MEDICINES AND RELATED SUBSTANCES ACT, 2025

MEDICAL DEVICES REGULATIONS, 2026

(Published on _____, 2026)

ARRANGEMENT OF REGULATIONS

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 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—

"accessory" means an article which, whilst not being a medical device itself, is intended by the manufacturer to be used together with a medical device to enable the medical device to achieve its intended purpose;

"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 medical device dependent on a source of energy other than that generated directly by the human body or gravity for its operation;

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

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

"authorised representative" means a natural or legal person established in Botswana who has received written authorisation from a manufacturer to act on their behalf in relation to specified tasks under these Regulations;

"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 a systematic and planned process to continuously generate, collect, analyse and assess clinical data pertaining to a medical device;

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

"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 a process demonstrating whether a medical device meets the requirements of these Regulations;

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

"Essential Principles" means the Essential Principles of Safety and Performance as set out in Schedule 3;

"Fees Regulations" means the Medicines and Related Substances (Fees) Regulations, 2025;

"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;

"General Regulations" means the Medicines and Related Substances (General) Regulations, 2025;

"guidelines" means documents issued by the Authority under regulation 96 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;

"in vitro diagnostic" or "IVD" means a medical device intended by the manufacturer for the in vitro examination of specimens derived from the human body or animals solely or

principally for the purpose of providing information concerning a physiological or pathological state, congenital abnormality, predisposition to a medical condition, compatibility with potential recipients, or therapeutic response;

"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;

"intended purpose" means the use for which a medical device is intended according to the data supplied by the manufacturer on the labelling, in the instructions for use or in promotional materials;

"labelling" means any written, printed or graphic matter affixed to a medical device or its packaging, or accompanying a medical device;

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

"manufacturer" means the natural or legal person responsible for the design, manufacture, packaging and labelling of a medical device before it is placed on the market, regardless of whether those operations are carried out by that person or on that person's behalf;

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

"medical device" has the meaning assigned to it under section 2 of the Act;

"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;

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

"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;

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

"safety" means freedom from unacceptable risk;

"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;

"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;

"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.

Application and scope

3. (1) These Regulations apply to—

(a) medical devices;

(b) in vitro diagnostic medical devices;

(c) accessories 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.

(3) These Regulations do not apply to—

(a) medical products as defined in the Act;

(b) human tissues, cells and organs;

(c) cosmetic products not making medical claims;

(d) food products; and

(e) personal protective equipment not intended for medical use.

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

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

(6) Applications under these Regulations shall be submitted through the electronic regulatory information management system established under regulation 93 of the General Regulations, except that manual processes shall remain valid where electronic systems are not implemented or are unavailable.

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 standards, including guidance of the African Medical Devices Forum, the International Medical Device Regulators Forum and the World Health Organization;

(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 regulation 96, 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 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.

Classification of in vitro diagnostic medical devices

7. (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 purpose of the device;

(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 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 in vitro diagnostic medical devices.

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

Borderline and combination products

8. (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.

Appeal against classification determination

9. (1) An applicant who is not satisfied with a classification determination may appeal to the Authority in writing within thirty days of the date of notification of the determination.

(2) An appeal under subregulation (1) shall include—

(a) the grounds for the appeal;

(b) supporting evidence; and

(c) the requested classification.

(3) The Authority shall determine the appeal within sixty working days.

(4) Further appeal shall lie to the Appeals Committee under sections 112 to 115 of the Act.

PART III — REGISTRATION AND LISTING

Requirement for registration

10. (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 may 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 18;

(b) medical devices for which a special access authorisation has been granted under regulation 81;

(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 regulation 19.

Application for registration

11. (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 therefor;

(d) technical documentation or summary in a dossier format 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 an authorised representative or 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 an application within five working days and assign a unique application reference number.

(4) The Authority shall, within thirty working days of receipt, conduct a validation review to determine whether the application is complete.

Local presence requirement

12. (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

13. (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; 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 ninety days, 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

14. (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 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) Recognised authorities 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 national regulatory authorities, International Medical Device Regulators Forum member authorities, African Medical Devices Forum recognised authorities, and recognised conformity assessment bodies.

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

(5) 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

15. (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) refuse 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) specific labelling requirements; and

(f) payment of annual retention fees.

Certificate of registration

16. Upon registration, the Authority shall issue a certificate of registration specifying—

(a) registration number;

(b) medical device name and model;

(c) medical device classification;

(d) applicant and manufacturer name and address;

(e) medical device nomenclature;

(f) intended purpose;

(g) any conditions of registration;

(h) validity period; and

(i) date of issue.

Validity and renewal of registration

17. (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) a summary of any changes since registration;

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

(f) 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

18. (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 85;

(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 80;

(k) a medical device for special access under regulation 81; and

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

(3) An application for exemption shall be made in Form BOMRA/MD 8 and shall be accompanied by the prescribed fee as set out in the Fees Regulations.

Registration during public health emergencies

19. (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

20. (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

21. (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 regulation 16 of the General Regulations.

(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.

Notifications

22. The marketing authorisation holder shall notify the Authority in accordance with regulation 17 of the General Regulations.

Cancellation, suspension and withdrawal of registration

23. (1) The Authority may cancel, suspend or withdraw a registration in accordance with section 41 of the Act and regulation 18 of the General Regulations.

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

Maintenance of registers

24. In accordance with section 42 of the Act, the Authority shall maintain registers of medical devices in accordance with regulation 19 of the General Regulations.

PART IV — CONFORMITY ASSESSMENT

Conformity assessment requirements

25. (1) Before placing a medical device on the market, the manufacturer shall demonstrate conformity with applicable requirements through appropriate conformity assessment procedures.

(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 accept conformity assessment from bodies recognised under regulation 27 or as set out in the guidelines.

Quality management system certification

26. (1) Manufacturers of all medical devices shall implement a quality management system.

(2) Manufacturers of Class B, C and D medical devices shall maintain a valid quality management system certificate.

(3) The quality management system shall—

(a) comply with ISO 13485 or an equivalent standard;

(b) cover all aspects of design, manufacture and post-market activities;

(c) be certified by a recognised conformity assessment body; and

(d) be subject to surveillance audits.

(4) Quality management system certification shall be renewed at intervals not exceeding three years.

Recognised conformity assessment bodies

27. (1) The Authority shall recognise conformity assessment bodies that—

(a) are accredited by a recognised accreditation body;

(b) are designated by regulatory authorities with comparable standards;

(c) participate in the Medical Device Single Audit Programme or equivalent programmes; or

(d) meet criteria specified in guidelines.

(2) The Authority shall maintain and publish a list of recognised conformity assessment bodies.

Declaration of conformity

28. (1) The manufacturer shall draw up a declaration of conformity stating that the medical device meets applicable requirements.

(2) The declaration of conformity shall include—

(a) manufacturer identification;

(b) medical device identification;

(c) risk classification;

(d) standards and specifications applied;

(e) conformity assessment body details, where applicable; and

(f) date and signature of an authorised signatory.

Reliance on prior assessments

29. (1) In accordance with section 109 of the Act, the Authority may rely on—

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

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

(c) World Health Organization prequalification;

(d) regulatory approval from World Health Organization Listed Authorities or Maturity Level 3 authorities;

(e) Medical Device Single Audit Programme audit reports;

(f) certificates from recognised conformity assessment bodies; and

(g) such other recognised authorities as may be set out in the guidelines.

PART V — MANUFACTURERS AND AUTHORISED REPRESENTATIVES

Manufacturer obligations

30. (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) implement and maintain a risk management system;

(d) conduct post-market surveillance;

(e) report incidents to the Authority;

(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 an authorised representative in accordance with regulation 34.

Quality management system requirements

31. (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

32. (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

33. 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.

Authorised representative requirements

34. (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 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 VI — IMPORTATION AND DISTRIBUTION

Import permit procedures

35. (1) Import permits for medical devices shall be obtained in accordance with regulation 47 of the General Regulations.

(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 Regulations.

(3) Import permits shall be issued for registered medical devices or medical devices otherwise authorised for importation.

(4) Expedited permit procedures shall be available for urgent medical needs.

Distribution requirements

36. (1) Distributors of medical devices shall comply with the licensing requirements under the General Regulations.

(2) Distributors shall—

(a) maintain traceability records;

(b) implement storage and handling controls;

(c) cooperate with recalls;

(d) report incidents to the Authority;

(e) verify the registration status of medical devices; and

(f) 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.

Storage and handling requirements

37. (1) Medical devices shall be stored and handled in accordance with—

(a) the manufacturer's instructions;

(b) Good Distribution Practice; and

(c) applicable standards.

(2) Temperature-sensitive medical devices shall have documented cold chain management.

(3) Sterile medical devices shall be protected from contamination.

Installation and servicing

38. (1) Medical devices requiring installation shall be installed by the manufacturer, an authorised service provider, or a biomedical engineer or qualified personnel following the manufacturer's instructions.

(2) Servicing shall be conducted by a biomedical engineer or relevant qualified personnel in accordance with the manufacturer's specifications.

(3) Records of installation and servicing shall be maintained.

Tracking requirements

39. (1) In accordance with section 117 of the Act, the following medical devices shall be trackable—

(a) Class D medical devices;

(b) implantable medical devices; and

(c) such other medical devices as may be specified in guidelines.

(2) Tracking shall enable identification of all medical devices by batch or serial number, all facilities that distributed the medical device, and patients who received implantable medical devices, to the extent permitted by law.

PART VII — IN VITRO DIAGNOSTIC MEDICAL DEVICES

Additional requirements for in vitro diagnostics

40. (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 and the General Regulations.

(2) In vitro diagnostic risk classification shall follow regulation 7 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

41. (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

42. (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 C and D in vitro diagnostics shall have third-party quality management system certification.

Self-testing in vitro diagnostics

43. (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

44. (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 shall be regulated as prescribed in the General Regulations and guidelines.

Laboratory developed tests

45. (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 — SOFTWARE AND DIGITAL HEALTH

Software as a medical device

46. (1) Software intended for medical purposes that is not part of a hardware medical device shall be regulated as a medical device.

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

(a) is intended to diagnose, prevent, monitor, treat or alleviate disease;

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

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

(d) provides information for medical decisions.

(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

47. 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

48. 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

49. (1) Medical devices with software or network connectivity shall address cybersecurity throughout the product lifecycle, including confidentiality, integrity, availability and accountability.

(2) Manufacturers shall conduct security risk assessments, implement appropriate security controls, monitor for vulnerabilities, provide security updates and provide guidance to users on security.

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

Artificial intelligence and machine learning in medical devices

50. (1) Medical devices incorporating artificial intelligence or machine learning shall demonstrate algorithm transparency appropriate to device classification, training data quality, measures to identify and mitigate bias, performance monitoring methodology and change management protocols.

(2) Adaptive algorithms that continue learning after deployment shall require predetermined change control plans approved as part of registration.

Software updates and modifications

51. Software changes shall be classified in accordance with guidelines, and security patches addressing vulnerabilities may be implemented with notification to the Authority.

Interoperability requirements

52. Medical devices intended to exchange information with other medical devices or systems shall use recognised standards where available, specify interoperability capabilities and maintain safety and cybersecurity when connected, as prescribed in guidelines.

PART IX — CLINICAL INVESTIGATIONS

Clinical investigation authorisation

53. (1) In accordance with section 46 of the Act, clinical investigations of medical devices shall require authorisation from the Authority and ethics committee approval.

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

(3) Specific requirements for medical device clinical investigations shall be specified in guidelines.

Good clinical practice for medical devices

54. Medical device clinical investigations shall comply with ISO 14155 or equivalent standards and the Clinical Trials Regulations, with specific considerations for investigator training, device accountability procedures, malfunction reporting and device-specific adverse event assessment.

Ethical requirements

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

Clinical investigation conduct

56. Investigations shall be conducted according to the approved protocol, deviations shall be documented and reported, and the Authority may inspect investigation sites.

Safety reporting for clinical investigations

57. (1) Serious adverse events and medical device deficiencies that might have led to serious adverse events shall be reported within the timelines prescribed in the Clinical Trials Regulations and guidelines.

(2) Periodic safety reports shall be submitted as required.

Clinical investigation reports

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

PART X — POST-MARKET SURVEILLANCE AND VIGILANCE

Post-market surveillance system

59. (1) In accordance with section 74 of the Act and the national materiovigilance programme established under regulation 72 of the General Regulations, a manufacturer or marketing authorisation holder shall establish, document and maintain a post-market surveillance system appropriate to the classification and risk of the medical device.

(2) The system shall gather and evaluate data, identify trends, assess the need for corrective actions, update risk management documentation, feed into the clinical evaluation, and monitor the performance of the medical device.

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

Incident reporting

60. (1) Manufacturers, marketing authorisation holders, authorised representatives, importers and healthcare facilities shall report incidents to the Authority.

(2) Reports shall be submitted using Form BOMRA/MD 6, which shall be used in lieu of Form GEN-16 of the General Regulations for medical device incidents, or through the electronic regulatory information management system.

(3) Reporting timelines shall be in accordance with regulation 73 of the General Regulations and as may be further prescribed in guidelines.

Trend reporting

61. Manufacturers shall analyse incident data for trends, and statistically significant increases in incidents or expected incidents with unexpected severity or frequency shall be reported to the Authority.

Field safety corrective actions

62. (1) Where a manufacturer or marketing authorisation holder initiates action to reduce a risk to the health of the user or patient during the use of a medical device on the market, such action constitutes a field safety corrective action.

(2) The Authority shall be notified of field safety corrective actions within the timelines prescribed in guidelines.

(3) The Authority may, in accordance with section 75 of the Act, without prior consultation from the holder of the marketing authorisation, order the recall of a medical device.

Periodic safety update reports

63. For Class B, C and D medical devices, manufacturers shall submit periodic safety update reports summarising post-market surveillance data, incident analysis, benefit-risk assessment updates and conclusions and actions, at such frequency as may be specified in guidelines or conditions of registration.

Post-market clinical follow-up

64. 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 XI — UNIQUE DEVICE IDENTIFICATION

Unique device identification system

65. (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 GS1, HIBCC, ICCBBA, or other agencies designated by the International Medical Device Regulators Forum or the World Health Organization.

Unique device identification carrier specifications

66. 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

67. Manufacturers shall submit unique device identification data to a database recognised by the Authority, and the Authority may establish a national database or rely on international databases.

Implementation timeline

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

Traceability requirements

69. 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.

Nomenclature system for medical devices

70. (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 XII — LABELLING AND INFORMATION

General labelling requirements

71. 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

72. 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

73. 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

74. Electronic instructions for use may be provided instead of paper instructions where the medical device is intended for professional users, paper instructions would impede performance, a risk assessment supports electronic provision, and conditions specified in guidelines are met, provided that patient-facing information shall generally be provided in paper form.

Language requirements

75. 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.

PART XIII — ADVERTISING AND PROMOTION

Advertising approval

76. (1) In accordance with section 83 of the Act, advertising of registered medical devices shall require prior approval from the Authority.

(2) Applications for advertising approval shall be made in Form BOMRA/MD 7 and shall be accompanied by the prescribed fee as set out in the Fees Regulations.

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

Advertising standards

77. 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.

Prohibited advertising practices

78. The following practices are prohibited—

(a) advertising unregistered medical devices;

(b) advertising high-risk 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 guidelines.

Online sale of medical devices

79. 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 XIV — SPECIAL PROVISIONS

Custom-made medical devices

80. (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

81. (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 8 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

82. (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

83. 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

84. (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

85. (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 XV — INSPECTION AND MARKET SURVEILLANCE

Inspection authority

86. (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

87. 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.

Market surveillance activities

88. 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 in accordance with the General Regulations.

Sampling and testing

89. (1) In accordance with sections 31 and 34 of the Act, the Authority may take samples of medical devices for testing.

(2) Testing may be conducted by the National Quality Control Laboratory, recognised testing laboratories, or international reference laboratories.

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

PART XVI — ENFORCEMENT

Cancellation, suspension and withdrawal of registration

90. The Authority may cancel, suspend or withdraw a registration in accordance with section 41 of the Act and regulation 18 of the General Regulations.

Recall procedures

91. (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 regulation 76 of the General Regulations and guidelines.

(3) Effectiveness checks shall verify recall completion.

Disposal of unfit products

92. Disposal of unfit medical devices shall be in accordance with section 76 of the Act and regulation 77 of the General Regulations and guidelines.

Maintenance of registers

93. The Authority shall maintain all registers of medical devices as prescribed in regulations 19 and 45 of the General Regulations and guidelines.

Offences and penalties

94. (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.

(2) Specific offences include—

(a) placing unregistered medical devices on the market;

(b) making false declarations;

(c) failing to report incidents;

(d) failing to comply with recalls;

(e) providing false labelling;

(f) advertising in contravention of these Regulations; and

(g) contravening any other provision of these Regulations.

Compounding of offences

95. Compounding of offences shall be in accordance with section 121 of the Act and the Fees Regulations.

PART XVII — TRANSITIONAL AND FINAL PROVISIONS

Guidelines

96. (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

97. (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

98. (1) Medical devices registered before the commencement of these Regulations shall remain valid until the expiry of such registration.

(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 quality management system certification: forty-eight months for existing local manufacturers.

(4) The Authority may specify additional transitional arrangements.

Repeal

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

Made this _____ day of _____, 2025.

_____

Minister of Health

SCHEDULES AND PRESCRIBED FORMS

TABLE OF CONTENTS

SCHEDULE 1

(Regulation 5(4) and 6)

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 of 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 7(4) and 40)

CLASSIFICATION RULES FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES

The following classification rules apply to in vitro diagnostic medical devices in accordance with regulation 7. 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 11(1)(f), 25, 28, 30, 71 and 80)

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, 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 65, 66, 67 and 68)

UNIQUE DEVICE IDENTIFICATION IMPLEMENTATION TIMELINE

This Schedule sets out the phased implementation timeline for the Unique Device Identification (UDI) system in Botswana, in accordance with regulation 68. The UDI system is mandatory for medical devices placed on the Botswana market. The Authority may, by guidelines, vary the implementation timeline 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	Implementation Period	Scope of Devices
Phase 1	36 months from commencement	Class D medical devices (all forms — label, packaging and direct marking where required by the Authority). Submission of UDI data to a recognised UDI database.
Phase 2	60 months from commencement	Class C medical devices and all active implantable devices. Direct marking required for reusable devices. UDI database submission required.
Phase 3	84 months from commencement	Class B medical devices. UDI label requirement on device label and all higher-level packaging.
Phase 4	120 months from commencement	Class A medical devices.
All Classes	From the date the UDI system is activated	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 ISBT 128 (as 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 11(1) and 17(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	
Date of most recent PSUR submitted to BoMRA (Class B, C and D)	

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 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 B, C and D)*	□ Y □ N □ N/A	
Periodic Safety Update Report (PSUR) — renewal applications, Class B, 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)

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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 21(2) and 22)

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 21(3) 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)

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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 12(3) and 34(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')*	
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, 2025. 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, 2025.

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

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

FORM BOMRA/MD 4

(Regulation 35(2))

APPLICATION FOR IMPORT PERMIT — MEDICAL DEVICE

INSTRUCTIONS

1. An import permit is required for all medical devices imported into Botswana in accordance with regulation 35 and regulation 47 of 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 18 or special access under regulation 81)*	
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, 2025, 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)

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Date of Receipt	
Import Permit Number	
Valid for Period	

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

FORM BOMRA/MD 5

(Regulation 18(3) and 81(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 18, or for a Special Access Authorisation under regulation 81.
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 18) □ Special Access Authorisation (reg 81)

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 18 or reg 81)*	
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)

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

FORM BOMRA/MD 6

(Regulation 60(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 60 and regulation 73 of 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 7 □ 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 76(2))

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 regulation 76.
2. Advertising of Class C and D medical devices to the general public is prohibited under regulation 78(b). 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)

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Date of Receipt	
Advertising Approval Reference Number	
Outcome: □ Approved □ Approved with Amendments □ Refused (reasons attached)	
Approval Validity Period	

FORM BOMRA/MD 8

(Regulation 62(2))

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 _____, 2025.

_____

Minister of Health