authorization shall be processed within one hundred and eighty (180) calendar days.

Any additional data: requested for Veterinary Medical device and/or IVDD shall be submitted within ninety (90) calendar days

2. APPLICATION REQUIREMENTS

Medical devices and/or IVDDs which are specifically intended by the manufacturer to be used in animal health care and which labels, mock-ups, and manuals specify **"for Veterinary use only" or "for animal use only"** shall submit an application dossier for market authorization.
The application dossier shall be organized into two main parts:

a) Administrative information
b) Technical documentation

The applicants shall submit the following:

2.1 Administrative Information

a) Signed and dated original copy of a cover letter (Appendix I)

b) Signed and dated and duly filled application form (Appendix II)

c) Proof of payment of veterinary notification fees as per relevant regulations governing service tariff/fees and charges at the time of dossier submission.

d) Administrative information and information about Medical devices and/or IVDDs (Technical Documentation in a selectable PDF).

e) A copy of a free sale certificate: evidence that goods**,** such as medical devices and/or IVDDs are legally sold or distributed in the open market, freely without restriction, and approved by the regulatory authorities in the country of origin. (In case that a free sale certificate is not provided, submit an equivalent document or a justification).

f) One (1) device sample in its commercial park or artwork. Please note that where required, additional samples might be requested.

g) Appointment letter of a Local technical representative (LTR): Any applicant who is not resident in Rwanda shall appoint a local technical representative who must be a company incorporated in Rwanda and authorized by Rwanda FDA to deal with medical devices and/or IVDDs and must hold an operating license. The appointment shall be notified to the Authority by submitting a letter of appointment supported by original copy of power of attorney duly notarized in country of origin (Attach a copy of a letter of appointment supported by original copy of power of attorney duly notarized in country of origin).

h) Certificate of conformity of the veterinary device issued by an authorized party (such as the manufacturer, an independent laboratory) stating that the device/product meets the required standards or specifications.

2.2 Technical documentation (Information about the veterinary medical device and/or IVDD)

The following documents that provide a clear description of the devices shall be submitted to the authority by the applicant.

The documents to be submitted under the technical documentation are:

a. The Device art works
b. Instructions for Use (IFU)
c. Statement of the intended use depending on the device
d. Device manufacturer
e. Device Description
f. Certificate of compliance to quality standards
g. Veterinary Medical device and/or IVDD Specification
h. Device's Labels

2.2.1 Device art work of immediate package, outer package

Provide pictures of the device in the commercial pack whereas all sides of the devices are clearly visible.

2.2.2 Instructions for Use (IFU) or User manual

Instructions for use refers to the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken. A copy of the current instructions for use must be submitted. If the device/product requires associated instrumentation, the instrument manual and/or associated operator manuals should also be provided.

The Instructions for Use should include the following minimum device details information:

a) **Name(s):** State the brand and generic name of the medical device and/or IVDD.

b) **Description:** Provide general information on design, characteristics, and performance of the medical device and/or IVDD. The description should also include information on device packaging.

c) **Category:** State the class of the medical device and/or IVDD and the applicable classification rule as per Appendix IV of these guidelines.

d) **Intended Use/Indication:** State the intended use of the medical device and/or IVDD and/or provide a general description of the disease or condition that the device will diagnose, treat, prevent, or mitigate.

e) **Instructions of Use:** Give a concise summary of information for safe use of the device including procedures, methods, frequency, duration, quantity and preparation to be followed.

f) **Contraindications:** State conditions under which the medical device and/or IVDD should not be used. For example, a limitation of an assay using specimens from patients who have received preparations of mouse monoclonal antibodies for therapy when tested with assay kits which employed mouse monoclonal antibodies. It may show either false elevated or depressed values.

g) **Warnings:** State the specific hazard alert information that a user needs to know before using the medical device and/or IVDD. E.g. for products containing biological material, radioactive material, explosive material and any other hazardous material, safety warnings must be included.

h) **Precautions:** State briefly precautions to be taken and any special care necessary for the safe and effective use of the medical device and/or IVDD.

i) **Adverse Effects:** Describe all adverse and side effects associated with the medical device and/or IVDD under normal conditions of use.

j) **Alternative Use:** Describe any alternative practices or procedures for diagnosing, treating, or mitigating the disease or condition for which the medical device and/or IVDD is intended.

k) **Storage conditions:** State the storage conditions for the medical device and/or IVDD.

l) **Recommended shelf-life:** State the recommended shelf-life of the medical device and/or IVDD (where applicable).

m) **Manufacturer Information:** Full Names, address and contact details (physical and postal) of the veterinary medical devices or IVDD manufacturer.

2.2.3 Statement of the device's intended use

The applicant should clearly state the intended use of the device.

Depending of the device, the statement should include the following information:

a) What the instrument is intended for and whether the test is qualitative or quantitative;

b) The clinical indication for the test (e.g. if it is for a specific disorder, or a condition or risk factor of interest that the test is intended to detect, define or differentiate);

c) That is detected by the assay (that is, the analytical use of the assay (e.g. the marker or nucleic acid sequence being detected));

d) The function of the product (screening, monitoring, diagnostic or aid to diagnosis, staging or aid to staging of disease);

e) The intended user (laboratory professional, farmer, Veterinary professional/technician, farmer, herds man/cow boy and /or lay person);

f) The intended testing animal species (e.g. Cow, goat, sheep, pigs, poultry, etc.);

g) Whether the device/product is for in vitro use, in vivo use, or other veterinary uses;

h) A general description of the principle of the assay method or instrument principles of operation;

i) A description of all components of the assay (e.g. reagents, assay controls and calibrators) and a description of the reactive ingredients of relevant components (e.g. antibodies, antigens, nucleic acid primers etc.);

j) A description of the specimen collection and transport materials provided with the product or recommended for use;

k) A description of any software to be used with the product;

l) A description or complete list of the various configurations/variants of product that will be made available;

m) Where applicable, a description of the accessories, and other products that are intended to be used in combination with the product but are not provided with the product;

n) Storage conditions, including storage conditions and stability of both the unopened and opened product, and working solutions. Where applicable, these instructions should include such information as conditions of temperature, light, humidity, and other pertinent factors;

o) If the test kit includes sterile accessories, an indication of that condition and any necessary instructions in the event of damage to sterile packaging;

p) If the test kit includes accessories that have been specified by the manufacturer as intended for single-use only, an indication of that statement;

q) Clear instructions on how to perform the assay, including instructions on specimen collection, handling, preparation and storage of reagents, the use of assay calibrators and controls and the interpretation of results;

r) Recommendations for quality control procedures;

s) Clear instructions on the correct usage of any equipment or software that is required for the performance of the assay;

t) Any warning and precautions to be considered related to the use of the assay including but not limited to interpreting the results, the disposal of the assay and/or its accessories (e.g. lancets), to any consumables used with it (e.g. reagents) that may be carcinogenic, mutagenic or toxic, or to any potentially infectious substances of human or animal origin;

u) Any residual risks;

v) Precautions and measures to be taken in the event of performance changes or product malfunction;

w) Limitations of the assay, including information on interfering substances that may affect the performance of the assay;

x) Any requirements for special training or particular qualifications of the assay user;

y) Any requirements for routine maintenance. Include details of frequency of maintenance and who should perform this maintenance (for example: the user, a representative of the manufacturer, or a third party;

2.2.4 Device manufacturer

Provide the name and contact details of manufacturer of the veterinary medical device and/or IVDD .

2.2.5 Device Description

Provide general information on the design, characteristics, and performance of the veterinary medical device and/or IVDD. The description should also include information on device packaging**.**

Where applicable provide a description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with it.

2.2.6 Certificate of compliance to quality standards

Provide a valid Certificate of compliance to ISO 13485 standards or its equivalent from the manufacturer (s) of the veterinary medical devices or IVDD. The certificate of compliance should be issue by a recognized Conformity Assessment Body (CAB). The veterinary medical devices and/or IVDDs must be manufactured by facilities that complies with requirements of recognized quality standards such as the latest/current ISO 13485 Quality management systems (QMS) for regulatory purposes.

A ISO 13485 certificates issued by Notified Bodies designated in Europe for the purposes of the veterinary medical devices and /or IVDD Directive (98/79/EC) will also be accepted. The later may also be referred to as an European Union (EU) Certificate, an European Commission (EC) certificate or an European Economic Community (EEC) Certificate.

Note: CE (conformité européenne French for "European conformity") and ISO 13485 certificates will only be accepted if they include acceptable evidence of good manufacturing practice (GMP) for devices:

Full legal name of the manufacturer (s) of the goods, including trading names (if appropriate).

a) Detailed physical address of the manufacturing site (PO box is not acceptable)
b) Date of the last audit/inspection.
c) Standard of manufacture with which the manufacturer of the Device (s) complies.
d) Device (s) or type(s) of the device (s) in sufficient detail to determine if the scope of the certificate is relevant to the medical device or IVDD to be supplied.
e) Date of issue
f) Period of validity or expiry date (must be current).
g) Notified Body number
h) Notified Body name

2.2.7 Veterinary Medical device and/or IVDD Specification

Information under product specification should contain a list of the features, dimensions and performance attributes of the medical device, its variants, and accessories, that would typically appear in the product specification made available to the end user, e.g. in brochures, catalogues and alike.

Where relevant to demonstrating conformity to the Essential Principles, and where applicable to provide general background information such as:

a) An overview of the manufacturer's previous generation(s) of the device (if such exist).

b) Similar devices available on the market (Where applicable).

For IVDDs, the specifications should also include a description of functional characteristics and technical performance specifications for the device including as relevant, accuracy, sensitivity, specificity of measuring and other specifications including chemical, physical, mechanical, electrical and biological.

2.2.8 Veterinary medical device and/or IVDD's Labels

A complete set of labelling associated with the medical device and/or IVDD including immediate and outer container labels on the medical device and/or IVDD should be provided**.** Labelling information shall be either in English, French, and/or Kinyarwanda. The labelling shall be expressed in a legible, permanent, and prominent manner that can be easily understood by the intended user.

a) General requirements

Depending on the type of device, the following minimum information should be provided on the label:

i. The name of the medical device and/or IVDD shall be indicated. If the name does not uniquely identify the medical device and/or IVDD, an additional means of identification shall also be provided. Examples: Catalogue number, commodity number.

ii. The name, address and contact details of the veterinary device manufacturer and manufacturing site (s).

iii. The identifier of the device, including the identifier of a device that is part of a system, test kit, or device class.

iv. Device batch or lot number/Serial Number

v. Device Contents: if the device contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as size, net weight, length, volume or number of units, volume after reconstitution shall be indicated.

vi. The words **"Sterile"** if the manufacturer intends to sell the veterinary medical device and/or IVDD in a sterile condition.

vii. The word **"For Single Use Only"** shall be included if the veterinary medical device and/or IVDD is intended for single use.

viii. In-vitro diagnostics use of the device shall be indicated e.g. **"For In vitro diagnostics use"** or graphical symbol for "**In vitro diagnostic device"**.

ix. The Expiry date (where applicable): An expiry date based upon the storage instructions shall be indicated and shall follow the requirements of ISO 8601. Expiry dates shall be expressed as the year, the month and where relevant, the day. E.g. "YYYY-MM-DD" or "YYYY-MM".

x. Unless self-evident to the intended user, the medical conditions, purposes, 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.

xi. The directions for use, unless directions are not required for the device to be used safely and effectively.

xii. Warning and precautions: If a veterinary medical device and/or an IVDD is considered hazardous, the outer container label shall include the appropriate danger wording or symbol(s) e.g. chemical, radioactive and biological hazards.

xiii. Storage and Handling conditions: The storage conditions necessary to maintain the stability of the device, reagents, calibrators, or control materials in the unopened state shall be indicated. If there are any other conditions that may affect the handling or storage of veterinary medical device and/or IVDDs shall be specified. e.g. Fragile.

xiv. Intended use: If the intended use is not indicated by the name of the medical device and/or IVDD, then an abbreviated intended use statement shall be given or included in the instruction for use. e.g. For measurement of plasma glucose concentration.

xv. For all devices intended for animal uses/animal health care, it shall be indicated " **For Veterinary Use**" or "**Device for Veterinary Uses Only/ for animal use only**" .

xvi. Names of all included reagents, and components in each box on the outer package label. (Where Applicable).

xvii. In case the veterinary device is intended to be sold to the general public, labeling information: Specimen label(s), promotional material(s) and user manual(s) should be provided.

Note: Requirements that have been described in a respective standard should also be followed when labelling a device. E.g: ISO 18113: In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling)

b) Kits' label requirements

All Veterinary medical devices and /or IVDDs to be included in the kit should have an intact label with all required information as per Rwanda FDA requirements.
The label on the co-packaging kit must contain the following information

i. Name of the co-packaging kit
ii. Intended use of the kit
iii. List of medical devices or IVDD in the kit
iv. Expiry date where applicable (as per shortest expiry medical device or IVDD)
v. Name and address of the manufacturer who conduct co-packing of devices
vi. Batch number
vii. Manufacturing date
viii. Storage conditions

Note: Device's Instructions for use or user manual and copies of the labels on the Veterinary medical device and/or IVDDs and its packaging in primary and secondary levels of packaging (either in English, French or Kinyarwanda and in original colour) must be provided for all the components of Veterinary medical device and/or IVDD system, members of medical devices and /or IVDD family and accessories submitted for registration. Alternatively, a representative label may be submitted for variants, provided the variable fields on the artwork are annotated, and the range of values for the variable fields are indicated.

3. REFERENCES

1. IMDRF/IVD WG/N64FINAL: 2021(formerly GHTF/SG1/N045:2008). Principles of In Vitro Diagnostic (IVD) Medical Devices Classifications.

2. GHTF/SG1/N77:2012 Principles of Medical Devices Classification.

3. EAC/TF-MED/MER/FD/DEVICES/N2R0. Requirements for Assessment and Market Authorization of In Vitro Diagnostic Medical Devices.

4. GHTF/SG1/N12:2000 Role of Standards in the Assessment of Medical Devices.

5. GHTF/SG1/N40:2006 Principles of Conformity Assessment for Medical Devices.

6. IMDRF/GRRP WG/N47 FINAL:2018 Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices.

7. IMDRF/GRRP WG/N52 FINAL:2019 Principles of Labelling for Medical Devices and IVD Medical Devices.

8. GHTF/SG1/N15:2006: The Global Harmonization Task Force-Principles of Medical Devices Classification.

9. GHTF/SG1/N046:2008 Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices

ENDORSEMENT OF THE GUIDELINES

	Prepared by	**Checked by**		**Approved by**
Title	**Division Manager**	**Head of Department**	**QMS Division Manager**	**Director General**
Names	Dr. Doreen INGABIRE	Dr. Védaste HABYALIMANA	Théogène NDAYAMBAJE	Prof. Emile BIENVENU
Signature		 Digitally signed by Vedaste Habyalimana Date: 2024.03.13 15:34:49 +02'00'	Theogene Ndayambaje Digitally signed by Theogene Ndayambaje Date: 2024.03.13 17:59:26 +02'00'	 Digitally signed by Rwanda FDA (Director General) Date: 2024.03.17 16:36:31 +02'00'
Date	12th March, 2024			

APPENDICES

Appendix 1: COVER LETTER

<Applicant>
<Address>
<Postal Code><Town>
<Date>

<Applicant's reference>
<Rwanda FDA>
<P.O.Box:1948><Kigali_Rwanda>

Dear Sir/Madam,

Subject: Submission of Application Dossier(s) for Marketing Authorization of Veterinary Medical device(s) or in Vitro Diagnostics devices (IVDDs)

We are pleased to submit our Application Dossier(s) for a registration of Veterinary medical devices/ Veterinary In Vitro Diagnostics Devices (IVDDs) that details are as follows:

Name of the Medical device(s) /IVDD(s): ……

Classification of the Medical Device(s)/IVDD(s): ……

Intended use of the Medical Device(s)/IVDD(s): …….....

Targeted Species: ……

You will find enclosed the submission dossier as specified hereafter:

- ☐ Administrative and technical documentation in selectable and searchable PDF format
- ☐ The proof of payment.
- ☐ We confirm that the electronic submission has been checked with up-to-date and state-of-the-art antivirus software.

Type of Submission: ☐Full registration Application ☐Abridged Application

- ☐ sample(s) submitted

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge

Yours sincerely,

<Signature>

<Name>

<Title>

<Phone number(s)>

<Email address>

Appendix 2: Application form for Market Authorisation of Veterinary Medical devices and /or In Vitro Diagnostics Devices (IVDD).

Doc No: DD/VMDR/FOM/006
Revision No:0
Effective Date: 18/03/2024

Application Form for Market Authorization of Veterinary Medical Devices and /or In Vitro Diagnostics Devices (IVDDs)

Application Number	**Rwanda FDA use only**	
Date of submission of dossier	**Rwanda FDA use only**	
1.0 PARTICULARS OF THE MEDICAL DEVICE or IVDD (**Bold or Tick** the right type of application)		
1.1	Type of application • New • Renewal • Variation* * If variation has been made, information supporting the changes should be submitted.	
1.2	Name: Brand Name of the Veterinary Medical Device or IVDD	
1.2.1	Common/generic Name of Veterinary Medical Device or IVDD	
1.3	Global Medical Device Nomenclature (GMDN) Name (Where Applicable)	
1.3.1	GMDN Code (Where applicable)	
1.3.2	GMDN Category (where Applicable)	
1.4	Category: Type of Device	☐ Veterinary Medical Device ☐ Veterinary IVDD ☐ Others, Specify…….
1.4.1	State the Class of the Medical Device or IVDD (Device Risk class)	☐ A ☐ B ☐ C ☐ D
1.4.2	State applicable **Classification rule** of the Medical Device or IVDD as appended in Annex IV and V of these guidelines	

1.5	**Intended use** of the Veterinary Medical Device or IVDD (i.e conditions that require its usage)	
1.6	**Intended user** of the Veterinary Medical Device or IVDD	☐ Veterinarian/Professional Vet Use ☐ Herds man/Farmer /General use ☐ Others (Specify;……)
1.7	Targeted Species	
1.8	The number of unit products/devices in a commercial pack	
1.9	Any associated products/Devices that work together with the device (examples; reagents, controls, accessories etc)	☐ Yes ☐ No ☐ If yes, specify:
1.10	Full Names, address and contact details (physical and postal) of Applicant	Name: Address: Country: Telephone: Telefax: E-Mail
1.11	Full Names, address and contact details (physical and postal) of the Local Technical Representative (LTR) (Attach a valid copy of a letter of appointment supported by original copy of power of attorney duly notarized in country of origin)	Names Address: Country: Telephone: Telefax: E-Mail
1.12	Manufacturer Information: Full Names, address and contact details (physical and postal) of veterinary Medical devices or IVDD manufacturer	Name: Address: Country: Telephone: Telefax: E-Mail
1.12.1	Full Name(s) and physical address(es) of the manufacturing site(s) of the Medical Device or IVDD. Alternative sites/Contract Manufacturer (s) should be also declared here. All manufacturing sites involved in the manufacturing process of the device, stating the role of each including quality control / in-process testing sites should be listed.	Name: Address: Country: Telephone: Telefax: E-Mail
1.13	Visual description of the Medical Device or IVDD	

1.14	Proposed shelf life (in months) (where applicable).	
1.15	Proposed storage conditions (where applicable).	
1.16	Device's Serial Number (Where Applicable)	
1.17	Commercial Presentation (Number of Units Presented in Pack (Where applicable).	
1.18	Model/Series/Family of the Veterinary Medical device or IVDD (List all sizes applicable).	
1.19	Registration status in different countries along with supporting documents (marketing authorization approval, free sale certificate, etc.)	
1.20	Country of origin (where the device was manufactured).	

1.23. DECLARATION BY THE APPLICANT

I, ,the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge.
I further confirm that the information referred to in my application dossier is available for verification during Quality audit inspection. I also agree that I shall carry out Materiovigilance and Post Marketing Surveillance to monitor the safety, quality and performance of the device on the market and provide safety, quality and performance update reports to Rwanda FDA.

I further agree that I am obliged to follow the requirements of Rwanda Legislations and Regulations, which are applicable to Medical Devices and IVDDs. I also consent to the processing of information provided to Rwanda FDA. It is hereby confirmed that fees will be paid/have been paid according to the authority's rules*

Signature:
Date:
* **Note**: If fees have been paid, attach proof of payment

Appendix III: CLASSIFICATION OF MEDICAL DEVICES

1. Medical Devices

Medical devices are classified into four classes, based on a risk assessment. Class A represents the group with the lowest risk and Class D represents the group with the highest risk to the individual and/or to public health (Table 1).

Table 1: Classification for Medical Devices

CLASS	RISK LEVELS
A	Low (examination gloves, tongue depressors…)
B	Low-Moderate (electronic thermometers, tubes for blood transfusion, non-medicated impregnated gauze dressings.…)
C	Moderate-High (surgical adhesive, infusion pumps…)
D	High (absorbable suture….)

The classification of device risks is based on the intended use and indications for use as specified by the manufacturer, the technical/scientific/medical expertise of the intended user (lay person or healthcare professional), the importance of the information to the diagnosis (sole determinant or one of several), taking into consideration the natural history of the disease or disorder including presenting signs and symptoms which may guide a physician/ veterinarian and the impact of the result (true or false) to the individual and/or to public health.

2. In-vitro diagnostics

In Vitro Diagnostics Devices (IVDD) are classified into four classes based on risk levels. Class A represents the class with the lowest risk and Class D represents the class with the highest risk to the individual and/or to public health (Table 2).

Table 2: Classification examples for IVDDs

CLASS	RISK LEVELS
A	Low individual and low public health Risk (e.g: reagents, specimen receptacles, urine cup, pipette tips, slides, wash solutions)
B	Low-moderate individual and or public health Risk (CMT kit with Accessories, Vitamin B12 level test)
C	Moderate-High individual and or public health risk (Lacto Scan [Milk analyzer])
D	High individual and or public health (H5N1 test kit)

Classification should be done based on classification rules appended as Appendix IV of these guidelines.

Where an In-Vitro Diagnostic Device (IVDD) falls into more than one class, the class representing the higher class shall apply. Where one IVDD is intended to be used together with a different IVDD, that may or may not be from the same manufacturer, a separate submission should be made and the conformity assessments of the IVDD shall be applied separately to each of the devices. The manufacturer has the primary responsibility to classify its devices but the Authority may challenge the classification and will have the final say in deciding the class of the IVDDs based on the IVD device classification rules.

2.1. Accessories

Where applicable, the following considerations should apply:

a) Calibrators intended to be used with an in vitro diagnostic reagent should be placed in the same class as the in vitro diagnostic reagent.
b) Stand-alone control materials with no assigned values intended for use with multiple or single analyte (s) should not be placed in the same class as the in vitro diagnostic reagent(s).
c) Stand-alone control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analyte (s) should be placed in the same class as the in vitro diagnostic reagent(s).

2.2. Software

While most software are incorporated into the IVDD itself, some are not. Provided that such stand-alone software falls within the scope of the definition for an IVDD it should be classified as follows:

a) Where it controls or influences the intended output of a separate IVDD, it will have the same class as the device itself.
b) Where it is not incorporated in an IVDD, it is classified in its own right using the classification rules.

Appendix IV: MEDICAL DEVICE CLASSIFICATION RULES.

The actual classification of each device depends on the claims made by the manufacturer and on its intended use. While the provision of illustrative examples in the table that follows is helpful when interpreting the purpose of each rule, it must be emphasized that the actual classification of a particular device must be considered individually, taking account of its design and intended use (**GHTF/SG1/N15:2006:** ***The Global Harmonization Task Force-Principles of Medical Devices Classification***)

Duration of use:

Transient: Normally intended for continuous use for less than 60 minutes.

Short term: Normally intended for continuous use for between 60 minutes and 30 days.

Long term: Normally intended for continuous use for more than 30 days.

NON-INVASIVE DEVICES	
RULES	**ILLUSTRATIVE EXAMPLES**
Rule 1. All non-invasive devices which come into contact with injured skin:	Devices covered by this rule are extremely claim sensitive.
are in Class A if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates only, i.e. they heal by primary intent;	**Examples:** bandages; cotton wool.
are in Class B if they are intended to be used principally with wounds which have breached the dermis, including devices principally intended to manage the microenvironment of a wound.	**Example**: non-medicated impregnated gauze dressings.
unless they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, in which case they are in Class C.	Devices used to treat wounds where the subcutaneous tissue is at least partially exposed and the edges of the wound are not sufficiently close to be pulled together. To close the wound, new tissue must be formed within the wound prior to external closure. The device manufacturer claims that they promote healing through physical methods other than „primary intent". **Examples:** dressings for chronic ulcerated wounds; dressings for severe burns.

Rule 2(i). All non-invasive devices intended for channelling or storing 2.1. liquids, or 2.2. gases for the purpose of eventual infusion administration or introduction into the body are in Class A,	Such devices are „indirectly invasive" in that they channel or store liquids that will eventually be delivered into the body. **Examples:** administration sets for gravity infusion; syringes without needles
unless they may be connected to an active medical device in Class B or a higher class, in which case they are Class B;	**Examples**: syringes and administration sets for infusion pumps; anaesthesia breathing circuits. **Note:** "Connection" to an active device covers those circumstances where the safety and performance of the active device is influenced by the non-active device and *vice versa*.
Rule 2(ii). All non-invasive devices intended to be used for 2.1. channeling blood, or 2.2. storing or channeling other body liquids, or storing organs, parts of organs or body tissues, for the purpose of eventual infusion, 2.3. administration or introduction into the body are Class B.	**Examples:** tubes used for blood transfusion, organ storage containers
unless they are blood bags, in which case they are Class C.	**Examples:** Blood bags that do not incorporate an anti-coagulant. **Note:** In some jurisdictions, blood bags have a special rule that places them within a different class.
Rule 3. All non-invasive devices intended for modifying the biological or chemical composition of 3.1. blood, 3.2. other body liquids, or 3.3. other liquids, intended for infusion into the body are in Class C,	Such devices are „indirectly invasive" in that they treat or modify substances that will eventually be delivered into the body. They are normally used in conjunction with an active device within the scope of either Rule 9 or 11. **Examples:** hemodialyzers Note: For the purpose of this part of the rule modification" does not include simple mechanical filtration or centrifuging which are covered below:
unless the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class B.	**Examples:** Devices to remove carbon extracorporeal circulation system

Rule 4. All other non-invasive devices are in Class A.	These devices either do not touch the patient or contact intact skin only. **Examples:** urine collection bottles; compression hosiery; non-invasive electrodes, hospital beds.
INVASIVE DEVICES	
RULE	**ILLUSTRATIVE EXAMPLES**
Rule 5. All invasive devices with respect to body orifices? (other than those which are surgically invasive) and which: 5.1. are not intended for connection to an active medical device, or 5.2. are intended for connection to a Class A medical device only.	Such devices are invasive in body orifices and are not surgically invasive (refer to definition in Section 4). Devices tend to be diagnostic and therapeutic instruments used in ENT, ophthalmology, dentistry, proctology, urology and gynaecology. Classification depends on the duration of use and the sensitivity (or vulnerability) of the orifice to such invasion.
5.3.are in Class A if they are intended for transient use;	**Examples**: examination gloves; enema devices.
5.4.are in Class B if they are intended for short-term use;	**Examples**: urinary catheters, tracheal tubes.
unless they are intended for short-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class A,	**Examples**: dressings for nose bleeds**.**
1. are in Class C if they are intended for long-term use;	**Example:** urethral stent; contact lenses for long-term continuous use (for this device, removal of the lens for cleaning is considered as part of the continuous use).
unless they are intended for long-term use in the oral cavity as far as the pharynx, inan ear canal up to the ear-drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class B.	**Examples:** orthodontic materials, removable dental prosthesis.

All invasive devices with respect to body orifices (other than those which are surgically invasive) that are intended to be connected to an active medical device in Class B or a higher class, are in Class B.	**Examples**: tracheal tubes connected to a ventilator; suction catheters for stomach drainage; dental aspirator tips. **Note**: Independent of the time for which they are invasive.
Rule 6. All surgically invasive devices intended for **transient use** are in Class B,	A majority of such devices fall into several major groups: those that create a conduit through the skin (e.g. syringe needles; lancets), surgical instruments (e.g. single-use scalpels; surgical staplers; single-use aortic punch); surgical gloves; and various types of catheter/sucker etc.
unless they are reusable surgical instruments, in which case they are in Class A; or	**Examples**: Manually operated surgical drill bits and saws. **Note**: A surgical instrument connected to an active device is in a higher class
unless intended to supply energy in the form of ionizing radiation, in which case they are in Class C; or	**Example:** catheter containing sealed radioisotopes.
unless intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class C; or	**Notes**: (a) The „biological effect" referred to is an intended one rather than unintentional. The term „absorption" refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body. (b) This part of the rule does not apply to those substances that are excreted without modification from the body. **Example:** Insufflation gases for the abdominal cavity.

unless intended to administer medicinal products by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class C; or	**Example:** insulin pen for self- administration. **Note**: The term „administration of medicines" implies storage and/or influencing the rate/volume of medicine delivered not just channeling. The term „potentially hazardous manner" refers to the characteristics of the device and not the competence of the user.
unless they are intended specifically for use in direct contact with the central nervous system in which case they are in Class D; or	**Example:** spinal needle.

unless intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.	**Examples:** angioplasty balloon catheters and related guide wires; dedicated disposable cardiovascular surgical instruments.
Rule 7. All surgically invasive devices intended for **short-term use** are in Class B,	Such devices are mostly used in the context of surgery or post-operative care, or are infusion devices, or are catheters of various types. **Examples:** infusion cannulae; temporary filling materials; non-absorbable skin closure devices; tissue stabilizers used in cardiac surgery. **Note:** Includes devices that are used during cardiac surgery but do not monitor or correct a defect.
unless they are intended to administer medicinal products, in which case they are in Class C; or	**Note**: The term „administration of medicines" implies storage and/or influencing the rate/volume of medicine delivered not just channeling.
unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class C; or	**Example:** surgical adhesive.
unless they are intended to supply energy in the form of ionizing radiation, in which case they are in Class C; or	**Example:** brachytherapy device.
unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or	**Example:** absorbable suture; biological adhesive. **Note**: The „biological effect" referred to is an intended one rather than unintentional. The term „absorption" refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body.
unless they are intended specifically for use in direct contact with the central nervous system in which case they are in Class D;	**Example**: neurological catheter.
unless they are intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.	**Examples:** cardiovascular catheters; temporary pacemaker leads; carotid artery shunts

Rule 8. All implantable devices, and long-term surgically invasive devices, are in Class C,	Most of the devices covered by this rule are implants used in the orthopaedic, dental, ophthalmic, and cardiovascular fields. **Example:** maxilla-facial implants; bone plates and screws; bone cement; non- absorbable internal sutures; posts to secure teeth to the mandibula bone (without a bioactive coating).
unless they are intended to be placed into the teeth or on prepared tooth structure, in which case they are in Class B; or	**Examples:** materials for inlays, crowns, and bridges; dental filling materials.
unless they are intended 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 D; or	**Examples:** prosthetic heart valves; cardiovascular stents; pacemaker leads and electrodes; deep brain stimulation electrodes; cerebrospinal catheter.
unless they are intended to be life supporting or life sustaining, in which case they are in Class D; or supporting or life sustaining, in which case	
unless they are intended to be active implantable medical devices, in which case they are Class D; or	**Example**: pacemakers; implantable defibrillators.
unless they are intended to have biological effect or to be wholly or mainly	**Example:** implants claimed to be bioactive.
absorbed, in which case they are in Class D; or	**Note**: Hydroxy-apatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer.
unless they are intended to administer medicinal products, in which case they are in Class D; or	**Example:** subcutaneous infusion ports for long-term use.
unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class D; or	**Example:** surgical adhesives intended for long term use. **Note**: Bone cement is not within the scope of the term „chemical change in the body" since any change takes place in the short rather than long term.
unless they are breast implants, in which case they are in Class D.	

ACTIVE DEVICES	
Rule 9(i). All active therapeutic devices intended to administer or exchange energy are in Class B,	Such devices are mostly electrically powered equipment used in surgery; devices for specialised treatment and some stimulators. **Examples:** muscle stimulators; powered dental hand pieces; hearing aids; neonatal phototherapy equipment; ultrasound equipment for physiotherapy.
unless their characteristics are such that they may administer or exchange energy to or from the human/Animal body in a potentially hazardous way, including ionizing radiation, taking account of the nature, the density and site of application of the energy, in which case they are in Class C.	**Examples:** lung ventilators; baby incubators; electrosurgical generators; external pacemakers and defibrillators; surgical lasers; lithotriptors; therapeutic X-ray and other sources of ionizing radiation. **Note**: The term „potentially hazardous" refers to the type of technology involved and the intended application.
Rule 9(ii). All active devices intended to control or monitor the performance of active therapeutic devices in Class C, or intended directly to influence the performance of such devices, are in Class C.	**Examples:** external feedback systems for active therapeutic devices.
Rule 10(i). Active devices intended for diagnosis are in Class B:	Such devices include equipment for ultrasonic diagnosis/imaging, capture of physiological signals.
10.1. if they are intended to supply energy which will be absorbed by the Animal/human body (except for devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum, in which case they are Class A), or	**Examples:** magnetic resonance equipment; diagnostic ultrasound in non- critical applications; evoked response stimulators.
10.2. if they are intended to image *in vivo* distribution of radiopharmaceuticals, or	**Example:** gamma/nuclear cameras.
10.3. if they are intended to allow direct diagnosis or monitoring of vital physiological processes,	**Example:** electronic thermometers, stethoscopes and blood pressure monitors; electrocardiographs.

unless they are specifically intended for: 1. monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of central nervous system, or 2. diagnosing in clinical situations where the patient is in immediate danger, in which case they are in Class C.	**Example:** monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnoea monitors. **Example:** ultrasound equipment for use in interventional cardiac procedures.
Rule 10. Active devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology, including devices which control or monitor such devices, or those which directly influence their performance, are in Class C.	**Example:** devices for the control, monitoring or influencing of the emission of ionizing radiation.
Rule 11. All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are in Class B,	Such devices are mostly drug delivery systems or anaesthesia equipment. **Examples:** suction equipment; feeding pumps; jet injectors for vaccination; nebuliser to be used on conscious and spontaneously breathing patients where failure to deliver the appropriate dosage characteristics is not potentially hazardous.
unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode and route of administration, in which case they are in Class C.	**Examples:** infusion pumps; anaesthesia equipment; dialysis equipment; hyperbaric chambers; nebuliser where the failure to deliver the appropriate dosage characteristics could be hazardous.
Rule 12. All other active devices are in Class A.	**Examples:** examination lamps; surgical microscopes; powered hospital beds & wheelchairs; powered equipment for the recording, processing, viewing of diagnostic images; dental curing lights.
ADDITIONAL RULES	

Rule 13. All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the animal/human body with action ancillary to that of the devices, are in Class D.	These medical devices incorporate medicinal substances in an ancillary role. **Examples:** antibiotic bone cements; heparin-coated catheters; wound dressings incorporating antimicrobial agents to provide ancillary action on the wound; blood bags incorporating an anti-coagulant.
Rule 14. All devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable, are in Class D,	**Example:** porcine heart valves.
unless such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only in which case they are in Class A.	**Examples:** leather components of orthopaedic appliances.
Rule 15. All devices intended specifically to be used for sterilising or disinfecting medical devices are in Class B.	**Example:** desk-top sterilisers for use with dental instruments.
unless they are disinfectant solutions or washer-disinfectors intended specifically for invasive medical devices, as the end point of processing, in which case they are in Class C; or	**Examples:** solutions intended to be used for the disinfection of medical devices without further processing (for example in a sterilizer) including those where the infective agent is a prion; washer-disinfector equipment specifically for disinfecting an endoscope or another invasive device.
unless they are intended to clean medical devices by means of physical action only, in which case they are in Class A.	
Rule 16. All devices that are intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class C.	**Note:** In some jurisdictions such products: are considered to be outside the scope of the medical device definition; may be subject to different controls.
Rule 17. All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class C,	**Examples**: contraceptive diaphragms. condoms;
unless they are implantable or long-term invasive devices, in which case they are	**Example**: contraceptive intrauterine device.

in Class D.	

Appendix V: CLASSIFICATION RULES OF IN-VITRO DIAGNOSTICS DEVICES (IVDDS)

Rule 1:	IVDDs intended for the following purposes are classified as Class D: 1. Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs or any of their derivatives, in order to assess their suitability for transfusion, transplantation or cell administration. 2. Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening, disease with a high or suspected risk of propagation; Rationale: The application of this rule as defined above should be in accordance with the rationale that follows: Devices in this Class are intended to be used to ensure the safety of blood and blood components for transfusion and/or cells, tissues and organs for transplantation. In most cases, the result of the test is the major determinant as to whether the donation/product will be used. Serious diseases are those that result in death or long-term disability, that are often incurable or require major therapeutic interventions and where an accurate diagnosis is vital to mitigate the public health impact of the condition. **Examples**: Tests to detect infection by HIV, HCV, HBV, HTLV; HIV blood donor screening and HIV blood diagnostics. This rule applies to first-line assays, confirmatory assays, and supplemental assays.
Rule 2:	IVDDs intended to be used for blood grouping, or to determine foetomaternal blood group incompatibility, or tissue typing to ensure the immunological compatibility of blood, blood grouping for cell administration, blood components, cells, tissue, or organs that are intended for transfusion or transplantation, are classified as Class C, except when intended to determine the presence of the antigen or antibody for any of the following markers: ABO system [A (ABO1), B (ABO2), AB (ABO3)], Rhesus system [RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e), and weak or partial Rh(D)], Kell system [Kel1 (K)], Kidd system [JK1 (Jka), JK2 (Jkb)]; or Duffy system [FY1 (Fya), FY2 (Fyb)], in which case they are classified as Class D. Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule, which is as follows: A high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation, places the device into Class D. The rule divides blood-grouping devices into two subsets, Class C or D, depending on the nature of the blood group antigen the IVD medical device is designed to detect, and its importance in a transfusion setting. **Examples**: HLA, Rhesus system, Duffy system (other Duffy systems except those

	listed in the rule as Class D are in Class C).
Rule 3:	IVDDs are classified as Class C if they are intended for use: 1. In detecting the presence of, or exposure to, a sexually transmitted agent. **Examples**: Sexually transmitted diseases, such as Chlamydia trachomatis, Neisseria gonorrhoeae. 2. In detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation. **Examples**: Neisseria meningitidis or Cryptococcus neoformans. 3. In detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual, foetus or embryo being tested or to the individual`s offspring. **Examples**: diagnostic assay for CMV, Chlamydia pneumoniae, Methicillin Resistant Staphylococcus aureus. 4. In pre-natal screening of women in order to determine their immune status towards transmissible agents. **Examples**: Immune status tests for Rubella or Toxoplasmosis. 5. In determining infective disease status or immune status, and where there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation or severe disability for the patient or for the patient`s offspring. **Examples**: Enteroviruses, CMV and HSV in transplant patients. 6. In screening for selection of patients for selective therapy and management as companion diagnostics 7. In screening, diagnosis or staging of cancer; **Examples**: PSA, CEA, and CA 125. **Note:** those IVDDs where the therapy decision would usually be made only after further investigation and those used for monitoring would fall into class B under rule 6. 8. In human genetic testing **Examples**: Huntington's Disease, Cystic Fibrosis. 9. To monitor levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient or for the patient`s offspring. **Examples**: Troponin, Cyclosporin, Prothrombin time testing. 10. In the management of patients suffering from a life-threatening disease or condition. Examples: HBV monitoring marker, HCV viral load, HIV Viral Load and HIV and HCV geno- and subtyping 11. In screening for congenital disorders in the foetus or embryo. **Examples**: Spina Bifida, Down Syndrome, Glucose-6-Phosphate Dehydrogenase Deficiency, and Tay-Sachs disease. 12. In screening for congenital disorders in new-born babies where failure to detect and treat such disorders could lead to life-threatening situations or severe disabilities. Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule, which is as follows: devices in this Class present a moderate public health risk, or a high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation, or would have a major negative impact on outcome. The devices provide the critical, or sole, determinant for the correct diagnosis and monitoring. They may also present a high individual risk because of the stress and anxiety resulting from the information and the nature of the possible follow-up measures.

Rule 4:	IVDDs intended for use by lay users (such as for self-testing or nearpatient testing) are classified as Class C, except: those devices from which the result is not determining a critical situation, in which case they are classified under Class B, and those devices which are classified under Class D by Rule 1 and/or Rule 2. Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule, which is as follows: in general, these devices may be used by lay user. Example for self-testing class C: Blood glucose monitoring. Example for self-testing class B: Pregnancy self-test, fertility testing, and urine test strips.
Rule 5:	The following IVDDs are classified as Class A: 1. Reagents or other articles, which possess no critical characteristics intended by the manufacturer to make them suitable for in vitro diagnostic procedures related to a specific examination; 2. Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures. 3. Specimen receptacles. **Note 1**: Any product for general laboratory use which is not specifically intended by the manufacturer to be used in in vitro diagnostic applications is not deemed to be an IVDD, as defined in this document. Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: these devices present a low individual risk and no or minimal public health risk. **Examples:** General culture media (excluding the dehydrated powders which are considered not to be a finished IVDD), wash solutions, plain urine cup, and microbiological specimen collection devices. **Note 2**: The performance of software or an instrument that is specifically required to perform a particular test will be assessed at the same time as the respective reagent(s).
Rule 6:	IVDDs not covered in Rules 1 through 5 are classified as Class B. Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: These devices present a moderate individual risk as they are not likely to lead to an erroneous result that would cause death or severe disability, have a major negative impact on patient outcome or put the individual in immediate danger. The devices give results that are usually one of several determinants. If the test result is the sole determinant, but other information is available, such as presenting signs and symptoms or other clinical information, which may guide a physician, classification into Class B may be justified. Other appropriate controls may also be in place to validate the results. This Class also includes those devices that present a low public health risk because they detect infectious agents that are not easily propagated in a population. **Examples**: Blood gases, H. pylori test, physiological markers such as hormones, vitamins, and enzymes, metabolic markers, specific IgE assays and celiac disease markers, and tests for anti-nuclear antibody, sex hormone-binding globulin (SHBG), blood urea nitrogen (BUN), aspartate aminotransferase (AST), alkaline phosphatase (ALP), creatinine and HbA1c.

Rule 7:	IVDDs that are controls without a quantitative or qualitative assigned value will be classified as Class B. Rationale: For such controls, the qualitative or quantitative value is assigned by the user and not the manufacturer. **Examples**: Urinalysis controls and chemistry controls.

Appendix VI: Registration Certificate of Veterinary Medical Devices and In Vitro Diagnostics

Doc No: DD/VMDR/FMT/009
Revision No:0
Effective Date: 18/03/2024

RWANDA FDA
Rwanda Food and Drugs Authority

REGISTRATION CERTIFICATE OF VETERINARY MEDICAL DEVICES AND IN VITRO DIAGNOSTICS

Made under Law No. 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning in his article 3 and article 8 and regulations DFAR/HMDAR/TRG/002 Rev_2. *The Authority here issues*

Registration number: Rwanda FDA-VMD -MA-0000 or VIVDD (for IVDs)

This is to certify that the Veterinary Medical Device or in vitro diagnostic described below has been registered in Rwanda subject to conditions indicated at the back of this certificate.

Device's name: ----------

Class of the device: ----------

Brief intended use of the device: ----------

Intended User of the device: ----------

Targeted Specie (s): ----------

Visual description of the Device: ----------

The number of unit products/devices in a commercial pack: ----------

Packaging type: ----------

Recommended Shelf life in months and Storage statement: ----------

Name and address of the Marketing Authorization Holder: ----------

Name and address of the Manufacturer: ----------

Name and address of the Local Technical Representative: ----------

Issued on: DD/MM/YYYY
Expires on: DD/MM/YYYY

Dr. Emile BIENVENU
Director General

Conditions for Veterinary Medical Device Registration

1. This certificate must be returned to the Authority if canceled, invalidated or if the registered Veterinary Medical Device is withdrawn.

2. Any change in the information submitted for the purpose of registration must be notified to the Authority within 30 days of the change.

3. This certificate shall be invalid immediately after the expiry date and the Marketing Authorization Holder shall ensure that the application for renewal of registration is made 90 days before the expiry of registration.

4. A registered Veterinary Medical Device cannot be advertised without prior approval of the Authority.

5. The Veterinary Medical Device shall comply with all relevant provisions of Rwanda FDA regulations at all times.

6. The Marketing Authorization Holder shall ensure that the Veterinary Medical Device complies with Rwandan labeling and packaging requirements at all times.

7. The Marketing Authorization Holder shall ensure that the manufacturing facilities where a registered Veterinary Medical Device is produced comply at all times with Rwanda FDA Quality Management System and / or Good Manufacturing Practice requirements.

8. The Marketing Authorization Holder shall notify Rwanda FDA of the change of a Local Technical Representative at all times.

9. The registration of the veterinary Medical Device shall continue to be valid for five (5) years provided that the annual retention fee is paid.

The Authority reserves the right to withdraw this certificate when conditions 1 to 7 are contravened and when the risks of using this veterinary medical device outweigh the benefits or it is in public interest to do so.

End of document