MEDICINES AND RELATED SUBSTANCES ACT, 2025

MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS (IVDS) REGULATIONS, 2026

(Published on _____, 2026)

ARRANGEMENT OF REGULATIONS

SCHEDULES

Schedule 1 — Classification Rules for Medical Devices

Schedule 2 — Classification Rules for In Vitro Diagnostic Medical Devices

Schedule 3 — Essential Principles of Safety and Performance

Schedule 4 — Unique Device Identification Implementation Timeline

IN EXERCISE of the powers conferred on the Minister of Health by sections 80, 81, 82 and 123 of the Medicines and Related Substances Act, 2025, the following Regulations are hereby made—

PART I — PRELIMINARY

Citation and commencement

1. (1) These Regulations may be cited as the Medical Devices including In Vitro Diagnostics (IVDs) Regulations, 2026.

(2) These Regulations shall come into operation on such date as the Minister may, by Order published in the Gazette, appoint.

(3) Different dates may be appointed for different provisions of these Regulations.

(4) For the purposes of these Regulations, the term "medical device" shall, unless the context otherwise requires, be inclusive of in vitro diagnostic medical devices.

Interpretation

2. In these Regulations, unless the context otherwise requires—

"abridged regulatory pathway" means the regulatory procedures facilitated by reliance, whereby a regulatory decision is solely or partially based on application of reliance. This usually involves some work by the regulatory authority that is practicing reliance.

"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 that device to be used in accordance with its intended use.

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

"Act" means the Medicines and Related Substances Act, 2025;

"active implantable medical device" means an active medical device intended to be totally or partially introduced into the human body and to remain there after the procedure;

"active medical device" means a Any medical device, operation of 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. Standalone software is considered to be an active medical device.

“active therapeutic device” means any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.

“active device intended for diagnosis” means any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or to support in treating physiological conditions, states of health, illnesses or congenital deformities.

“adverse event” means an event associated with a medical device that led to death or serious injury of a patient, user or other person, or that might lead to death or serious injury of a patient, user or other person if the event recurs.

“advertisement” means are used interchangeably and include any representation

by any means whatever for the purpose of promoting directly or indirectly the sale or

disposal of any medicinal product. It encompasses written or spoken words and refers to all informational and persuasive activities by stakeholders, the effect of which is intended to induce and encourage the prescription or supply, purchase and/or use of medicines by

means of highlighting qualities of medicines (product claims). Point of sale material,

information leaflet, booklets and other promotional material which include specific product claims, and which are supplied separately from the product may also be considered

“analytical Performance of an IVD Medical Device” means the ability of an IVD medical device to detect or measure a particular analyte.

“applicant” means a company or entity registered in terms of the Companies Act and operating in Botswana;

“audit” means systematic independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

“authorised person" in relation to a regulated establishment, means:

(i) a person designated in the license or authorization as having overall responsibility for the operations of the regulated establishment;

(ii) holds qualifications and experience appropriate to the activities authorized;

(iii) is accountable to the Authority for compliance with this Act and conditions of the licence and or authorization; and

(iv) has authority to bind the licensee in regulatory matters; or

(b) any key personnel means:

(i) performs critical functions in the manufacture, quality assurance, quality control, distribution, storage, or dispensing of regulated products;

(ii) holds qualifications and competencies required by the Authority for their designated role;

(iii) is specifically designated in the licence or approved by the Authority; and

(iv) exercises professional judgment that directly affects product quality, safety, or regulatory compliance;

and includes:

Biomedical engineers, biomedical engineering technicians, doctors, dentists, pharmacists, nurses production managers, quality assurance managers, quality control managers, regulatory affairs officers, and such other persons as may be designated by the Authority in guidelines

"Authority" means the Botswana Medicines Regulatory Authority continued under section 5 of the Act;

"batch" means a defined quantity of starting material, packaging material or product processed in a single process or series of processes so as to ensure homogeneity, and in the case of continuous manufacture, a defined fraction of the production characterised by its intended homogeneity, and includes lot;

biomedical engineer" is a health professional registered under Botswana Health Professions Act or any Professional Body as such.

"biomedical engineering technician" is a health professional registered under Botswana Health Professions Act as such.

"b**iomedical Engineering (BME)"** is defined as the application of engineering principles and design concepts to medicine and biology for healthcare purposes (e.g. diagnostic or therapeutic). This field seeks to close the gap between engineering and medicine: It combines the design and problem solving skills of engineering with

medical and biological sciences to advance healthcare treatment, including diagnosis, monitoring, and therapy.

"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;

"borderline product" means a product the classification of which is unclear, falling between medical devices and other regulated products;

"clinical data" means safety and performance information generated from the use of a medical device;

"clinical evidence" means clinical data and clinical evaluation pertaining to a medical device;

"clinical evaluation" means the assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer.

"clinical investigation" means a systematic investigation in human subjects to assess the safety or performance of a medical device;

"clinical performance" means the ability of a medical device to achieve clinical outcome(s) in its intended purpose as claimed by the manufacturer.

"combination product" means a product comprised of a medical device combined with a medical product, biological product or any other regulated product;

"conformity assessment" means the systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Regulatory Authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the Essential Principles of Safety and Performance for Medical Devices.

"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.

"custom-made device" means a medical device specifically made in accordance with a written prescription for an individual patient;

“disinfection” means reduction of the number of viable microorganisms on a product to a level previously specified as appropriate for its intended further handling or use.

“distributor” means premises procuring, purchasing, holding, storing, selling, supplying, importing, exporting or facilitating the movement of medical devices, excluding premises dispensing or providing medical devices directly to a patient or his or her agent;

“electronic instructions for use” means instructions for use which are provided in an electronically accessible form supplied by the manufacturer related to a medical device or IVD medical device.

“electronic labelling” means any form of labelling content provided in an electronically accessible form supplied by the manufacturer related to a medical device or IVD medical device.

“essential Principles” means the Essential Principles of Safety and Performance as set out in Schedule 3;

“expected Lifetime/Expected Service Life” means the time period specified by the manufacturer during which the medical device or IVD medical device is expected to maintain safe and effective use.

“expiry Date/Expiration Date” means the upper limit of the time interval during which the safety and performance characteristics of a material stored under specified conditions can be assured.

“fees regulations” means the Medicines and Related Substances Fees, Levies and Penalties Regulations.

“field safety corrective action” means action taken by a manufacturer to reduce a risk of death or serious deterioration of health associated with a medical device that is already placed on the market;

"field safety notice” means a communication sent out by a manufacturer or its representative to the device users in relation to a field safety corrective action.

“general regulations” means the Medicines and Related Substances (General) Regulations.

"good distribution practices (GDP) "are the part of quality assurance that ensures the quality, safety, and integrity of health products, including medical devices, are maintained throughout all stages of the distribution process, from receipt and storage to transportation and delivery to the end user.

"good storage practices" are the part of quality assurance that ensures health products, including medical devices, are consistently stored, handled, and maintained under suitable conditions required by the manufacturer so that their quality, safety, and performance are preserved throughout their storage life.

“guidelines” means documents issued by the Authority under regulation 120 providing detailed technical requirements and procedures;

“implantable medical device” means a medical device intended to be totally or partially introduced into the human body by surgical intervention or medical procedure and to remain in place after the procedure;

“incident” means any malfunction or deterioration in characteristics or performance, or inadequacy in labelling or instructions for use, of a medical device that, directly or indirectly, led to or might have led to the death of a patient or user or of another person or to a serious deterioration in the state of health of a patient or user or of another person;

“indications for use” means a general description of the disease or condition the medical device or IVD medical device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the medical device or IVD medical device is intended.

“intended use / intended purpose” means the objective intent regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer. The intended use can include the indications for use.

“instructions for use” or “IFU” means information provided by the manufacturer to inform the device user of the medical device’s intended purpose and proper use and of any precautions to be taken.

“in vitro diagnostic” or “IVD” means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimen derived from the human or animal solely or principally to provide information for

diagnostic, monitoring or compatibility purposes which includes but not limited to re-agents used for in-vitro diagnostics purposes, calibrators, control chemicals, specimen receptacles, software and related instruments or apparatus or other articles and are used for diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction or determination of physiological status;

"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.

"labelling" 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.

"lay user" means an individual who does not have formal training in a relevant field or discipline.

"local technical representative" means a person resident or incorporated in Botswana appointed by a non-resident applicant to act on their behalf;

"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 or not such a medical device is designed and/or manufactured by that person themselves or on their behalf by another person(s).;

"marketing authorisation" means a registration certificate issued by the Authority permitting a medical device to be placed on the market;

"medical device" means any instrument, apparatus, implement, machine, appliance, implant, in-vitro re-agent or calibrator, software, material or other similar or related article -

(a) intended by the manufacturer to be used, alone or in combination, for humans or animals for

(i) diagnosis, prevention, monitoring, treatment or alleviation of diseases,

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

(iii) investigation, replacement, modification or support of the anatomy or of a physiological process, (iv) supporting or sustaining life,

(v) control of conception,

(vi) cleaning, disinfection or sterilisation of medical devices, or

(vii) providing information for medical or diagnostic purpose by means of in-vitro examination of specimens derived from the human body; and

(b) which does not achieve its primary intended action in human or animal body by pharmacological, immunological or metabolic means but which may be assisted in its intended function by such means;

"medical device malfunction" means a failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions for use.

"near-patient testing" means testing that is performed near a patient and outside of centralized laboratory testing facilities.

"packaging" means the product to be used for the containment, protection, handling, delivery, storage, transport and presentation of goods, from raw materials to processed goods, from the producer to the user or consumer, including processor, assembler or other intermediary.

"predetermined change control plan (PCCP)" means a plan, proposed by a manufacturer, that states:

1. the specific planned changes to the medical device software,
2. the change plan/protocol for implementing and controlling those changes with 55 predefined acceptance criteria/pre-specified performance criteria, and
3. the assessment of impacts from those changes.

"performance" means the ability of a medical device to achieve its intended purpose as claimed by the manufacturer;

"post-market surveillance" means all activities carried out by the manufacturer in cooperation with other economic operators to collect and evaluate experience gained from medical devices that have been placed on the market;

"recognition" means the routine acceptance by the Authority of regulatory decision of another regulatory authority or other credible institution, whereby evidence of conformity with the regulatory requirements of another regulatory authority or credible institution is sufficient to meet the regulatory requirements of the Authority.

“reference regulatory authority” or “RRA” means a national or regional authority or a trusted institution, which can include the WHO prequalification program or a conformity assessment body, whose regulatory decisions and/or regulatory work products are relied upon by another regulatory authority to inform its own regulatory decisions;

“refurbished medical device” means a used medical device that has been restored to its original specifications by the original manufacturer or an authorised party;

"regulated establishment" means any premises, facility, structure, body, organization,

or undertaking that:

- (i) manufactures, imports, exports, distributes, stores, sells, dispenses, repackages, relabels, or otherwise handles regulated products; or
- (iii) provides laboratory services for testing, analysis, or quality control of regulated products; or
- (iv) operates as a vaccines and biologics establishment; or
- (v) carries out any other activity in relation to regulated products,
- (vi) any other premises designated by the Authority as requiring oversight;

and which is required to be authorized, licensed, or registered by the Authority under the Act and these Regulations

“regulatory authority (RA)” means a government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements;

“reliance” means the practice whereby the Authority considers the regulatory work products of another competent regulatory authority to inform its own regulatory decisions while retaining full decision–making authority;

“remanufactured medical device” means a used medical device that has been rebuilt by a party other than the original manufacturer using the original medical device specifications;

"retailer" means an establishment licensed by the Authority to sell or supply regulated products directly to the end user or consumer for personal, medical, veterinary or household use, and who is not authorised to engage in wholesale distribution.

“risk” means the combination of the probability of occurrence of harm and the severity of that harm;

“safety” means freedom from unacceptable risk;

“self-testing” means the use of a medical device or IVD medical device by a lay user who is responsible for collecting the data or specimen, by themselves and on themselves, relying solely on the instructions provided by the manufacturer. This use can also include performing the test and interpreting the results by themselves and on themselves.

“scientist” is a health professional registered under Botswana Health Professions Act or any Professional Body as such.

“serious incident” means an incident that directly or indirectly led to, might have led to or might lead to the death of a patient or user or of another person, or the serious deterioration of the state of health of a patient or user or of another person, or a serious public health threat;

"serious injury" (also known as serious deterioration in state of health) is either:

a. Life threatening illness or injury.

b. Permanent impairment of a body function or permanent damage to a body structure. The term “permanent” means irreversible impairment or damage to a body structure or function, excluding minor impairment or damage.

c. A condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

“stability” means the ability of a medical device and IVD medical device to maintain its safety and performance characteristics within the manufacturer’s specifications over a specified period of time.

“software as a medical device” or “SaMD” means software intended to be used for one or more medical purposes that performs those purposes without being part of a hardware medical device;

“state of the art” means the developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience.

“summary technical documentation (STED)” means a summary of technical documentation held or submitted for conformity assessment purposes.

"table of contents (ToC)": A standardized, harmonized framework developed by the International Medical Devices Forum (IMDRF) that defines the structure, headings, and organization of information submitted in a medical device regulatory application.

“unique device identifier” or “UDI” means a series of numeric or alphanumeric characters created through internationally accepted device identification and coding standards that allows the unambiguous identification of a specific medical device on the market.

“user” The person who uses or operates a medical device. This may include healthcare professionals, lay persons, caregivers, patients, or other operators, depending on the device's intended use and intended user population.

“use error” means an act, or omission of an act, that has a different result to that intended by the manufacturer or expected by the operator. Use errors include slips, lapses, mistakes, and reasonably foreseeable misuse.

“validation” means confirmation through provision of objective evidence that the requirements for a specific intended use or application have been fulfilled

“variation” means a change to an approved marketing authorisation or to the particulars, conditions, scope, or specifications of a licence issued under the Act, classified as major, minor or notification based on potential impact.

“verification” means confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled.

“wholesaler” means the premise procuring, purchasing, holding, storing, selling, supplying, importing, exporting or movement of medical devices, excluding premises. dispensing or providing medical products directly to a patient or his or her agent and licensed as such under these regulations.

Application and scope

3. (1) These Regulations apply to—

(a) medical devices;

(b) in vitro diagnostic medical devices;

(c) accessories, consumables and spares to medical devices and in vitro diagnostic medical devices;

(d) software as a medical device; and

(e) any other product determined by the Authority to be a medical device.

(2) These Regulations shall be read together with the General Regulations, Clinical Trials Regulations and Fees Regulations.

(3) For combination products containing both a medical device and a cosmetic, medical or biological product, the Authority shall determine the primary mode of action and the applicable regulatory pathway.

(4) Where there is any conflict between these Regulations and the Clinical Trials Regulations and the General Regulations, these Regulations shall prevail to the extent of the inconsistency.

(5) Applications under these Regulations shall be submitted through the electronic regulatory information management system established under the General Regulations, except that manual processes shall remain valid where electronic systems are not implemented or are unavailable.

(6) Matters of general application including governance and administration of the Authority, the National Quality Control Laboratory, international cooperation, electronic regulatory systems, fees and the general offences framework are governed by the General Regulations and the Fees Regulations. and apply to the extent they are not inconsistent with these Regulations.

Regulatory principles

4. (1) These Regulations shall be administered in accordance with the following principles—

(a) protection of public health as the paramount consideration;

(b) risk-based and proportionate regulatory requirements;

(c) alignment with international and regional best practices and standards such as; International Organization for Standardization (ISO), the International Medical Device Regulators Forum (IMDRF) and the World Health Organization (WHO).

(d) recognition and reliance on assessments by recognised regulatory authorities;

(e) transparency and consistency in decision-making;

(f) facilitation of access to safe and effective medical devices; and

(g) support for local manufacturing and innovation.

(2) Detailed technical requirements shall be set out in guidelines issued by the Authority under these Regulations which may be amended without amendment to these Regulations.

PART II — CLASSIFICATION OF MEDICAL DEVICES

Classification of medical devices

5. (1) In accordance with section 80 of the Act, medical devices shall be classified according to the risk they present, as follows—

(a) Class A — low risk medical devices;

(b) Class B — low to moderate risk medical devices;

(c) Class C — moderate to high risk medical devices; and

(d) Class D — high risk medical devices.

(2) Classification shall be based on—

(a) the manufacturer's intended purpose of the medical device;

(b) the duration of contact with the body;

(c) the degree of invasiveness;

(d) the part of the body affected;

(e) the potential hazards associated with design and manufacture;

(f) any local or systemic effects; and

(g) such other criteria as may be prescribed in guidelines.

(3) Where a medical device falls into multiple classes, the Authority shall classify it in the higher risk class.

(4) Classification rules for medical devices are set out in Schedule 1.

(5) The Minister may, whenever it becomes necessary to do so, declare any other classification and description of medical devices in line with international best practices.

Classification of in vitro diagnostic medical devices

6. (1) In accordance with section 81 of the Act, in vitro diagnostic medical devices shall be classified as follows—

(a) Class A — low individual risk and low public health risk;

(b) Class B — moderate individual risk and low public health risk;

(c) Class C — high individual risk and moderate public health risk; and

(d) Class D — high individual risk and high public health risk.

(2) Classification criteria shall take into account—

(a) the intended use and indications for use as specified by the manufacturer;

(b) the mode of transmission, the efficacy of transmission, and the nature of the disease and the availability of treatment;

(c) the technical, scientific or medical expertise of the intended user (d) the specimen type;

(e) the impact of the diagnostic test result on the individual, their offspring or the public; and

(f) 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

(f) the public health significance as may be prescribed in guidelines

(3) The Minister may, whenever it becomes necessary to do so, declare any other classification and description of IVDs in line with international best practices.

(4) Classification rules for in vitro diagnostic medical devices are set out in Schedule 2.

Borderline and combination products

7. (1) In accordance with section 82 of the Act, the Authority shall determine classification for products that are—

(a) borderline between medical devices and other regulated products; or

(b) combination products.

(2) An applicant may request a classification determination from the Authority before submitting a registration application, and such request shall be accompanied by the prescribed fee as set out in the Fees Regulations.

(3) The Authority shall make a classification determination within such period as may be prescribed in guidelines.

(4) The Authority may consult with other regulatory units or external experts in making a classification determination.

PART III — MARKETING AUTHORIZATION

Requirements for registration

8. (1) In accordance with section 35 of the Act, a person shall not import, manufacture, export, sell, supply, distribute, promote, advertise, store or dispense any medical device unless such medical device is registered by the Authority.

(2) The Authority shall register a medical device if it is satisfied that such medical device meets the required standards for safety and performance.

(3) Subregulation (1) does not apply to—

(a) medical devices exempted under regulation 21;

(b) medical devices for which a special access authorisation has been granted under regulation 112;

(c) medical devices imported for personal use in accordance with section 64 of the Act;

(d) investigational medical devices used in approved clinical investigations;

(e) samples imported for registration purposes in quantities approved by the Authority; and

(f) medical devices imported under emergency provisions in accordance with regulations 21 and 22.

Application for registration

9. (1) An application for registration of a medical device shall be made to the Authority in Form BOMRA/MD 1 and shall be accompanied by—

(a) the prescribed fee as set out in the Fees Regulations;

(b) a complete description of the medical device and its intended purpose;

(c) the risk classification and justification therefore;

(d) technical documentation or summary in a dossier format (STED / TOC) or as prescribed in guidelines;

(e) clinical evidence as prescribed in guidelines;

(f) evidence of compliance with the Essential Principles of Safety and Performance as set out in Schedule 3;

(g) labelling and instructions for use;

(h) a declaration of conformity;

(i) evidence of quality management system certification for the manufacturer;

(j) proof of regulatory approval from a recognised regulatory authority, where applicable;

(k) appointment of a local technical representative, where applicable;

(l) details of any relevant grouping of the medical device, including system, test kit, cluster, group or family; and

(m) such other documentation as may be prescribed in guidelines.

(2) Documentation requirements shall be proportionate to the risk classification of the medical device.

(3) The Authority shall acknowledge receipt of the application and assign a unique application reference number.

(4) The Authority shall conduct a validation review to determine whether the application is complete upon application receipt and may:

(a) accept the application for evaluation; or

(b) Reject the application if incomplete

Local technical representative requirement

10. (1) In accordance with section 36 of the Act, an applicant for registration of a medical device who is not resident in Botswana shall appoint a local technical representative who shall be resident or incorporated in Botswana.

(2) The local technical representative shall—

(a) be responsible for all communications with the Authority;

(b) monitor medical devices on the market and inform the Authority immediately upon the detection of any problem relating to a registered medical device which may endanger public health;

(c) facilitate communication between the applicant and the Authority;

(d) handle medical device recalls; and

(e) provide technical support and services to users of registered medical devices.

(3) The appointment of a local technical representative shall be documented using Form BOMRA/MD 3.

Assessment of applications

11. (1) The Authority shall assess applications for registration having regard to—

(a) screening for completeness;

(b) administrative and medical device information review;

(c) technical documentation review;

(d) clinical evidence, including performance evaluation;

(e) quality management system verification;

(f) labelling review;

(g) post-market surveillance plan and

(g) any other relevant assessment.

(2) The Authority may—

(a) request additional information from the applicant;

(b) request samples or require testing;

(c) conduct or rely on manufacturer audits;

(d) consult external experts or technical committees; and

(e) rely on assessments by recognised regulatory authorities.

(3) Where additional information is requested, the assessment timeline shall stop until a complete response is received, and the applicant shall respond within the stipulated time, failing which the application shall be deemed withdrawn.

(4) An applicant may withdraw a registration application in accordance with procedures prescribed in guidelines.

Registration pathways

12. (1) The following registration pathways shall apply—

(a) Full Evaluation Pathway — for medical devices with no prior approvals from national regulatory authorities recognised by the Authority, novel technologies, or medical devices not meeting abridged pathway requirements;

(b) Abridged Evaluation Pathway — for World Health Organization prequalified medical devices or medical devices meeting abridged pathway requirements as prescribed in guidelines;

(c) Notification Pathway — for Class A medical devices, veterinary use only medical devices and such other medical devices as may be prescribed in guidelines.

(2) The target assessment timelines shall be as set out in the guidelines.

(3) Reference regulatory authorities and recognized institutions for reliance purposes shall be determined by guidelines and may include World Health Organization prequalified medical devices, World Health Organization Listed Authorities, Maturity Level 3 and 4 national regulatory authorities, International Medical Device Regulators Forum member authorities, African Medical Devices Forum recognised authorities, and recognised conformity assessment bodies.

(4) Specific regulatory activities to be included in the reliance program will be specified in the guidelines.

(5) The Authority may reassign a medical device to a different pathway based on assessment.

Reliance on regulatory assessment approvals

13. (1) Before placing a medical device on the market, the manufacturer shall demonstrate compliance with applicable requirements through evidence acceptable to the Authority.

(2) The Authority may rely on regulatory assessment decisions, approvals, authorisations, certificates, or marketing authorisations issued by recognised regulatory authorities or assessment systems.

(3) Such reliance may include, but is not limited to—

(a) regulatory approvals from International Medical Device Regulators Forum member authorities;

(b) approvals from African Medical Devices Forum recognised authorities;

(c) World Health Organization prequalification;

(d) listings by World Health Organization Listed Authorities or Maturity Level 3 regulatory authorities; and

(e) other regulatory assessment decisions as specified in guidelines.

(4) The extent of reliance shall be proportionate to the risk classification of the medical device.

Reliance on Quality Management System certification

14. (1) The Authority may rely on valid Quality Management System (QMS) certification as evidence of conformity with quality system requirements.

(2) Manufacturers of all medical devices shall implement and maintain a Quality Management System appropriate to the nature and risk classification of the device.

(3) For Class B, C, and D medical devices, the Authority may rely on certification demonstrating compliance with ISO 13485 or an equivalent standard.

(4) QMS certification relied upon by the Authority shall—

(a) be issued by a recognised conformity assessment body;

(b) cover relevant stages of design, manufacture, and post-market activities;

(c) be subject to ongoing surveillance and periodic re-certification; and

(d) remain valid for the duration of reliance.

(5) Medical Device Single Audit Programme (MDSAP) audit outcomes.

Recognition of conformity assessment bodies

15. (1) The Authority may recognise conformity assessment bodies and auditing organisations based on accreditation, designation, participation in recognised international programmes, or criteria specified in guidelines.

(2) Conformity assessment procedures shall be proportionate to the risk classification of the medical device—

(a) Class A: manufacturer self-declaration;

(b) Class B: self-declaration with quality management system certification;

(c) Class C: third-party certification of quality management system and technical documentation; and

(d) Class D: third-party certification including design examination and product verification.

(3) The Authority shall maintain and publish a list of recognised bodies whose outputs may be used for reliance purposes.

Declaration of conformity

16. (1) The manufacturer shall prepare a declaration of conformity confirming that the medical device complies with applicable requirements.

2) The declaration shall be supported by relevant regulatory assessment approvals and/or QMS certification relied upon under these Regulations.

General provisions on reliance

17. (1) The Authority may rely on external regulatory assessments and QMS certifications in making regulatory decisions under these Regulations.

(2) Reliance does not preclude the Authority from requesting additional information where necessary to ensure safety, quality, and performance of medical devices.

(3) Reliance does not preclude the Authority from—

(a) requesting additional Botswana-specific information;

(b) imposing local conditions;

(c) conducting independent assessment where concerns arise; or

(d) taking independent regulatory action.

Registration decision

18. (1) Upon completion of the assessment, the Authority shall—

(a) register the medical device;

(b) register the medical device with conditions;

(c) request additional information; or

(d) reject registration with written reasons.

(2) Registration with conditions may include requirements for—

(a) post-market studies;

(b) enhanced surveillance;

(c) restricted distribution;

(d) user restrictions;

(e) additional risk minimisation measures

(e) specific labelling requirements; and

(f) payment of annual retention fees.

Certificate of registration

19. (1) Upon registration, the Authority shall issue a certificate of registration specifying—

(a) registration number;

(b) medical device name, product code model and components;

(c) medical device classification;

(d) the name and address of the applicant, the legal manufacturer and all manufacturing site(s) involved in the production of the medical device.

(e) medical device nomenclature;

(g) any conditions of registration;

(h) validity period; and

(i) date of issue.

Validity and renewal of registration

20.(1) A registration of a medical device issued under these Regulations shall be valid for a period of five years from the date of issue, subject to—

(a) payment of annual retention fees as set out in the Fees Regulations;

(b) continued compliance with conditions of registration; and

(c) no suspension or cancellation.

(2) An application for renewal shall be submitted at least six months before expiry in Form BOMRA/MD 1 and shall be accompanied by—

(a) the prescribed renewal fee as set out in the Fees Regulations;

(b) updated medical device information;

(c) a post-market surveillance summary;

(d) Periodic safety update reports

(e)updated risk management plan where necessary

(f) a summary of any changes since registration;

(g) evidence of continued quality management system compliance; and

(h) such other information as may be prescribed in guidelines.

(3) Where renewal is applied for within the prescribed time, the existing registration shall remain valid until a decision is made.

(4) Where renewal is applied for after the prescribed time, a late submission fee as set out in the Fees Regulations shall be payable.

Exemption from registration

21. (1) The Authority may, in accordance with section 35(4) of the Act, in such special circumstances as it considers appropriate, exempt in writing a medical device from the requirement for registration.

(2) A medical device in relation to which an exemption may be granted includes—

(a) a medical device which has not been registered but was prescribed outside Botswana for a patient's personal use;

(b) a medical device which is required by a medical practitioner, dentist or veterinary surgeon, for the treatment of a patient or animal under their care;

(c) a medical device intended for re-export in the form and packaging in which it was imported;

(d) a donated medical device in compliance with regulation 116;

(e) a medical device imported by a wholesaler where there are no registered alternatives;

(f) a medical device imported for research purposes or approved clinical investigations;

(g) a medical device required during a declared public health emergency or in the public interest;

(h) a medical device manufactured locally for registration purposes;

(i) samples for registration purposes;

(j) a custom-made device complying with regulation 111;

(k) a medical device for special access under regulation 112; and

(l) such other circumstances as may be prescribed in guidelines.

(3) An application for exemption shall be made in Form BOMRA/MD 5 and shall be accompanied by the prescribed fee as set out in the Fees Regulations.

Registration during public health emergencies

22. (1) In accordance with section 38 of the Act, during a declared public health emergency, the Authority may—

(a) operate expedited assessment procedures;

(b) grant conditional or emergency use authorisations;

(c) waive or reduce fees;

(d) rely on emergency use authorisations from recognised authorities; and

(e) accept rolling submissions of data.

(2) Medical devices registered under emergency provisions shall be subject to enhanced post-market surveillance and review when the emergency ends.

Listing of medical devices

23. (1) The Authority may establish a provisional listing register for unregistered medical devices already on the market prior to the commencement of these Regulations.

(2) Annual retention fees as set out in the Fees Regulations shall be applicable to listed medical devices.

(3) A listing shall be valid until the medical device is called for registration or for a period of five years, whichever is earlier.

Variation of registration

24. (1) In accordance with section 40 of the Act, the holder of a marketing authorisation for a medical device who wishes to make any change to the particulars contained in the registration shall apply to the Authority for a variation.

(2) An application for a variation shall be made in Form BOMRA/MD 2 and shall be accompanied by the prescribed fee as set out in the Fees Regulations.

(3) Variations shall be classified as major variations, minor variations or notifications in accordance with General Regulations as indicated below;

a) **Major Changes**- These are the significant changes that have been confirmed through risk analysis, to have a potential higher impact on the function, performance, usability, or safety of the approved medical devices or IVDs. Change may affect either product's safety, quality, performance or all.

b) **Minor Changes**- These are the significant changes that have been confirmed through risk analysis, to have a potential lower impact on the function, performance, usability, or safety of the approved product.

c) **Notification Changes**- These are type of changes whose implementation has no impact to product safety, quality and performance.

(4) Changes that are not permissible as variations shall be specified in guidelines.

(5) The Authority may cancel the marketing authorisation of a medical device where major changes are made without the prior approval of the Authority.

Cancellation, suspension and withdrawal of registration

25. (1) The Authority may cancel, suspend or withdraw a registration in accordance with section 41 of the Act and with the General Regulations.

(2) The marketing authorisation holder may voluntarily withdraw a registration in accordance with procedures prescribed in guidelines.

Notifications

26. In accordance with the General Regulations, the marketing authorisation holder shall notify the Authority of the following within thirty days of occurrence;

(a) any restriction, suspension or withdrawal of the medical device in any other country;

(b) any new safety alerts or information that may affect the benefit-risk balance;

(c) any regulatory action taken by another authority;

(d) any change in quality management systems of the manufacturing facilities;

(e) discontinuation of marketing or manufacture; and

(f) any other matters specified in the guidelines.

Maintenance of registers

27. In accordance with section 42 of the Act, the Authority shall;

(1) maintain registers of—

(a) all authorised medical devices;

(b) medical devices whose registration has been cancelled, suspended or withdrawn

(c) applications for registration under consideration;

(d) licensed manufacturers, importers, distributors, wholesalers, and other authorised economic operators;

(e) medical devices that are exempt from registration or subject to alternative regulatory requirements; and

(f) adverse event, incident, field safety notification or quality compliant reports

(f) such other matters as may be required by the Authority.

(2) The registers may include—

(a) the registration number or unique device identifier, where applicable;

(b) the medical device name, model, catalogue number, and description;

(c) the intended purpose and intended user;

(d) the risk classification of the medical device;

(e) the name and address of the applicant, site of manufacturing and legal manufacturer;

(g) the name and address of the local technical representative, where applicable

(3) The registers shall be

(a) available for public inspection;

(b) published on the Authority's website or online service portal;

(c) updated accordingly on the online service portal

(d) maintained in a format facilitating searchability.

PART IV — MANUFACTURERS AND AUTHORISED REPRESENTATIVES

Manufacturer obligations

28. (1) A manufacturer shall—

(a) ensure that medical devices comply with applicable requirements and maintain technical documentation;

(b) implement and maintain a quality management system;

(c) establish, implement, documents and maintain a risk management system;

(d) conduct post-market surveillance;

(e) report adverse events and incidents to the Authority as prescribed in the guidelines

(f) implement field safety corrective actions when necessary;

(g) cooperate with the Authority in investigations;

(h) apply unique device identifiers to medical devices as required;

(i) apply the medical device nomenclature system;

(j) employ relevant qualified technical personnel as prescribed in guidelines;

(k) ensure adequate financial resources for liability; and

(l) take reasonable measures to ensure that every material used in the manufacture of medical devices is compatible with every other material with which it interacts and does not pose undue risk to any person.

(2) A manufacturer established outside Botswana shall appoint a local technical representative in accordance with regulation 32.

Quality management system requirements

29. (1) The quality management system shall be in accordance with ISO 13485 or an equivalent standard and shall address—

(a) management responsibility;

(b) resource management;

(c) design and development;

(d) purchasing controls;

(e) production and process controls;

(f) control of nonconforming product;

(g) monitoring and measurement;

(h) corrective and preventive actions;

(i) document control; and

(j) record control.

(2) Quality management system requirements shall be proportionate to the risk classification of the medical device.

Design and development controls

30. (1) Design and development shall include—

(a) design planning;

(b) design input requirements;

(c) design output specifications;

(d) design review;

(e) design verification;

(f) design validation;

(g) design transfer; and

(h) design change control.

(2) Design controls shall be commensurate with the risk classification of the medical device.

Production controls

31. Production shall be controlled through documented procedures, process validation, environmental controls, personnel competence requirements, equipment maintenance, incoming inspection, in-process controls and final inspection and testing, as prescribed in guidelines.

Local technical representative requirements

32. (1) Where a manufacturer is not established in Botswana, an authorised representative shall be appointed.

(2) The authorised representative shall—

(a) be established in Botswana;

(b) have a written mandate from the manufacturer;

(c) maintain copies of technical documentation;

(d) receive and respond to communications from the Authority;

(e) forward adverse event, and or incident reports and field safety notices;

(f) facilitate inspections; and

(g) have authority to act on behalf of the manufacturer.

(3) The appointment shall be documented using Form BOMRA/MD 3.

PART V — LICENSING OF REGULATED ESTABLISHMENTS

Requirement for licence

33. (1) In accordance with section 58 of the Act, no person shall

(a) manufacture;

(b) sell or supply;

(c) export or import;

(d) distribute;

(e) dispense; or

(f) store for commercial purposes,

(2) Any medical devices including IVDs unless that person holds a valid licence or authorisation issued by the Authority for that purpose.

(3) An application for licensing of medical devices establishments shall be submitted to the Authority, in a prescribed form accompanied by an application fee set out in Fees Regulations.

(4) The Authority may, having considered the application, grant the applicant an authorisation or licence and the Authority may attach conditions there to as it may consider necessary.

(5) The Authority shall inform an unsuccessful applicant in writing, of the decision not to licence the premises and the reasons, in line with the guidelines.

(6) Where premises are licensed, the premises shall be under the supervision of a qualified person in line with the guidelines.

(7) The Authority shall keep a database of all licenced medical devices establishments.

(8) Subregulation (1) does not apply to

(a) an individual purchasing or receiving medical devices for personal use; and

(b) persons exempted by the Authority by notice in the Gazette.

(9) A licence is specific to

(a) the person to whom it is issued;

(b) the premises specified;

(c) the activities authorised; and

(d) the product categories authorised.

Categories of licences

34. (1) The following categories of licences shall be issued under these Regulations

(a) manufacturing licences, which shall have the following categories;

i. full manufacturing licence, including device parts processing, assembly, in-process testing, finished device release testing and batch certification;

ii. secondary manufacturing and packaging licence;

iii. combination medical device manufacturer

iv. medical device with software manufacturer

v. Repackaging and relabelling licence

(b) import and export licences;

(c) distribution and wholesale licences;

(d) retailing and dispensing licences, which shall include;

i. Pharmacy

ii. Dispensary

iii. Veterinary retailer.

iv. Medical Devices including IVDs retailers.

v. Authorised premises.

vi. Combined facility: a licence issued under this category shall authorise an establishment to handle any combination of regulated scope of product

(e) bonded warehouse licences; and

(f) special licences.

Application for manufacturing licence

35. (1) An application for a manufacturing licence under section 58 of the Act shall be made to the Authority shall be submitted in the prescribed form with —

(a) the prescribed application fee as per Fee Regulations

(e) list of medical devices to be manufactured;

(g) list of key personnel for approval; and

(h) such other documents as may be required in the guidelines.

(2) The Authority shall issue manufacturing licences as in subregulation 34(1)

Key personnel requirements

36. (1) Every manufacturing licence application shall designate the following key personnel-

(a) A Qualified Person responsible for batch certification and release;

(b) A Production Manager responsible for production operations;

(c) A Quality Assurance Manager responsible for the quality system; and

(d) A Quality Control Manager responsible for quality control operations, who shall be independent of the Production Manager,

(e) any other key personnel as required by the Authority.

(2) Qualifications, experience and responsibilities of key personnel shall be as specified in Authority guidelines.

(3) The licence holder shall notify the Authority in writing of any change, resignation, removal, replacement of the appointed key personnel within a timeline specified in the guidelines and obtain approval for the replacement before any new key personnel assumes responsibilities.

Manufacturing Quality Management Systems Requirements

37. (1) No manufacturing licence shall be issued unless the manufacturing facility has been inspected and determined to comply with the applicable quality management system requirements recognized by the Authority, including ISO 13485 or an equivalent internationally recognized standard and any guidelines or requirements applicable to the specific category of Medical Devices.

(2) The Authority shall conduct a pre-licensing quality audit / inspection of the manufacturing facility to verify compliance with the applicable quality management system requirements before granting a manufacturing licence and shall issue an inspection / quality audit report, including any identified deficiencies within timelines specified in the guidelines.

(3) Routine compliance inspections / quality audit shall be conducted at intervals determined by the Authority based on the regulatory jurisdiction and manufacturer's compliance risk assessment.

Issuance of manufacturing licence

38. (1) The Authority shall issue a manufacturing licence specifying —

(a) the licence number, licensee name and premises;

(b) the manufacturing category of licence

(c) the authorised activities and device types;

(d) the names of approved key personnel;

(e) the validity period;

(f) any conditions of the licence; and

(g) the date of issue

(2) Every manufacturing licence is subject to the following standard conditions

(a) maintain quality management systems for medical devices compliance at all times;

(b) ensure approved key personnel are present during operations;

(c) manufacture only authorised products at the licensed premises;

(d) maintain records as specified by the guidelines; and

(e) such other conditions as the Authority may impose.

(3) The licensee shall display the manufacturing licence prominently at the licensed premises

(4) The Authority shall reject an application where key personnel requirements are not met, the applicant has provided false information, or the application is incomplete or otherwise deficient.

(5) The Authority shall not grant a licence unless the manufacturing facility complies with the applicable quality management system requirements and any standards prescribed by the Authority.

(6) The Authority shall conduct an inspection to verify quality management system compliance before granting a manufacturing licence.

(7) The inspection shall assess compliance with quality management system requirements as detailed in guidelines published by the Authority.

Certificate of Compliance with Quality Management System Requirements

39. (1) The Authority may issue a Certificate of Compliance with the applicable Quality Management System for medical devices requirements to a manufacturer where, following an inspection or assessment conducted in accordance with the Act and the applicable guidelines, the Authority is satisfied that the manufacturing facility complies with the prescribed quality management system requirements.

(2) A certificate issued under this regulation shall

(a) be specific to the manufacturing site, block, product category, and scope of activities inspected or assessed;

(b) state the date of issuance and period of validity; and

(c) be subject to such terms and conditions as the Authority may determine.

(3) The validity period of a Quality Management System compliance certificate shall be determined by the Authority on the basis of a quality risk assessment conducted in accordance with its determined guidelines.

(4) Notwithstanding the validity period specified in the certificate, the Authority may conduct announced or unannounced inspections, require additional information, suspend or revoke the certificate where there is evidence of non-compliance with applicable quality management system requirements or where such action is necessary to protect public or animal health.

(5) The issuance of a Quality Management System compliance certificate shall not relieve the manufacturer of its obligation to maintain continuous compliance with applicable medical device regulatory requirements and quality management system requirements throughout the period of validity of the certificate.

(6) A manufacturer shall apply for renewal of a certificate not later than three (3) months prior to its expiry, in the manner and form determined by the Authority

Application for Distribution and Wholesale Licence

40. (1) A person who intends to operate distribution or wholesale operations for medical devices, including in vitro diagnostics, shall apply to the Authority for a licence in the prescribed form, accompanied by—

(a) the prescribed application fee;

(b) company registration documents;
(c) have a biomedical engineer, biomedical engineering technician, or relevant key personnel registered with a relevant professional body, to deal with Class B, C and D medical devices and capital equipment requiring installation and maintenance; and
(d) such other information as may be specified in the guidelines.

(2) Applications under subregulation (1) shall specify the category of licence sought, which shall include—
(a) medical devices distribution
(b) medical devices wholesale

(3) A licensee shall not stock, sell, distribute, supply, or otherwise handle any medical device or in vitro diagnostics outside the scope of the licence category issued, and any contravention of this regulation shall constitute grounds for regulatory action under the Act.

Assessment and Inspection of Distribution and Wholesale Operations

41. (1) Upon receipt of a complete application, the Authority shall conduct an inspection of the premises to verify compliance with—
(a) Good Storage and Distribution Practices for Medical Devices and In Vitro Diagnostics as specified by the Authority;
(b) applicable storage, transportation, traceability, and quality management requirements for medical devices and IVDs; and
(c) such other standards and guidelines as may be specified by the Authority.

(2) The inspection under subregulation (1) shall verify—
(a) suitability of premises, storage facilities, and areas designated for receipt, storage, installation, servicing, demonstration, or supply of medical devices and in vitro diagnostics;
(b) adequacy of the quality management system and procedures governing distribution, storage, installation, servicing, maintenance, and post-market activities;
(c) temperature, humidity, and environmental monitoring capabilities, where applicable;
(d) qualification, competence, and training of personnel responsible for handling, storage, installation, servicing, maintenance, and distribution of medical devices and IVDs;
(e) documentation and record-keeping systems;

(f) traceability, inventory management, and product recall systems;
(g) transportation, delivery, installation, and field service arrangements, where applicable;
(h) security measures and access controls;
(i) procedures for management of nonconforming devices, corrective actions, and field safety corrective actions;
(j) procedures for complaint handling, adverse event reporting, and post-market surveillance activities;
(k) calibration, maintenance, and control of equipment used in storage, testing, servicing, or installation activities, where applicable; and
(l) such other requirements as may be specified by the Authority.

Application for Supply, Distribution and Service Licence

42. (1)A person who intends to conduct the supply, distribution, installation, servicing, maintenance, leasing, or provision of medical devices or in vitro diagnostics shall apply to the Authority for a licence in the prescribed form, accompanied by—
(a) the prescribed application fee;
(b) company registration documents;
(c) Medical devices requiring installation shall be installed by the manufacturer, an authorised service provider (biomedical engineer/technician or qualified personnel registered with relevant professional body) following the manufacturer's instructions.
(d) Servicing shall be conducted by a biomedical engineer/technician or relevant qualified personnel, registered with a relevant professional body, in accordance with the manufacturer's specifications;
(e) the scope of activities and categories of medical devices or IVD medical devices applied for; and
(f) such other information as may be specified in the guidelines.

(2) A licensee shall not stock, distribute, install, service, sell, lease, or supply any medical device or IVD medical device outside the scope of the licence category issued, and any contravention of this regulation shall constitute grounds for regulatory action under the Act.

Assessment and Inspection of Licensed Operations

43. (1) Upon receipt of a complete application, the Authority shall—

(a) conduct a documentary assessment; and

(b) conduct an inspection of the premises to verify compliance with Good Storage and Distribution Practices for Medical Devices, applicable quality management requirements, and other standards and guidelines as may be specified by the Authority.

(2) The inspection under subregulation (1)(b) shall verify—

(a) suitability of premises and facilities;

(b) adequacy of quality management systems;

(c) temperature and environmental monitoring capabilities, where applicable;

(d) qualification and competence of personnel;

(e) documentation and record-keeping systems;

(f) traceability and inventory management systems;

(g) installation, servicing, maintenance, and technical support capabilities, where applicable;

(h) security measures and access controls;

(i) availability of technical documentation, instructions for use, service manuals, and device information resources;

(j) calibration and maintenance systems for test, measurement, and servicing equipment, where applicable;

(k)cold-chain management systems for devices or IVDs requiring controlled storage conditions, where applicable;

(l) sterile medical devices shall be protected from contamination.

(m) complaint handling, vigilance, adverse event reporting, and field safety corrective action procedures;

(n) post-market surveillance systems; and

(m) such other requirements as may be specified by the Authority.

(3) Where an inspection is required, the applicant shall—

(a) facilitate access by inspectors at any reasonable time;

(b) make personnel available for interview;

(c) provide requested documentation and access to all evidence required; and

(d) demonstrate operational readiness.

Issuance of Licence

44. (1) The licence issued under regulation 42 shall specify—

(a) the name and address of the licensee;
(b) the category of licence;
(c) the scope of authorised activities;
(d) the licensed premises address;
(e) the name and qualifications of the responsible person or technical representative;
(f) conditions and restrictions, if any;
(g) the validity period; and
(h) the licence number and date of issue.

(2) The Authority may refuse to issue a licence where—

(a) the premises do not meet applicable good practice requirements;
(b) the applicant lacks suitably qualified responsible personnel;
(c) the quality management systems are inadequate;
(d) there is evidence of previous serious non-compliance; or
(e) the applicant has provided false or misleading information.

Bonded Warehouses

45. (1) A person shall not operate a bonded warehouse for the storage of medical devices or in vitro diagnostic medical devices unless licensed by the Authority.

(2) An application shall include particulars of the premises, customs authorisation, storage conditions, security and inventory controls, responsible personnel, and any other information required by the Authority.

(3) A bonded warehouse licence authorises the receipt, storage, and release of medical devices and IVDs under customs control in accordance with the licence conditions and does not

authorise distribution, supply, servicing, relabelling, repackaging, or any other activity unless expressly approved by the Authority.

(4) The licensee shall notify the Authority of any material change affecting the bonded warehouse, including changes to premises, operations, ownership, customs authorisation, or storage conditions.

Special Licences

46. (1) The Authority may issue special licences for activities requiring enhanced regulatory oversight, including—
(a) mobile, outreach, or temporary medical device service units;
(b) Healthcare / Professional services;
(c) third-party logistics providers handling medical devices and IVDs; and
(d) any other specialised activity determined by the Authority.

(2) A special licence shall specify the authorised activities and be subject to such conditions, restrictions, and validity periods as the Authority may determine.

General Licensing Provisions
47. (1) Applications for licences shall be submitted in the prescribed form and accompanied by the prescribed fee and such information as the Authority may require regarding the applicant, premises, personnel, equipment, quality management systems, and proposed activities.

(2) The Authority may conduct documentary reviews and inspections and may request additional information necessary to complete its assessment.

Conditions of Licence
48. (1) The Authority may impose conditions relating to—
(a) categories of medical devices or IVDs authorised;
(b) scope of activities;
(c) personnel and competency requirements;
(d) quality management systems;
(e) record retention and traceability;

(f) post-market surveillance and materiovigilance reporting; and
(g) any other matters necessary to ensure compliance and protection of public health.

Validity and Renewal

49. (1) Licences shall be valid for a period determined by the Authority using a risk based approach.

(2) In determining licence validity, the Authority shall consider the compliance history of the establishment, effectiveness of quality systems, suitability of facilities, competence of personnel, and any other relevant regulatory risk factors.

(3) Renewal applications shall be submitted in the prescribed manner before licence expiry and may be subject to inspection.

Change of Ownership

50. (1) A licensee shall obtain prior approval from the Authority before any change in ownership of a licensed establishment.

(2) The Authority may approve, approve with conditions, request additional information, or refuse the proposed change where regulatory compliance or public health may be adversely affected.

Suspension and Cancellation

Formatted: Font color: Custom Color(RGB(31,77,120))

51. (1) The Authority may suspend or cancel a licence where the licensee—
(a) contravenes the Act, these Regulations, or licence conditions;
(b) fails to maintain compliance with applicable standards;
(c) provides false or misleading information;
(d) fails to implement required corrective actions; or
(e) poses a risk to public health or safety.

(2) Where an imminent risk to public health or safety exists, the Authority may suspend a licence with immediate effect.

(3) Upon suspension or cancellation, the licensee shall cease the affected activities and manage medical devices and IVDs in accordance with directions issued by the Authority.

(4) Where a licence has been suspended, revoked or cancelled, the licensee shall comply with any directions issued by the Authority, including—

(a) ceasing the licensed activities to the extent specified by the Authority;

(b) surrendering the licence to the Authority within the period specified;

(c) securing, transferring, recalling or disposing of regulated products in accordance with the written directions of the Authority; and

(d) retaining and making available all records relating to the licensed activities for the prescribed retention period or such longer period as the Authority may require.

(5) The suspension, revocation or cancellation of a licence shall not preclude the Authority from taking any other enforcement action available under the Act.

Variation of Licence

52. (1)A licensee shall obtain prior approval from the Authority for any change that may affect the scope, premises, operations, quality system, responsible personnel, or compliance status of the licensed activity.

(2) Variations may be classified as minor or major according to the regulatory risk associated with the proposed change.

Minor variations may include—

(a) administrative changes, including change of business name or contact details;

(b) replacement of key personnel with equivalent qualifications;

(c) minor layout changes not affecting storage conditions or process flow; or

(d) such other changes as the Authority may determine.

Major variations may include—

(a) change of premises or expansion of licensed premises;

(b) change or extension of the scope of licensed activities or product categories;

(c) introduction of new systems, technologies, or distribution models;

(d) any change that increases regulatory risk or requires inspection or verification; or
(e) such other changes as the Authority may determine

(3) An application for variation shall be made in the form and manner determined by the Authority, accompanied by—
(a) the prescribed variation fee, determined according to whether the variation is minor or major; and
(b) such supporting information as the Authority may require.

(4) In assessing an application for variation, the Authority shall apply a risk-based assessment, and may—
(a) approve the variation, with or without conditions;
(b) require additional information, inspection, or verification; or
(c) refuse the variation, giving reasons in writing.

(5) The Authority may reclassify a proposed minor variation as a major variation where, upon assessment, the change is found to have a material regulatory or public health impact.

(6) An approved variation shall not extend the validity period of the licence, unless expressly determined by the Authority.

(7) A licensee shall not implement a proposed variation until written approval is granted by the Authority, except where the Authority authorises phased or conditional implementation.

Post-Licensure Notifications

53. (1) A licensee shall notify the Authority of any significant change or event affecting licensed activities, including—
(a) changes to key personnel;
(b) significant operational disruptions;
(c) theft, loss, or security breaches involving medical devices;
(d) quality defects, field safety corrective actions, recalls, or vigilance-related events;
(e) regulatory actions taken by other regulatory authorities; or
(f) any other matter specified by the Authority.

(2) A notification under this regulation shall be submitted within the period prescribed by the Authority, or where no period is prescribed, within fourteen days of the occurrence or awareness of the change or event.

(3) Upon receipt of a post-licensure notification, the Authority may
(a) acknowledge the notification without further action;
(b) require additional information or clarification;
(c) impose additional licence conditions or corrective actions; or
(d) require the licensee to submit an application for variation or take other regulatory action.

(4) Failure to submit a required post-licensure notification within the prescribed timeframe shall constitute non-compliance and may result in regulatory action.

Maintenance and Publication of Licensing and Inspection Registers by the Authority

54. (1) The Authority shall establish, maintain, and keep up to date official registers for the purpose of regulatory oversight, transparency, and enforcement in relation to licensed establishments and inspections conducted under the Act and these Regulations.

(2) Without limiting sub-regulation (1), the registers maintained by the Authority shall include—
(a) a register of licensed establishments, indicating the licence category, scope of authorised activities, validity period, and licence conditions;
(b) a register of suspended licences, indicating the grounds for suspension and duration;
(c) a register of cancelled or revoked licences, indicating the date and grounds for cancellation or revocation; and
(d) an inspection register, recording inspections conducted, inspection type, dates, and regulatory outcomes.

(3) The Authority shall ensure that the registers referred to in sub-regulation (2) are accurate, complete, and maintained in a manner that supports traceability, compliance monitoring, and risk-based regulatory decision-making.

(4) The Authority may publish or make accessible to the public such registers, or parts thereof, as it considers appropriate, subject to—

(a) the protection of confidential, commercially sensitive, or security-related information; and
(b) applicable data protection and access-to-information laws.

(5) The Authority may publish abridged inspection reports or inspection outcome summaries for specified categories of inspections, including routine, reliance-based, or risk-based inspections, where such publication—
(a) supports regulatory transparency and public confidence;
(b) does not compromise enforcement actions or confidentiality obligations; and
(c) is consistent with guidelines issued by the Authority.

(6) Abridged inspection reports published under sub-regulation (5) shall—
(a) exclude confidential or proprietary information;
(b) summarise the inspection scope, date, and overall compliance status; and
(c) present findings in a manner determined by the Authority.

(7) The maintenance and publication of registers and abridged inspection reports under this regulation shall not limit the Authority's powers to withhold information, conduct enforcement action, or rely on full inspection reports for regulatory decision-making

PART VI: IMPORT AND EXPORT CONTROL

Requirements for import and export authorization

55. (1) In accordance with section 62 of the Act and the general regulations, a person shall not import or export a medical device or in vitro diagnostics unless authorised by the Authority.

(2) An application for an import permit shall be made in Form BOMRA/MD 4 and shall be accompanied by the prescribed fee as set out in the Fees, Levies and Penalties Regulations.

(3) Authorisation shall require—

(a) An entity must hold a valid license or authorisation for import/export before applying for import/export permits of medical devices or IVDs and;

(b) a valid import, export, or transit permit for the specific consignment, where required by the Authority.

(4) The Authority may refuse authorisation where—

(a) the medical device is not registered, listed, or otherwise authorised, unless exempted by the Authority;

(b) the medical device is prohibited or restricted;

(c) the medical device is suspected to be falsified, unsafe, defective, or non-compliant with applicable regulatory requirements;

(d) the applicant does not hold a valid licence; or

(e) authorisation would otherwise be contrary to public health or safety

Application for Import and Export Permits

56. (1) An application for a permits shall be made in Form BOMRA/MD 4 set out in these regulations.

(2) The Authority shall process permit applications within set turnaround times in the relevant guidelines.

(3) Permits shall be issued as set out in General Regulations. These may cover any other information(s) that shall be specified in the relevant guidelines. For example;

a. All imported products should be within the prescribed shelf life.

b. Consignments shall be accompanied by a relevant authorisation at the port of entry or exit

c. Consignment should be labelled in Botswana's official language or accompanied by a translation from an official recognised entity.

d. The Authority shall vet purchasing orders and proforma invoices as part of the authorisation process

Revocation or suspension of import or export authorisation

57. (1)(a) In accordance with Section 65 of the Act the authority may cancel, suspend, withdrawal or revoke an import/export authorisation if the issued entity is seen to have not met or contravened regulatory requirements.

(a) Such cancellation, suspension, revocation or withdrawal shall be done as prescribed in the guidelines.

Authorised ports of entry

58. (1) In accordance with section 63 of the Act, medical devices and IVDs shall be imported or exported only through ports of entry designated in the general regulations or in the prescribed guidelines.

(2) The Authority shall liaise with the strategic partners to

(a) maintain import/export control arrangements at designated ports as per the MoU/MoA;

(b) facilitate inspection/verification of consignments;

(c) share information on imports and exports; and

(d) coordinate enforcement activities.

(3) Medical Devices shall not be imported through postal services except

(a) small quantities for personal use as approved;

(b) samples for registration purposes; and

(c) diagnostic specimens as authorised.

Medical Devices in Transit

59. (1) In accordance with section 70 of the Act, medical devices including IVDs transiting through Botswana shall require a transit permit as prescribed by the Authority.

(2) An application for a transit permit shall be made in a form as prescribed by the relevant guidelines.

(3) The holder of a transit permit shall—

(a) ensure medical devices including IVDs remain under customs control;

(b) not release medical devices including IVDs into the domestic market;

(c) not process, repackage, or alter products during transit;

(d) notify the Authority within forty-eight hours of departure from Botswana; and

(e) maintain records of the transit.

(4) Transit permit shall be valid for period as prescribed in the relevant guidelines.

(5) The importer of medical devices shall ensure that medical devices including IVDs in a bonded warehouse comply with requirements for transit as set out in the guidelines

(6) Contravention of transit permit conditions constitutes an offence punishable by a fine as prescribed in the general regulations and fee, levies penalties regulations.

Donated Medical Devices

60. (1) In accordance with section 66 of the Act, donated medical devices require authorisation from the Authority.

(2) An application for a donation permit shall be made in a form as prescribed in the relevant guidelines.

(3) Donated medical devices shall

(a) meet applicable safety, quality, and performance requirements;

(b) be suitable for their intended use within Botswana;

(c) be accompanied by instructions for use and labelling in English;

(b) have adequate remaining shelf / service life as specified in the guidelines

(d) include necessary accessories, consumables, software, and maintenance information where applicable;

(e) not be obsolete, unsafe, damaged, or otherwise unsuitable for use; and

(f) comply with the Authority's guidelines on donations, which shall align with World Health Organization guidelines.

(4) The Authority may waive or reduce fees for donated products intended for humanitarian purposes.

(5) Where donated products do not meet requirements, the Authority may seize, quarantine, confiscate or order re-export/disposal at the importers cost.

Personal Importation

61. (1) In accordance with section 64 of the Act, a person may import a medical device intended solely for personal use without an import permit, subject to conditions specified by the Authority.

(2) Personal importation shall not apply to—

(a) medical devices intended for commercial distribution or resale;

(b) medical devices requiring professional installation, or specialised training for safe use;

(c) medical devices prohibited in Botswana, or

(d) any category of a medical device specified by the Authority as requiring prior approval.

(3) The Authority may establish specific procedures for patients requiring access to unregistered medical devices including IVD medical devices for personal use.

(4) The quantities of imported personal use medical devices shall be as prescribed in the guidelines.

Additional Controls for High-Risk Devices

62. (1) The Authority may impose additional import or export controls on specified categories of medical devices including IVDs based on their classification, intended purpose, technology, or public health risk.

(2) Such controls may include—

(a) pre-shipment verification;

(b) batch, lot, serial number, or UDI reporting;

(c) enhanced traceability requirements;

(d) pre and post-importation inspection or testing; or

(e) any other measures necessary to protect public health and safety.

Records for Medical Devices and In Vitro Diagnostics

Formatted: Font color: Custom Color(RGB(31,77,120))

63. (1) Every manufacturer, authorised representative, importer, exporter, distributor, wholesaler, healthcare institution, or other licensed establishment handling medical devices or IVDs shall establish and maintain records sufficient to ensure traceability of devices throughout their lifecycle.

(2) Such records shall include, where applicable—

(a) device name, model, catalogue number, nomenclature system, serial number, lot number, or batch number;

(b) quantities received, supplied, distributed, returned, repaired, refurbished, destroyed, or otherwise disposed of;

(c) name and address of the supplier;

(d) date of receipt;

(e) import permit or export permit details, where applicable;

(f) name and address of the customer, consignee, healthcare facility, or end user, where applicable;

(g) date of supply, installation, commissioning, servicing, maintenance, recall, or disposal; and

(h) invoice, delivery note, service report, or other relevant reference number.

(3) For implantable medical devices, records shall additionally enable identification of the medical device supplied to a specific healthcare institution or patient, where required by the Authority.

(4) Records relating to the purchase, importation, exportation, distribution, installation, servicing, maintenance, complaint handling, recalls, field safety corrective actions, and disposal of medical devices and IVDs shall be retained for not less than five years, or such longer period as may be specified by the Authority.

(5) Records shall—

(a) be accurate, complete, and maintained in a manner that preserves integrity and traceability;

(b) be maintained in electronic or hard-copy form;

(c) be protected against unauthorised alteration, damage, loss, or destruction;

(d) be readily retrievable and available for inspection by the Authority; and

(e) include an auditable amendment history where records are maintained electronically.

(6) A person required to maintain records under these Regulations shall ensure that entries are made promptly and that periodic reconciliation of inventory and traceability records is conducted.

(7) Any correction to a record shall be attributable, dated, and shall not obscure the original entry.

PART VII — IN VITRO DIAGNOSTIC MEDICAL DEVICES

Additional requirements for in vitro diagnostics

64. (1) In vitro diagnostic medical devices shall comply with—

(a) the general requirements for medical devices in these Regulations;

(b) the specific requirements for in vitro diagnostics in this Part; and

(c) in vitro diagnostic specific guidelines, the General Regulations, Clinical Trial Regulations and Fees Regulations.

(2) In vitro diagnostic risk classification shall follow regulation 6 and Schedule 2.

(3) Devices that use human samples for medical or forensic purposes shall be classified and regulated as in vitro diagnostics as prescribed in guidelines.

Clinical and non-clinical evidence for in vitro diagnostics

65. (1) In vitro diagnostic medical devices shall undergo clinical and non-clinical evaluation demonstrating—

(a) analytical performance, including sensitivity, specificity, accuracy and precision;

(b) clinical performance, including clinical sensitivity and clinical specificity;

(c) stability data to support the stability claims for the product;

(d) stability and validation of specimens; and

(e) usability and human factors studies.

(2) Performance claims shall be supported by appropriate studies.

(3) Requirements shall be proportionate to the classification of the in vitro diagnostic medical device.

Quality management for in vitro diagnostics

66. (1) In vitro diagnostic manufacturers shall implement a quality management system covering general requirements and specific requirements for reference materials, metrological traceability, stability and such other requirements as prescribed in guidelines.

(2) Class B, C and D in vitro diagnostics may have third-party quality management system certification.

Self-testing in vitro diagnostics

67. (1) In vitro diagnostics intended for self-testing by lay users shall—

(a) be designed for use by non-professional users;

(b) have clear instructions suitable for lay users;

(c) have performance validated in the hands of intended users;

(d) provide clear indication of when to seek professional advice; and

(e) minimise risk from user error.

Companion diagnostics and orphan medical devices

68.(1) Companion diagnostics shall be developed in conjunction with the corresponding medical product where possible, have clinical performance validated for the intended use, have labelling referencing the corresponding medical product, and be classified based on risk.

(2) Orphan medical devices including IVDS shall be regulated as prescribed in the General Regulations and guidelines.

Laboratory developed tests

69. (1) Laboratory developed tests are in vitro diagnostics designed, manufactured and used within a single laboratory.

(2) Laboratory developed tests shall meet quality requirements specified in guidelines, be validated for their intended purpose, be used by qualified laboratory personnel, and be subject to laboratory quality system oversight.

PART VIII QUALITY CONTROL AND LABORATORY SERVICES

National Quality Control Laboratory

70. (1) In accordance with section 31 of the Act and the General regulations, the National Quality Control Laboratory shall

(a) analyse and test regulated medical devices including IVDs for quality, safety and performance;
(b) conduct batch release testing for selected medical devices including IVDs as prescribed in the guidelines.
(c) conduct lot-to-lot verification of selected IVDs as prescribed in the guidelines.
(c) support market surveillance through sampling and testing;
(d) conduct research relevant to quality control;
(e) provide training and capacity building;
(f) maintain and disseminate reference standards; and

(g) provide quality control services to public and private entities;
(h) adhere to any other provisions as prescribed in the General Regulations.

Application for laboratory services

71. (1) In accordance with section 33 of the Act and the General Regulations, applications for laboratory services shall be made to the Authority in the prescribed set out in General Regulations.

(2) Applications shall be accompanied by
(a) the prescribed fee;
(b) samples in required quantity and condition;
(c) product information including specifications;
(d) special handling instructions where applicable; and
(e) such other information as may be required.

(3) The Laboratory shall provide estimated timelines for testing upon receipt of samples.

Certificate of analysis

72. (1) In accordance with section 34 of the Act, the Laboratory shall
(a) analyse samples promptly upon receipt;
(b) issue a Certificate of Analysis upon completion;
(c) specify the tests performed and results obtained; and
(d) state whether the sample conforms to specifications.

(2) A Certificate of Analysis shall be signed by the Laboratory head or authorised delegate.

(3) The Certificate of Analysis shall constitute prima facie evidence of the matters stated therein in any legal proceedings.

Use of external laboratories

73. (1) In accordance with section 110 of the Act, the Authority may

(a) subcontract analysis to approved independent laboratories within or outside Botswana;
(b) rely on test results from accredited laboratories, recognized testing laboratories, or international reference laboratories that are competent for the relevant device type or test method and,
(c) utilise Government Laboratories where appropriate.

(2) External laboratories used by the Authority shall
(a) be accredited to ISO/IEC 17025 or equivalent for relevant methods;
(b) participate in proficiency testing; and
(c) be approved by the Authority.

(3) The Authority shall maintain and publish a list of approved external laboratories.

PART IX — SOFTWARE AND DIGITAL HEALTH

Software as a medical device

74. (1) Software intended for one or more medical purposes that performs those purposes without being part of a hardware medical device shall be regulated as a medical device.

(2) Software as a medical device includes software that intended to —

(a) to diagnose, prevent, monitor, predict, prognose, treat or alleviate disease;

(b) to diagnose, monitor, treat, alleviate or compensate for an injury or disability;

(c) to investigate, replace or modify the anatomy or a physiological process; or

(d) provides informationused to make decisions for diagnostic or therapeutic purposes.

(3) Software as a medical device does not include software intended only for administrative purposes, software that only stores, archives or communicates data, or general purpose software not intended for medical use.

Classification of software as medical devices

75. Software as a medical device shall be classified based on the significance of the information provided to a healthcare decision and the state of the healthcare situation or condition the

software is intended to address, in accordance with guidelines aligned with International Medical Device Regulators Forum guidance on software as a medical device.

Software lifecycle requirements

76. Software as a medical device development shall follow a software lifecycle process in accordance with IEC 62304 or equivalent standards, and risk management shall be applied throughout the software lifecycle.

Cybersecurity requirements

77. (1) Medical devices incorporating software or network connectivity shall be designed, developed and maintained to address cybersecurity throughout the total product lifecycle.

(2) Cybersecurity activities shall include, as appropriate—

(a) identification and assessment of cybersecurity risks;

(b) implementation of security controls to ensure confidentiality, integrity, availability and authenticity of data and systems;

(c) monitoring for vulnerabilities and cybersecurity incidents;

(d) coordinated vulnerability disclosure and incident response processes;

(e) timely provision of security updates and patches; and

(f) provision of information to users regarding secure configuration, operation and maintenance.

(3) Requirements shall be specified in guidelines aligned with International Medical Device Regulators Forum cybersecurity guidance.

Artificial intelligence and machine learning in medical devices

78. (1) Medical devices incorporating artificial intelligence or machine learning shall demonstrate, in a manner proportionate to the device classification and associated risks:

(a) adequate documentation of the model design, intended use, inputs, outputs and performance characteristics;

(b) evidence of the quality, representativeness, and governance of training, validation, and testing data, including measures to identify and mitigate bias;
(c) analytical validation, clinical validation where applicable and performance evaluation demonstrating safety and effectiveness for the intended population, conditions of use and use environment;
(d) post-market performance monitoring and risk management processes; and
(e) where applicable, a Predetermined Change Control Plan (PCCP), describing the scope of anticipated modifications and the methodology for implementing, validating, and controlling such changes in accordance with applicable regulatory requirements.

(2) A Predetermined Change Control Plan may be used to support ongoing changes to adaptive algorithms that continue learning after deployment, where appropriate. BoMRA's approach to Predetermined Change Control Plans shall be consistent with the principles described in relevant IMDRF guidance. The Authority shall issue guidelines consistent with relevant IMDRF guidance on machine learning-enabled medical devices.

Software updates and modifications

79. (1) Software modifications shall be assessed by the manufacturer to determine whether the change significantly affects the device's intended purpose, safety, effectiveness or performance.

(2) Changes shall be classified in accordance with guidelines issued by the Authority, taking into account relevant IMDRF guidance.

(3) Security patches and vulnerability mitigations that do not adversely affect the intended purpose, safety or performance of the device may be implemented with notification to the Authority in accordance with applicable guidelines.

Interoperability requirements

80 (1) Medical devices intended to exchange information with other medical devices, health information systems or digital health platforms shall—

(a) use recognised interoperability standards where appropriate;

(b) specify their intended interoperability characteristics, interfaces and limitations;

(c) maintain safety, effectiveness and cybersecurity when operating in interconnected environments; and

(d) support secure and reliable exchange of information consistent with their intended purpose.

(2) The Authority may prescribe recognised interoperability standards and technical specifications through guidelines.

PART X — CLINICAL INVESTIGATIONS

Clinical investigation authorisation

81. (1) In accordance with section 46 of the Act, clinical investigations of medical devices including IVDS shall require authorisation from the Authority and ethics committee for approval before commencement.

(2) Applications shall be submitted in accordance with the Clinical Trials Regulations, medical devices investigations guidelines, and shall be accompanied by the prescribed fee as set out in the Fees Regulations.

(3) An application for clinical investigation authorization shall be made and shall include—

(a) the clinical investigation plan;
(b) the investigator's brochure or device description;
(c) evidence of ethics committee approval;
(d) investigator qualifications and site information;
(e) informed consent forms and patient information leaflets;
(f) risk analysis and risk management plan; and
(g) insurance or indemnity arrangements.

(4) The Authority shall process clinical investigation applications within the timelines stipulated in the guidelines.

(5) For medical device investigations involving minimal risk, the Authority may waive certain requirements.

(6) Conducting a clinical trial without authorization is an offence under section 57 of the Act.

Good clinical practice for medical devices

82. Medical device clinical investigations shall be conducted in accordance with the Good Clinical Practice standards prescribed or adopted by the Authority through guidelines issued under these Regulations. The guidelines may prescribe requirements relating to investigator qualifications and training, device accountability, investigation procedures, reporting of device malfunctions, assessment and reporting of adverse events, and any other matter necessary for the proper conduct of clinical investigations.

Ethical requirements

83. (1) Ethics committee approval shall be obtained before commencing a clinical investigation, with informed consent requirements as specified in the Clinical Trials Regulations, medical devices investigation guidelines, and special considerations for investigations involving implantable medical devices, companion diagnostics, high-risk medical devices and vulnerable populations.

(2) The rights, safety and wellbeing of subjects shall take precedence over the interests of science and society.

Clinical investigation conduct

84. Investigations shall be conducted according to the approved protocol; deviations shall be documented and reported; and the investigator shall permit Authority inspection of clinical investigation records, facilities and data at any time.

Safety reporting for clinical investigations by sponsors

85. (1) The sponsor shall ensure that all reportable safety events occurring during a clinical investigation are reported to the authority within the timelines prescribed in the applicable guidelines. Reportable safety events include:

(a) any serious adverse event (SAE) affecting a participant, user, or any other person that is causally related to the investigational medical device, the clinical investigation procedures, or where a causal relationship cannot reasonably be excluded;

(b) any serious public health threat arising from the investigational medical device or the conduct of the clinical investigation; and

(c) any medical device deficiency that might have led to a serious adverse event had appropriate action or intervention not been taken, or had circumstances been less favorable.

(2) Periodic safety reports shall be submitted as required for adverse events that:

a. led to a death;

b. led to a serious deterioration in the health of the subject that either:

_____I) resulted in a life threatening illness of injury, or

_____II) resulted in a permanent impairment of a body structure or a body function, or

_____III) required in-patient hospitalization or prolongation of existing hospitalization, or

_____IV) resulted in medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function;

c. led to fetal distress, fetal death or congenital abnormality or birth defect

d. any other events as prescribed in the guidelines.

(3) the sponsor shall ensure that all safety reports are complete, accurate, and supported by appropriate follow-up information, including an assessment of casualty, severity, expectedness and any corrective or preventative actions implemented.

Clinical investigation reports

86. A clinical investigation report following ISO 14155, ISO 20916, or equivalent standards shall be submitted upon completion, regardless of outcome.

PART XI — POST-MARKET SURVEILLANCE AND VIGILANCE

Post-market surveillance system

87. (1) In accordance with section 74 of the Act a manufacturer or marketing authorisation holder or distributor shall establish, implement, document and maintain a risk management and post-market surveillance system appropriate to the classification and risk of the medical device.

(2) The post market surveillance system shall -

(a)gather and evaluate data on the quality, safety, and performance of the device;

(b)identify trends that may warrant action;

(c) assess the need for corrective actions and preventative actions;

(d) continuously assess the benefit-risk balance of the device

(d) update risk management documentation, implement risk minimization measures, and, feed into the clinical evaluation;

Formatted: Font color: Red

(e) include product complaint management;

(f) monitor the performance of the medical device;

(g) trend analysis and reporting;

(g)and include vigilance reporting;

(3) vigilance reporting shall include;

(a) a serious adverse event or incident that has led to death of a patient, user or other person;

(b)serious injury to a patient, user or other person;

(c) no death or serious injury occurred but the event might lead to death or serious injury of a patient, user or other person;

(d) field safety correction;

(f) field safety notification;

(g) submit periodic safety update reports to the Authority as per guidelines;

(h) updated risk management plans;

(i) safety labelling variations as prescribed in the guidelines;

(j) communication in consultation with the Authority regarding urgent and serious safety information to healthcare professionals and the public and;

(k) any other relevant safety and performance requirements as prescribed in the guidelines;

(4) The post market surveillance plan and risk management plan shall be part of the technical documentation submitted with the registration application.

(4) Post market surveillance data shall feed into the periodic safety update reports.

(5) For Class C and D medical devices, the system shall include proactive data collection.

Materiovigilance

88. (1) In accordance with section 71 of the Act and the national medical device materiovigilance system shall be maintained to facilitate the reporting, evaluation, investigation and monitoring of incidents and other safety-related information associated with medical devices placed on the market.

(2) The Marketing Authorization Holder (MAH) shall appoint a qualified person responsible for vigilance activities and correspondence with the Authority.

(3) The Authority may conduct Good Vigilance Practice Inspections for MAH's Vigilance systems.

Adverse event and Incident reporting

89. (1) Manufacturers, marketing authorisation holders, authorised representatives, importers, distributors and healthcare facilities shall report and or submit to the Authority any-

(a) suspected or unexpected adverse events related to registered medical devices;

(b) lack of expected efficacy or quality defects;

(c) safety signals;

(d) serious incident and/or serious injuries involving a registered medical device;

(e) field safety corrective action taken in relation to a registered device

(f) regulatory actions in other countries; and

(g) such matters as specified in the guidelines.

(2) Reports shall be submitted using Form BOMRA/MD 6 for medical device adverse events and incidents, or through the electronic regulatory information management system.

(3) Reporting timelines shall be as prescribed in guidelines.

(4) Initial reports may be submitted before full investigation is complete, with a follow-up report submitted within thirty days of completion of the investigation.

Formatted: Font: (Default) Times New Roman, 12 pt, Font color: Auto

(5) Healthcare professionals shall report

(a) Any suspected medical device associated incident and event that has occurred to both the Authority and the Marketing Authorisation Holder.

(b) The event led to a serious outcome for both the Authority and the Marketing Authorisation Holder.

(c) A near miss event to both the Authority and the Marketing Authorisation Holder.

d) Expected and foreseeable side effects to the Authority.

(f) Negligible likelihood of occurrence of death or serious injury

(g) Deficiency of a medical device found by the user prior to its use.

(6) Patients are encouraged to report adverse events and incidents voluntarily, and the Authority shall maintain a mechanism for voluntary reporting.

Trend reporting

90. ((1) Manufacturers shall establish and maintain procedures to collect, review and analyse post-market surveillance data to identify trends in incidents, adverse events, complaints and other relevant safety and performance information.

(2) Where trend analysis identifies a statistically significant increase in the frequency or severity of incidents, expected undesirable side effects, or other events that could have a significant impact on the benefit-risk determination of a medical device, the manufacturer shall notify the Authority in accordance with guidelines.

(3) Trend reporting requirements, including reporting thresholds, content and timelines, shall be specified in guidelines having regard to the classification of the medical device and the nature of the identified risk.

Field safety corrective actions

91. (1) Any corrective action taken by a manufacturer or marketing authorisation holder to reduce a risk of death or serious deterioration in the state of health associated with a medical device that has been placed on the market shall constitute a field safety corrective action.

(2) Field safety corrective actions may include the recall, modification, replacement, destruction, software update, relabelling, inspection or provision of additional safety information relating to the affected medical device.

(3) A manufacturer or marketing authorisation holder shall notify the Authority of any field safety corrective action and issue a field safety notice to affected users, where appropriate, within the timelines specified in guidelines.

(4) The Authority may, in accordance with section 75 of the Act, require or order a field safety corrective action, including the recall of a medical device, where necessary to protect public health; this may be submitted using FORM BOMRA/MD 8 or equivalent.

Periodic safety update reports

92. (1) In accordance with section 72 of the Act, manufacturers shall prepare and maintain post-market surveillance reports or periodic safety update reports appropriate to the risk classification of the medical device.

(3) For low to moderate risk medical devices, manufacturers shall prepare and maintain post-market surveillance reports and make them available to the Authority upon request.

(4) For moderate to higher-risk medical devices, manufacturers shall prepare and submit periodic safety update reports containing—

(a) a summary of the results and conclusions of post-market surveillance data;

(b) an analysis of serious incidents and field safety corrective actions;

(c) trend analysis;

(d) conclusions of the benefit-risk determination;

(e) a summary of preventive and corrective actions taken; and

(f) any other information specified by the Authority.

(5) The format, content, submission frequency and classes of medical devices requiring periodic safety update reports shall be specified in guidelines and conditions of registration.

Risk management for medical devices

93. (1) The Authority may require marketing authorisation holders to implement risk management measures for medical devices.

(2) Risk management measures may include risk control activities, additional monitoring, and post-market studies and any other risk management communications as prescribed in the guidelines

(3) The MAH of a medical device shall submit to the Authority information in respect of any serious risk of injury to public health that the MAH receives or becomes aware of and that is relevant to the safety of the device, regarding

a. changes that have been made to the labelling of any medical device and that have been communicated to or requested by any regulatory authority as prescribed in the guidelines

b. recalls or regulatory decisions as prescribed in the guidelines

Post-market clinical follow-up

94. Post-market clinical follow-up shall be conducted for Class C and D medical devices, implantable medical devices, medical devices where required by conditions of registration, and medical devices where clinical data gaps exist, as prescribed in guidelines.

PART XII — UNIQUE DEVICE IDENTIFICATION

Unique device identification system

95. (1) In accordance with section 117 of the Act, manufacturers shall assign and apply a unique device identifier to medical devices.

(2) The unique device identifier shall consist of a device identifier and a production identifier.

(3) Unique device identifier standards shall be those issued by International Medical Device Regulators Forum designated issuing agencies, including global system of standards (GS1), Health Industry Business Communications Council (HIBCC), International Council for Commonality in Blood Banking Automation (ICCBBA), or other agencies designated by the International Medical Device Regulators Forum or the World Health Organization.

Unique device identification carrier specifications

96. The unique device identifier shall be presented in human-readable interpretation and machine-readable form, placed on the medical device label, all higher levels of packaging, and directly on the medical device where feasible and required, with direct marking required for reusable medical devices intended for reprocessing.

Unique device identification database

97. Manufacturers shall submit unique device identification data to a database recognised by the Authority, and the Authority will rely on the existing UDI international databases.

Implementation timeline

98. Unique device identification implementation shall be phased as prescribed by the Authority in Schedule 4.

Traceability requirements

99. Economic operators shall maintain records enabling traceability, including unique device identifiers or equivalents, supplier and customer identification, and transaction dates, for such period as may be prescribed in guidelines.

Tracking requirements

100. (1) All medical devices placed on the market shall be subject to traceability requirements appropriate to their classification and intended purpose.

(2) Enhanced tracking requirements shall apply to:
(a) Class D medical devices;
(b) implantable medical devices; and
(c) any other medical devices specified by the Authority in guidelines based on risk.

(3) The traceability system shall, as applicable, enable the identification of:

(a) the medical device by its Unique Device Identifier (UDI), where implemented, or by the applicable batch, lot, or serial number;

(b) the economic operators and healthcare facilities involved in the distribution and supply of the medical device; and

(c) for implantable medical devices, the patient to whom the device was supplied or implanted, to the extent permitted by applicable guidelines.

Nomenclature system for medical devices

101. (1) The Authority shall use medical device nomenclature systems to standardise naming, classification and identification of medical devices.

(2) The nomenclature systems used by the Authority shall include the Global Medical Device Nomenclature, the European Medical Device Nomenclature System, the Universal Medical Device Nomenclature System, or other harmonised systems designated by the International Medical Device Regulators Forum, African Medical Devices Forum or World Health Organization.

PART XIII — LABELS, LABELLING AND INFORMATION

General labelling requirements

102. In accordance with section 84 of the Act, labelling of medical devices shall enable safe and effective use and shall be accurate, legible, indelible, understandable by intended users, in English, and compliant with the Essential Principles.

Label content

103. Medical device labels shall include, as applicable, the medical device name and model, manufacturer name and address, authorised representative details, lot or serial number, unique device identifier carrier, expiry date or shelf life, storage and handling conditions, sterility status, single use indication, warnings and precautions, symbols in accordance with ISO 15223 or equivalent internationally recognised standard, and the registration number as prescribed in guidelines.

Instructions for use

104. Instructions for use shall accompany medical devices except where safe use is possible without instructions, and shall include the medical device description, intended purpose, intended users, indications and contraindications, instructions for use, warnings and precautions, maintenance requirements, troubleshooting, disposal instructions, specimen collection and storage information where applicable, and such other requirements as may be prescribed in guidelines.

Electronic labelling provisions

105. (1) Manufacturers may provide electronic labelling, including electronic instructions for use (eIFU), where the safety and effective use of the medical device are not adversely affected and the conditions specified in these Regulations or applicable guidelines are met.

(2) The use of electronic instructions for use in place of paper instructions shall be supported by a documented risk assessment demonstrating that—

(a) the intended users can access and use the electronic information safely and effectively;

(b) the electronic format does not increase the risk associated with the use of the medical device;

(c) appropriate measures are in place to ensure that the information is readily available throughout the expected lifetime of the medical device; and

(d) users are informed of how to access electronic instructions for use.

(3) Paper instructions for use shall be provided—

(a) where required by these Regulations or applicable guidelines;

(b) where necessary to ensure the safe and effective use of the medical device, having regard to the intended users and use environment; or

(c) upon request by a user, without additional cost and within a reasonable period.

(4) Electronic labelling shall—

(a) be accurate, complete and consistent with any paper labelling;

(b) be readily accessible to intended users throughout the expected lifetime of the medical device;

(c) be maintained in a manner that preserves its integrity, security and traceability; and

(d) comply with any technical and accessibility requirements specified in applicable guidelines.

(5) The Authority may prescribe, by guideline, the categories of medical devices eligible for electronic labelling, the circumstances in which paper instructions for use remain mandatory, and the technical requirements applicable to electronic labelling.

Language requirements

106. (1) Labels and instructions for use shall be in English, and additional languages may be required based on intended users, use setting and patient safety considerations, as prescribed in guidelines.

(2) Where necessary, the authority may publish product information and patient information leaflets of registered medical devices.

PART XIV — ADVERTISING AND PROMOTION

Advertising approval

107.(1) In accordance with section 83 of the Act, no person shall advertise or promote medical devices without prior approval from the Authority.

(2) Promotion and Advertisement for Medical devices is only permitted for registered medical devices

(3) Applications for advertising approval shall be made through the electronic regulatory management system or in FORM BOMRA/MD 7 and shall be accompanied by the prescribed fee as set out in the Fees Regulations and references supporting claims made

(4) All advertisements and promotional materials shall comply with the standards prescribed in the guidelines.

Advertising standards

108 (1) Advertising of medical devices shall be accurate and not misleading, balanced in presenting benefits and risks, based on evidence and appropriate for the audience, and shall not make claims beyond the registered intended purpose, make unsubstantiated claims, discourage users from seeking professional advice, or target inappropriate audiences.

(2) Advertising claims shall be consistent with the intended purpose, clinical evidence, and approved labelling of the medical device.

Prohibited advertising practices

109. The following practices are prohibited—

(a) advertising unregistered medical devices;

(b) advertising of unapproved indications

(b) advertising high-risk professional use medical devices, being Class C and D medical devices, to the general public;

(c) comparative claims without substantiation;

(d) inducements that may improperly influence prescribing; and

(e) such other practices as may be prohibited in the guidelines.

Online sale of medical devices

110. In accordance with section 61 of the Act, online sale of medical devices shall require an appropriate licence, verification of registration status, accurate product information, appropriate sales controls and compliance with advertising requirements, as prescribed in the General Regulations and guidelines.

PART XV — SPECIAL PROVISIONS

Custom-made medical devices

111. (1) Custom-made medical devices do not require registration but shall be made according to a written prescription, intended for sole use of a particular patient, meet the Essential Principles, have a manufacturer's statement, and be subject to incident reporting.

(2) Custom-made medical devices shall not be mass-produced.

Medical devices for special access

112. (1) Unregistered medical devices may be authorised for named patients with serious conditions and no suitable alternatives, emergency use, compassionate use programmes, and approved clinical investigations.

(2) An application for special access shall be made in Form BOMRA/MD 5 and shall be accompanied by the prescribed fee as set out in the Fees Regulations.

(3) Conditions of special access shall include enhanced monitoring and reporting.

Refurbished and remanufactured medical devices

113. (1) Refurbished medical devices may be placed on the market if restored to original manufacturer specifications, refurbished by the manufacturer or an authorised party, subjected to appropriate testing, labelled as refurbished, warranted and documented.

(2) Remanufactured and refurbished medical devices shall be subject to registration requirements as prescribed in guidelines.

Reprocessing of single-use medical devices

114. The reprocessing of a single-use medical device as labelled by its manufacturer shall not be permitted unless authorised by the Authority.

Research use only medical devices

115. (1) Medical devices labelled "For Research Use Only" shall not be used for diagnostic or clinical purposes.

(2) Distribution shall be limited to research institutions.

(3) Promotional activities shall not suggest clinical use.

Donated medical devices

116. (1) In accordance with section 66 of the Act, donated medical devices shall meet registration requirements or be authorised under special access provisions.

(2) Donated medical devices shall meet the Essential Principles, have adequate remaining useful life, be appropriately labelled, include necessary accessories and documentation, and comply with guidelines on donated medical devices.

PART XVI — INSPECTION AND MARKET SURVEILLANCE

Inspection authority

117. (1) In accordance with sections 77 and 78 of the Act, the Authority may inspect manufacturers, authorised representatives, importers, distributors, wholesalers, healthcare facilities, service providers and any other entity dealing with medical devices.

(2) Inspections may be announced or unannounced.

(3) Inspection powers and procedures shall be as specified in the General Regulations and guidelines.

Risk-based inspection

118.(1) Inspection frequency and intensity shall be based on risk assessment, taking into account the risk classification of the medical device, compliance history, post-market surveillance data, complaints and incidents, and such other factors as may be prescribed in guidelines.

(2) In determining inspection frequency, scope, and intensity, the Authority may apply reliance principles and take into account relevant and verifiable outcomes from other recognised regulatory authorities and competent conformity assessment bodies.

(3) Without limiting the generality of subregulation (2), the Authority may, where appropriate and subject to verification, rely on or take into account—
(a) valid ISO 13485 certification issued by an accredited certification body;
(b) Medical Device Single Audit Program (MDSAP) audit reports;
(c) conformity assessment body audit outcomes, where applicable; and
(d) inspection reports, assessment outcomes, or regulatory decisions issued by recognised regulatory authorities/institutions.

(4) The Authority may use the information referred to in subregulation (3) to determine whether to—
(a) reduce inspection frequency;
(b) limit the scope of inspection to specific risk areas;
(c) conduct desk-based assessments in lieu of on-site inspection; or
(d) prioritise inspection resources toward higher-risk establishments or activities.

(5) Nothing in this regulation limits the Authority from conducting an inspection where it determines, on reasonable grounds, that such inspection is necessary for the protection of public health, including where there are signals relating to non-compliance, adverse events, recalls, or other safety concerns.

Market surveillance activities

119. (1) Market surveillance activities shall include proactive monitoring programmes, reactive investigations following incidents or complaints, sampling and testing, verification of labelling compliance, and international cooperation, applied on a risk-based approach.

(2) In conducting market surveillance, the Authority may take into account information, alerts, and findings from other regulatory authorities, international databases, and recognised medical devices vigilance systems.

(3) Procedures shall be as specified in the General Regulations and guidelines.

Sampling and testing

120. (1) In accordance with sections 31 and 34 of the Act, the Authority may take samples of medical devices for testing where justified by a risk-based assessment, including market surveillance, complaint investigation, suspected non-compliance, safety or performance concerns, filed safety corrective action verification, public health emergency, or other documented public health justification

(2) Testing may be conducted by the National Quality Control Laboratory, recognized testing laboratories, or international reference laboratories that are competent for the relevant device type or test method

(3) Procedures shall be as specified in the General Regulations and guidelines, and shall include requirements for sampling rationale, sampling method, sample quantity, storage and handling conditions, retention or return of samples where appropriate, test method validation, and communication of test results to the manufacturer, authorized representative, importer or marketing authorization holder.

(4) Sampling and testing shall not be required routinely as a condition of registration, renewal, importation or release of registered medical devices and IVDs unless the Authority determines that such testing is necessary based on documented risk, public health concern, suspected non-compliance, complaint, or insufficient evidence from the manufacturer, recognized conformity assessment body, accredited laboratory or reference Regulatory authority.

PART XVII — ENFORCEMENT

Cancellation, suspension and withdrawal of registration

121. The Authority may cancel, suspend or withdraw a registration in accordance with section 41 of the Act and the General Regulations.

Recall procedures

122. (1) In accordance with section 75 of the Act, recalls may be initiated voluntarily by the manufacturer or marketing authorisation holder, or ordered by the Authority.

(2) Recall procedures shall be as specified in the General Regulations and guidelines.

(3) Effectiveness checks shall verify recall completion.

Disposal of unfit products

123. Disposal of unfit medical devices shall be in accordance with section 76 of the Act and the General Regulations and guidelines.

Maintenance of registers

124. The Authority shall maintain and publish all registers of medical devices, where applicable, as prescribed in the General Regulations and guidelines.

Offences and penalties

125. (1) A person who contravenes any provision of these Regulations for which no specific penalty is provided commits an offence and is liable to the penalties specified in section 119 of the Act, General Regulations, and Fees Regulations.

(2) Specific offences include—

(a) manufactures, imports, exports, distributes, sells, stores, possess or supplies a medical device without the required registration, licence or relevant authorization by the Authority;

(b) making false declarations to the Authority or relevant bodies working in partnership or on behalf of the Authority;

(c) failing to report incidents;

(d) failing to implement or comply with recalls;

(e) providing false labelling;

(f) advertising in contravention of these Regulations;

(h) fails to maintain required records;

(i) fails to comply with conditions of registration or licence;

(j) imports or exports through an unauthorised port;

(k) sells expired, substandard or falsified medical devices; or

(l) contravenes any provision of these Regulations for which no specific penalty is provided. and

(g) contravening any other provision of these Regulations.

Compounding of offences

126. Compounding of offences shall be in accordance with section 121 of the Act and the Fees, Levies and Penalties Regulations.

PART XVIII — TRANSITIONAL AND FINAL PROVISIONS

Guidelines

127. (1) The Authority shall issue guidelines on matters requiring detailed specification.

(2) Guidelines may be issued, amended or revoked without amendment to these Regulations.

(3) Guidelines shall be developed in consultation with stakeholders and aligned with international standards.

(4) Guidelines shall be published on the Authority's website and official platforms.

International cooperation and harmonisation

128. (1) In accordance with sections 107 to 111 of the Act, the Authority shall participate in-

(a) the African Medical Devices Forum;

(b) regional medical device harmonisation initiatives;

(c) the International Medical Device Regulators Forum;

(d) the Global Harmonization Working Party;

(e) World Health Organization medical device programmes; and

(f) such other relevant international and regional initiatives.

(2) The Authority shall align requirements with regional and international standards where appropriate.

Transitional provisions

129. (1) Medical devices authorised before the commencement of these Regulations shall remain valid until the expiry of such registration or authorization.

(2) Applications submitted before commencement shall be processed under the regulations in force at the time of submission, unless the applicant elects otherwise.

(3) The following transitional periods shall apply—

(a) for unique device identification implementation: as specified in guidelines;

(b) for compliance with ISO 13485 quality management system by existing local manufacturers and distributors: as specified in the guidelines or implementation plan.

(c) for ISO 13485 quality management system certification for manufacturers and distributors: as specified in guidelines or implementation plan.

(d) for registration or authorization of all medical devices: as specified in guidelines or implementation plan.

(4) The Authority may specify additional transitional arrangements.

Repeal

130. Any regulations relating to medical devices made under the repealed Medicines and Related Substances Act are hereby repealed.

Made this _____ day of _____, 2026.

_____

Minister of Health

SCHEDULES AND PRESCRIBED FORMS

TABLE OF CONTENTS

SCHEDULE 1

(Regulation 5(4))

CLASSIFICATION RULES FOR MEDICAL DEVICES

The following classification rules apply to medical devices other than in vitro diagnostic medical devices. Where a device falls under more than one rule, the highest risk classification shall apply. Classification shall take into account the intended purpose of the device. Where a device has multiple intended purposes, the classification rule leading to the highest risk class applies.

Rule	Classification Rule
PART A — NON-INVASIVE DEVICES	
Rule 1	All non-invasive devices are classified as Class A, unless one of the rules set out hereinafter applies.
Rule 2	All non-invasive devices intended for channelling or storing blood, body liquids, cells, tissues, organs or other substances for the purpose of eventual infusion, administration or introduction into the body are classified as: (a) Class A if intended for use with a Class A or B active device; (b) Class B if intended for use with a Class C or D active device or with an active implantable device; (c) Class C if they may be connected to an active medical device in Class C or D, or if they are intended for use in a contact with active tissues.
Rule 3	All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body are classified as Class C, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are classified as Class B.
Rule 4	All non-invasive devices which come into contact with injured skin or mucous membrane: (a) are classified as Class A if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates; (b) are classified as Class B if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent; (c) are classified as Class C in all other cases, including devices principally intended to manage the micro-environment of a wound.
PART B — INVASIVE DEVICES	
Rule 5	All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active medical device or which are intended for connection to a Class A active medical device: (a) are classified as Class A if they are intended for transient use; (b) are classified as Class B if they are intended for short-term use; (c) are classified as Class C if they are intended for long-term use and are not intended to be absorbed by the mucous membrane.

Rule	Classification Rule
Rule 6	All surgically invasive devices intended for transient use are classified as Class B unless they are: (a) intended to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as Class D; (b) reusable surgical instruments, in which case they are classified as Class A.
Rule 7	All surgically invasive devices intended for short-term use are classified as Class B unless they are intended: (a) to be placed in direct contact with the heart or central circulatory or central nervous system, in which case they are classified as Class D; (b) to be used in direct contact with the central nervous system, in which case they are classified as Class D; (c) to supply energy in the form of ionising radiation, in which case they are classified as Class C; (d) to have a biological effect or to be wholly or mainly absorbed, in which case they are classified as Class C; (e) to undergo chemical change in the body or to administer medicines, in which case they are classified as Class C, except if the devices are placed in the teeth.
Rule 8	All implantable devices and long-term surgically invasive devices are classified as Class B unless they are: (a) intended to be placed in the teeth, in which case they are classified as Class A or B; (b) intended to be used in direct contact with the heart or the central circulatory system or the central nervous system, in which case they are classified as Class D; (c) intended to have a biological effect or to be wholly or mainly absorbed, in which case they are classified as Class C; (d) intended to undergo chemical change in the body or to administer medicines, in which case they are classified as Class C; (e) breast implants or total or partial joint replacement devices, in which case they are classified as Class C; (f) spinal disc replacement devices or devices that come into contact with the spinal column, in which case they are classified as Class D, unless they are devices touching only the posterior column fixation components.
PART C — ACTIVE DEVICES	
Rule 9	All active therapeutic devices intended to administer or exchange energy are classified as Class B unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as Class C. Active devices intended to control or monitor the performance of active therapeutic Class C or D devices, or intended directly to influence the performance of such devices, are classified as Class C.

Rule	Classification Rule
Rule 10	Active devices intended for diagnosis are classified as Class B unless they are: (a) intended to supply energy which will be absorbed by the human body, in which case they are classified as Class B; (b) intended to image in vivo distribution of radiopharmaceuticals, in which case they are classified as Class C; (c) intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations could result in immediate danger to the patient, in which case they are classified as Class C.
Rule 11	Active devices intended to administer or remove medicines, body liquids or other substances to or from the body are classified as Class B, unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, the part of the body concerned and the mode of application, in which case they are classified as Class C.
Rule 12	All other active devices are classified as Class A.
PART D — SPECIAL RULES	
Rule 13	All devices incorporating, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in the Act and which is liable to act on the human body with action ancillary to that of the devices are classified as Class D.
Rule 14	All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are classified as Class B, unless they are implantable or long-term invasive devices, in which case they are classified as Class D.
Rule 15	All devices intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses are classified as Class C.
Rule 16	Devices specifically intended for recording X-ray diagnostic images are classified as Class B.
Rule 17	All devices manufactured utilising animal or human tissues or cells, or their derivatives, which are non-viable or have been rendered non-viable, are classified as Class C, unless such devices are intended to come into contact with intact skin only, in which case they are classified as Class A. Where such devices are intended to be placed in contact with the heart or central circulatory system or central nervous system, or where they are implanted and incorporated into the body, they are classified as Class D.
Rule 18	Blood bags are classified as Class C.
Rule 19	All devices using nanotechnology that are intended to be ingested, inhaled, or administered into the body by any other means are classified as Class D.
Rule 20	Medical devices that are intended to be used in direct contact with the heart, the central circulatory system, or the central nervous system are classified as Class D.

Note: Classification rules in this Schedule are aligned with the Global Harmonization Task Force (GHTF) Study Group 1 Document N77:2012, the International Medical Device Regulators Forum (IMDRF) GRRP Working Group Document N47:2018, the European Union Medical Device Regulation 2017/745, and the African Union Model Medical Devices Regulations 2023. Differences may apply to account for Botswana's regulatory context and local public health priorities. Where any inconsistency exists between this Schedule and the body of these Regulations, the body of these Regulations shall prevail.

SCHEDULE 2

(Regulation 6(4))

CLASSIFICATION RULES FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES

The following classification rules apply to in vitro diagnostic medical devices in accordance with regulation 6. Classification is based on individual health risk and public health risk. Where a device may be classified under more than one rule, the rule resulting in the higher classification applies. Classification takes into account the intended purpose of the device, the nature of the specimen, and the consequences of an incorrect result.

Rule	Class	Classification Rule
PART A — CLASS D: HIGH INDIVIDUAL RISK, HIGH PUBLIC HEALTH RISK		
Rule 1	**Class D**	Devices intended to be used for the following purposes are classified as Class D: (a) Detection of human immunodeficiency virus (HIV 1 and 2); (b) Detection of human T-lymphotrophic virus (HTLV) Type I and Type II; (c) Detection of hepatitis B, C, and D viruses; (d) Blood grouping — ABO system, Rhesus (C, c, D, E, e), Kell, Kidd and Duffy blood group systems; (e) Detection and identification of irregular anti-erythrocyte antibodies; (f) Detection of Trypanosoma cruzi; (g) Detection of cytomegalovirus (CMV) in blood products; (h) Confirmatory testing for the above analytes.
PART B — CLASS C: HIGH INDIVIDUAL RISK, MODERATE PUBLIC HEALTH RISK		
Rule 2	**Class C**	Devices intended to be used for the following are classified as Class C: (a) Testing for genetic pre-disposition to serious hereditary conditions; (b) Diagnosis of serious heritable conditions in foetuses or young children; (c) Determining infectious disease status or immune status where a false result would present significant risk of death or severe harm; (d) Detection of Treponema pallidum (syphilis); (e) Human leukocyte antigen (HLA) typing; (f) Detection of dengue virus, malaria, tuberculosis and similar communicable diseases of public health significance in Botswana; (g) Detection of antimicrobial resistance and virulence markers; (h) Companion diagnostics for Class C or D medicinal products; (i) Devices for near-patient testing for management of life-threatening conditions.
PART C — CLASS B: MODERATE INDIVIDUAL RISK, LOW PUBLIC HEALTH RISK		

Rule	Class	Classification Rule
Rule 3	**Class B**	Devices intended for the following purposes are classified as Class B: (a) Performance evaluation tests (intended for use in a performance evaluation study only); (b) Blood glucose self-monitoring; (c) Urinalysis instruments and reagents not falling under Class C; (d) Tests for general health monitoring not covered by higher classification rules; (e) Near-patient testing for blood gases and electrolytes; (f) Ovulation and fertility testing; (g) Self-testing intended for general health monitoring with low individual risk.
PART D — CLASS A: LOW INDIVIDUAL RISK, LOW PUBLIC HEALTH RISK		
Rule 4	**Class A**	All other IVD devices that are not covered by Rules 1 to 3 above are classified as Class A. Class A devices include: (a) Specimen receptacles (laboratory vessels, capillary blood collection tubes); (b) General laboratory instruments not intended for diagnosis; (c) Buffer solutions, washing solutions and similar IVD ancillary products; (d) Devices intended for general purpose laboratory use.
PART E — SELF-TESTING DEVICES		
Rule 5	**Class C**	Devices intended for self-testing are classified as Class C, except where they are intended for the monitoring of a disease or condition that is already been diagnosed (other than Class D conditions), in which case they are classified as Class B. This rule applies notwithstanding the classification that would apply under Rules 1 to 4 where the self-testing classification results in a higher class.
PART F — NEAR-PATIENT TESTING		
Rule 6	**Per intended purpose**	Devices intended for near-patient testing are classified by applying the rules above according to the intended purpose of the device. Near-patient testing devices shall not be classified lower than Class B.

Note: The classification rules in this Schedule are aligned with the IMDRF IVD Medical Devices Guidance Document on Classification (IMDRF/GRRP WG/N58FINAL:2020), the GHTF Study Group 1 IVD classification framework, the WHO Global Benchmarking Tool (GBT) IVD requirements, and the EU In Vitro Diagnostic Regulation 2017/746. Botswana-specific public health priorities have been incorporated, including classification of devices for communicable diseases of significance in the Southern African region.

SCHEDULE 3

(Regulation 9(1)(f), 95, 104(1), 109(2))

ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE

The Essential Principles set out in this Schedule establish the requirements that medical devices must meet to be safe and perform as intended. Manufacturers shall demonstrate compliance with the applicable Essential Principles in the technical documentation submitted with every registration application. Compliance with a recognised international standard creates a presumption of conformity with the Essential Principles covered by that standard. Where compliance with a standard is claimed, the manufacturer shall specify the standard and the extent to which it has been applied.

Ref.	Essential Principle
PART I — GENERAL ESSENTIAL PRINCIPLES	
1	**General Requirements**
1.1	Medical devices shall be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, in light of the technical knowledge, experience, education or training and the use environment and medical and physical conditions of intended users, they shall not compromise the clinical condition or the safety of patients, or the safety and health of users or other persons. Any risks associated with use must be acceptable when weighed against the benefits to the patient and compatible with a high level of protection of health and safety.
1.2	The design and manufacture of devices shall conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer shall apply the following principles in the order listed: (a) eliminate or reduce risks as far as possible through safe design and construction; (b) where appropriate, take adequate protection measures in relation to risks that cannot be eliminated; (c) inform users of the residual risks due to any inadequacy of the protection measures adopted.
1.3	Devices shall achieve the performances intended by the manufacturer and shall be designed, manufactured and packaged in a suitable manner. Devices shall be fit for the purpose for which they are intended, taking account of the generally acknowledged state of the art.
1.4	The characteristics and performances referred to in the Essential Principles shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons is compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.
2	**Design and Construction**

Ref.	Essential Principle
2.1	Devices shall be designed and manufactured in such a way as to remove or minimise, as far as possible, the risk of injury in connection with their physical features, including volume/pressure ratio, dimensional and, where appropriate, accuracy features.
2.2	Devices shall be designed and manufactured in such a way as to minimise the risk presented by contaminants and residues to the persons involved during transport, storage and use.
2.3	Devices shall be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures. If the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned.
3	**Infection and Microbial Contamination**
3.1	Devices and manufacturing processes shall be designed to reduce as far as possible the risk of infection to the patient, user and third parties. The design shall allow easy handling and, where necessary, minimise contamination of and leakage from the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen.
3.2	Devices labelled 'STERILE' shall be designed, manufactured and packaged to ensure they remain sterile when placed on the market and under storage and transport conditions specified by the manufacturer until the protective packaging is damaged or opened. Sterilisation shall be carried out by an appropriate, validated method.
3.3	Devices intended to be sterilised shall be manufactured and packaged under appropriate controlled conditions. Packaging shall be designed to maintain the sterility of the device throughout the specified shelf life and during the conditions of transport and storage.
4	**Devices Incorporating a Measuring Function**
4.1	Devices that incorporate a measuring function shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability, given the intended purpose of the device. The limits of accuracy shall be indicated by the manufacturer.
4.2	The measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose of the device.
4.3	Measurement, monitoring and display scale graduations shall be calibrated in accordance with the applicable standards.
PART II — REQUIREMENTS FOR ACTIVE DEVICES AND DEVICES CONNECTED TO THEM	
5	**Energy Sources and Electrical Safety**

Ref.	Essential Principle
5.1	Active medical devices shall be designed and manufactured in such a way as to protect against, as far as possible, accidental electric shocks during normal use and in single fault condition, where applicable.
5.2	Active medical devices shall be designed and manufactured in such a way as to ensure electrical safety in accordance with applicable international standards (IEC 60601 series or equivalent), taking into account the intended use environment and user profile.
5.3	Active devices shall be designed, manufactured and tested to ensure: (a) the risks of electromagnetic interference which could impair the operation of the device or of other devices or equipment in the intended environment are reduced to an acceptable level; (b) the device has an adequate level of intrinsic immunity to electromagnetic disturbance to enable it to operate as intended.
6	**Protection Against Mechanical and Thermal Risks**
6.1	Devices shall be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.
6.2	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.
6.3	Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from emitted noise, taking into account technical progress and the means available for reducing noise, particularly at source.
7	**Devices Emitting Radiation**
7.1	Devices emitting ionising radiation shall be designed and manufactured in such a way as to ensure that the quantity, geometry and quality of radiation emitted can be varied and controlled. Devices shall emit only the radiation required for the specified purpose.
7.2	Devices emitting potentially hazardous, visible and/or invisible radiation shall be fitted with visual and/or acoustic warning devices.
PART III — REQUIREMENTS FOR DEVICES CONNECTED TO OR EQUIPPED WITH AN ENERGY SOURCE	
8	**Software and Cybersecurity**
8.1	Devices incorporating electronic programmable systems, including software, and software as a medical device in itself, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.

Ref.	Essential Principle
8.2	Software that drives a medical device or influences the use of a medical device shall be designed in accordance with the state of the art taking into account principles of development lifecycle, risk management, validation and verification.
8.3	Manufacturers shall establish, implement, document and maintain processes for the management of cybersecurity risks throughout the lifecycle of the device. Identified cybersecurity risks shall be managed in line with the general risk management principles established in these Essential Principles.
PART IV — REQUIREMENTS FOR MEDICAL DEVICES WITH A DIAGNOSTIC FUNCTION	
9	**Clinical Performance of In Vitro Diagnostic Medical Devices**
9.1	In vitro diagnostic medical devices shall be designed and manufactured in such a way as to give a sufficiently accurate, precise and reliable performance for their intended purpose. In particular, the sensitivity, specificity, trueness, repeatability and reproducibility, including control of known relevant interference, shall be appropriate and the required limit of detection shall be achievable.
9.2	Traceability of values assigned to calibrators or control materials shall be assured through available reference measurement procedures and/or available reference materials of a higher order.
10	**Labelling, Instructions for Use and Information Supplied by the Manufacturer**
10.1	Each device shall be accompanied by the information needed to identify the device and its manufacturer, and to inform the user, and, where applicable, the patient. Labels and instructions for use shall be clear, accurate, unambiguous, and written in English.
10.2	Each device label shall include: (a) the name or trade name of the device; (b) the name, physical address and, where applicable, the registration number of the manufacturer; (c) the authorised representative details where applicable; (d) the medical device nomenclature code, where available; (e) a lot or batch code, or serial number; (f) the unique device identifier carrier where applicable; (g) an unambiguous indication of the expiry date, where applicable; (h) any special storage or handling conditions; (i) the sterility status and the sterilisation method where applicable; (j) a single-use indication, where applicable; (k) indications for reprocessing, where applicable; (l) instructions for use; and (m) the registration number.
10.3	Instructions for use shall contain all information needed to use the device safely and correctly and shall include: (a) the intended use/purpose and any restrictions; (b) the contraindications and warnings; (c) instructions for proper installation, calibration, maintenance, decontamination, and disposal; (d) performance characteristics; (e) method of calibration; (f) information about any residual risks; and (g) reference to any accessories required.

Note: The Essential Principles in this Schedule are aligned with GHTF/SG1/N68:2012 (Essential Principles of Safety and Performance of Medical Devices), IMDRF/GRRP WG/N47:2018, the WHO

Global Benchmarking Tool (GBT) ML3 requirement BM-RSA/07 and ML4 requirements relating to technical review, the EU MDR 2017/745 (Annex I) and EU IVDR 2017/746 (Annex I). Compliance with the Essential Principles is a prerequisite for placement of any medical device on the Botswana market.

SCHEDULE 4

(Regulation 27(2)(a), 88, 89, 90, 91, 92, 96)

UNIQUE DEVICE IDENTIFICATION IMPLEMENTATION

This Schedule sets out the implementation phases for the Unique Device Identification (UDI) system in Botswana, in accordance with regulation 88. The UDI system is mandatory for medical devices placed on the Botswana market. The Authority shall share the implementation timelines to account for the state of UDI adoption globally, the availability of issuing agencies in the region, and developments in the national regulatory information management system.

PART A — IMPLEMENTATION PHASES

Implementation Phase	Scope of Devices
Phase 1	Class D medical devices (all forms — label, packaging and direct marking required by the Authority). Submission of UDI data to a recognised UDI database.
Phase 2	Class C medical devices and all active implantable devices. Direct marking required for reusable devices. UDI database submission is required.
Phase 3	Class B medical devices. UDI label requirements on device label and all higher-level packaging.
Phase 4	Class A medical device.
All Classes	New registrations submitted after the commencement of these Regulations shall include a UDI-DI or equivalent identifier at the time of registration. Where an issuing agency-assigned UDI-DI is unavailable, a BoMRA-assigned identifier may be used temporarily pending full UDI implementation.

PART B — UDI SYSTEM COMPONENTS AND STANDARDS

UDI Component	Description	Applicable Standard
UDI-DI (Device Identifier)	A mandatory, fixed portion of a UDI that identifies the labeller and the specific version or model of a device.	GS1, HIBCC, ICCBBA or International Council for Commonality in Blood Banking Automation (ISBT 128) (as may be recognised by IMDRF)

UDI Component	Description	Applicable Standard
UDI-PI (Production Identifier)	A conditional, variable portion of a UDI that identifies one or more of: lot/batch number, serial number, software identification and/or expiry date.	GS1, HIBCC, ICCBBA or ISBT 128
UDI Carrier	The means of conveying the UDI — human readable interpretation (HRI) and machine-readable form (barcode, RFID or equivalent).	ISO/IEC 15420, ISO/IEC 15417, ISO/IEC 16022 or equivalent
Direct Marking	UDI applied directly to the device for reusable medical devices intended for reprocessing.	ISO 15223-1; applicable to Class C and D reusable devices

Note: This Schedule is aligned with the IMDRF Unique Device Identification System for Medical Devices (IMDRF/UDI WG/N7FINAL:2013), the WHO Global Benchmarking Tool ML3 and ML4 requirements relating to product registration and traceability, and with UDI implementation frameworks applied by the United States FDA, the European Union, Australia (TGA), Japan (PMDA), South Africa (SAHPRA) and Health Canada. The Authority shall publish guidelines on the accepted UDI issuing agencies and the UDI database system.

FORM BOMRA/MD 1

(Regulation 9(1) and 20(2))

APPLICATION FOR REGISTRATION / RENEWAL OF REGISTRATION OF A MEDICAL DEVICE

INSTRUCTIONS TO APPLICANTS

1. Complete all sections in full in BLOCK LETTERS or typed text. Incomplete applications will be returned without assessment.
2. Attach all documents specified in the Documentation Checklist in Section G. Documents must be submitted in English. Certified translations are required for source documents in other languages.
3. Submit the completed form, all supporting documents, and proof of payment of the prescribed fee as set out in the Fees Regulations to the Botswana Medicines Regulatory Authority, or through the Authority's electronic regulatory information management system.
4. An application reference number will be assigned upon acceptance of a complete application.
5. Indicate whether this is a new registration application or a renewal application by ticking the appropriate box below.

Application Type*	□ New Registration □ Renewal of Registration □ Reliance Application □ Notification Pathway (Class A only)

SECTION A — ADMINISTRATIVE DETAILS

Application Reference No. (BoMRA use only)	
Date of Submission (DD/MM/YYYY)*	
Full Legal Name of Applicant / Registration Holder*	
Physical Address of Applicant*	
Postal Address of Applicant	
Telephone Number*	
Email Address*	
BoMRA Establishment / Licence Number (if existing)*	
Name of Authorised Contact Person*	
Designation of Authorised Contact Person*	

SECTION B — MANUFACTURER DETAILS

Full Legal Name of Manufacturer*	
Physical Address of Principal Manufacturing Site*	
Country of Manufacture*	
Name and Address of Authorised Representative in Botswana (if applicable)	
Name and Address of Local Technical Representative in Botswana (if applicable)	
Manufacturer's ISO 13485 Certificate Number and Certifying Body (Class B, C, D)	
Name and Address of Notified / Recognised Conformity Assessment Body (if applicable)	

SECTION C — DEVICE IDENTIFICATION

Trade Name of Device*	
Generic / Common Name of Device*	
Medical Device Nomenclature Code (GMDN/EMDN/UMDNS)*	
Device Classification*	□ Class A □ Class B □ Class C □ Class D
Device Type*	□ General Medical Device □ In Vitro Diagnostic (IVD) □ Active Implantable Device □ Software as a Medical Device (SaMD)
Model / Reference Number(s)*	
Unique Device Identifier — Device Identifier (UDI-DI), if assigned	

Intended Use / Intended Purpose*	
Intended Users*	
Intended Patient Population (if applicable)	
Indications*	
Contraindications	
Accessories and Related Devices (list all)	
Is the device sterile?*	□ Yes □ No
Method of Sterilisation (if sterile)*	
Is the device for single use only?*	□ Yes □ No
Shelf Life (months)*	
Storage Conditions*	
Country(ies) where device is registered / approved*	
Reference SRA / WHO PQ Number (Reliance / Abridged pathway)*	

SECTION D — REGISTRATION PATHWAY

Registration Pathway*	□ Full Evaluation □ Abridged Evaluation □ Notification Pathway
Basis for Abridged / Reliance application (specify SRA or WHO PQ reference)*	

SECTION E — RENEWAL INFORMATION

(Complete this Section only for renewal applications.)

BoMRA Registration Number (current)*	

Current Registration Expiry Date (DD/MM/YYYY)*	
Have any changes been made to the device since the last registration or last variation approval?*	□ Yes □ No
If yes, provide reference to approved variation(s) covering such changes	
PUSR (Class C & D)/PMSR (Class A & B) number, version and date of most recently submitted to BoMRA	

SECTION F — DOCUMENTATION CHECKLIST

Attach all applicable documents. Documents not applicable must be indicated 'N/A' with a brief justification.

Document	Enclosed (Y / N / N/A)	Reference / Version / Date
Complete technical documentation / dossier in the format (STED / TOC) prescribed in guidelines (risk class proportionate)*	□ Y □ N □ N/A	
Declaration of Conformity signed by authorised representative of manufacturer*	□ Y □ N □ N/A	
ISO 13485 Quality Management System Certificate (Class B, C and D)	□ Y □ N □ N/A	
Certificate of Conformity from Notified / Recognised Conformity Assessment Body (Class C and D)	□ Y □ N □ N/A	
Clinical Evaluation Report (CER) — IMDRF/GHTF compliant (Class C and D)	□ Y □ N □ N/A	
Performance Evaluation Report (IVD devices — Class B, C and D)	□ Y □ N □ N/A	
Risk Management File Summary — ISO 14971 (Class B, C and D)	□ Y □ N □ N/A	

Biocompatibility assessment — ISO 10993 series (where applicable)	□ Y □ N □ N/A	
Software documentation — IEC 62304 / IMDRF SaMD guidance (where applicable)	□ Y □ N □ N/A	
Labelling — all variants, languages and packaging levels**	□ Y □ N □ N/A	
Instructions for Use (IFU)**	□ Y □ N □ N/A	
Certificate of Free Sale from country of manufacture or principal market**	□ Y □ N □ N/A	
Proof of regulatory approval from Reference SRA (Abridged / Reliance pathway)	□ Y □ N □ N/A	
Post-Market Surveillance Plan (Class A and B, C and D)*	□ Y □ N □ N/A	
Periodic Safety Update Report (PSUR) — renewal applications, Class C and D*	□ Y □ N □ N/A	
Appointment of Authorised Representative / Local Technical Representative (Form BOMRA/MD 3, where applicable)	□ Y □ N □ N/A	
Proof of payment of prescribed fee (Fees Regulations)**	□ Y □ N □ N/A	
Power of Attorney / Written Mandate (where agent signing on behalf of applicant)*	□ Y □ N □ N/A	

SECTION G — DECLARATION BY APPLICANT

I/We, the undersigned, being duly authorised to make this application on behalf of the above-named applicant, hereby declare that:
(a) the information furnished in this application form and in all documents submitted herewith is, to the best of my/our knowledge and belief, true, complete and accurate;
(b) the medical device to which this application relates conforms to the Essential Principles of Safety and Performance set out in Schedule 3 to these Regulations;
(c) I/We undertake to notify the Authority immediately of any change in the particulars provided in this application that may affect the safety or performance of the device, and to comply with any conditions imposed by the Authority;
(d) I/We acknowledge and accept that the submission of false, misleading or incomplete information in this application constitutes an offence under the Medicines and Related Substances Act, 2025, and may result in cancellation of any registration granted; and
(e) I/We accept full legal responsibility for the accuracy and completeness of all information submitted.

Name of Authorised Signatory	Signature	Date (DD/MM/YYYY)

FOR OFFICIAL USE ONLY

Date of Receipt	
Received by (Name and Designation)	
Application Status: □ Accepted for Assessment □ Returned — Incomplete □ Rejected (reasons attached)	
Application Reference Number Assigned	
Pathway Assigned: □ Full Evaluation □ Abridged Evaluation □ Notification	
Fee Receipt Number	

FORM BOMRA/MD 2

(Regulation 24(2)))

APPLICATION FOR VARIATION TO REGISTRATION OF A MEDICAL DEVICE

INSTRUCTIONS TO APPLICANTS

1. Complete all sections fully. Variations must be classified in accordance with regulation 24(2) and the General Regulations before submission.
2. A major variation or minor variation (Type IB) shall not be implemented before written approval or acknowledgement, as applicable, is received from the Authority.
3. Attach all supporting documentation relevant to the variation. The level of documentation required is proportionate to the nature and classification of the variation.

SECTION A — CURRENT REGISTRATION DETAILS

BoMRA Registration Number*	
Trade Name of Device*	
Device Classification (Class A / B / C / D)*	
Full Name of Marketing Authorisation / Registration Holder*	
Full Name of Manufacturer*	

SECTION B — VARIATION TYPE

Variation Type	Definition	
□ **Major Variation (Type II)**	A change that may significantly affect the safety, performance, quality or clinical use of the device. Requires prior written approval from the Authority before implementation.	Prior written approval required
□ **Minor Variation (Type IB)**	A change that may have a minor effect on the	Prior notification; implementation after acknowledgement

	safety, performance or quality of the device. Requires prior notification and acknowledgement before implementation.	
□ **Notification (Type IA)**	A change with no anticipated impact on safety, performance or quality. Must be notified within 30 days of implementation.	Notification within 30 days of implementation
□ **Administrative Change**	A change to administrative particulars only (e.g. change of name, address, authorised representative contact details). Notification required.	Notification within 30 days

SECTION C — DESCRIPTION OF PROPOSED VARIATION

Reference number / code for this variation (manufacturer internal reference)	
Description of current approved status (what is currently registered)*	
Description of proposed change (what is being changed, in full)*	
Justification and reason for variation*	

Has this change been notified to or approved by any other regulatory authority?*	□ Yes □ No
If yes, specify authority and reference number	
Proposed date of implementation (if applicable)	

SECTION D — SUPPORTING DOCUMENTATION

List all documents attached in support of this variation application	

SECTION E — DECLARATION

I/We declare that the information provided in this application is true, accurate and complete. I/We confirm that the proposed change has been assessed in accordance with the manufacturer's change control procedures, and that the proposed change does not adversely affect the safety, performance or quality of the device beyond levels documented in the approved registration dossier. I/We undertake not to implement any major variation or minor variation (Type IB) prior to receipt of written approval or acknowledgement from the Authority.

Name of Authorised Signatory	Signature	Date (DD/MM/YYYY)

FOR OFFICIAL USE ONLY

Date of Receipt	
Variation Classification by BoMRA: □ Type II (Major) □ Type IB (Minor) □ Type IA (Notification) □ Administrative	
Assessment Reference Number	

Outcome: □ Approved □ Acknowledged □ Refused (reasons attached)	

FORM BOMRA/MD 3

(Regulation 10(3) and 32(3))

APPOINTMENT / CHANGE OF AUTHORISED REPRESENTATIVE OR LOCAL TECHNICAL REPRESENTATIVE

INSTRUCTIONS

1. This form must be completed for every appointment of a new authorised representative or local technical representative, and for every change of authorised representative or local technical representative. It shall be signed by both the manufacturer and the representative.
2. Attach the written mandate or authorisation letter from the manufacturer confirming the scope of authority of the representative.
3. A copy of the representative's proof of registration or incorporation in Botswana must be attached.

Type of Appointment*	□ New Appointment □ Change of Representative □ Termination of Appointment

SECTION A — MANUFACTURER DETAILS

Full Legal Name of Manufacturer*	
Physical Address (Principal Manufacturing Site)*	
Country of Incorporation*	
Name of Authorised Signatory of Manufacturer*	
Designation of Authorised Signatory*	
Email / Telephone of Manufacturer*	

SECTION B — REPRESENTATIVE DETAILS

Type of Representative*	□ Authorised Representative □ Local Technical Representative
Full Legal Name of Representative*	
Physical Address in Botswana*	
Postal Address	

Telephone Number*	
Email Address*	
Companies Act Registration Number (Botswana)*	
BoMRA Licence / Establishment Number (if applicable)	
Name of Key Contact Person at Representative*	

SECTION C — SCOPE OF APPOINTMENT

Medical devices covered by this appointment (trade names / registration numbers, or 'All registered devices')*	
Roles and responsibilities of representative (Job Descriptions) (list all applicable)	
Effective date of appointment (DD/MM/YYYY)*	
Effective date of termination (DD/MM/YYYY), if applicable	
Name and contact details of previous representative (change/termination only)	

SECTION D — DECLARATIONS

Declaration by Manufacturer:

I/We, the manufacturer, hereby appoint the above-named person as authorised representative / local technical representative for the purposes of the Medicines and Related Substances Act, 2025 and the Medical Devices Regulations, 2026. The representative is authorised to act on our behalf in respect of regulatory matters relating to the medical devices specified above. We acknowledge that this appointment does not transfer our responsibility as manufacturer.

Manufacturer's Authorised Signatory	Date (DD/MM/YYYY)

Declaration by Representative:
I/We, the representative, hereby accept the appointment as authorised representative / local technical representative for the above-named manufacturer. I/We confirm that we are established in Botswana and accept all responsibilities assigned to an authorised representative / local technical representative under the Medical Devices Regulations, 2026.

Representative's Authorised Signatory	Date (DD/MM/YYYY)

FOR OFFICIAL USE ONLY

Date of Receipt	
Acknowledged by (Name and Designation)	
BoMRA Reference Number	

FORM BOMRA/MD 4

(Regulation 55(2)) and 56(1)

APPLICATION FOR IMPORT PERMIT — MEDICAL DEVICE

INSTRUCTIONS

1. An import permit is required for all medical devices imported into Botswana in accordance with regulation 50 and the General Regulations.
2. Import permits are issued for registered medical devices or medical devices otherwise authorised for importation. Unregistered devices may only be imported under an applicable exemption or special access authorisation.
3. Expedited permits are available for urgent medical needs. Indicate this in Section C.

Permit Type*	□ Registered Device □ Unregistered — Exempted / Special Access □ Urgent / Expedited

SECTION A — IMPORTER DETAILS

Full Legal Name of Importer*	
Physical Address in Botswana*	
BoMRA Licence / Establishment Number*	
Telephone Number*	
Email Address*	
Name of Authorised Contact Person*	

SECTION B — DEVICE AND CONSIGNMENT DETAILS

Trade Name / Description of Device	BoMRA Reg. No.	Quantity	Country of Origin

Name and Address of Supplier / Exporter*	
Estimated Arrival Date (DD/MM/YYYY)	
Port of Entry*	

SECTION C — UNREGISTERED DEVICE / URGENT IMPORT

(Complete this section only where the device is unregistered or urgent.)

Basis for import of unregistered device (cite applicable exemption category under regulation 21 or special access under regulation 112)*	
Approving authority or authorisation reference (where applicable)	
Justification for urgent / expedited processing	

SECTION D — DECLARATION

I/We declare that the information provided in this application is true, accurate and complete, that the medical devices described comply with the requirements of the Medical Devices Regulations, 2026, and that the imported devices will be used strictly for the purposes stated herein. I/We undertake to store, handle and distribute the imported devices in accordance with the manufacturer's instructions and Good Distribution Practice.

Name of Authorised Signatory	Signature	Date (DD/MM/YYYY)

FOR OFFICIAL USE ONLY

Date of Receipt	
Import Permit Number	
Valid for Period	

Permit Issued by (Name and Designation)	
Conditions Attached: □ Yes □ No	

FORM BOMRA/MD 5

(Regulation 21(3) and 112(2))

APPLICATION FOR EXEMPTION FROM REGISTRATION / SPECIAL ACCESS AUTHORISATION — MEDICAL DEVICE

INSTRUCTIONS

1. Use this form to apply for an exemption from the requirement for registration under regulation 21, or for a Special Access Authorisation under regulation 112.
2. Attach all relevant supporting documentation including clinical justification, manufacturer information and, where available, evidence of regulatory approval in another jurisdiction.
3. The prescribed fee as set out in the Fees Regulations must accompany this application.

Application Type*	□ Exemption from Registration (reg 21) □ Special Access Authorisation (reg 112)

SECTION A — APPLICANT DETAILS

Full Legal Name of Applicant*	
Physical Address in Botswana*	
BoMRA Licence / Establishment Number (if applicable)	
Telephone Number*	
Email Address*	

SECTION B — DEVICE DETAILS

Trade Name of Device*	
Generic Name of Device*	
Manufacturer Name and Country*	

Intended Purpose*	
Risk Classification (if known)	
Quantity Required	
Is the device registered in any other jurisdiction?*	□ Yes □ No
If yes, specify jurisdiction(s) and registration number(s)	

SECTION C — JUSTIFICATION

Category of exemption or special access being applied for (cite specific sub-regulation of reg 21 or reg 112)*	
Clinical / medical justification for the application*	
Are registered alternatives available on the Botswana market?*	
If yes, state why the registered alternative cannot be used*	
Name of prescribing medical practitioner or institution (if applicable)*	

SECTION D — DECLARATION

I/We declare that the information provided in this application is true, accurate and complete, and that the device for which exemption or special access is sought is required for the purposes stated. I/We undertake to comply with any conditions imposed by the Authority and to ensure that the device is used only for the stated purpose.

Name of Authorised Signatory	Signature	Date (DD/MM/YYYY)

FOR OFFICIAL USE ONLY

Date of Receipt	
Application Reference Number	
Outcome: □ Approved □ Approved with Conditions □ Refused (reasons attached)	
Conditions (if any)	

FORM BOMRA/MD 6

(Regulation 89(2))

ADVERSE EVENT / INCIDENT REPORT — MEDICAL DEVICE

URGENT NOTICE: Events involving death or serious injury to a patient or user must be reported IMMEDIATELY and in any event not later than 72 hours from the time the reporter becomes aware of the event. Submit to the Botswana Medicines Regulatory

INSTRUCTIONS

1. Manufacturers, marketing authorisation holders, authorised representatives, importers and healthcare facilities are required to report incidents in accordance with regulation 83 and the General Regulations.
2. Reports may also be submitted through the Authority's electronic regulatory information management system.
3. For reporting purposes, 'incident' and 'serious incident' have the meanings assigned to them in regulation 2 of these Regulations.
4. Reporter identity will be treated as confidential to the maximum extent permitted by law.

Report Type*	□ Initial Report □ Follow-Up Report (provide initial report reference below) □ Final Report
Reference Number of Initial Report (follow-up and final reports only)	

SECTION A — REPORTER DETAILS

Reporter Category*	□ Healthcare Professional □ Patient or Consumer □ Manufacturer or Authorised Representative □ Importer or Distributor □ BoMRA Staff
Name of Reporter (optional — report may be submitted anonymously)	
Name of Institution or Organisation	
Telephone Number / Email Address (optional)	
Date of Report (DD/MM/YYYY)*	

SECTION B — DEVICE DETAILS

Trade Name of Device*	

Manufacturer*	
Model / Catalogue Number*	
Lot / Batch Number or Serial Number (if known)*	
UDI (if labelled)*	
BoMRA Registration Number (if known)	
Expiry Date of Device (if applicable)	

SECTION C — EVENT DESCRIPTION

Date Event Occurred (DD/MM/YYYY)*	
Date Event Was Discovered / Reported to You (DD/MM/YYYY)*	
Location / Facility Where Event Occurred*	
Outcome of Event*	□ Death □ Serious Injury □ Non-Serious Injury □ Malfunction / No Injury □ Near Miss
Description of the Event — describe what happened and how the device was involved in full*	
Patient Information (age range, sex, relevant clinical history — anonymised)*	
Concomitant devices, medicines or other potential contributory factors (if any)	
Corrective Action Taken (if any)	

SECTION D — MANUFACTURER / DISTRIBUTOR REPORTING FIELDS

(Complete this section if the report is submitted by a manufacturer, marketing authorisation holder, authorised representative, or importer.)

Has this event been reported to the manufacturer's home country regulatory authority?*	□ Yes □ No □ Not Applicable
If yes, specify authority and date of report	
Has a Field Safety Corrective Action been initiated?*	□ Yes — complete Form BOMRA/MD 8 □ No □ Under Evaluation
Internal complaint / reference number in manufacturer's system (if applicable)	

SECTION E — DECLARATION

I/We declare that, to the best of my/our knowledge, the information provided in this report is accurate and complete. I/We understand that the Authority may contact me/us for further information. I/We consent to the information in this report being used by the Authority for regulatory and public health purposes, in accordance with the Botswana Data Protection Act, 2024.

Name of Authorised Signatory	Signature	Date (DD/MM/YYYY)

FORM BOMRA/MD 7

(Regulation 107(3))

APPLICATION FOR APPROVAL OF ADVERTISING / PROMOTIONAL MATERIAL — MEDICAL DEVICE

INSTRUCTIONS

1. Advertising of registered medical devices requires prior written approval from the Authority in accordance with regulations 107.
2. Advertising of professional use only Class C and D medical devices to the general public is prohibited under these regulation. Applications for advertising of high-risk devices shall be limited to advertising directed at healthcare professionals.
3. Submit the completed application form with the proposed advertising material and prescribed fee.

SECTION A — APPLICANT AND DEVICE DETAILS

Full Name of Applicant / Marketing Authorisation Holder*	
BoMRA Registration Number of Device*	
Trade Name of Device*	
Device Classification (Class A / B / C / D)*	
Intended Audience for Advertisement*	

SECTION B — ADVERTISING MATERIAL DETAILS

Type of Advertising Material*	□ Print □ Digital / Online □ Broadcast (TV / Radio) □ Point of Sale □ Direct Mailing □ Other
Title / Description of Advertising Material*	
Claims made in the Advertisement*	
Evidence supporting claims (attach summary)*	

Are the advertising claims consistent with the approved intended purpose?*	□ Yes □ No
Has this advertising material been approved by any other regulatory authority?*	□ Yes □ No
If yes, specify authority and approval reference	

SECTION C — DECLARATION

I/We declare that the advertising material submitted herewith is accurate, not misleading, and consistent with the approved labelling and intended purpose of the registered medical device. All claims are supported by evidence which is available for inspection by the Authority. I/We accept that approval of advertising material does not constitute a waiver of any condition of registration.

Name of Authorised Signatory	Signature	Date (DD/MM/YYYY)

FOR OFFICIAL USE ONLY

Date of Receipt	
Advertising Approval Reference Number	
Outcome: □ Approved □ Approved with Amendments □ Refused (reasons attached)	
Approval Validity Period	

FORM BOMRA/MD 8

(Regulation 91)

FIELD SAFETY CORRECTIVE ACTION NOTIFICATION — MEDICAL DEVICE

URGENT NOTICE: Field Safety Corrective Actions involving a risk of death or serious injury to patients or users must be notified to the Authority IMMEDIATELY upon decision to initiate such action, and in any event not later than 3 calendar days. Submit to: fsca@bomra.co.bw

INSTRUCTIONS

1. A Field Safety Corrective Action (FSCA) includes product recalls, withdrawals, device modifications, software updates for safety reasons, and field corrections. It does not include routine maintenance.
2. The notification obligations in this form apply to manufacturers, marketing authorisation holders and authorised representatives.
3. An initial notification must be submitted immediately upon decision to initiate the FSCA. A final completion report must be submitted within 60 calendar days of completion of all corrective actions.

Report Type*	□ Initial Notification □ Progress Update □ Final Completion Report

SECTION A — DEVICE AND NOTIFIER DETAILS

Full Legal Name of Manufacturer / Marketing Authorisation Holder*	
Authorised Representative / Local Technical Representative in Botswana*	
Contact Person for this FSCA*	
Telephone / Email of Contact Person*	
BoMRA Registration Number of Device*	
Trade Name and Model Number(s) of Affected Device(s)*	
UDI-DI (if assigned)	

Lot / Batch or Serial Numbers Affected (or state 'All lots to date')*	
Estimated Number of Units Distributed in Botswana*	
Manufacturer's FSCA Reference Number*	
Date FSCA Initiated (DD/MM/YYYY)*	

SECTION B — DESCRIPTION OF SAFETY ISSUE

Description of the safety issue, deficiency or malfunction giving rise to this FSCA*	
Summary of root cause analysis (if completed at time of notification)*	
Risk Level*	□ Critical (death or serious injury likely) □ High □ Moderate □ Low / No injury expected
Description of potential adverse health consequences if no action is taken*	

SECTION C — CORRECTIVE ACTION DETAILS

Type of FSCA*	□ Product Recall □ Product Withdrawal from Market □ Device Modification / Upgrade □ Software / Firmware Update □ Labelling Correction □ Field Safety Notice Only □ Other
Description of corrective action(s) to be taken*	
Instructions to device users and/or patients*	

Proposed timeline and target completion date for the FSCA*	
Has a Field Safety Notice (FSN) been issued to device users?*	□ Yes (attach copy) □ No □ To be issued (specify date)
Date FSN issued or to be issued (DD/MM/YYYY)	
List of healthcare facilities, distributors or other entities notified in Botswana	

SECTION D — MULTI-MARKET REPORTING

Has this FSCA been reported to regulatory authorities in other countries?*	□ Yes □ No
If yes, list authorities notified and their reference numbers	

SECTION E — DECLARATION

I/We confirm that the information provided in this notification is, to the best of our knowledge, accurate and complete. We undertake to submit a final FSCA completion report to the Authority within 60 calendar days of completion of all corrective actions, and to cooperate fully with any regulatory assessment or inspection activities arising from this notification.

Name of Authorised Signatory	Signature	Date (DD/MM/YYYY)

FOR OFFICIAL USE ONLY

Date of Receipt	
BoMRA FSCA Reference Number	
Assessed by (Name and Designation)	

BoMRA Actions Required: □ None □ Inspection □ Market Withdrawal Order □ Other (specify)	

Made this _____ day of _____, 2026.

_____

Minister of Health