RWANDA FDA
Rwanda Food and Drugs Authority

# REGULATIONS GOVERNING THE REGISTRATION OF MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS

(Rwanda FDA law nº 003/2018 of 09/02/2018, article 9)

**Regulation development history**

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| 08/06/2021 | 1 | 1. The article on reliance is included.<br>2. The article on authorization for emergency use is included.<br>3. The article on donation of medical products included.<br>interline is changed from 1.5 to 1.15 as per sop on internal document control. |
| 22/08/2022 | 2 | 1. In this version, in vitro diagnostics devices were added as products regulated under this regulation.<br>2. Notification application was added in the following articles 6, 7, 13, 19, 22, 26, 28.<br>3. The article 8, 15 were revised.<br>4. This regulation will now regulate both human and veterinary medical devices including in vitro diagnostic device.<br>5. Editorial Changes |

## Adoption and Approval of the Regulations

*In EXERCISE of the powers conferred upon Rwanda Food and Drugs Authority by article n° 9 of the Law n° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning, hereby ADOPTS and ISSUES these Regulations No: DFAR/HMDAR/TRG/002 Rev_2 Governing Registration of Medical Devices Including In Vitro Diagnostics on this 20/ 09 / 2022.*

20/9/2022

**Dr Emile BIENVENU**
**Director General**

**Arrangement of the Regulations**

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## CHAPTER ONE: GENERAL PROVISIONS

### Article One: Purpose of these Regulations

The purpose of these regulations is to enforce the legal framework to ensure effective and efficient registration of human and veterinary Medical Devices including In Vitro Diagnostics, and to provide an open, transparent and non-discriminatory process for the registration of Medical Devices including In Vitro Diagnostics.

### Article 2: Citation

These regulations may be cited as Rwanda FDA regulations governing the registration of Medical Devices including In Vitro Diagnostics.

### Article 3: Application

These regulations apply to all regulated human and veterinary medical devices including in vitro diagnostics dossiers submitted to the Authority for the purpose of marketing authorization.

### Article 4: Definitions

in these regulations, unless the context otherwise requires:

1. **"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 Authorisation Holder".".
2. **"Authority"** means Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established under law no. 003/2018 of 09/02/2018;
3. **"Certificate of Notification"** means a certificate issued by the Authority after its approval to be marketed; applicable to some devices falling under class a, depending on their extremely low risk- to the user or health care providers.;
4. **"Certificate of Registration"** means a certificate issued by the Authority after its approval to market and sell a product in the country;
5. **"Conditional Registration"** the approval of a medical device including IVD that addresses unmet medical needs of patients on the basis of less comprehensive data than normally required. The available data must indicate that the medical device or IVD's benefits outweigh its risks and the applicant should be in a position to provide the comprehensive clinical data in the future.
6. **"Documentation"** a compilation of required information for registration including samples and any other additional information requested for registration.
7. **"Fee"** means the fee prescribed in regulation CBD/TRG/004 related to regulatory service tariffs/fees and fines;
8. "**Implantable device"** means any device which is intended: - to be totally introduced into the human or animal bodies 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.
9. **"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.

10. **"In Vitro Diagnostic Device"** means a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human or 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; IVD medical 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;
11. "**Label**" means any tag, brand, mark, pictorial or other descriptive matter, written, printed stencilled, marked, embossed or impressed on or attached to a container of any medical device or medical devices and in vitro diagnostics devices;
12. "L**abelling**" is all labels 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.
13. **"Law"** means law no. 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning.
14. **"Local Technical Representative (LTR)"** means any corporate body registered in Rwanda and authorized by the Rwanda FDA to deal with medical devices and in vitro diagnostics that has received a mandate from the applicant to act on his/her behalf with regard to matters pertaining to the registration of medical devices including IVDs.
15. "**Manufacture**" means all operations that involve preparation, processing, filling transforming, packaging, repackaging and labelling of medical devices and in vitro diagnostic devices;
16. "**Manufacturer**" means a person or a firm that is engaged in the manufacture of medical devices and in vitro diagnostic devices;
17. **"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;
18. **"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.
19. **"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.
20. **"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.

21. "**Medical device system":** a medical device comprising a number of components or parts intended to be used together to fulfil some or the entire device's intended functions and that is sold under a single name.

## CHAPTER II: REGISTRATION OF MEDICAL DEVICES AND IN VITRO DIAGNOSTICS DEVICES

### Article 5: Classification of Medical Devices and In Vitro Diagnostics Devices

There shall be four (4) classes of medical devices and in vitro diagnostics, as provided in the rules set out in the schedule of these regulations depending on their levels of risk as follows:

a. Low risk class
b. Low to moderate risk class
c. Moderate to high risk class
d. High risk class.

Where a medical device including in vitro diagnostics falls into more than one class, the class representing the higher class shall apply. The Authority shall have a final decision on the classification of a medical device and in vitro diagnostics based on different factors such as the intended use, device risk, and regional endemics, among others.

### Article 6: Application and requirements for registration of medical devices and in vitro diagnostic devices

All medical devices including in vitro diagnostics shall be registered or given a notification (where applicable) by the Authority before they are placed on the Rwandan market. Aperson who intends to manufacture, import or export 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 registration or notification.

An application for registration or notification of medical devices including in vitro diagnostics shall be made to the Authority in writing by the applicant, the manufacturer or a local technical representative.

Application for registration or notification of medical devices including in vitro diagnostics shall be made in electronic copies as detailed in Rwanda FDA guidelines for submission of documentation for registration of medical devices or guidelines on submission of documentation for registration of in vitro diagnostic devices.

Every application shall be accompanied by the following:

a. Proof of payment of non-refundable registration fee; and
b. sample or samples of the device, where applicable and, or artwork.

### Article 7: Technical requirements

All applications for registration or notification of medical devices including in vitro diagnostics shall comply with the technical requirements demonstrating quality, safety and performance as

determined by Rwanda FDA Guidelines on submission of documentation for registration or notification of medical devices and guidelines on submission of documentation for registration of in vitro diagnostic devices.

**Article 8: Language for application**

All applications and supporting documents shall be submitted in **English**, **French or Kinyarwanda** language. Where some documents are submitted in a language other than English, French or Kinyarwanda, the applicant shall submit translated copies to expedite the review process.

**Article 9: Authenticity of documents**

Any document submitted to the Authority must be authentic. The Authority shall reject an application for registration or notification of a medical device or in vitro diagnostic if it is satisfied that the submitted documents are not authentic or the integrity of data is questionable. Any applicant is responsible for the authenticity of the contents of his/her application.

**Article 10: Safe custody and confidentiality of information**

The Authority shall ensure safe custody of information related to the registration or notification of medical devices or in vitro diagnostic devices submitted by an applicant.

All information submitted by an applicant shall be treated confidentially and shall not be disclosed to any third party without a prior written consent of the applicant or his/her representative.

**Article 11: Assessment process of Medical Devices and In Vitro Diagnostics**

The Authority shall, upon being satisfied by the completeness of the application, conduct assessment to verify the compliance with safety, quality and performance requirements through full or abridged assessment procedures. The Authority shall set out guidelines, sops (to recheck), forms, and tools for full and abridged assessment procedures.

The authority may, during the assessment of the device, request the applicant to submit additional samples, documents, information, data or clarification to support the application for registration.

Where the Authority requires the information stated above, the processing of the application shall not proceed untilthe applicant provides the required additional information.

Where the applicant fails to submit the requested information, within the period of ninety (90) days from the date of request, the application shall be considered withdrawn.

The applicant may by giving reasons in writing request for an extension of time for submission of additional samples, documents, information, data and or clarification requested by the Authority.

If the applicant fails to provide satisfactory responses to the requested informationfor a fourth time, the application shall be rejected.

An application withdrawn or rejectedshall only be considered for registration upon submission of a new application as per the requirements of these regulations.

**Article 12: Quality Management System audit for medical devices including In Vitro Diagnostics requirements**

During the assessment of medical devices and in vitro diagnostics, the Authority shall, as it may deem necessary, conduct quality management system audits of manufacturers, and production site to confirm the authenticity, precision and integrity of information and data submitted.

**Article 13: Certificate of registration or notification of Medical Devices including In Vitro Diagnostics**

The Authority shall issue a certificate of registration or a certificate of notification to medical devices or in vitro diagnostics only if:

a. The medical device or in vitro diagnostic dossier is assessed and fulfils all the requirements of safety, quality and performance,
b. The manufacturing site of the medical device or in vitro diagnostic is compliant with Quality Management System requirements,
c. Medical devices or in vitro diagnostics fulfil the requirements of laboratory quality tests.

**Article 14: Conditional registration (to be defined) of medical devices and in vitro diagnostics**

The Authority shall specify the conditions which need to be fulfilled by the applicant to acquire conditional registration prior to issuance of full registration certificate.

**Article 15: Authorization for emergency use**

The Authority may issue the authorization for emergency use when a national public health emergency has been declared and the device fulfils one of the following requirements:

a. Listed as prequalified or granted authorization for emergency use by the World Health Organization (WHO) or world organisation for animal health (OIE),
b. Registered or granted authorization for emergency use by Stringent Regulatory Authorities,
c. Registered or granted authorization for emergency use by countries having
d. Collaborative agreements with the Authority, and
e. The normal device registration process is ongoing and the Authority decides to grant
f. Authorization for emergency use based on the severity of the declared public health emergency.

The Authority may issue the authorization for emergency use when a national public health emergency has been declared by the Ministry of Health.

The Authority may permit the emergency use of an unregistered medicinal product or may permit an unapproved use of a registered medicinal product.

Furthermore, a medicinal product may or may not have undergone human efficacy trials, due to risk, feasibility or ethical considerations.

**Article 16: Reliance**

The Authority may rely on regulatory decisions from regional, international and other stringent regulatory authorities' decisions regarding product market authorization when deemed necessary.

**Article 17: Approval of Medical Devices including In Vitro Diagnostics**

Upon approval of registration of medical devices or in vitro diagnostics, the Authority shall:

a. Enter in the register the prescribed particulars of the medical device or in vitro diagnostic;
b. Allocate a registration number to the medical device or in vitro diagnostic device;
c. Issue to the applicant a certificate of full, conditional or emergency registration or a certificate of notification as per the prescribed format.

**Article 18: Publication of a registered Medical Device including In Vitro Diagnostic**

The Authority shall publish a list of registered medical devices or in vitro diagnostics on the authority's website including but not limited to the following:

a. The brand name, generic name, and model, where applicable of the devices;
b. The registration number allocated to the device on registration;
c. The intended purpose or use of the device;
d. The name and the country of the marketing authorization holder of the certificate registration or the certificate of notification;
e. The name and country of the original manufacturer;
f. The date of registration of the device and registration status;
g. The class of the device; and
h. The device nomenclature code allocated to the device;
i. Local technical representative;
j. Expiry date of the registration certificate or the certificate of notification.

**Article 19: Validity of registration or notification**

A certificate of full registration issued under article 13 shall, unless earlier suspended or revoked, and subject to payment of prescribed annual retention fees, be valid for a period of five (5) years from the date of issuance and may thereafter be renewed. The certificate of notification, however, will be valid for a period of 3 years.

A certificate of conditional registration shall be valid for a period specified in the certificate and that period shall not exceed three (3) years.

**Article 20: Applicant's obligations**

The applicant shall ensure and keep objective evidence to establish that the medical device meets all safety and performance requirements.

**Article 21: Application for variation of a registered medical device including in vitro diagnostic**

Any variation to a registered medical device or in vitro diagnostic information shall be notified in writing to the Authority through an application in the approved format.

An application for variation shall be submitted as per the requirements set out in the relevant guidelines for variation of registered medical devices including in vitro diagnostics in force at the time of submission.

A distinction shall be made between major and minor variations in accordance with the relevant guidelines for variation of registered medical devices including in vitro diagnostics and there shall be a distinction in the payment of applicable fees.

**Article 22: Retention of Medical Devices including In Vitro Diagnostics on the register**

The registered medical device or in vitro diagnostic is retained on the register annually after fulfilling the requirements including payment of prescribed fees.

An application for retention on the register shall be submitted one (1) month before the due date.

The medical device or in vitro diagnostic shall be removed from the register if the application and payment of prescribed fees are not effected.

**Article 23: Application for renewal of the certificate of registration or notification**

Application for renewal of registration or notification shall be made to the Authority at least ninety (90) calendar days before its expiry.

A grace period for renewal shall extend to ninety (90) days after the specified expiry date.

Failure to renew the certificate of registration or notification within the grace period, the application shall be considered as new.

The application shall be in the prescribed format as per Rwanda FDA guidance for renewal of registration of medical devices including in vitro diagnostics.

**Article 24: Suspension of a registered Medical Device including In Vitro Diagnostic**

The Authority may suspend registered devices if it is satisfied that:

A registered device has been advertised in a manner which is false or misleading or does not comply with the provisions of the laws and regulations currently enforced by the Authority;

The marketing authorization holder has contravened these regulations or any other provision of the laws;

The marketing authorization holder made a false or misleading statement or misrepresentation in the application;

The marketing authorization holder has failed to comply with the terms and conditions of the registration as provided for in the certificate of registration or notification;

The marketing authorization holder has failed to pay the prescribed retention fees within the prescribed time;

The marketing authorization holder has failed to submit periodic post-marketing surveillance reports;

The marketingauthorization holder, intentionally and without justifiable reasons has failed to submit reports on adverse effects, and the renewal of registration has defaulted beyond the specified grace period.

**Article 25: Notice of suspension of a registered Medical Device including In Vitro Diagnostic**

Any suspension shall be effected upon a written notice thereof. the notice for suspension of registered devices shall:

Set out the reason for the proposed suspension, any corrective action required to be taken and the time within which it must be taken;

Require the marketing authorization holder to show reasons in writing along with evidence (if any) as to why the suspension should not be effected.

**Article 26: Cancellation or revocation of a certificate of registration or notification**

The Authority may cancel or revoke the marketing authorization of a registered medical device or in vitro diagnostic if:

a. It is not in the public interest that the registered device should be made or continue to be made available;
b. The device has been banned in Rwanda;
c. The device no longer meets the quality, safety and performance requirements; and
d. The marketing authorization has been suspended for a period of more than 12 months.

Under the provision of article 25 (a), a written notice of cancellation or revocation shall then be issued to the marketing authorization holder, stating the reasons for cancellation or revocation.

**Article 27: Suspension or cancellation of the certificate of registration or notification without notice**

The Authority may if deemed necessary suspend or cancel the certificate of registration or notification of a medical device or in vitro diagnostic without prior notice in case the medical device or in vitro diagnostic does not meet the safety, quality and performance.

The marketing authorization holder may apply to the Authority, in writing, requesting that the cancelation or suspension be uplifted. The Authority may, within thirty (30) days after the date of receiving the application review its decision.

**Article 28: Voluntary cancellation of the certificate of registration or notification**

The Authority may, upon request of the applicant of a medical device or in vitro diagnostic, cancel the certificate of registration or notification.

**Article 29: Restoration of a cancelled or suspended certificate of registration or notification**

Pursuant to the provision of articles 21, 22 and 23, the Authority may, upon satisfaction that the reasons of the suspension or cancellation of a registered device have been corrected or if such reasons for suspension or cancellation were unfounded, restore the certificate of registration or notification.

**Article 30: Refusal to issue a certificate of registration or notification**

The Authority may refuse to issue or amend a certificate of registration or notification if:

a. The applicant does not comply with these regulations or any provisions of the law relating to medical devices or in vitro diagnostics;
b. The applicant has made a false or misleading statement in the application;
c. The medical device or in vitro diagnostic does not comply with the labelling requirements set out in these regulations; and
d. The applicant has not complied with a request for additional information or samples by the day specified in the request.
e. The device does not meet the quality, safety and performance requirements, or if the information or samples provided with the application are insufficient to enable the Authority to determine if the device meets these requirements.

Where the Authority refuses to issue or amend a certificate of registration or notification, the Authority shall:

a. Notify the applicant in writing of the reasons for the refusal; and
b. Allow the applicant to show reasons in writing along with evidence, if any, on the decision of the Authority.

**Article 31: Label and labelling of Medical Devices or In Vitro Diagnostics**

All Medical Devices including In Vitro Diagnostics intended to be marketed in Rwanda shall be labelled in at least one of the official languages used in Rwanda. other detailed information for labelling will be determined by relevant guidelines.

**Article 32: Usage of a medical device**

A medical device shall not, when used for the medical conditions, purposes or uses for which it is manufactured, sold or represented, adversely affect the health or safety of a patient, user or another person.

A medical device shall be used as intended by the manufacturer and shall be effective for the medical conditions and purposes for which it is manufactured, sold or represented.

During the projected useful life of a medical device, its characteristics and performance shall not deteriorate under normal use to such a degree that the health or safety of a patient, user or other person is adversely affected.

The characteristics and performance of medical devices shall not be adversely affected by transport or conditions of storage, taking into account the manufacturer's instructions and information for transport and storage.

**Article 33: Donation of Medical Devices or In Vitro Diagnostics**

Medical Devices and In Vitro Diagnostics to be donated shall comply with the established relevant guidelines.

## CHAPTER III: RESTRICTION FOR SALE OF UNREGISTERED MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTIC

**Article 34: Prohibitions**

No person shall manufacture, prepare**,** store, export, sell, dispense, distribute or import Medical Devices or In Vitro Diagnostics Devices unless the person must hold the appropriate certificate of registration or notification issued by the Authority.

No person shall manufacture, prepare**,** store, export, sell, dispense, distribute or import an adulterated; counterfeit; or generally harmful medical device. Medical devices should be in accordance with the provisions of these regulations.

**Article 35: Exemptions from registration**

Notwithstanding the provision of article 29, these regulations shall not apply to devices intended to be used in research and development studies, without prejudice to the provisions of the regulations on clinical trials in force.

## CHAPTER IV: MISCELLANEOUS PROVISIONS

### Article 36: Advisory or scientific committee

The Authority shall appoint an advisory or scientific committee, including external experts, to assist the Authority in making decisions, particularly in cases when greater knowledge is required or when a public health emergency occurs.

### Article 37: Appeals

Any person aggrieved by a decision of the Authority may appeal to the Authority for review of the decision showing grounds for dissatisfaction within thirty (30) calendar days from the date of notice.

The Authority shall, within forty-five (45) calendar days from the date of receiving the application, review, reject or uphold its own decision according to applicable laws, and regulations.

The applicant shall not be barred from appealing to the minister/ board of directors without applying to the Authority for review. If a person is dissatisfied with the decision after review, he/she may appeal to the supervising Authority whose decision shall be final.

### Article 38: Regulatory tools

The Authority shall issue guidelines, SOPs, and forms necessary for the implementation of these regulations

### Article 39: Administrative faults and sanctions

A person who manufactures, sells, distributes, imports or exports an unapproved Medical Device including In Vitro Diagnostic commits an administrative fault. He/She shall be liable for administrative fines equivalent to double the value of condemned products plus tests related costs, when testing is compulsory.

### Article 40: Commencement and repealing

This regulation shall enter into force on the date of its signature and publication. All prior contrary provisions to these regulations are hereby repealed.

End of document