RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR CHANGE TO REGISTERED OR NOTIFIED MEDICAL DEVICES

NOVEMBER, 2025

Doc. No.: …….. Version

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 medical devices including In vitro Diagnostics in order to protect public health by increasing their access and availability.

Considering the provisions of the technical regulations Governing Registration of Medical Devices including In Vitro Diagnostics in its article which gives the power to issue guidelines, Rwanda Food and Drugs Authority (Rwanda FDA) has issued Guidelines for registration of medical devices.

These guidelines were developed in reference to the Africa Medical Devices Forum (AMDF), World Health Organization (WHO) and the International Medical Device Regulators Forum (IMDRF).

The purpose of these guidelines is to provide guidance to importers, manufacturers and distributors of notified or registered medical devices including In Vitro Diagnostics intending make changes on these devices, on the requirements by Rwanda FDA to assess such changes.
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 changes to medical devices by Rwanda FDA.

We wish to acknowledge all the efforts of key stakeholders and express our gratitude to all individuals who actively participated in the development and validation of these guidelines.

Prof. Emile BIENVENU
Director General

DOCUMENT DEVELOPMENT HISTORY

First issue date	……/2025
Effective date of this revision	……/2025

Document Revision History

Revision number	Changes made and/or reasons for revision
0	First issuance

TABLE OF CONTENTS

ACCRONYMES AND ABBREVIATIONS

CAB	Conformity Assessment Body
DOC	Declaration of Conformity
EAC	East African Community
FIFO	First In First Out
GMP	Good Manufacturing Practice
IMDRF	International Medical Devices Regulators Forum
ISO	International Organization for Standardization
ISRC	Internal Scientific Review Committee
IVD	In Vitro Diagnostic
QMS	Quality Management Systems
LTR	Local Technical Representative
RWANDA FDA	Rwanda Food and Drugs Authority
MA	Marketing Authorization

GLOSSARY / DEFINITIONS

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

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

2. **"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 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. Stand-alone software is considered to be an active medical device;

3. **"Active diagnostic medical device**" means an active device that whether used alone or in combination with another medical device, is intended for the use of detecting, monitoring or treating a physiological condition, state of health, illness or congenital deformity;

4. **"Active therapeutic medical device"** means an active device that whether used alone or in combination with another medical device, is intended to support, modify, replace or restore a biological function or structure for the purpose of treating or mitigating an illness or injury or symptom of an illness or injury;

5. **"Applicant"** means a person who applies for registration of a product to Rwanda FDA, who must be the owner of the product. He may be a manufacturer or a person to whose order and specifications, the product is manufactured. After the product is registered, the applicant shall be the "Marketing Authorization Holder"

6. **"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.

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

8. **"Local Technical Representative (LTR)"** means any company registered in Rwanda and licensed by Rwanda FDA to deal with regulated products that has received a mandate from the Applicant to act on his/her behalf with regard to matters pertaining to the registration of regulated products;

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

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

11. **"Medical Device System"** means 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 are sold under a single name;

12. **"Active implantable medical device"** means 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 human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure;

13. **"Implantable device"** means any device which is intended to be totally introduced into the human body or, to replace an epithelial surface or the surface of the eye, by surgical intervention which is intended to remain in place after the procedure. Any device intended to be partially introduced into the 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;

14. **"Invasive device"** means 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;

15. **"In vitro diagnostic device (IVD)**" means a device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles

    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;

16. "**Accessory to a Medical Device**" means an article intended specifically by its manufacturer to be used together with a particular medical device to enable or assist the device to be used in accordance with its intended use;

17. "**Label**" means written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices.

    Note: The definition above refers to the human readable label.

18. **"Labeling**" means the label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents.

    Note 1: Labeling can also be referred to as "information supplied by the manufacturer."

    Note 2: Labeling can be in printed or electronic format and may either physically accompany the medical device or direct the user to where the labeling information can be accessed (such as through a website).

19. "**Manufacture**" means all operations that involve preparation, processing, filling transforming, packaging, repackaging and labelling of an IVD;

20. "**Manufacturer**" means any natural or legal person1 with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under their name; whether such a medical device is designed and/or manufactured by that person themselves or on their behalf by another person(s). (Modified from

GHTF/SG1/N055:2009)

Note 1: This 'natural or legal person' has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority within that jurisdiction.

Note 2: The manufacturer's responsibilities are described in other GHTF and IMDRF guidance documents. These responsibilities include meeting regulatory requirements at various points during the product lifecycle, such as adverse event reporting and notification of corrective actions.

Note 3: 'Design and/or manufacture', as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labeling, relabeling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.

Note 4: Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.

Note 5: Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.

Note 6: An authorized representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labeling, is not considered a manufacturer.

Note 7: To the extent that an accessory is subject to the regulatory requirements of a medical device2, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

21. "Medical device" means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- 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 of a physiological process,
- supporting or sustaining life,
- control of conception,
- cleaning, disinfection, or sterilization of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body;

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

Note 1: Products which may be considered to be medical devices in some jurisdictions but not in others include:

- cleaning and disinfection substances,

- aids for persons with disabilities,
- devices incorporating animal and/or human tissues,
- devices for in-vitro fertilization or assisted reproduction technologies.

Note 2: For clarification purposes, in certain regulatory jurisdictions, devices for cosmetic/aesthetic purposes are also considered medical devices.

Note 3: For clarification purposes, in certain regulatory jurisdictions, the commerce of devices incorporating human tissues is not allowed.

22. **"Fee"** means the fee prescribed in Regulation related to regulatory services and fines;

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

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

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

26. **"Intended use/purpose"** means the objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer;

27. **"Dossier"** means a file that contains detailed information on the device description, manufacturing, quality control and biomedical studies that demonstrates quality, safety and performance of the finished medical device;

28. **"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 quality system;

29. **"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;

30. **"Medical Devices with Measuring Function"** a device has a measuring function if;

a. The device is intended by the manufacturer to measure: - quantitatively a physiological or anatomical parameter, or - a quantity or a qualifiable characteristic of energy or of substances delivered to or removed from the human body,

b. The result of the measurement - is displayed in legal units or other internationally acceptable units or - is compared to at least one point of reference indicated in legal units or other acceptable units.

c. The intended purpose implies accuracy, claimed explicitly or implicitly, where a non-compliance with the implied accuracy could result in a significant adverse effect on the patient's health and safety.

31. **"Notified Medical Devices"** means medical devices that have been granted marketing authorization through the notification process.

32. **"Marketing authorization/ Notification, Registration certificate"** means a legal document issued by the competent authority for the purposes of marketing or free distribution of a product which has been approved after evaluation for safety, quality and performance.

33. **"Marketing Authorization holder"** means a company which holds an authorization to place a medical device on the Rwandan market and is responsible for that device.

INTRODUCTION

1.1. Background

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

Considering the provisions of the technical regulations governing the registration of medical devices including IVDs, especially in its article which grants the authority the power to issue guidelines, the authority has issued Guidelines for Change to Registered or Notified Medical Devices.

Manufacturers that have made changes to registered medical devices including IVDs are expected to demonstrate conformity to the Essential Principles of Safety and Performance (where applicable), through the preparation and holding of relevant documentation that showcases which changes/changes of have been made on the devices

1.2. Scope

These guidelines shall apply to all registered or notified medical devices including In Vitro Diagnostics that have undergone change(s). They provide guidance on the relevant documentation to be submitted to Rwanda Food and Drugs Authority (Rwanda FDA) for assessment and approval.

1.3. General principles

For the purpose of changes/changes assessment, the manufacturer should assemble relevant information of the applicable changes/changes made to the device. This information shall accurately reflect the change of the medical device including IVD made after pre-market authorization.

The submission should contain relevant information on changes made to a registered medical device including IVD and all information should be submitted in any of the official language(s)languages to allow a reviewer to understand the subject and assess the validity of that information.

1.4. Submission of Application

An application for change to registered devices for either locally manufactured or imported shall be made in writing via a cover letter and application form dated and signed by the applicant. The application for change should be submitted to Rwanda FDA by the applicant via Rwanda FDA Online portal. Only samples (if requested) can be submitted along with the cover letter (**Appendix 1**) together with a printed email notification bearing an application reference number generated at the time of application submission, at Rwanda FDA head Quarters reception to the following address:

Director General
Rwanda Food and Drugs Authority
P. O. Box 1948 Kigali-Rwanda

1.5. Types of changes

1.5.1. Notifiable changes

Notifiable changes are those whose implementation has no impact to the device safety, quality and performance. These changes may be implemented by the manufacturer without prior approval from the Authority; However, should be reported upon completion of their implementation, as a notification.

The following are some examples of notifiable changes:

a) Labeling changes:

- that only involve changes in layout, colour, font sizes and design, without change in prominence of precautions, warnings and contraindications.
- that involve an addition and/or removal of languages not required by the Authority.
- that involve an addition/removal of reference agency approvals (e.g. CE Marking).
- that involve an update of distributor information, including EU authorised representative, and which does not affect the registered device information.
- that involve an addition/change or removal of barcodes, and which does not change the registered device information.
- Labelling changes that involve an addition of a Unique Device Identifier (UDI) or other relevant codes, and which does not change the registered device information.
- Labelling changes that involve the change in date format of an existing labelling date field.
- Change in the shelf life of the device

b) Change in regulatory status on rejection or withdrawal in any reference agencies for models registered on medical devices register.

c) Change in raw material supplier(s) (except medicinal substances and biological material suppliers) that do not change the registered device specifications

Notifiable changes should be report at the latest, within **12 months** from the date of the implementation.

1.5.2. Minor changes

These are the significant changes that have been confirmed through risk analysis, to have a potential of lower impact on the function, performance, usability, or safety of the registered device.

The applicant may group one or more minor changes of several registered devices under a single application provided that the changes are the same for all concerned registered devices.

The following are some examples of minor changes:

a) All changes to certificates for manufacturing and sterilization facilities that involves an update of certificate QMS validity date only

Change in scope of the QMS certification which affect the registered medical device

Change involving the expansion of scope of the QMS

Change involving the cancellation of scope of the QMS on the certificate for any of the multiple existing manufacturing facilities that is related to the registered medical device

b) Changes in design or specifications of a registered device which do not affect the quality safety and performance of the registered device

c) Change in software version that does not affect safety or performance of the registered device
d) Changes to labeling of medical devices where the change only involves a reduction of indications for use not arising due to the registered device safety or performance concerns
e) Labeling changes that only involve the addition of Recognized Countries' approvals (e.g. CE marking)
f) Changes to registered devices registration information which involves an addition of Class A medical device accessories that complement the registered medical device as a system or family, Changes affecting grouped registered devices involving their reduction in number or Changes of the applicant or Local Technical Representative (LTR).

Minor changes should be reported at the latest, within **1 month** from the date of the implementation.

1.5.3. Major changes

It is important to note that reporting of changes to the Authority should occur prior to its implementation. Applicants should submit applications early in the process of designing and validating the change, to allow sufficient time for assessment by the Authority before its approval.

The following are some examples of major changes:

a) Changes to Manufacturing Process, Facility or Equipment
b) Changes in a supplier's manufacturing process facility or equipment
c) Changes in sterilization procedures or methods
d) Changes in Manufacturing Control Procedures that alter the design specification of the device
e) Changes in design control mechanism,
   Change in the source of energy used by the device,
   Change to the design specification, physical description, patient or user interface, software or firm affect indications for use
f) Changes in a sterilization process of the device that affects the bioburden alert or action levels or that introduces a more difficult to kill organism
   Changes in the device design or material that affects the sterilization process
   Change made from a non-parametric release to a parametric release
g) Change to software:
   -That impacts the way data is read or interpreted which might alter the diagnosis or delivered therapy of the device
   -That introduces or removes and alarm function which may change the course of treatment in comparison to the previous version
   -That may alter the operating system which in turn may alter the final professional decision making
   -That corrects an error for which there is a safety risk to the patient should the error remain
h) Change to IVD materials which may be of animal of human origin that requires testing of additional testing of clinical samples to determine its performance
   Change in material of surgically invasive device intended to be absorbed by the body or to remain in the body for at least thirty consecutive days
   Change in the material used for a device intended to remain in contact with the body tissues or fluids
i) Changes in labelling indications for use that are not within an approved set of indications
   Changes/removal or addition of warnings and precautions or contraindication

Major changes should be reported prior their implementation.

1.5.4. Critical changes

These types of changes require the applicant to apply for a new application for registration in accordance with the relevant guidelines.

The following are some examples of critical changes:

a) Change that will result in the changes in risk classification of the approved medical devices or IVDDs.
b) Change to the specific disorder, condition or risk factor of interest that the IVDDs is intended to detect, define or differentiate.
c) Change in approved intended use of the medical devices or IVDDs.
d) Change to what is detected (i.e. the analyte or measurand).
e) Changes in antigens, antibodies, primers or solid phase of the IVDDs.
f) Change of the drug substance combined with the registered medical device.
g) Change of the registrable drug of a device with the registrable drug in a secondary role.
h) Addition of model that does not fulfil the grouping criteria as per i.e Medical devices or IVDDs Family/ Procedure Kit/ Group definitions.
i) Addition of medical devices with device brand names different from the registered medical devices or IVDDs.
j) Change in the test result format from qualitative to quantitative or vice versa.
k) Change in biological or chemical principle of the test.
l) Change in design of test technology.
m) Combination of several changes can also result in the need for a new registration application.
n) Significant change to software that affects safety, quality and performance of the registered medical device
o) Change to the type, concentration or drug specifications (DS) of medicinal substance in a medical device that incorporates a medicinal product as an ancillary role shall be refer to medicine registration guideline; and
p) Addition of model(s) that do not fulfil the grouping criteria, including permissible variants, as listed in the Grouping of Medical Devices for Product Registration.
q) Change in the device proprietary names different from the one of a registered device

Applicants with other combination of multiple changes are advised to apply for a new application as these changes could be considered as critical changes,

Note:
When the proposed change is not considered a minor change and the Authority is of the opinion that it may have a significant impact on the quality, safety or efficacy of the medicinal product, the MAH will be requested to revise its application and to complete it in accordance with the requirements for a major variation.

1.6. Timelines for processing change to a registered medical device

Dossiers requesting change to a registered medical device shall be scheduled for assessment according to the First in First out (FIFO) basis upon compliance with the requirements.

An application for changes shall be processed within:

- Twenty (20) working days for notifiable changes applications
- Thirty (30) working days for minor changes applications
- Sixty (60) working days for major changes applications

Any additional data shall be submitted within:

- Five (5) working days for notifiable changes applications
- Tent (10) working days for minor changes applications
- Twenty (20) working days for major changes applications

1.7. Receiving new applications for change

The application for change of registered devices is only received via the Authority's online platform after the payment relevant fees is effected. After receiving an application for change, a reference number is assigned to the application and it will be used in all subsequent correspondences relating to the application. An acknowledged receipt will be issued.

Where applicable, samples can be submitted along with the cover letter (**Appendix 1**) together with a printed email notification bearing an application reference number generated at the time of application submission at Rwanda FDA head Quarters reception to the following address:

Director General
Rwanda FDA Rwanda Food and Drugs Authority
P. O. Box 1948 Kigali- Rwanda

Note:
In case samples are not provided, a letter explaining the reason of non-submission should be provided and where possible, a real life 3D pictures should be included the submitted documentation.

1.8. Processing applications for change

After receiving an application requesting minor or major change, the Authority shall proceed with the assessment of the dossier based on the First in First out (FIFO) rules.
An application is assessed by two assessors who review the conformity of the device to requirements.

During the assessment, additional data and/or samples may be requested through an official communication pathway. Once a query has been issued to the applicant, the process stops until the Authority receives a written response to the raised queries and resumes once a response to the query has been received. Failure to comply with this condition or if the queries have been reissued for a **second** 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 the specified timeline 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.

In case the dossier is complete, the application will be scheduled and approved by the Internal Scientific Review Committee (ISRC). The applicant shall then receive an approval letter in due time.

1.9. Application Requirements

Application requirements for notifiable changes will be found under **table 1**
Application requirements for minor changes will be found under **table 2**
Application requirements for major change will be found under **table 3**

Table 1: Application requirements for notifiable changes

Types of change	**Documents to be submitted**
All applicants requesting changes falling under this classification will be required to submit the documents listed in the right column	-Cover letter (Appendix I) -Application form (Appendix II for notified devices, Appendix III for registered medical devices)

Table 2: Application requirements for minor changes

Types of change	**Documents to be submitted**
1. Change in manufacturing facility, process and quality management system (QMS)	
All changes to certificates for manufacturing and sterilization facilities that involves an update of certificate QMS validity date only	-Cover letter (Appendix I) -Application form (Appendix II for notified devices, Appendix III for registered medical devices) -Valid QMS certificate/ISO 13485 or equivalent
Change in scope of the QMS certification which affect the registered medical device	
Change involving the expansion of scope of the QMS	
Change involving the cancellation of scope of the QMS on the certificate for any of the multiple existing manufacturing facilities that is related to the registered medical device	
2. Changes in design or specifications of a registered medical device	
Change in software version that does not affect safety or performance of the registered device	-Cover letter -Application form

	-Detailed summary of the software changes -Current validation report of the software
Changes in software solely to correct an inadvertent software error which does not add new functions	
Software changes which augment interfacing to other non-medical peripherals such as printers or VDUs	
3. Changes in labelling	
Changes to labeling of medical devices where the change only involves a reduction of indications for use not arising due to the registered device safety or performance concerns	-Cover letter -Application form (Appendix II for notified devices, Appendix III for registered medical devices) -Current artworks/mockups -Detailed new indication for use/ Instruction for Use -Valid certificates from relevant bodies (where applicable).
Labeling changes that only involve the addition of Recognized Countries' approvals (e.g. CE marking)	
4. Changes to registered devices registration information	
Changes involving an addition of Class A medical device accessories that complement the registered medical device as a system or family.	-Cover letter -Application form (Appendix II for notified devices, Appendix III for registered medical devices) -Declaration of Conformity -Current artworks/mockups -Current list of the device configuration -Letter of Appointment (letter appointing a local technical representative)
Changes affecting grouped registered devices involving their reduction in number	
Changes of the applicant or Local Technical Representative (LTR)	

Table 3: Application requirements for major changes

1. Change in manufacturing facility, process and quality management system (QMS)	
Changes to Manufacturing/sterilization Facility	-Cover letter -Application form (Appendix II for notified devices, Appendix III for registered medical devices)

	-Current QMS certificate (revised) -Current artworks/mockups -Declaration that there is no change in the manufacturing and sterilization process
Changes to manufacturing processes that result in a change in specifications	-Cover letter -Application form (Appendix II for notified devices, Appendix III for registered medical devices) -Current QMS certificate -Summary of the new manufacturing process (where applicable) -Validation of the new manufacturing process (where applicable) -pre clinical studies (where applicable) -Software validation report (for software) -Clinical safety report (for operating principles and design characteristics change) (where applicable) -Risk analysis -Current specifications of the device
Changes in sterilization procedures or methods	-Cover letter -Application form (Appendix II for notified devices, Appendix III for registered medical devices) -Current QMS certificate -Current artworks/mockups/labeling -Sterilization technique -Sterilization validation report
2. Changes in design or specifications of a registered medical device	
Changes in Manufacturing Control mechanism, operating principles that alter the design specification of the device	-Cover letter -Application form (Appendix II for notified devices, Appendix III for registered medical devices) -Current QMS certificate -Current artworks/mockups/labeling -Pre clinical studies or clinical studies (where applicable) -Clinical safety report (where applicable); -Software validation report (where applicable) -Detailed summary of software changes (where applicable) -Risk analysis -Stability studies (where applicable)
All change in specifications (including shelf life and stability)	

Changes in design that do not affect the safety or performance of the device such as aesthetic modifications	-Cover letter -Application form (Appendix II for notified devices, Appendix III for registered medical devices) -Current QMS certificate -Risk analysis -Usability testing report (where applicable)
Change to software that impacts the way data is read or interpreted which might alter the diagnosis or delivered therapy or that introduces or removes and alarm function which may change the course of treatment in comparison to the previous version	-Cover letter -Application form (Appendix II for notified devices, Appendix III for registered medical devices) -Current QMS certificate -Software validation report -Detailed summary of software changes -Risk analysis
3. Changes to materials in a medical device	
Changes to biological materials that involve a change in type, source, processing and/or supplier of cells, tissues and/or derivatives of animal, human, microbial or recombinant origin without a change in the intended purpose of the biological material.	-Cover letter -Application form (Appendix II for notified devices, Appendix III for registered medical devices) -Current QMS certificate -Pre-clinical studies, including biological safety data -Clinical safety report (where applicable) -Risk analysis -Information of sources/donors -List of materials making direct/indirect contact with the human body (where applicable)
All changes to materials or material formulation (of non-biological origin), including changes to medical device coating or surface modification techniques	
All changes to materials that are used for shielding in medical devices emitting ionizing radiation and All changes to the radiation source	-Cover letter -Application form (Appendix II for notified devices, Appendix III for registered medical devices) -Current QMS certificate -Information on materials for shielding of radiation; -Information on radiation source -Radiation safety test/test report; -Risk analysis.

4. Changes to materials in an In-vitro Diagnostic (IVD)	
All changes to the radiation source (e.g. radioisotopes in radioimmunoassay).	-Cover letter -Application form (Appendix II for notified devices, Appendix III for registered medical devices) -Current QMS certificate -Pre-clinical performance evaluation data -Clinical performance evaluation data; -Information on source of the material; -Radiation safety test/test report; -Risk analysis.
5. Changes to labelling of medical devices	
All changes to the labelling of medical devices that involve addition, removal and/or revision of warnings, precautions and/or contraindications	-Cover letter -Application form (Appendix II for notified devices, Appendix III for registered medical devices) -Current QMS certificate (where applicable) -Current artworks/mockups and labelling -Preclinical studies (where applicable) -Clinical safety report (where applicable) -Software validation (where applicable)
Labeling changes that modify the approved method of use; OR involve a change from 'Professional use only' to 'home use'	
6. Changes to registered medical devices registration information	
Change of registration information to a device grouping involving an addition of new devices of the same design	-Cover letter -Application form (Appendix II for notified devices, Appendix III for registered medical devices) -Current QMS certificate (where applicable) -List of configurations of medical devices (where applicable) -Medical device information -Current artworks/mockups and labelling -Declaration of conformity -Pre-clinical studies (where applicable) -Software validation report (where applicable) -Manufacturing information (where applicable)
Change of registration information involving an addition of a new device with design change that does not affect the safety or performance of the device	
Change of registration information involving an addition of active, with measuring function or sterile Class A device accessories that complements the registered medical device as a system.	-Cover letter -Application form (Appendix II for notified devices, Appendix III for registered medical devices) -Current QMS certificate (where applicable)

	-Declaration by the applicant/Manufacturer stating that the added models are class A sterile; the name of the medical device affected; the medical device identifier; no change in manufacturer for the class A sterile medical device; Name and address for the manufacturing site(s) for class A sterile medical device -List of configurations of medical devices (where applicable) -Declaration of conformity -Validation report and Certificate of Analysis
Changes to device registration certificate involving an increase or reduction in the number of devices in a set grouping of a registered medical device	-Cover letter -Application form (Appendix II for notified devices, Appendix III for registered medical devices) -Current QMS certificate (where applicable) -Declaration of conformity; -Declaration from the applicant/manufacturer stating that there is no change to a device in all aspects, including intended use, technical specifications; -List of configurations of medical devices; -Current artworks/ mockups and labelling
Changes to the medical device name and/or medical device identifier.	

REFERENCE

1. World Health Organization: *Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices*
2. African Medical Devices Forum: *Guidelines on regulatory requirements for issuance of market authorization of medical devices including in-vitro diagnostic medical devices*
3. Tanzania Medicines and Medical Devices Authority: *Guidelines On Submission Of Application For Change(s) To Approved Medical Devices and In-Vitro Diagnostics*
4. Ethiopian Food and Drug Authority: *Guideline for Medical device Post-approval Change Notification*

ENDORSEMENT OF THE GUIDELINES

	Prepared by	**Checked by**		**Approved by**
Title	**Division manager**	**Head of Department**	**QMS Division Manager**	**Director General**
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Date & Signature				

RWANDA FDA
Rwanda Food and Drugs Authority

Doc No: DD/HMDR/DOC.TYPE/….
Revision No:1
Effective Date: dd/mm/yyyy

APPENDIX 1:
cover letter

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

Rwanda FDA,
1948 Kigali-Rwanda

Dear Sir/Madam,

Subject: Submission of Application Dossier(s) for Marketing Authorization of < Medical device(s) or Change on registered/notified Medical device (s)>

We are pleased to submit our Application Dossier(s) for the registration of medical devices/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): …….....

You will find enclosed the submission dossier as specified hereafter:

□ We confirm that the application dossier has been well checked for completion prior submission.

Type of Submission: □Full registration Application □Abridged Application □Notification Renewal Application for registration □Renewal Application for notification □ Application for change on registered/notified medical device
□ sample(s) submitted (where applicable)

□ Application for QMS audit to Rwanda FDA, where applicable (as per relevant guidelines)

 I confirm that the Product Dossier information submitted is the same in all aspects as the product registered with the relevant SRA, WHO PQ and EAC (Only for Abridged Applications)

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>

RWANDA FDA
Rwanda Food and Drugs Authority

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APPENDIX 2

Application Form for Medical Devices Including In Vitro Diagnostics Devices (IVDDS) Notification

Application Number	**Rwanda FDA use only**
Date of submission of dossier	**Rwanda FDA use only**
1.0 PARTICULARS OF THE MEDICAL DEVICE or IVD (**Bold or Tick** the right type of application)	
1.1	Name of the Medical Device or IVD
1.2	Type of application • New • Renewal • Change* • Notifiable change • minor change • major change * In case change (s) has(ve) been made to registered/notified medical device (s), fill in the following 2 rows
	Reason for change
	Detailed description of the change (s)
1.3	Classification of the Medical Device or IVD and Classification rule(s) applied
1.4	Intended use of the Medical Device or IVD

<table>
<tr><td></td><td>Intended user:
• Professional user
• self user</td></tr>
<tr><td>1.5</td><td>Name and address (physical and postal) of Applicant
Address:
Country:
Telephone:
Telefax:
E-Mail:</td></tr>
<tr><td>1.6</td><td>Name and address (physical and postal) of legal manufacturer
Address:
Country:
Telephone:
Telefax:
E-Mail</td></tr>
<tr><td>1.7</td><td>Visual description of the Medical Device or IVD</td></tr>
<tr><td>1.8</td><td>Proposed shelf life (in months) (where applicable):</td></tr>
<tr><td>1.9</td><td>Proposed storage conditions (where applicable):</td></tr>
<tr><td>1.10</td><td>Other regulatory authority(ies) approval(s) (i.e. European conformity (CE) mark, United States Food and Drug Administration (USFDA) approval, etc)
<table><tr><td>Regulatory Authority’s (ies’) Approval(s)</td><td>Approval/Authorization number</td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr></table></td></tr>
<tr><td>1.11</td><td>Country of origin (where the device was manufactured)</td></tr>
<tr><td>1.12</td><td>Name(s) and physical address(es) of the manufacturing site(s) of the Medical Device or IVD. Alternative sites 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.
Address:
Country:
Telephone:
Telefax:
E-Mail:</td></tr>
</table>

1.13	Name and address (physical and postal) of the Agent/Local Technical Representative (LTR) (Attach a valid appointment letter notarized from the country of origin): Address: Country: Telephone: Telefax: E-Mail:
1.14	Version of the product insert (attach a copy of relevant labeling including the Instruction For Use (IFU))

2.0 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 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 including IVDs. I also consent to the processing of information provided to Rwanda FDA

Signature:

Date:

APPENDIX 3:

Application Form for Medical Devices and In Vitro Diagnostics Devices (IVDDS) Registration

Application Number	**Rwanda FDA use only**
Date of submission of dossier	**Rwanda FDA use only**
1.0 PARTICULARS OF THE MEDICAL DEVICE or IVD (**Bold or Tick** the right type of application)	
1.1	Name of the Medical Device or IVD
1.2	Type of application • New • Renewal • Change* • Notifiable change • minor change • major change * In case change (s) has(ve) been made to registered/notified medical device (s), fill in the following 2 rows
	Reason for change
	Detailed description of the change (s)
1.3	Classification of the Medical Device or IVD and Classification rule(s) applied

1.4	Intended use of the Medical Device or IVD
1.5	Name and address (physical and postal) of Applicant Address: Country: Telephone: Telefax: E-Mail:
1.6	Name and address (physical and postal) of the legal manufacturer Address: Country: Telephone: Telefax: E-Mail
1.7	Name(s) and physical address(es) of the manufacturing site(s) of the Medical Device or IVD. Alternative or contract manufacturing sites 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. Address: Country: Telephone: Telefax: E-Mail:
1.8	Visual description of the Medical Device or IVD
1.9	Proposed shelf life (in months) (where applicable):

<table>
<tr><td></td><td></td></tr>
<tr><td>1.10</td><td>Proposed storage conditions (where applicable):</td></tr>
<tr><td>1.11</td><td>Other sister/variants of the medical device (s) or IVD (s) registered or applied for registration with Rwanda FDA</td></tr>
<tr><td>1.12</td><td>list all accessories that are manufactured/ sold with the devices</td></tr>
<tr><td>1.13</td><td>Have you applied for Marketing Authorization(s) of medical device(s) or In Vitro Diagnostics Devices (IVDs) in any of the country of East African Community (EAC)?
• Yes
• No
If yes state
Medical Device name or IVD:
Regulatory Authority(ies) where you have applied for registration:</td></tr>
<tr><td>1.14</td><td>Device Marketing Authorization in the country of origin (Attach Marketing Authorization of the Medical Device or IVD from the National Regulatory Authority). If not registered, state reasons
<table>
<tr><td>• Authorized Country:
Date of authorization:
Authorization number:

• Refused Country:
Date of refusal:
Reason of refusal:</td><td>• Withdrawn (by the applicant after authorization) Country:
Date of withdrawal:
Reason of withdrawal:

• Suspended/revoked (by competent authority) Country:
Date of suspension/revocation:
Reason for suspension/revocation:</td></tr>
</table>
</td></tr>
<tr><td>1.16</td><td>Name and address (physical and postal) of the Agent/Local Technical Representative (LTR) (Attach a valid appointment letter notarized from the country of origin):
Address:
Country:
Telephone:</td></tr>
</table>

	Telefax: E-Mail:
1.17	Name and address (physical and postal) of the person or company responsible for Pharmacovigilance and Post Marketing Surveillance: Address: Country: Telephone: Telefax: E-Mail:
1.18	Qualitative and Quantitative composition of the Medical Device or IVD (If applicable)
1.19	Name and address (physical and postal) of the Contract Research Organisation(s) where the clinical studies of the Medical Device or IVD were conducted. (If applicable) Address: Country: Telephone: Telefax: E-Mail:
2.0 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 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. I also consent to the processing of information provided to Rwanda FDA. Signature:	

Date: