RWANDA FDA
Rwanda Food and Drugs Authority

REGULATION GOVERNING THE REGISTRATION OF MEDICAL DEVICES

(Rwanda FDA law N° 003/2018 of 09/02/2018, Article 9)

REGULATION DEVELOPMENT HISTORY

DRAFT ZERO BY COUNSULTANTS	14 August 2019
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STAKEHOLDERS CONSULTATION	18 February 2020
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Document Revision History

Date of revision	Revision number	Changes made and/or reasons for revision
08/06/2021	1	1. The Article on reliance is included 2. The article on authorization for emergency use included 3. The article on Donation of medicinal products included 4. Interline is changed from 1.5 to 1.15 as per SOP on internal document control.

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 Regulation N° CBD/TRG/012Rev_1 Governing the Registration of Medical Devices, made this 16th day of July, 2020.

Dr. Charles KARANGWA
Ag. Director General

ARRANGEMENT OF THE REGULATIONS

CHAPTER I: GENERAL PROVISIONS

Article 1: Purpose of these Regulations

The purpose of these Regulations is to enforce the legal framework to ensure effective and efficient registration of medical devices, and to provide an open, transparent and non-discriminatory process for the registration of medical devices

Article 2: Citation

These regulations may be cited as the *Rwanda FDA Regulations Governing the Registration of Medical Devices.*

Article 3: Application

These regulations shall apply to all regulated medical devices that are manufactured, imported, distributed, stored, sold and used in Rwanda

Article 4: Definitions

In these regulations, unless the context otherwise requires-

1. **"Authority"** means the Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established under Law No. 003/2018 of 09/02/2018.
2. "**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
3. **"Active medical device"** means a 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 patients, without any significant change, are not considered to be active medical devices. Stand-alone software is considered to be an active medical device.
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 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 Authorisation Holder".
6. **"Law"** means Law No. 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning.
7. **"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 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 notarised in country of origin. b

8. **"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;
9. **"Medical device group"** means 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 fulfil some or the entire device's intended functions and that is sold under a single name.
12. **Active implantable medical device:** Any active medical device, together with any accessories for its proper functioning, which is intended to be totally or partially introduced, surgically or medically, into the 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. "**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.
16. . "**Labeling**" 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.
    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). "

17. "**Manufacture**" means all operations that involve preparation, processing, filling transforming, packaging, and repackaging and labelling of medicinal products;
18. "**Manufacturer**" means a person or a firm that is engaged in the manufacture of medicinal products;
19. **"Medical device"** means any instrument, machine, appliance, material intended by the manufacturer to be used alone or in combination for the purpose of diagnosis, testing, vaccination, cure, surgery or for human or animal health protection;
20. **"In Vitro Diagnostic device (IVD)"** A medical device is an *in vitro* diagnostic medical device (IVD) if it is a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with other diagnostic goods for *in vitro* use. It must be intended by the manufacturer to be used *in vitro* for the examination of specimens derived from the human body, solely or principally for the purpose of giving information about a physiological or pathological state, a congenital abnormality or to determine safety and compatibility with a potential recipient, or to monitor therapeutic measures.
    The definition of an IVD does not encompass products that are intended for general laboratory use that are not manufactured, sold or presented for use specifically as an IVD.
21. **"Fee"** means the fee prescribed in Regulation CBD/TRG/004 related to regulatory services and charges.

CHAPTER II: REGISTRATION OF MEDICAL DEVICES

Article 5: Classification of medical devices

a. There are four (4) classes of medical devices as provided in the rules set out in Schedule 1 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

b. Where a medical device falls into more than one class, the class representing the higher class shall apply

Article 6: Application and requirements for registration of medical devices

a. All medical devices shall be registered with the authority before they are placed on Rwanda market. A person who intends to manufacture, import or export a single medical device, a medical device group, a medical device family, a medical device group family or a medical device system shall apply to the Authority for registration.
b. An application for registration of a medical device shall be made to the Authority in writing by the Marketing authorization holder, the manufacturer or local technical Representative
c. Application for registration of medical devices shall be made in hard or electronic copies as detailed in Rwanda FDA Guidelines for submission of documentation for registration of medical devices.

Article 7: Data requirements for registration of a medical device

All applications for registration of medical devices shall comply with the technical requirements as determined by the Authority in Rwanda FDA Guidelines for submission of documentation for registration of a medical device and shall be accompanied by data to demonstrate quality, safety and performance.

Article 8: Language

All applications and supporting documents shall be in **English.**

Article 9: Authenticity of documents

Any document submitted shall be authentic when approved by the applicant or by the authorized person.

The Authority shall reject an application for registration of a medical device if it is satisfied that the submitted documents are not authentic or integrity of data is questionable.

Article 10: Safe custody and confidentiality of information

a. The Authority shall ensure safe custody of information related to the registration of medical devices submitted by applicants.
b. All information submitted shall be treated confidential and shall not be disclosed to any third party without a written consent of the applicant.

Article 11: Assessment process of medical devices

a. The Authority shall, upon being satisfied by the application, conduct an assessment to verify the compliance with safety, quality and performance requirements through full or abridged assessment procedures. The authority shall set out guidelines, SOPs, forms, and tools for full and abridged assessment procedures.
b. The Authority may, during the assessment of the product, require the applicant to submit additional samples, documents, information, data or clarification to support the application for registration.
c. Where the Authority requires additional samples, documents, information, and data and or clarification pursuant to Article 11 b, the processing of the application shall not proceed until when the applicant makes submission.
d. Where the applicant fails to submit requested information according to Article 11 b, within the period of ninety (**90**) days from the date of request letter, the application shall be considered **withdrawn**.
e. Pursuant to the requirements of Article 11 d, the applicant may by giving reasons in writing request for extension of time for submission of additional samples, documents, information, data and or clarification requested by the Authority.
f. If the applicant fails to provide satisfactory responses to the requested information according to Article 11 b for a fourth time, the application shall be rejected.
g. An application withdrawn pursuant to article 11 d shall only be considered for registration upon submission of a new application as per the requirements of these Regulations

Article 12: Good Manufacturing Practice and Good Clinical Practice

During the assessment of medical devices, the Authority shall as it may deem necessary conduct on-site inspection and causal inspection of the non-clinical studies, clinical trials, bio-studies and production site inspection to confirm the authenticity, precision and integrity of information and data submitted.

Article 13: Registration of medical devices

The authority shall issue a certificate of registration of medical devices only if:

1. The medical device dossier is assessed and fulfil requirements of Safety, quality and performance

2. The manufacturing site of the medical device is compliant to the Good Manufacturing Practices
3. Medical devices fulfil the requirements of laboratory quality tests

Article 14: Conditional registration of medical devices

Approval issued for conditional registration shall specify the conditions which need to be fulfilled by marketing authorization holder to acquire full registration.

Article 15: Authorization for Emergency Use

The Authority may issue the Authorization for emergency use only if:

1. The medicinal product dossier is assessed and fulfils requirements of quality, safety, and efficacy
2. The manufacturing site of the medicinal product is compliant to the Good Manufacturing Practices
3. Medicinal product fulfils the requirements of laboratory quality tests

Article 16: Reliance

The Authority may rely on regulatory decisions from regional, international and other Stringent Regulatory Authorities decisions in regard to product market authorization when it deems necessary.

Article 17: Approval of medical devices

Upon approval of registration of medical devices, the Authority shall:

a) Enter in the register the prescribed particulars of the medical device;
b) Allocate a registration number to the medical device;
c) Issue to the marketing authorization holder a certificate of full or conditional registration as per prescribed format.

Article 18: Publication of a registered medical device

The Authority shall publish a list of registered medical devices on the authority's website specifying:

a. The name and group or family, and the make and model, where applicable of the medical device;
b. The registration number allocated to the medical device on registration;
c. In the case of a combination device, the name and quantity of the scheduled substances or biological substances in the medical device;
d. The intended purpose or use of the medical device;

e. The name and the country of the marketing authorization holder of the certificate of registration;
f. The name and country of the original manufacturer;
g. The date of registration of the medical device;
h. The class of the medical device; and
i. The nomenclature system code allocated to the medical device.
j. Local Technical Representative (LTR)
k. Expiry date of the registration certificate

Article 19: Validity of registration

a. A certificate of full registration issued under Article 15 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.
b. Notwithstanding the provision in Article 17 a, 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: Application for variation of a registered medical device

a. Any variation to registered medical devices information shall be notified in writing to the Authority through an application in the approved format.
b. An application for variation shall be submitted as per the requirements set out in the relevant *Guidelines for submission of documentation for Variation to a Registered medical device* in force at the time of submission.
c. A distinction shall be made between major and minor variations in accordance with the relevant *Guidelines for submission of documentation for Variation to a Registered medical device* and there shall be a distinction in the payment of applicable fees.

Article 21: Retention of medical devices on the register

a. The registered medical device is retained on the register annually after payment of fees.
b. Application for retention on the register shall be submitted one (1) month before the due date.
c. The medical device shall be removed from the register if application and payment of fees is not effected as stated in article 19 a and 19 b.

Article 22: Application for renewal of registration certificate

a. Application for renewal of registration shall be made to the Authority at least ninety (**90**) calendar days before its expiry.
b. A grace period for renewal shall extend to ninety (**90**) days after the specified expiry date.
c. Failure of renewal within the grace period, the application shall be considered as **new**.
d. The application shall be in the prescribed format as per Rwanda FDA *Guidance for renewal of registration of medical devices.*

Article 23: Suspension of a registered medical device

The Authority may suspend a registered medical device if it is satisfied that:

a) A registered medical device has been advertised in manner which is false or misleading or does not comply with the provisions of the Laws and Regulations currently enforced by the Authority;
b) The marketing authorization holder has contravened these Regulations or any other provision of the Laws;
c) The marketing authorisation holder made a false or misleading statement or misrepresentation in the application;
d) The marketing authorisation holder has failed to comply with the terms and conditions of the registration as provided in certificate of registration;
e) The marketing authorisation holder has failed to pay the prescribed retention fees within the prescribed time;
f) The marketing authorisation holder has failed to submit periodic post-marketing surveillance reports;
g) The marketing authorisation holder, intentionally and without justifiable reasons has failed to submit reports on adverse effects; and
h) Renewal of registration has been defaulted beyond the specified grace period.
i) On the basis of information obtained after the medical device was registered, the Quality Management System and Good Manufacturing Practices under which the medical device has been designed in the case of Class C and D medical devices, or manufactured, assembled, processed, packaged, refurbished or modified in the case of Class B, C or D medical devices, is inadequate to ensure that the medical device meets its specifications.

Article 24: Notice of suspension

Any suspension shall be effected upon a written notice thereof.

The notice for suspension of a registered medical device shall:

a) Set out the reason for the proposed suspension, any corrective action required to be taken and the time within which it must be taken;
b) Require the marketing authorisation holder to show reasons as to why the suspension should not be effected.

Article 25: Suspension or cancellation of registration without notice

a) The Authority may cancel or suspend the registration of a medical device without prior notice if it is necessary to do so in order to prevent injury to the health or safety of patients, users or other persons.
b) The marketing authorization holder may apply to the Authority, in writing, requesting that the cancelation or suspension be uplifted.

c) The Authority may, within thirty (**30**) days after the date of receiving the application review its decision.

Article 26: Voluntary cancellation of registration

The Authority may, upon request made to it and upon the application made by the applicant of a medical device, cancel the registration of the medical device.

Article 27: Restoration of a cancelled or suspended registered medical device

Pursuant to the provision of Articles 21, 22 and 23, the Authority may, upon satisfaction that the reasons of the suspension or cancellation of the registered medical device has been corrected or if such reason for suspension or cancelation was unfounded, reinstate the registered medical device.

Article 28: Refusal to issue Registration Certificate

a. The Authority may refuse to issue or amend a medical device registration if-
   1. The applicant does not comply with these Regulations or any provisions of the Law relating to medical devices;
   2. The applicant has made a false or misleading statement in the application;
   3. The medical device does not comply with the labelling requirements set out in these Regulations; and
   4. The applicant has not complied with a request for additional information or samples made pursuant to these Regulations by the day specified in the request.

b. The Authority may refuse to issue or amend a medical device registration certificate if the medical device does not meet the safety and performance requirements, or if the information or samples provided with the application are insufficient to enable the Authority to determine if the medical device meets these requirements.

c. Where the Authority refuses to issue or amend a medical device registration certificate, the Authority shall
   1. Notify the applicant in writing of the reasons for the refusal; and
   2. Give the applicant an opportunity to give representations on the Authority's decision.

Article 29: Cancellation or revocation of marketing authorisation

a. The Authority may cancel or revoke the marketing authorization of a registered medical device if:
   1. It is not in the public interest that the registered medical device should be made or continue to be made available;
   2. The medical device has been banned in Rwanda;
   3. The medical device no longer meets the quality, safety and performance requirements; and
   4. The marketing authorisation has been suspended for a period of more than 12 months.

b. Pursuant to the provision of Article 27 a, a written notice of cancellation shall then be issued to the marketing authorisation holder, stating the reasons for cancellation.

Article 30: Label and Labelling

a. All medical devices intended to be marketed in Rwanda shall be labelled in at least one of the official languages used in Rwanda according to the relevant Guidelines.

b. The accompanying information shall be provided in the labeling (refer to the relevant guidelines

Article 31: Donation of medicinal products

Medicinal products to be donated shall comply to the relevant established Guidelines for donation of medical products.

CHAPTER III: RESTRICTION FOR SALE OF UNREGISTERED MEDICAL DEVICE

Article 32: Prohibitions

No person shall manufacture, prepare, store, export, sell, dispense, distribute or import medical devices by either manufacturer, wholesale or retail unless it is in accordance with the provisions of these Regulations, and that person holds the appropriate registration certificate issued by the Authority.

Article 33: Exemptions

Notwithstanding the provision of Article 29, these Regulations shall not apply to:

a. A medical device in Class A may be exempted from registration due to the low risk associated with their use as provided in the Classification Rules for Medical Devices (refer to the Guidelines for the summary of technical documentation (STED) for medical devices).
b. Where the proposed intended purpose of a medical device is different from that specified then the medical device shall require registration
c. Medical devices intended to be used in research and development studies, without prejudice to the provisions of the Regulations on clinical trials in force;
d. The authority may issue an expression of interests where the product is or are intended for treatment of rare diseases

CHAPTER IV: MISCELLENIOUS PROVISIONS

Article 34: Appeals and review

a. Any person aggrieved by a decision of the Authority may apply to the Authority for review of the decision showing grounds for dissatisfaction within thirty (**30**) days from the date of notice.
b. The Authority shall, within fifteen (**15**) days from the date of receiving the application, review, reject or vary its own decision.
c. Notwithstanding the provision of Article 31a, the applicant shall not be barred from appealing to the Minister without applying to the Authority for review.
d. If a person is dissatisfied with the decision after review, he may appeal to the Minister whose decision shall be final.

Article 35: Power to issue guidelines

The authority shall issue guidelines, SOPs, forms necessary for the implementation of these Regulations

Article 36: Offences and penalties

A person contravening a provision of these regulations commits an offence and shall be liable to any of the penalties as stipulated in the regulations related to regulatory service tariff/ fees and fines in force at the time of application issued by the Authority.

Article 37: Commencement and repealing

a. These regulations shall enter into force on date of their signature and publication.
b. All prior contrary provisions to these regulations are hereby repealed.

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