Botswana Medicines Regulatory Authority

BOMRA
MEDICINES REGULATORY AUTHORITY

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1. Purpose

The intention and purpose of this guideline is to provide guidance to those submitting applications for registration of In Vitro Diagnostic (IVD) Medical Devices. The guideline guides applicants on the following registration pathways; abridged and full registration assessment pathways.

Note: Applicants are strongly encouraged to familiarize themselves with the criteria and requirements for review process outlined in this guideline and other relevant documents before submitting their applications. Incomplete submissions, untimely responses to queries, incorrect risk classification of device may result in the rejection and resubmission of application.

2. Scope

These guidelines apply to products that fall within the definition of In Vitro Diagnostic (IVD) Medical Devices. These guidelines apply to all class B, C and D IVD medical devices.

Out of scope:

- Submission for registration of general medical devices
- Class A devices: refer to guideline for notification **(BOMRA/ER/MED/P04/G08**) of medical devices registered through notification process.

  The document is intended to provide guidance for industry to adapt to the variety of products and future products and for consistency of format. Applicants are strongly encouraged to familiarize themselves with the criteria and requirements outlined in this guideline and the other relevant guidance documents before submitting their applications. Incomplete submissions and untimely responses to queries will result in unnecessary delays to the registration process.

3. Definitions and Abbreviations

3.1 Definitions

The following definitions shall apply:

3.1.1 Accessory

An accessory is a finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices.

3.1.2 Act

Medicines and Related Substances Act. 2013

3.1.3 Applicant

The applicant shall be a legal manufacturer or registered company or entity in term of Companies Act requesting for service and taking responsibility for ensuring the medical devices and IVDs' requirements are in compliance with the laws and regulation in force in Botswana. If the applicant is not a resident in Botswana, then he/she shall appoint a Local Technical Representative (LTR) also referred to as Authorized Representative who must be residing in Botswana or company incorporated in Botswana.

3.1.4 Authority

Means Botswana Medicines Regulatory Authority

3.1.5 Clinical Evaluation

Means the review of relevant scientific literature and/or the review and assessment of data collected through clinical investigation.

3.1.6 Clinical Investigation

Means any designed and planned systematic study in human or animal subjects undertaken to verify performance of a specific device.

3.1.7 Conformity Assessment

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

3.1.8 Distributor

Any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.

3.1.9 Dossier

Means a file that contains detailed information on the device description, manufacturing, quality control and biomedical studies that demonstrate quality, safety and performance of the finished medical device.

3.1.10 Importer

Any natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed.

3.1.11 Intended use/purpose

The objective intent of the manufacturer regarding the use of a device, process, or service as reflected in the specifications, instructions and information provided by the manufacturer of the medical device.

3.1.12 In Vitro Diagnostic

Means a medical device whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens delivered from the human body and animals principally to provide information for diagnostic, monitoring or compatibility purposes. They include reagents, calibrator, control materials, specimen's receptacles, software, general laboratory equipment and

related instruments or apparatus or other articles and are used for examples, for the following test purposes; diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction and determination of physiological state.

3.1.13 Label

Means written, printed or graphic information provided upon the medical device itself. Where physical constraints prevent this happening, this term includes information provided on the packaging of each unit or on the packaging of multiple devices.

3.1.14 Labelling/information supplied by the manufacturer

Means written, printed or graphic matter affixed to a medical device or any of its containers or wrappers or, accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents.

3.1.15 Local Technical Representative

A company incorporated in Botswana and authorized by BoMRA to operate in medical devices. The company should have received a written mandate from the manufacturer to act on his behalf for specified tasks regarding the latter's obligations under Botswana's legislation.

3.1.16 Manufacturer

A legal person or company that carries out at least one step of the manufacture of a medical device, which includes the responsible person and/or company that designs and/or manufactures a medical device with the intention of making the medical device available for use, under his/her/its name, whether or not such medical device is designed and/or manufactured by that person or on behalf of that person by another person(s).

3.1.17 Manufacture (manufacturing)

All operations involved in the production, preparation, processing, compounding, formulating, filling, refining, transformation, assembling, packaging, re-packaging and labelling of medical devices regulated under MRS Act.

3.1.18 Medical device

It means any instrument, apparatus, implement, machine, appliance, implant, in vitro

reagent or calibrator, software, material or other similar or related article -

a) intended by the manufacturer to be used, alone or in combination, for humans or animals for-
   i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
   ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
   iii. investigation, replacement, modification or support of the anatomy or of a physiological process;
   iv. supporting or sustaining life;
   v. control of conception;
   vi. cleaning, disinfection or sterilization of medical devices; or

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

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

3.1.19 National Standard

Means a standard as prescribed by the Botswana Bureau of Standards (BOBS) under the Standards Act.

3.1.20 Objective Evidence

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

3.1.21 Performance Evaluation

Means review of the performance of a medical device based upon data already available, scientific literature and, where appropriate, laboratory, animal or clinical investigations.

3.1.22 Process Validation

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

3.1.23 Quality Management System

Means a management system to direct and control an organization with regard to quality, from establishing quality policy, quality objectives and implementing and maintaining quality system.

3.1.24 Recognized Standards

Means national or international standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.

3.1.25 Reference Regulatory Authority

NRAs recognised by BoMRA as per Policy "Recognition and-or Reliance on Information on Medical Devices including IVDs from Regional and International Regulatory Agencies **BOMRA-ER-MED-Policy No.1**" available on BoMRA website.

3.1.26 Technical Documentation

Means documented evidence, normally an output of the Quality Management System that demonstrates compliance of a device to the Essential Principles of Safety and Performance of Medical Devices.

3.1.27 Unique Device Identification System (UDI system)

A system that is intended to provide single, globally harmonized positive identification of medical devices through distribution and use, requiring the label of devices to bear a globally unique device identifier (to be conveyed by using AIDC and, if applicable, its HRI) based upon standard, with the UDI-DI of that unique identifier being also linked to a jurisdiction-specific public UDI database.

For more information on the fundamental concepts of the unique device identification system, see IMDRF/WG UDI/N7Final:2013.

3.1.28 **Unique Device Identifier (UDI)**

The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market. The UDI is comprised of the UDI-DI (Device Identifier) and UDI-PI (Production Identifier).

Note: The word "Unique" does not imply serialization of individual production units.

3.1.29 **Verification**

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

3.2 ABBREVIATIONS

The following abbreviations shall apply:

3.2.1 **AIDC** - Automatic Identification and Data Capture

3.2.2 **BRIMS** - BoMRA Regulatory Information Management System

3.2.3 **BoMRA** – Botswana Medicines Regulatory Authority

3.2.4 **BSE** - Bovine Spongiform Encephalopathy

3.2.5 **CE** - European Conformity

3.2.6 **DoC** - Declaration of Conformity

3.2.7 **EPSP** - Essential Principles of Safety and Performance

3.2.8 **FDA** - Food and Drug Administration

3.2.9 **GMDN** - Global Medical Devices Nomenclature

3.2.10 **GMP** - Good Manufacturing Practice

3.2.11 **HRI** - Human Readable Interpretation

3.2.12 **IFU** - Instructions for Use

3.2.13 **IMDRF** - International Medical Device Regulators Forum

3.2.14 **ISO** - International Organization for Standardization

3.2.15 **IVD** - In Vitro Diagnostic

3.2.16 **IVDMD**- In Vitro Diagnostic Medical Device

3.2.17 **LTR** - Local Technical Representative

3.2.18 **NRA** - National Regulatory Authority

3.2.19 **PDF**- Portable Document Format

3.2.20 **QMS** - Quality Management System

3.2.21 **QSR** - Quality System Regulation

3.2.22 **RRA** - Reference Regulatory Authority

3.2.23 **SRA** - Stringent Regulatory Authority as per WHO definition prior to 23 Oct. 2015

3.2.24 **STED** - Summary of Technical Documentation

3.2.25 **TSE** - Transmissible Spongiform Encephalopathy

3.2.26 **UDI** - Unique Device Identifier

3.2.27 **WHO** - World Health Organisation

4. GENERAL REQUIREMENT

This section describes application procedures and provides other useful information to applicants. Applicants are therefore advised to carefully read this section before compiling dossiers and assembling applications ready for submission to **BOMRA**. Therefore, the applicant shall take note of the following pointers when preparing a dossier for submission:

4.1 Data Presentation

All technical dossier submission for registration applications shall be submitted in an electronic format through BRIMS Self Service Portal at https://brims.bomra.co.bw/ . The folders should be named as per the technical dossier requirements for medical device. Data shall be presented on a paper with readily readable letters of at least 12 font size. The prepared STED dossier must contain all sections. Where there are sections not applicable to the medical device, the reason for the non-applicability should be provided under the section heading.

The applicant should create all PDF files directly from source whenever feasible rather than creating them by scanning. PDF documents produced by scanning paper documents are far inferior to those produced directly from the source document, such as a Word document, and thus should be avoided if at all possible. Files should not have any security setting, specifically:

A. File must not have password protection preventing the file from opening

B. File should be set to allow printing, selecting text and graphics

4.2 Language

All applications and supporting documents shall be in English.

4.3 Responsibility of the applicant

The applicant, as per the definition indicated, shall be responsible for the product information supplied in support of the application for registration, renewal and variations thereof. Whenever any serious safety concerns are noted, the applicant shall take appropriate actions including but not limited to informing the Authority, withdrawing registration, recalling the product from the market or revising labels by adding precautions or warnings.

4.4 Responsibility of Local Technical Representative

The LTR shall be responsible for:

i. Monitoring the device on the market and inform BoMRA immediately after the detection of any problem relating to a registered device such as serious manufacturing defects which may endanger public health.

ii. Facilitating communication between the applicant and BoMRA on regulatory matters relating to the medical devices.

iii. Handling device recalls.

iv. Any other responsibilities as assigned by the manufacturer.

4.5 Applications

The applicant should have the following information before submitting the dossier to BoMRA: -

i. Class of the device

ii. Intended purpose of the device

iii. GMDN code and term

iv. Conformity assessment certification

v. Declaration of conformity

IVD Medical devices are classified into four risk classes based on its inherent risk which depends substantially on its intended purpose and the effectiveness of the risk management techniques applied during design, manufacture, and use. Other considerations in risk classification include its intended user(s), its mode of operation and the technology used.

Examples of factors influencing risk classification of an in vitro diagnostic (IVD) device include the intended use of the device, the nature of the information provided by the IVD, the potential impact of the diagnostic result on individual patient management, and the consequences of an incorrect result. Additional considerations encompass whether the IVD is intended for self-testing or point-of-care testing, the complexity of the technology used, the degree of novelty of the analyte or marker being measured, and the potential for the device to influence public health decisions. An IVD device may also be integrated with software to interpret results or manage data, further influencing its risk classification

4.5.1 Classification system for IVD Medical Devices

IVD Medical devices are classified into four risk classes (A, B, C, D) as indicated below.

Table 1: Classification system for In Vitro Diagnostic Medical Devices.

CLASS	RISK LEVEL	EXAMPLES
A	Low Individual Risk and Low Public Health Risk	Specimen collection tubes, General culture media
B	Moderate Individual Risk and/or Low Public Health Risk	Pregnancy tests, Anti-Nuclear Antibody tests, Urine test strips
C	High Individual Risk and/or Moderate Public Health Risk	Blood glucose tests, HLA typing tests, PSA screening tests, Rubella tests
D	High Individual Risk and High Public Health Risk	Screening for HIV, ABO blood grouping tests

If more than one classification rule is applicable to the device, the rules resulting to the highest risk classification shall be applicable to the device. However, the Authority reserves the right to decide on the class of the device.

For more information regarding the risk classification rules for general medical devices can be found in **Guideline for IVD Medical Device Classification BOMRA/ER/MED/P04/G06.**

4.6 Medical Devices Grouping Requirements for Product Registration

Each product registration application shall contain **only one grouping** of IVD medical devices as prescribed in the **Guideline for Grouping of Medical Devices including IVDs BOMRA/ER/MED/P04/G07.**

Each submitted application shall contain **only one** of the following groupings of medical devices:

i. a SINGLE IVD medical device;
ii. one IVD medical device FAMILY
iii. one IVD medical device SYSTEM
iv. one IVD TEST KIT
v. one IVD CLUSTER (only class A and B reagents)
vi. one IVD medical device GROUP

4.7 Product Dossier

A separate and complete product dossier in an electronic format is required for each single medical device or a medical device group or medical device family or a medical device system or IVD test kit or IVD Cluster. Applicants are required to arrange the application dossier as follows:

4.7.1 Class A

Please note class A devices are covered in the **Guideline for Notification for Registration of Medical Devices including In Vitro Diagnostics (Class A) BOMRA/ER/MED/P04/G08**

4.7.2 Class B, C and D

i. The application form on the online platform
ii. Letter of authorization (section 8 of the guidelines)
iii. Proof of Quality Management System (QMS) e.g. ISO 13485 certificate.
iv. Information on Device details (section 5 of the guidelines)
v. Summary technical documentation (section 6 of the guidelines)
vi. Labeling information (section 7 of the guidelines)
vii. Essential Principles Checklist (**Guideline for Essential Principles Applicable to Medical Devices BOMRA/ER/MED/P04/G04**)

Failure to arrange the application dossier accordingly might lead to rejection of the application at the time of submission.

4.7.3 Class B, C and D Registration Pathways

BoMRA has different IVD medical devices registration pathways as indicated below;

b) Registration through full evaluation

c) Registration through abridged assessment

Refer to the table below for the registration evaluation pathway applicable to class B, C and D medical devices.

Table 2: Registration Pathways Eligibility Criteria

Evaluation Pathways	Eligibility Criteria
Notification (Class A and other notifiable devices)	Please refer to the **Guideline for Notification for Registration of Medical Devices including In Vitro Diagnostics (Class A) BOMRA/ER/MED/P04/G08**
Full Evaluation (Class B to Class D)	The following medical devices applications may be subjected to the full evaluation route;

	(i) A medical device that has not obtained any prior approval from any of RRA or SRA and/or (ii) Any Novel Device and/or (iii) Not identical to registered medical devices in Botswana. (iv) Not meeting requirements for abridged evaluation.
Abridged Assessment for (Class B)	Class B medical device may qualify for registration via the abridged evaluation route if it fulfils the following conditions at the point of submission: (i) Obtained approval from at least one of the RRA's or WHO. (ii) No prior rejection/withdrawal of the medical device by/from any foreign jurisdiction(s) due to quality, performance/ efficacy, or safety issues. This includes non-registration such as refusal to register of specific models in an application.
Abridged Assessment for Class C	Class C medical devices including IVDs may qualify for registration via the Abridged Evaluation route if it fulfils the following conditions at the point of submission: (i) Obtained approval from at least one of SRA agencies or WHO. (ii) Marketed for at least three years in the any SRA jurisdiction. **As per template IV** (iii) No safety issues globally associated with the use of the medical device(s) when used as intended by the product owner, in the last three years, defined as a) no reported deaths; b) no reported serious deterioration in the state of health of any person; and c) no open field safety corrective actions (including recalls) at the point of submission. **As per template II.** (iii) No prior rejection/withdrawal of the medical device by/from any SRA reference regulatory agency/that foreign jurisdiction(s) due to quality, performance/ efficacy, or safety issues. This includes non-registration such as refusal to register specific models in an application.
Abridged Evaluation for Class D	Class D medical device may qualify for registration via the Abridged Evaluation route if it fulfils the following conditions at the point of submission: (i) Obtained approval from at least two of RRA (including one SRA/WHO) agencies.

	(ii) Marketed for at least three years in reference to regulatory agency's jurisdiction. **As per template IV** (iii) No safety issues globally associated with the use of the medical device(s) when used as intended by the product owner, in the last three years, defined as a) no reported deaths; b) no reported serious deterioration in the state of health of any person; and c) no open field safety corrective actions (including recalls) at the point of submission. **As per template II.** (iii) No prior rejection/withdrawal of the medical device by/from any reference regulatory agency/that foreign jurisdiction(s) due to quality, performance/ efficacy, or safety issues. This includes non-registration such as refusal to register of specific models in an application.

Below is a summary of requirements per registration pathways. Applicants are required to arrange the application dossier as follows:

Table 3:
Summary of Dossier Submission requirements for Class B, C & D evaluation pathways

Documents Requirements	Full	Abridged
Product device details (section 5 of this guideline)	√	√
Letter of appointment (if applicable) (Section 8 of this guideline)	√	√
Declaration of Conformity (Section 8 of this guideline)	√	√
Certificate of Compliance with Recognized Standards (Section 8 of this guideline)	√	√
Medical Device Quality Management System (Section 8 of this guideline)	√	√
Proof of Reference Regulatory Agency	x	√
Proof of Marketing Reference Regulatory Agency	x	√
Post Marketing Surveillance Plan (Section 8 of this guideline)	√	√
Executive Summary (Section 8 of this guideline)	√	√
Summary Technical Documentation (Section 6 of this guideline)	√	√
Device Labelling (section 7 of this guideline)	√	√

4.8 Processing of applications

i. Once an application has been accepted and screening fees paid, the processing of

applications will follow the timeline specified in point 4.15

ii. Once a query or a request has been raised, the processing shall halt until after the response to the query has been received. If no response to the query or request has been received within the timeline specified in point 4.15, it will be deemed that the application has been withdrawn by the applicant and a rejection letter will be issued.

iii. A maximum of two query cycles will be permitted. If the applicant fails to submit all required documents after these two query cycles, the application will be considered rejected

iv. Once the query has been resolved, the application will be approved for screening and an approval screening letter will be issued through the online platform. The Applicant will be expected to submit the application for evaluation using the online platform.

v. If the applicant has trouble in responding in full or within the specified timeframe, he should contact the Authority to discuss the queries as soon as possible after receipt of the input request for information/clarification.

vi. If the applicant wishes to resubmit the application in future, it will be processed as a new application. As part of evaluation of the medical device, quality system audit of the manufacturing site may be conducted to verify compliance thereof (if applicable).

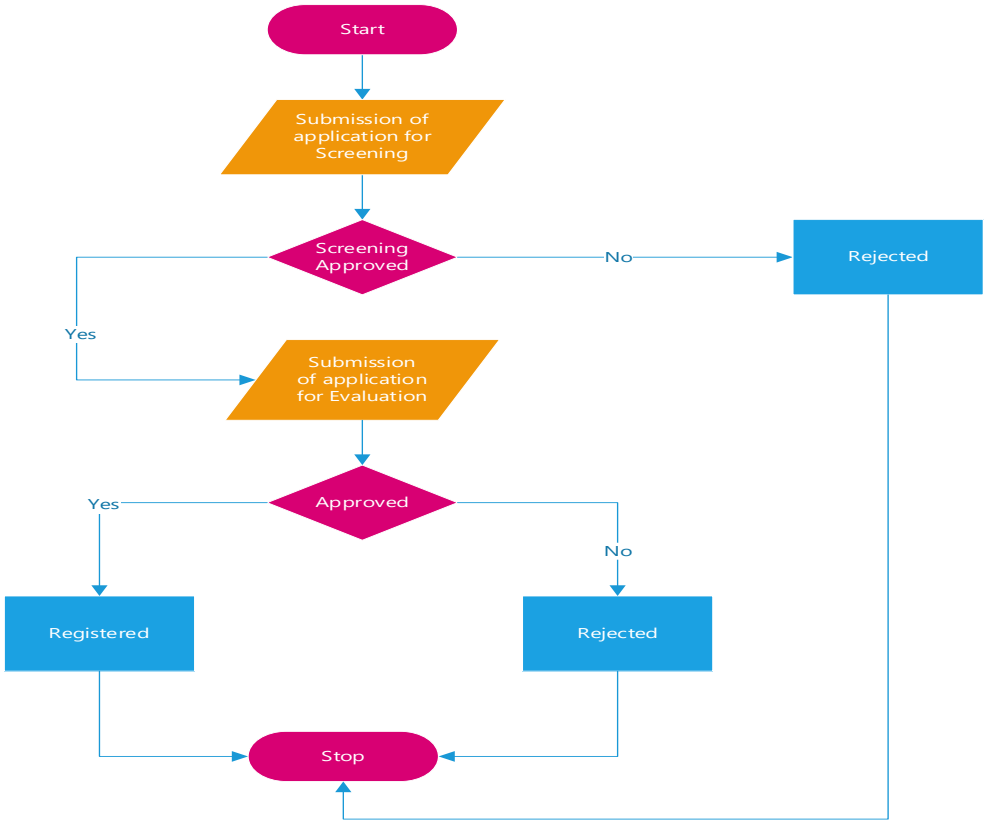
vii. Once the evaluation application has been accepted and evaluation fees paid, the application will take timeline specified in point 4.15.

viii. If additional information requires a query or a request has been raised, the processing shall halt until after the response to the query has been received. If no response to the query or request has been received within the timeline specified in point 4.15, it will be deemed that the application has been withdrawn by the applicant and a rejection letter will be issued.

ix. A maximum of three query cycles will be permitted. If the applicant fails to submit all required documents after these two query cycles, the application will be considered rejected

x. Once the query has been resolved, the application will be approved for registration and an approval registration certificate will be issued through the online platform.

xi. A summary of the registration process of applications is shown in the diagram below.



4.9 Registration of the device

When a device is found to have complied with all the prescribed registration requirements, the applicant will be informed to that effect. A certificate of registration together with such conditions as the BoMRA may determine shall be issued. Registration of a device shall be sites specific.

4.10 Validity of registration

The registration of a medical device shall be valid for five (5) years unless suspended or revoked by BoMRA or terminated by the registrant. The validity of registration shall be subject to: -

a) Payment of annual retention fees as prescribed in the current Fees and Charges Regulations in force.

b) Submission of post-marketing surveillance reports.

c) Submission of adverse effect reports associated with the use of device.

4.11 Termination of registration

BoMRA may give reasons in writing to suspend or revoke the registration of a device or amend the conditions of its registration. The applicant may issue BoMRA a written notice and reasons to terminate registration of a device as per the withdrawal guidelines.

4.12 Appeals

Any person aggrieved by a decision of the Authority in relation to any application for registration of a medical device may make representations in writing to BoMRA.

4.13 Changes to a registered medical device

a) The Authority should be informed on any significant change(s) that could reasonably be expected to affect the safety or effectiveness of a medical device including In vitro Diagnostics.

b) MAHs are required to submit a "Variation" application. Refer to the **Medical Devices Variation Guidelines BOMRA/ER/MED/P09/G01** for the types of changes and required documents to be provided for submission.

c) Certain changes are so fundamental that they alter the terms of the registered medical device and consequently cannot be considered as a change. For these cases a new dossier must be submitted. Any other change(s) should be notified immediately to the Authority.

4.14 Renewals

Applications for renewal of registration shall be made before the expiry of existing registration by submitting all the applicable requirements indicated in the renewal guidelines. Refer to the renewal guidelines with a document name and reference.

4.15 Registration Timelines in months

Registration Route	Notification	Class B	Class C	Class D
Screening	3 months	1 month	2 months	2 months
Abridged	NA	4 month	6 months	8 months
Full Evaluation (for local manufacturer)	NA	6 months	8 months	10 months
Full Evaluation (for foreign manufacturer)	NA	8 months	10 months	12 months
Expedited	NA	4 months	6 months	8 months
WHO CRP	3 months			
Query Response	1 Month			
Exemptions	72 Hours			
Major Variations	3 months			
Minor Variations	3 months			
Notification variations	1 Month			

4.15 Payment of fees

a) Every application shall be accompanied by appropriate fees as specified in the Fees and Charges Regulations (Schedule 5, MRSR, 2019) currently in force at the time of application.

b) Screening fees shall be paid at the time of lodging an application for screening.

c) Evaluation fees shall be paid at the time of lodging an application for evaluation.

d) Any application that will not be accompanied by appropriate fees will not be accepted.

e) All fees are non-refundable once paid to the Authority

5. DEVICE DETAILS

5.1 Name(s)

State the generic name, brand name of the device.

5.2 Description

Provide a summary of information on design, characteristics and performance of the device. The description should also include information on device packaging.

5.3 Category

State the GMDN category of the device. If the device is not categorized according to GMDN and is coded based on other system, please specify.

5.4 Intended Use/Indication(s)

State the intended use(s) of the device and/or provide a general description of the disease or condition that the device will diagnose, treat, prevent, cure or mitigate. The description of the target patient population for which the device is intended should also be included.

The statement of intended use should specify the therapeutic or diagnostic function provided by the device and may describe the medical procedure in which the device is to be used and whether the device is intended for single use or multiple uses.

5.5 Instructions for Use

Give a concise summary of information for safe use of the device including procedures, methods, frequency, duration, quantity and preparation to be followed.

5.6 Contraindications

State conditions under which the device should not be used. The statement should specify the clinical conditions of a patient that would make use of the device inadvisable.

5.7 Warnings

State the specific hazard alert information that a user needs to know before using the device.

5.8 Precautions

State briefly precautions to be taken and any special care necessary for the safe and effective use of the device.

5.9 Adverse Effects

Describe all adverse and side effects associated with the device under normal conditions of use.

5.10 Alternative Use

Describe any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the device is intended.

5.11 Storage conditions

State the storage conditions for the device. This should be based on results of stability studies conducted (where applicable)

5.12 Recommended shelf-life / Service – life (where applicable)

State the recommended shelf-life or service life of the device.

5.13 UDI

State the UDI number of device (if available).

6.0 SUMMARY TECHNICAL DOCUMENTATION

6.1 Device description and features

Provide the name of the device and detailed description of the device attributes that are necessary to explain how the device functions. If it is part of a system, the relationship of the components in the system should also be described. The details should include: -

i. The principle of operation of the device.
ii. Risk class and applicable classification rule for the medical device.
iii. Description of the key functional elements of the device including software and its release version, if applicable. e.g. its parts/components, formulation, composition and functionality.
iv. A description of the accessories, other IVD medical devices and other products that are not medical devices, which are intended to be used in combination with the medical device.
v. Components or accessories that can be sold separately and used in conjunction with other IVD medical devices, systems, or units should be clearly identified. Variants of the IVD device must also be specified, along with the parameter ranges of these variants (e.g., diagnostic assays with different detection sensitivities or reagents with varying concentrations)
vi. Labeled pictorial representation of the device in the form of diagrams, photographs or drawings with sufficient explanation should be provided.

6.2 Evidence of Conformity to Essential Principles

Provide evidence of conformity to Essential Principles of Safety and Performance (EPSP) by completing the checklist appended as Guideline for Essential Principles Applicable to Medical Devices **BOMRA/ER/MED/P04/G04.**

Note:

i. Manufacturers should identify the essential principles of safety and performance that are applicable to the device and the general methods used to demonstrate conformity to each applicable Essential Principle. The methods that may be used include: -

- Compliance with a recognized or other standard(s)
- Internal industry methods
- Comparison to another similar marketed device

ii. When the manufacturer uses national, international or other standards to demonstrate conformity with the Essential Principles, full title of the standard, identifying numbers, date of the standard and the organization that created the standard should be provided.

6.3 Risk Analysis

6.3.1 The STED should contain a summary of the risks identified during the risk analysis process and how these risks have been controlled to an acceptable level. Preferably, this risk analysis should be based on international or recognized standards (e.g. ISO 14971), be appropriate to the complexity and risk class of device and should be part of the manufacturer 's risk management plan (Not applicable for non-sterile and non-measuring Class A Device).

6.3.2 Summaries or reference or contain the results of the risk analysis. This risk analysis should be based upon international or other recognised standards and be appropriate to the complexity and risk class of the device

6.3.3 A list of possible hazards for these devices must be prepared. Indirect risks from medical devices may result from device-associated hazards, such as moving parts, which lead to sustained injury, or from user-related hazards. The evaluation of these risks against the claimed benefits of the device and the method(s) used to reduce risk to acceptable levels must be described. The individual or organisation that carries out the risk analysis must be clearly identified. The technique used to analyse risk must be specified, to ensure that it is appropriate for the medical device and the risk involved.

6.4 Design and manufacturing information

6.4.1 Product Design

Provide information such as to give a general understanding of the design applied to the IVDMD. It should include a description of the critical ingredients of an assay such as antibodies, antigens, enzymes and nucleic acid primers provided or recommended for use with the IVDD:

a) For instruments include a description of major subsystems, analytical technology (e.g. operating principles, control mechanisms), dedicated computer hardware and software.

b) For instruments and software, give an overview of the entire system, including an Architecture Design Chart, which is typically a flowchart of the relationships among the major functional units in the software, including relationships to hardware and to data flows such as networking.

c) For standalone software, include a description of the data interpretation methodology (i.e. algorithms).

d) For self-testing devices the design should include a description of the design aspects that make it suitable for lay person use.

e) If design takes place at multiple sites, a controlling site must be identified

6.4.2 Formulation and Composition

6.4.2.1 **Materials**- This section must include complete details of material specifications, including raw materials

a) All components of the IVD medical device shall be listed and chemically and biologically characterised, including antibodies, antigens, assay controls, substrates used to detect antigen-antibody complexes, and test reagents. Appropriate references shall be cited.

b) If synthetic peptides are used, the peptide sequence shall be provided.

c) If components are of biological origin or recombinant, the source must be indicated and details on production must be provided. These details would include the strain of the virus, the cell line for cultivation of the virus, sequences of relevant nucleic acids and amino acids, etc., used in the manufacturing process of viral lysate, purified proteins, recombinant and synthetic proteins.

d) If applicable, process validation results to be provided to substantiate that manufacturing procedures are in place to minimise biological risks, in particular, with regard to viruses and other transmissible agents. This also includes inactivation of infectious organisms in reagents and the production of reagents.

e) if applicable, information to be provided on irradiating components, nonionizing.

f) if applicable, information to be provided on the poison or controlled substance (e.g. Buprenorphine in drug assay kit)

6.4.2.2 **Biological safety**- The STED should contain a list of all materials of animal or human origin used in the device. For these materials, detailed information should be provided concerning the selection of sources/donors; the harvesting, processing, preservation, testing, and handling of tissues, cells and substances of such origin should also be provided. Process validation results should be included to substantiate that manufacturing procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents. The system for record-keeping to allow traceability from sources to the finished device should be fully described

6.4.2.3 **Documentation of design change**

Provide records of each design change, if any, with reasons for these changes along with associated validation/verification data. Include evidence that the change achieves the desired effect, and that the product continues to comply with the Essential Principles of Safety and Performance.

6.4.3 Manufacturing process

6.4.3.1 Overview of manufacturing process

Provide information on the manufacturing process, which may be in form of a process flow chart, showing an overview of production including technologies used, assembly and packaging of the finished IVDMD. Include details of any in-process and final product testing (e.g. the manufacturer's QC release program).

6.4.3.2 Sites of manufacture

Provide the following information;

a) Name of site,

b) Physical address of the site,

c) Description of the component manufacture/stage of manufacturing process carried out at the site,

d) A simple sight plan highlighting production areas and number of employees at the site,

e) A description of any other manufacturing that occurs at the site;

For all the critical manufacturing sites that are involved in the manufacture of this product (i.e. including design, warehousing and quality control stages of manufacture)

6.4.3.3 Key suppliers

Provide a list of key suppliers of ingredients/products/services for the manufacture of the IVDMD, indicating the;

a) Name of the supplier,

b) Supplier's manufacturing site physical address,

c) A description of the ingredient/product/service supplied,

d) Evidence of purchasing and verification procedures for the ingredients/products/services sourced from these suppliers.

6.5 Device Specifications

a) Describe functional characteristics and technical performance specifications for the device including as relevant, accuracy, sensitivity, specificity of measuring and other specifications including chemical, physical, mechanical, electrical and biological.

b) A list of the features, dimensions and performance characteristics of the IVDMD its variants and accessories should be provided in the dossier and also made available to the end user

6.5.1 Device validation and verification

Summarize the results of validation and verification studies undertaken to demonstrate compliance of the IVDMD with Essential Principles that apply to it. Whenever applicable the information should cover:-

a) The complete study protocol,

b) The method of data analysis,

c) Complete study report,

d) The study conclusion,

e) Any published literature regarding the device or substantially similar devices.

f) Summaries or reports of tests and evaluations based on other standards, manufacturer methods and tests or alternative ways of demonstrating compliance. Declarations/certificates of compliance to a recognized standard as applied by the manufacturer should be provided.

When a recognized standard exists that contains the protocol and the method of data analysis, this information can be substituted by a declaration/certificate of conformity to the recognized standard. However, a summary of the data and conclusions should be provided. Where appropriate actual test results summaries with their acceptance criteria should be provided and not just pass/fail statements

6.5.2 Specimen type- This section should describe the different specimen types that can be used. This should include their stability and storage conditions and is typically applicable to all systems and assay types. Stability includes storage and, where applicable, transport conditions. Storage includes elements such as duration, temperature limits, and freeze/thaw cycles

6.6 Analytical performance characteristics

6.6.1 Accuracy of measurement

6.6.1.1 **Trueness of measurement**- This section should provide information on the trueness of the measurement procedure and summarize the data in sufficient detail to allow assessment of the adequacy of the means selected to establish the trueness. Trueness measures apply to both quantitative and qualitative assays only when a reference standard or method is available. Typically for Class C and D IVD medical devices, detailed information should always be provided.

6.6.1.2 **Precision of measurement**- The analytical performance in this section should describe repeatability and reproducibility studies

a) **Repeatability**- This section should include repeatability estimates and information about the studies used to estimate, as appropriate, within-run variability. Repeatability data is obtained for instrumentation in conjunction with an appropriate assay. Typically for Class C and D IVD medical devices, detailed information should be provided.

Note: Such studies should include the use of samples that represent the full range of expected analyte (measurand) concentrations that can be measured by the test as claimed by the manufacturer.

Note: If a recognized standard is used, a declaration/certificate of conformity to the recognized standard along with a summary of the data and conclusions should be provided.

b) **Reproducibility**- This section should include reproducibility estimates and information about the studies used to estimate, as appropriate, variability between days, runs, sites, lots, operators, and instruments. Such variability is also known as Intermediate Precision. Reproducibility data is obtained for instrumentation in conjunction with an appropriate assay. Typically for Class C and D IVD medical devices, detailed information should be provided.

Note: Such studies should include the use of samples that represent the full range of expected analyte (measurand) that can be measured by the test as claimed by the manufacturer.

Note : If a recognized standard is used, a declaration/certificate of conformity to the recognized standard, along with a summary of the data and conclusions, should be provided.

6.6.2 Analytical Sensitivity

The analytical sensitivity should provide a description of specimen type and preparation including matrix, analyte (measured) levels, and how levels were established. The number of replicates tested at each concentration should also be provided as well as a description of the calculation used to determine assay sensitivity. Typically for Class C and D IVD medical devices, detailed information should be provided.

For example:

i. Number of standard deviations above the mean value of the sample without analyte (measurand), commonly referred to as limit of blank (LoB).

ii. Lowest concentration distinguishable from zero, based on measurements of samples containing analyte (measurand), commonly referred to as limit of detection (LoD).

iii. Lowest concentration at which precision and/or trueness are within specified criteria, commonly referred to as the limit of quantitation (LoQ).

6.6.3 Analytical specificity

This section should describe interference and cross reactivity studies to determine the analytical specificity, defined as the ability of a measurement procedure to detect or measure only the analyte (measurand) to be detected, in the presence of other substances/agents in the sample. The applicant should provide information on the evaluation of potentially interfering and cross-reacting substances/agents on the assay. Information should be provided on the substance/agent type and concentration tested, sample type, analyte (measurand) test concentration, and results. Interferents and cross-reacting substances/agents, which vary greatly depending on the assay type and design, could derive from exogenous or endogenous sources such as:

i) Substances used for patient treatment (e.g., therapeutic drugs, anticoagulants, etc.)

ii) Substances ingested by the patient (e.g., over-the-counter medications, alcohol vitamins, foods, etc.).

iii) Substances added during sample preparation (e.g., preservatives, stabilizers);

iv) Substances encountered in specific specimens' types (e.g., hemoglobin, lipids, bilirubin, proteins);

v) Analytes of similar structure (e.g., precursors, metabolites) or medical conditions unrelated to the test condition, including specimens negative for the assay but positive for a condition that may mimic the test condition (e.g., for a hepatitis A assay, test specimens negative for hepatitis A virus, but positive for hepatitis B virus).

vi) Typically, interference studies involve adding the potential interferent to the sample and determining any bias of the test parameter relative to the control sample to which no interferent has been added. Typically for Class C and D IVD medical devices, detailed information should be provided.

6.6.4 Metrological traceability of calibrator and control material values

Where applicable, summarize the information about metrological traceability of values assigned to calibrators and trueness control materials. Include, for example, methods and acceptance criteria for the metrological traceability to reference materials and/or reference measurement procedures and a description of value assignment and validation. Precision control materials, used when establishing the reproducibility of a measurement procedure, do not require the assessment of metrological traceability to a reference material or a reference method. Typically for a Class D IVD medical device, detailed information should be provided

6.6.4.1 Measuring range of the assay

This section should include a summary of studies which define the measuring range (linear and non-linear measuring systems) including the limit of detection and describe information on how these were established. This summary should include a description of specimen type, number of samples, number of replicates, and preparation including information on matrix, analyte (measurand) levels and how levels were established. Typically for Class C and D IVD medical devices, detailed information should be provided

6.6.4.2 **Validation of assay cut-off-** This section should provide a summary of analytical data with a description of the study design including methods for determining the assay cut-off, including:
i. The population(s) studied (demographics/ selection/ inclusion and exclusion criteria/number of individuals included).

ii. Method or mode of characterization of specimens; and,

iii. Statistical methods, e.g., Receiver Operator Characteristic (ROC), to generate results and, if applicable, define gray zone/ equivocal zone. Typically, for Class C and D IVD medical devices, detailed information should be provided.

6.6.4.3 Validation of assay procedure – reading time

Provide information on how the reading time (either end point or reading window) claimed in the Instructions for Use was determined.

6.7 Stability (excluding specimen stability)- This section should describe claimed shelf life, in-use stability, and shipping studies

6.7.1 Claimed shelf life- This section should provide information on stability testing studies to support the claimed shelf life. Testing should be performed on at least three different lots manufactured under conditions that are essentially equivalent to routine production conditions (these lots do not need to be consecutive lots). Accelerated studies or extrapolated data from real time data are acceptable for initial shelf-life claim but need to be followed up with real time stability studies. Typically for Class C and D IVD medical devices, detailed information should be provided. Such detailed information should describe:

(a) The study report (including the protocol, number of lots, acceptance criteria, and testing intervals);

(b) When accelerated studies have been performed in anticipation of the real time studies, the method used for accelerated studies; and,

(c) Conclusions and claimed shelf life.

6.7.2 In use stability- Information on in-use stability studies for one lot reflecting actual routine use of the device (real or simulated) should be provided. This may include open vial stability and/or, for automated instruments, onboard stability. In the case of automated instrumentation, if calibration stability is claimed, supporting data should be included. Such detailed information should describe:

(a) The study report (including protocol, acceptance criteria, and testing intervals); and,

(b) Conclusions and claimed in-use stability

6.7.3 Shipping stability- This section should provide information on shipping stability studies for one lot to evaluate the tolerance of products to the anticipated shipping conditions. Shipping studies can be done under real and/or simulated conditions and should include variable shipping conditions such as extreme heat and/or cold. Such information should describe:

(i) The study report (including the protocol, acceptance criteria);

(ii) Method used for simulated conditions; and,

(iii) Conclusion and recommended shipping conditions.

6.7.4 Robustness studies- Provide information to demonstrate that the product design is robust e.g. insensitive to environmental and usage variation. Robustness (flex) studies are designed to challenge the system under conditions of stress to identify potential device deficiencies, including failures, and determine the robustness of the product. The manufacturer must consider multiple skill levels of users, as well as potential instrument and reagent problems. Below is a list of factors that may need to be considered when performing robustness studies:

a) Operator error/ human factors, including not limited to;

i. Use of incorrect specimen type,

ii. Incorrect application of the specimen to the device (e.g., incorrect placement, incorrect volume),

iii. Incorrect handling of reagents including those in self- contained unitized test devices, incorrect placement of device (e.g., non-level surface),

iv. Incorrect placement of reagents, including strips, or other components that contain reagent, use of incorrect reagents (for example, reagents that are not specific for the particular device or lot or generic reagents),

v. Incorrect order of reagent application, use of incorrect amount of reagent, incorrect timing of procedures (e.g., specimen application, running the test, or reading results),

vi. Incorrect reading of test results, incorrect reading due to color blindness etc.

b) Specimen integrity and handling including errors in specimen collection, use of inappropriate anticoagulant, clotted specimens, error in specimen handling, incorrect specimen transport and/or storage, presence of interfering substances, presence of bubbles in the specimen etc.

c) Reagent integrity (Reagent viability) including use of improperly stored reagents, use of outdated reagents, use of improperly mixed reagents, use of contaminated reagents etc

d) Hardware, software, and electronics integrity including power failure, power fluctuation, incorrect voltage, repeated plugging and unplugging of the device, hardware failure, software failure, electronic failure, physical trauma to unit etc.

e) Stability of calibration and internal controls including factors that affect calibrator and calibration stability, factors that may interfere with calibration

f) Environmental factors including impact of key environmental factors (heat, humidity, barometric pressure changes, altitude (if applicable), sunlight, surface angle, device movement, etc.) on reagents, specimens, and test results, impact of key environmental factors (including changes in parameters such as pH or temperature) etc. The following should be provided:

i. A summary of the evidence that falls within this category,

ii. State the test environment and relation to the intended use environment,

iii. A discussion of what tests were considered for the device and why they were or were not performed,

iv. A discussion to demonstrate why the evidence presented is sufficient to support the application,

v. If a performance study has been conducted that includes human factors/usability end points, reference to the studies and endpoints should be made, but full results do not need to be repeated.

6.8 Software verification and validation (if applicable)

The STED should contain information on the software design and development process and evidence of the validation of the software, as used in the finished device. This information should typically include the summary results of all verification, validation, and testing performed both in-house and in a simulated or actual user environment prior to final release. It should also address all the different hardware configurations and, where applicable, operating systems identified in the labelling.

6.9 Clinical performance

Where relevant, the STED should contain data on the clinical performance of the IVD medical device. This clinical performance data is one of the elements of clinical evidence that demonstrates the conformity of the IVD medical device to the essential principles that apply to it. Analytical performance and clinical performance are elements of clinical evidence More detail and format for clinical evaluation report is described in the **BOMRA/ER/MED/P03/G02** "**Guidance on Clinical Evaluation"**

7.0 LABELLING REQUIREMENTS

Labeling information shall be in English and shall be expressed in a legible, permanent manner that can be easily understood by the intended user.

Detailed labelling requirements are stipulated in "**Guideline for Labelling of Medical Devices including IVDs BOMRA/ER/MED/P04/G03.**

8.0 ADDITIONAL REGISTRATION REQUIREMENTS

8.1 Authorisation from Product owner/ Manufacturer to LTR

a) In cases where the manufacturer in not Botswana, a letter should be made between the manufacturer of the medical device for registration and the agent responsible for the import, distribution, and sale of the product in Botswana (As per Template 1).

b) In case the manufacturer wishes to have more than one distributor, this must be mentioned in the letter. The appointed agent(s) is responsible for correspondence and complete compliance with regulatory requirements pertaining to the product 's distribution life cycle in the country.

c) If any fraud or unsuspected and unacceptable adverse event occurs to the consumer under normal utilization, both parties will be responsible for collecting the product from the market and are responsible for substantiating any event.

d) Both parties are responsible for vigilance reporting and post-marketing reporting of the medical devices.

e) The agent representing the manufacturer for importation should hold a license issued by

the ministry of trade and/or license issued by the BoMRA at the time of importation of the product.

8.2 Declaration of Conformity- The manufacturer should attest and submit Declaration of Conformity (DOC) as per **Template III**. DoC must be as per recommend template, other templates for DoC will not be acceptable.

8.3 Certificate of Compliance with Recognized Standards

The applicant should submit the applicable certificate of GMP, product certificate, TSE/BSE risk free attestation letter, standards for sterilization (such as ISO 11135, ISO 11137, ISO 17665, ISO 13408, etc.) with information on sterilization method (s) and certificate of conformity in line with the DoC declared.

8.4 Quality Management System

Information regarding: Quality control and quality management system, including quality control and general quality management system of source and authorization of raw materials, component handling, packaging, release, recall procedures, and handling of compliance and out of specifications e.g. ISO13485 or FDA QSR (21 CFR 80) should be provided about the manufacturer of the product.

8.5 Reference Agency Approval and Marketing History

Proof of product registration approval(s) and marketing history from regulatory agencies recognized by BoMRA policy **BOMRA/ER/MED/Policy2**.

8.6 Post-Marketing Surveillance Plan

a. Prior to and after placing the product on the market, the manufacturer should put a process in place, as part of its quality management system, to assess the continued conformity of the device to the essential principles of safety and performance through the post-marketing phase. This process will include complaint handling, post-market vigilance reporting, and corrective and preventive actions.

b. Applicants need to submit post marketing surveillance plan for Botswana market. PMS plan addressing other regulatory markets will not accept.

c. The manufacturer and/or local representative should provide annual post-marketing vigilance and post-marketing reports of Class A (sterile, active & measurable), Class B and higher devices.

8.7 Executive Summary

An executive summary shall be provided with the common submission dossier template, which shall include the following information.

8.7.1 An overview, e.g., introductory descriptive information on the medical device, the intended uses and indications for use of the medical device including IVDs, any novel features and a synopsis of the content of the STED.

8.7.2 Commercial marketing history-the list of countries from SRA/RRA regulatory agency jurisdictions where the medical device including IVDs is marketed and the dates of introduction into each country is to be provided.

8.7.3 For applications submitted via the abridged evaluation route, as part of the list of regulatory approvals or marketing clearances obtained and status of any pending request for market clearance, the following information is required.

(a) the registration status (i.e. submitted, not submitted, pending approval, rejected or withdrawn) and intended use and indications of the medical device in all reference agencies. This information is to be provided in a tabular format as given below.

(b) copies of certificates or approval letters from each reference agency for the medical device are to be provided as an annex to the STED submission. For CE marked devices, the declaration of conformity by the product owner must be submitted together with the EC certificate issued by the notified bodies.

Reference agency	**Intended use**	**Indications of use**	**Registration status and date**	**Reason for rejection or withdrawal (if applicable)**

8.7.4 Status of any pending request for market clearance; and

8.7.5 Important safety/performance related information:

(a) summary of reportable adverse events and field safety corrective actions (FSCAs) for the medical device including IVDs since its first introduction on the global market. This is to be provided in a tabular format as given below. If there have been no adverse events or FSCAs to date, an attestation that this is the case is required (prepared on product owner letterhead).

(b) For FSCAs that are 'open', product owner's root cause analysis of the issue, corrective and preventive actions (CAPA) implemented to address the root cause of issue in the FSCA shall be provided.

Description of adverse event	**Frequency of occurrence (number of reports / total units sold) in the period of dd/mm/yyyy to dd/mm/yyyy**

Date of FSCA	Reason for FSCA	Countries where FSCA was conducted

(c) if the medical device contains one or more of the following, a description of the following must be provided (not applicable to IVDs);

(c.1) animal cells, tissues and/or derivatives thereof, rendered non-viable (e.g. porcine heart valves, catgut sutures, etc);

(c.2) derivatives of cells or tissues of human origin, rendered nonviable.

(c.3) cells, tissues and/or derivatives of microbial or recombinant origin (e.g. dermal fillers based on hyaluronic acid derived from bacterial fermentation processes).

(c.4) irradiating components, non-ionizing (e.g. lasers, ultrasound, etc.).

9.0 OTHER MEDICAL DEVICES

9.1 Repairs

i. Where a registered device is "repaired" and returned to its original owner after the repair the components used in the repair would not require registration. The device should returned to its owner.

ii. If the repaired device was not registered, then registration process will be required.

9.2 Second-hand and fully refurbished devices

i. Second-hand medical devices are those which are already on the market and have been "pre-owned" and used and that are subsequently "sold on" for the same continued use. These products are considered to be already registered and do not require second registration by their new owner.

ii. A medical device that has been fully refurbished is not the same as one that has been repaired or undergone maintenance. Therefore, it requires to be registered as a new medical device.

iii. They will be considered to be the "manufacturer" under the regulations and are required to place the product on the market under their own name. "Fully refurbished" is considered to mean that a device has been completely rebuilt / made as new from used devices and is assigned a new "useful life". It would also be considered as a new device if a new intended purpose was assigned.

9.3 Software

Software may be considered to be medical devices provided that the purpose fits the definition of a medical device. The definition of a medical device includes stand-alone

software and specifies that when software is used in combination with a device which is "intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes" that it will be considered to be a medical device. For more information, please refer to the guideline "**Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations IMDRF/SaMD WG/N12FINAL**."

10 Accessories

Accessories should be necessarily take the classification of the device with which they are intended to be used. A product can only become an accessory to a medical device if there is an established intended use in conjunction with a medical device. The registration of accessories will follow the requirements of these guidelines if not registered with IVD medical device.

10.1 Spare parts

Spare parts, registered with devices supplied for the replacement of existing components of a medical device that has already been registered are not considered to be medical devices unless they are likely to significantly change the characteristics or performance of the finished device. If this is the case then such spare parts are likely to be considered to be medical devices in their own right and therefore may require registration.

Template 1
Letter of Authorisation Template

[To be printed on Company Letterhead of Product Owner]
Medical Devices Unit
Department of Products Evaluation and Registration
The Botswana Medicines Regulatory Authority

[Date]

Dear Sir/Madam,

Subject: Letter of Authorisation for [LTR (Company Name)]

We, [name of Product Owner (Company Name)], as the Product Owner, hereby authorise (Company Name), as the LTR to deal with all matters for the regulation of medical devices to the Botswana Medicines Regulatory Authority (BoMRA)on our behalf.

This authorisation shall apply to the following medical devices:

[List containing product names of medical devices]

We also authorise [(Company Name)] to make declarations and to submit documents on our behalf, regarding the above medical devices. These declarations and submissions are made pursuant to the requirements of the MRSA Act & Regulations and any other applicable laws that may also be in force.

This authorisation shall remain in effect until our notification to the Botswana Medicines Regulatory Authority in writing (either by postal mail or facsimile transmission) that the authorisation is revoked.

We undertake to provide post-market support and assistance to the applicant as may be required in relation to any matter involving the above medical devices.

We acknowledge that any non-compliance with any registration condition issued by the Botswana Medicines Regulatory Authority in relation to medical devices registered on the Botswana Medical Device Register may result in the suspension or cancellation of the medical device registration.
We agree to assist the Botswana Medicines Regulatory Authority with any request for information on the above medical devices.

Yours Sincerely,

[Signature]
[Full Name and Title of Company Official]
[Name and address of company]

Template II

Safety Declaration Template

[To be printed on Company Letterhead of Applicant]

Medical Devices Unit
Department of Products Evaluation and Registration
Botswana Medicines Regulatory Authority
[Date]

Dear Sir/Madam,

I, *[name of Company]*, the Applicant for registration of the medical device(s) stated below, hereby declare that there are no safety issues globally associated with the use of the medical device(s) when used as intended by the Product Owner, in the last three years from *[dd/mm/yyyy] to [dd/mm/yyyy]* **(Condition 1) or** since market introduction of the medical device(s), globally **(Condition 2)**:

- ☐ No reported deaths.
- ☐ No reported serious deterioration in the state of health of any person; **and**
- ☐ No open field safety corrective actions (including recalls) at the point of submission of this application.

This declaration is made with respect to the following medical device(s):
[List containing product names of medical devices]

I, the Applicant, am aware that making a declaration which I know to be false is an offence and may result in the cancellation of registration of the above medical devices.

Yours Sincerely,
[Signature]

[Full Name and Title of Company Official]
[Name and Address of Company]

Template III
Declaration of Conformity

[To be printed on Company Letterhead of Product Owner]

Name and Address of Product Owner:

We hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance.

Manufacturing Site:
(Physical manufacturing site(s) including sterilization site(s))

Medical Device(s):
(e.g., product name and model number)

Global Medical Device code and term for the device(s).
(Generic names used to identify all medical device products)

Risk Classification: e.g., Class B, rule
(Risk Classification of medical device(s) according to the classification rule, and the rule(s) used to determine the classification)

Quality Management System Certificate:
(Certification Body and Certificate Number, issue date, expiry date)

For Class B, Class C and Class D medical devices, declaration of conformity to either of the following QMS standards is mandatory:

☐ ISO 13485/ Quality Audit

☐ US FDA Quality System Regulations

☐ Japan MHLW Ordinance 169

Standards Applied:
(International standards; OR Regional Standard)

This declaration of conformity is valid from (Day Month Year)

Authorised Signatory:

_____ _____

Name, Position Date

Template IV
Marketing History Declaration Template

[To be printed on Company Letterhead of Product Owner]

Medical Devices Unit
Department of Products Evaluation and Registration
Botswana Medicines Regulatory Authority
[Date]

Dear Sir/Madam,

I, [name of Company], the Applicant for registration of the medical device(s) stated below, hereby declare that the medical devices have been marketed in the independent reference regulatory agency's jurisdiction for at least three years. The first date of market introduction in [jurisdiction/country] was [mm/yyyy].

This declaration shall apply to the following medical device(s):

[List containing product names of medical devices]

I, the Applicant, am aware that making a declaration which I know to be false is an offence under Medicines Related Substance Act, and may result in the cancellation of registration of the above medical devices.

Yours Sincerely,

[Signature]

[Full Name and Title of Senior Company Official]
[Name and Address of Company