



LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)

P. O. Box 1994

Monrovia, Liberia

Cell: +231 – 777140555/888140555

Email: info@lmhra.gov.lr Website: www.lmhra.gov.lr

REGULATIONS ON MEDICAL DEVICES REGISTRATION



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DECLARATION

This Regulation, made in fulfillment of the Liberia Medicines and Health Products Regulatory Authority Act of 2010, confers upon the Authority the responsibility of regulating medicines and health products within the Republic of Liberia. The Management, with approval of the Board of Directors, hereby promulgates this regulation designed for Medical Devices this **20th** day of **April**, 2023.

ACRONYMS

CAB	Conformity Assessment Body
GHTF	Global Harmonization Taskforce
GMP	Good Manufacturing Practice
IVD	In vitro Diagnostic Devices
LMHRA	Liberia Medicines & Health Products Regulatory Authority
POCT	Point-of-Care Testing
RA	Regulatory Authority

CHAPTER I PRELIMINARY

Section 1. Title

This Regulation shall be cited as the Regulation on Medical Devices

Section 2: Application and Scope

This regulation shall apply to the Medical Devices that are manufactured, imported, distributed, stored, sold, and used in Liberia.

Section 3: Purpose

The purpose of this regulation is to provide a legal framework for the effective and efficient handling of Medical Devices.

Section 4. Definitions

In this Regulation, unless the context otherwise requires, the following words and phrases shall have the meanings as ascribed to them in this section.

Abridged Assessment

Abridged Assessment is an assessment that includes performance evaluation, manufacturing site inspection of abridged scope, and labeling review;

Act

Act means the Liberia Medicines and Health Products Regulatory Authority Act of 2010

Accessory

An article that is intended specifically by its manufacturer to be used together with a parent device to enable that device to be used per its intended use as an In vitro Diagnostic Devices (IVD) to augment or extend the capabilities of the parent device in fulfillment of its intended use as an IVD, and therefore should be considered an IVD.

An Applicant”

An Applicant means a person or entity who applies for product registration to the Authority and responsible for all the product information

Analytical performance

The ability of an IVD to detect or measure a particular analyte

Assay

Investigative (analytic) procedure in the laboratory for qualitatively assessing or quantitatively measuring the presence, amount, or functional activity of a target entity (the analyte)

Authority

Authority means the Liberia Medicines and Health Products Regulatory Authority

Calibrator

Any substance, material, or article intended by its manufacturer/ owner to be used in the calibration of a measuring instrument or measuring system.

Certified Copy

A true copy of the original document certified by a person registered to practice law in the manufacturer’s country of origin and endorsed with the legal practitioner’s official stamp and signature.

Clinical Performance

The ability of an IVD to yield results that are correlated with a particular clinical condition/ physiological state per target population and intended use

Conformity Assessment

The systematic examination of evidence generated, and procedures undertaken by the manufacturer, under requirements established by the Authority, to determine that an IVD is safe and performs as intended by the manufacturer and, therefore, conforms to the Essential Principles of Safety and Performance of In vitro Medical Devices.

Conformity Assessment Body

A body engaged in the performance of procedures for determining whether the relevant requirements in technical regulations or standards are fulfilled. A Conformity Assessment Body (CAB) is authorized to undertake specified conformity assessment activities by a Regulatory Authority (RA) that will ensure the performance of the CAB is monitored and, if necessary, withdraw the designation.

Preliminary Dossier Review

A systematic process to ensure that all required sections of the product dossier are submitted.

Dossier Evaluation/Assessment

Review and assessment of documentation including data, protocols, reports, procedures, etc., to support the quality, safety, and performance of a product and labeling for LMHRA registration

High Dose Hook Effect

Wrong low measurement of analyte (s) that is present in the specimen in a very high concentration

Intended use

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

Inspection of manufacturing site(s)

Means a check on a pharmaceutical manufacturing facilities either to enforce Good Manufacturing Practice (GMP) compliance or to provide authorization to manufacture specific pharmaceutical products, usually in relation to an application for marketing authorization.

In vitro diagnostic medical device (IVD)

A medical 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

Note: IVDs 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.

Label

Any written, printed, or graphic representation that appears on or is attached to the IVD or active ingredient or any part of its packaging and includes any informational sheet or leaflet that accompanies the in vitro diagnostics or active ingredient when it is being supplied

Labeling review

Review and assessment of the instructions for use and label on the product

Local Agent

A local agent is a natural person residing in Liberia or a corporate body registered in Liberia who has received a mandate from the applicant to act on behalf applicant concerning matters on registration in Liberia.

Manufacturer

Any natural or legal person with responsibility for the design and/or manufacture of a medical device to make the medical device available for use, under its name; whether or not such a medical device is designed and/or manufactured by that manufacturer itself or on behalf of the manufacturer by another person(s)

Medical Device(s)

Any instrument, apparatus, laboratory equipment and reagents, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material, or another similar or related article which: is intended by the manufacturer to be used, alone or in combination for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment, or alleviation of diseases 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 for medical or diagnostic purposes using in vitro examination or specimens derived from human body. However, this does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but may be assisted in its intended function by such means.

Near Patient Testing

Any testing performed outside the laboratory environment by qualified personnel, generally near to or at the side of the patient, also known as Point-of-Care Testing (POCT)

Objective Evidence

Information that can be proved true, based on facts obtained through observation, measurement, testing, or other means

Performance Evaluation

Assessment and analysis of data to establish or verify the performance (analytical performance and where applicable, clinical performance) of an IVD

Process Validation

Confirmation by objective evidence that a process consistently produces a result or product meeting its pre-determined requirements

Risk assessment

The overall process comprises a risk analysis and a risk evaluation

Quality Audit

The process of systematic examination of a quality system of IVDs manufacturing facilities carried out by the Authority to demonstrate conformity for regulatory purposes

Quality Management System

The collection of business processes aims to direct and control an organization concerning quality, from establishing quality policy, and quality objectives and implementing and maintaining a quality system

Reagent

Any chemical, biological, or immunological component, solution, or preparation intended by the manufacturer to be used as IVD

Re-brander

A manufacturer of a rebranded IVD

Rebranded product

A rebranded product is identical in every respect to the product manufactured by the original manufacturer, except that the product is labeled with the “rebranded” product name and product code, and bears the re-branders name

Recall

Any action taken by its manufacturer, importer, supplier, or the Authority to remove the medical device from the market or to retrieve the medical device from any person to whom it has been supplied, because the medical device may: be hazardous to health; fail to conform to any claim made by its manufacturer or importer relating to its quality, safety or performance

Regulatory version

Relates to the information associated with a submission for approval by a regulatory authority. The submitted version is defined by all of the documentation related to the development, manufacture, and intended use, labeling, and post-market surveillance of the product and all the documented evidence supporting the safety and performance claims associated with that submission. If any aspect of this documentation differs in any way between the submissions to different regulatory authorities or assessment bodies (United States Food and Drug Administration, Health Canada, a Notified Body for CE marking, etc.) it is considered to be a different regulatory version

Recognized Standards

National or international standards deemed to offer the presumption of conformity to specific Essential Principles of Safety and Performance

Market Authorization Holder

The person who applied for and obtained market authorization or registration of the medical devices including IVD

Risk

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

Specimen receptacles

Devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for IVD examination

Technical Documentation

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 IVD

Validation

Confirmation by examination and provision of objective evidence that the requirements for a specific intended use have been fulfilled

Verification

Confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled.

CHAPTER II REQUIREMENTS FOR MEDICAL DEVICES REGISTRATION

Section 1 GUIDING PRINCIPLES FOR MEDICAL DEVICES

Regulation of medical devices including in vitro diagnostics in Liberia is in its infancy compared to other developing countries. As the capacity to regulate medical devices including in vitro diagnostics in Liberia grows, the process will be guided by three main principles:

- The WHO Global Framework Model Regulation of medical devices including diagnostics is based on the Global Harmonization Taskforce (GHTF/IMDRFT) principles.
- Harmonized requirements for submission, assessment, and registration of medical devices including diagnostics
- Risk-based joint assessment, recognition, and reliance outside Liberia may be implemented to accelerate registration and reduce duplication.

Section 2 Classification of IVDs

Risk classification during the assessment of IVD in Liberia will be based on GHTF recommendations based on the following criteria:

- The intended use and indications for use as specified by the manufacturer (specific disorder, condition, or risk factor for which the test is intended),
- The technical/scientific/medical expertise of the intended user (layperson or professional),
- The importance of the information to the diagnosis (sole determinant or one of several), taking into consideration the natural history of the disease or disorder including presenting signs and symptoms which may guide a physician,
- The impact of the result (true or false) on the individual and/or public health.

Therefore, applicants aiming to submit the IVD for assessment in Liberia shall classify IVD into four (4) risk classes A, B, C, or D using classification rules appended as **Annex I** of these requirements. If more than one classification rule applies to the device, the rules resulting in the highest risk classification shall apply to the device. However, the LMHRA reserves the right to decide on the class of the device. Examples of IVD are shown in Table 1.

Table 1: Examples of IVDs in different risk classes

CLASS	RISK LEVEL	EXAMPLES
A	Low Individual Risk and Low Public Health Risk	Specimen receptacles, Selective/differential microbiological media, identification kits for cultured microorganisms, wash solutions, instruments, and plain urine cups.
B	Moderate Individual Risk and/or Low Public Health Risk	Vitamin B12 level test, Pregnancy Self -Testing, Anti-Nuclear Antibody, and Urine Test Strips.
C	High Individual Risk and/or Moderate Public Health Risk	Blood Glucose Test, Human Leukocyte Antigen (HLA) Test, Prostate Specific Antigen (PSA) Screening, and Rubella Antibodies Test.
D	High Individual Risk and High Public Health Risk	Screening and confirmatory tests for HIV, HIV NAT assays, Hepatitis B, Hepatitis C, Malaria, CD4 technologies

Table 2 summarizes the conformity assessment approaches of the different risk classes which will be implemented by Liberia

Table 2 Conformity assessment processes as determined by device class

Conformity assessment element	Class A	Class B	Class C	Class D
Quality management system (QMS)	Regulatory audits are normally not required, except where assurance of sterility or accuracy of the measuring function is required.	The regulatory authority should have confidence that a current and appropriate QMS is in place or otherwise conduct a QMS audit before marketing authorization.	The regulatory authority should have confidence that a current and appropriate QMS is in place or otherwise conduct a QMS audit before marketing authorization.	The regulatory authority should have confidence that a current and appropriate QMS is in place or otherwise conduct a QMS audit before marketing authorization.
Technical documentation	Premarket submission is normally not requested.	Not normally reviewed premarket. The regulatory authority may request and conduct a premarket or post-marketing review sufficient to determine conformity with	The regulatory authority will undertake a review sufficient to determine conformity with Essential Principles before the device is	The regulatory authority will undertake an in-depth review to determine conformity with Essential Principles before the device is placed on the market.
Declaration of conformity	Submission is normally not requested.	Review and verify compliance with requirements by the regulatory authority (see footnote to Table A4.1).	Review and verify compliance with requirements by the regulatory authority (see footnote to Table A4.1).	Review and verify compliance with requirements by the regulatory authority (see footnote to Table A4.1).

Section 3 Responsibilities

3.1 Applicant

3.1.1 Application for registration of an IVD can be made by the manufacturer of the device or their representatives or by a person who orders the IVD to be manufactured for sale in Liberia. The applicant shall be responsible for:

- quality and safety of the product,
- information supplied in support of the application for registration
- variations that may occur
- nomination of a local representative
- submission of a formal agreement or any other official authorization by an applicant as official proof of nomination of a Local Representative

3.1.2 An applicant who is not a resident of Liberia shall nominate a Local Representative. A certified copy of the power of attorney, formal agreement, or any other official authorization shall be submitted by an applicant as official proof of nomination of a local representative.

3.2 Local representative

3.2.1 The Local Representative shall:

- Monitor the device on the market and inform the Authority immediately after detection of any problem relating to a registered device such as serious manufacturing defects which may endanger public health;
- Facilitate communication between the Applicant and the Authority on matters relating to the product;
- Handle device recalls implementation.
- Provide technical support and service maintenance of registered device(s);
- Collect and submit PMS data on behalf of the manufacturer.

Section 4 Registration of Medical Devices

Section 4.1 Restriction for sale of unregistered medical devices

A person shall not sell, manufacture, import or export, distribute, provide as a grant or gift, or offer for sale any medical device unless it is registered by the Authority.

Section 4.2 Application and requirements for registration of medical devices

- 4.2.1 An application for registration of medical devices shall be required for every single medical device or a medical device group or medical device family or medical device system.
- 4.2.2 Every application shall be accompanied by the following:
- a) a non-refundable application fee as set out in fees Regulations in force at the time of application; and
 - b) sample or samples of the medical device and, or artwork as the case may be at the time of application.
- 4.2.3 The application referred to in sub-regulation (4.2.2) shall contain the following information:
- a) the name of the medical devices;
 - b) the class of medical devices;
 - c) the identification of the medical device, including the identification of any medical device that is part of a system, test kit, medical device group, medical device family, or medical device group family; and
 - d) the name and address of the applicant or the applicant and the manufacturer in case the two are different.

Section 4.3 Submission of an application form for registration

- 4.3.1 An application for registration of a medical device shall be submitted to the Authority by the applicant or a local agent appointed on its behalf.
- 4.3.2 The Authority shall issue a format of the application form per the guidelines in force.
- 4.3.3 The applicant shall be responsible for the product, the information supplied in support of the application for registration, and variations thereof.
- 4.3.4 An applicant who is not a resident of Liberia shall appoint a local agent.
- 4.3.5 An original certificate of power of attorney, a certified copy of a formal agreement, or any other official authorization shall be submitted by an applicant as proof of appointment of a local agent.

Section 4.4 Obligation of the Local Agent

4.4.1 The local agent shall:

- a) Monitor the medical devices on the market and inform the Authority immediately after the detection of any problem relating to a registered medical device that may endanger public health;
- b) Facilitate communication between the applicant and the Authority on matters relating to the Medical devices;
- c) Handle medical device recalls; and
- d) Provide technical support and services to users of registered medical device(s).

Section 4.5 Application for registration of Class A non-exempted medical devices

4.5.1 An application for registration of Class A non-exempted medical device shall contain the following-

- a) copies of the label of the medical device for both primary and secondary components of a medical device system, members of a medical device family, and accessories submitted for registration;
- b) the instructions for use;
- c) the patient information leaflet where applicable;
- d) for sterile medical devices: the sterilization validation report;
- e) for medical devices with measuring function: certification on medical devices metrology or equivalent;
- f) for active medical devices, certification to electrical safety standards;
- g) any other information as may be required by the Authority.

Section 4.6 Registration of Class B, C, and D medical devices

4.7.1 An application for registration of Class B, C and D medical devices shall contain, in addition to the information and documents set out in Section 4.7 of these Regulations, the following:

- a. a description of the medical devices and the materials used in their manufacture and packaging;

- b. a description of the features of the medical devices that permit them to be used for the medical conditions, purposes, and uses for which it is manufactured, sold, or represented;
- c. a list of the countries other than the country of origin where the device has been sold and a summary of any reported problems with the medical device and any recalls of the medical device in those countries; if applicable.
- d. a risk assessment comprising analysis and evaluation of the risks, and the risk reduction measures adopted to satisfy the safety and effectiveness requirements as provided in ISO 14971;
- e. a quality plan setting out the specific quality practices, resources, and sequence of activities relevant to the medical device;
- f. the specifications of the materials used in the manufacture and packaging of the medical devices;
- g. the manufacturing process of medical devices;
- h. a list of the standards complied with in the design and manufacture of the medical devices to satisfy the safety and performance requirements;
- i. a detailed summary of information of all studies which the manufacturer relies on to ensure that the medical device meets the safety and performance requirements, including-
 - 1) pre-clinical and clinical studies,
 - 2) process validation studies,
 - 3) if appropriate, software validation studies, and
 - 4) literature reviews;
- j. in the case of a medical device other than an in vitro diagnostic device, manufactured from or incorporating human tissue or their derivative, objective evidence of the biological safety of the medical devices;
- k. in the case of a near patient in vitro diagnostic medical devices, detailed information on investigational testing conducted on the device using human participants representative of the intended users and under conditions similar to the conditions of use;
- l. a bibliography of all published reports dealing with the use, safety, and effectiveness of medical devices;
- m. a copy of the medical devices label; and

- n. a copy of the quality management system certificate as a stipulation certifying that the quality management system under which the medical device is designed and manufactured satisfies the requirements stipulated in the guideline in force at the time of application.

Section 4.7 Additional Information and Samples

- 4.7.1 When the information and documents submitted in respect of an application for registration of a medical device or variation of a medical device registration are insufficient to enable the Authority to determine whether a medical device meets the safety and performance requirements, the Authority may request the applicant to submit, on or before a specified day, additional information necessary for making the determination.
- 4.7.2 In the course of examining the application, the Authority may require the applicant to provide additional information or samples of the medical devices.

Section 4.8 Exemption from registration

- 4.8.1 A medical device in Class A, may be exempted from registration due to the low risk associated with their use as provided for in the Classification Rules for Medical devices in the First Schedule and their specific intended purpose as prescribed in the third column of the Second Schedule to these Regulations;
- 4.8.2 Where the proposed intended purpose of a medical device is different from that specified in the Second Schedule, then the medical device shall require registration.

Section 4.9 Issuance of registration certificate

- 4.9.1 When the Authority determines that a medical device in respect of which an application is submitted meets the safety and performance requirements, the Authority shall:
 - a) issue to the applicant of the medical device a medical device registration certificate, or
 - b) amend the registration certificate of a medical device, in the case of an application amendment of the registration.
- 4.9.2 The Authority may set out in the registration certificate of a medical device terms and conditions with respect to-

- a) the tests to be performed on a medical device to ensure that it continues to meet the safety and performance requirements; and
- b) the requirement to submit the results and protocols of any tests performed.

4.9.3 The Authority may amend the terms and conditions of the registration certificate of medical devices to take into account any new development concerning the medical device.

Section 4.10 Refusal of Issuance of Registration

4.10.1 The Authority may refuse to issue or amend a medical device registration if-

- a) the applicant does not comply with these Regulations or any provisions of the Act relating to medical devices;
- b) the applicant has made a false or misleading statement in the application;
- c) the medical device does not comply with the labeling requirements set out in these Regulations; and
- d) the applicant has not complied with a request for additional information or samples made according to these Regulations by the day specified in the request.

4.10.2 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 according to these Regulations are insufficient to enable the Authority to determine whether the medical device meets those requirements.

4.10.3 When the Authority refuses to issue or amend a medical device registration certificate, the Authority shall:

- a) notify the applicant in writing of the reasons for the refusal; and
- b) allow the applicant to be heard by the Authority.

Section 4.11 Additional information after registration

4.11.1 When the Authority believes on reasonable grounds, after reviewing a report or information brought to the Authority's attention, that a registered medical device may not meet the safety and performance requirements, the Authority may request the manufacturer to submit information or samples to enable the Authority to determine whether the Medical device meets the requirements.

4.11.2 The manufacturer shall, upon receipt of the request made under sub-regulation (4.11.1), and within the time specified in the request, submit to the Authority information or samples requested.

Section 4.13 Validity of Registration, Retention, and Renewal

4.13.1 Under subsection **4.14.1(a)**, unless earlier suspended or revoked, the medical device shall be subjected to payment of prescribed annual retention fees which shall be valid for three years from the date of issuance and may thereafter be renewed.

4.13.2 Every applicant shall, in addition to the fees related to registration of each medical device, pay an annual maintenance fee.

4.13.3 The applicant shall be required to submit biennial post-market surveillance reports including any adverse events.

4.13.4 Application for renewal of registration shall be made to the Authority at least 90 days before its expiry.

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

4.13.6 Defaulters shall pay a penalty as stipulated in the fees Regulations in force after the expiry of a grace period.

Section 4.14 Suspension or cancellation of registration

4.14.1 Notwithstanding the provision of regulation 17, the Authority may suspend or cancel the registration of a medical device if the Authority has reasonable grounds to believe that-

- a) the registration has contravened these Regulations or any provision of the Act relating to medical devices;
- b) the applicant has made a false or misleading statement in the application;
- c) the applicant has failed to comply with the terms and conditions of the registration;
- d) the applicant has not complied with a request for information or samples made according to Regulation 16 of these regulations by the day specified in the request, or the information or samples provided are insufficient to enable the Authority to determine whether the medical devices meet the safety and effectiveness requirements;
- e) the medical devices no longer meet the safety and effectiveness requirements;

- f) based on information obtained after the Medical device was registered, the Quality Management System and Good Manufacturing Practices under which the medical devices have 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;
- g) the applicant of the medical devices fails to pay the prescribed maintenance fee which is in force within the prescribed time;
- h) the applicant has failed to submit biannual post-market surveillance as provided under these Regulations;
- i) The applicant, intentionally and without justifiable cause, fails to submit reports on adverse effects.

Section 4.15 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 devices.

Section 4.16 Notice of suspension or cancellation

4.16.1 The Authority shall not suspend or cancel the registration of medical devices until:

- (a) the Authority has sent the applicant a written notice that sets out the reason for the proposed suspension, any corrective action required to be taken, and the time within which it must be taken;
- (b) the time set out in the notice for corrective action, if required, has passed without the action been taken; and
- (c) the applicant has been allowed to be heard in respect of the suspension.

Section 4.17 Application for variation of registered product

4.17.1 The Applicant for any variation to a registered medical device shall notify the Authority by filling in the application form as set out in **Third Schedule** to these regulations.

4.17.2 Application for variation shall be submitted as per the requirements set out in the regulation for Variation of Registered medical devices in force at the time of submission.

4.17.3 Any payment for variation shall be made per the fees of the regulations in force.

Section 4.18 Manufacture of Medical Devices

Section 4.18.1 Manufacture, Sale, and Supply of Medical Device

4.18.1.1 No person shall manufacture for sale, import, or supply any medical device unless-

- a) the medical device is registered;
- b) he/she holds a valid premises license and importer's license issued by the Authority; and
- c) the manufacture, sale, and supply of any medical device is carried out per the conditions of the licences issued.

Section 4.18.2 Prohibition of manufacture, importation, sale, and supply of certain medical devices

4.18.2.1 No person shall manufacture, import, sell, supply or procure or arrange for the manufacture of, any medical device which is:

- a) an adulterated medical device;
- b) a counterfeit medical device; or
- c) an unwholesome medical device

CHAPTER III: FEES FOR MEDICAL DEVICE REGISTRATION

The fee for medical device registration shall be as prescribed in the Medical Device Guidelines.

1. The applicant shall pay the amount of Three Hundred and Fifty United States Dollars (**US\$300.00**) for registration of a medical device;
2. The applicant shall also pay an annual retention fee in the amount of Fifty United States Dollars (US\$50.00)
3. Fees paid to the Authority for Registration of Medical Devices shall not be refundable to the applicant.

CHAPTER IV: OFFENCES AND PENALTIES

In keeping with Part VIII, Sections 1, 2 & 3 of the Authority Act of 2010, the following measures shall apply:

This Regulation shall take effect immediately upon the approval of the Board of Directors.

A Regulation on Medical Devices Registration is Hereby Promulgated and Submitted for Approval to the Board of Directors on this 20th Day of April A. D. 2023 by the Managing Director of the Authority.



*Dr. Keturah C. Smith-Chineh
Managing Director / LMHRA*

A Regulation on Medical Devices Registration is Hereby Approved by the Board of Directors.

Approved This 20th Day of April A. D. 2023

A handwritten signature in black ink, appearing to read 'L. Bawa', written over a horizontal line.

**Pharm. Luke Bawa
Chairman / Board of Directors/LMHRA**