Botswana Medicines Regulatory Authority

BOMRA
MEDICINES REGULATORY AUTHORITY

Approved By: _____ 06/12/24

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Date of approval (DD/MM/YY)

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7.0 Revision status sheet

Page	Changes made	Issue No	Process owner (Title)	Reviewer's name	Date
4-43	Removed all requirements related to IVD medical devices	2.0	Director, DPER	Medical Devices Unit	05/11/2024
6-7	Added definitions 3.1.17 to 3.1.29	1.0	Director, DPER	Medical Devices Unit	07/09/2023
8	Added abbreviation 3.2.11 to 3.2.24	1.0	Director, DPER	Medical Devices Unit	07/09/2023
10	4 "Risk Classification for Medical Devices" to 4.5	1.0	Director, DPER	Medical Devices Unit	07/09/2023
8	Changed 5 "General Requirement" to 4	1.0	Director, DPER	Medical Devices Unit	07/09/2023
13	Changed 6 "Registration of Medical Devices including IVDs",7 "Medical Devices Incorporating Medicinal Product" and 8 Registration Submission Requirement to 6 "Product Dossier"	1.0	Director, DPER	Medical Devices Unit	07/09/2023
19	Changed 9 "Summary Technical Documentation (STED) format for Medical Devices and IVDs" to 7	1.0	Director, DPER	Medical Devices Unit	07/09/2023
39	Changed 10 "Other Medical Devices" to 9	1.0	Director, DPER	Medical Devices Unit	07/09/2023
41	Changed 10.3 "Accessories" to 10	1.0	Director, DPER	Medical Devices Unit	07/09/2023
42-43	Added 12,13,14,15	1.0	Director, DPER	Medical Devices Unit	07/09/2023

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Revision status sheet..... 2

1. Purpose..... 4

2. Scope..... 4

3. Definitions and Abbreviations..... 4

3.1 Definitions..... 4

3.2 Abbreviations.....8

4. General Requirement..... 9

5. DEVICE DETAILS..... 17

6.0 SUMMARY TECHNICAL DOCUMENTATION..... 18

7.0 LABELLING REQUIREMENTS..... 25

8.0 ADDITIONAL REGISTRATION REQUIREMENTS..... 25

9.0 OTHER MEDICAL DEVICES..... 28

10.0 Accessories..... 30

Template I.....32

Template II.....33

Template III.....34

Template IV.....35

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1. Purpose

The intention and purpose of this guideline is to provide guidance to those submitting applications for registration of Medical Devices excluding In Vitro Diagnostic medical devices (IVDs). 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 medical devices or devices except in vitro diagnostic devices. These guidelines apply to all class B, C and D medical devices.

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 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 and /or rejection of the application

Out of scope:

a) Submission for registration of In Vitro Diagnostic medical devices

b) Submission for registration for Class A medical devices including IVDs

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 a company residing in Botswana or company incorporated in Botswana.

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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.

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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.

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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 Stringent Regulatory Authority (SRA)

A regulatory authority which is:

a) A regulatory authority which is: a member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency;

b) or an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada;

c) or a regulatory authority associated with an ICH member through a legally binding, mutual recognition agreement including Australia, Iceland, Liechtenstein and Norway.

3.1.27 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.

3.1.28 Unique Device Identification System (UDI system)

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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.

3.1.29 **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.

3.1.30 **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 **AMDF**- Africa Medical Device Forum

3.2.2 **ARSO**- African Organisation for Standardisation

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

3.2.4 **BSE**-Bovine Spongiform Encephalopathy

3.2.5 **DoC**- Declaration of Conformity

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

3.2.7 **FDA**-Food and Drug Administration

3.2.8 **GMP**-Good manufacturing practice

3.2.9 **IFU** - Instructions for Use

3.2.10 **ISO**-International Organization for Standardization

3.2.11 **QMS** - Quality Management System

3.2.12 **QSR**-Quality System Regulation

3.2.13 **IVD** - In Vitro Diagnostic.

3.2.14 **SRA** - Stringent Regulatory Authority

3.2.15 **WHO** - World Health Organisation.

3.2.16 **CE**- European Conformity

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3.2.17 **GMDN**- Global Medical Devices Nomenclature

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

3.2.19 **LTR**- Local Technical Representative

3.2.20 **NRA**- National Regulatory Authority

3.2.21 **RRA**- Reference Regulatory Authority

3.2.22 **STED**- Summary of Technical Documentation

3.2.23 **UDI**- Unique Device Identifier

3.2.24 **TSE-**Transmissible Spongiform Encephalopathy

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

i. 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 devices. Documents shall be presented on paper with readily readable letters. 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.

ii. 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. File 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, and adding or changing notes and form fields

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 on, 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

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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 as per the definition at 3.1.15 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. Providing technical support and services to users of registered device (s).

v. 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

4.5.1 Classification system for General Medical Devices

I. 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.

II. Examples of factors influencing risk classification of a general medical device include the contact duration with the body, degree of invasiveness, whether the medical device delivers medicinal products or energy to the patient, whether they are intended to have a biological effect on the patient and local versus systemic effects, etc. A general medical device may also be incorporated with a medicinal product in an ancillary role to achieve its intended purpose

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

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Table 1:

CLASS	RISK LEVEL	EXAMPLES
A	Low Risk	Wheelchairs, Tongue depressors
B	Low-moderate Risk	Hypodermic needles, Suction equipment
C	Moderate-high Risk	Ventilators, Bone fixation plates
D	High Risk	Heart valves, Implantable defibrillators

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 Medical Device Classification - BOMRA/ER/MED/P04/G05.**

4.6 Medical Devices Grouping Requirements for Product Registration

Each product registration application shall contain **only one grouping** of 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 medical device
ii. one medical device family
iii. one medical device system
iv. one 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. Applicants are required to arrange the application dossier as follows:

4.7.1 Class A

Please note class A devices and notifiable medical 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

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ii. Letter of authorization (section 8 of the guidelines)

iii. Proof of Quality Management System (QMS) e.g. ISO 13485 certificate or equivalent.

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 medical devices registration pathways as indicated below;

a) Registration through full evaluation

b) Registration through abridged assessment

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

Registration Pathways Eligibility Criteria
Table 2:

Evaluation Pathways	Eligibility Criteria
Notification (Class A and other notifiable devices)	Please refer to the notification registration guidelines: **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 SRA, RRA 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 SRA or WHO with ISO 13485 or equivalent

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	(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 specific models in an application.
Abridged Assessment for Class C	Class C medical devices 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 with valid ISO 13485 certification or equivalent (ii) Marketed for at least three years in 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. Note that abridged assessment can be done for contraceptive medical devices that have been registered in any of the SADC Countries.
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) agencies with valid ISO 13485 certificate or equivalent (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.**

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	(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 are paid the processing of application for class B, C and D 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. There shall be two query cycles.

iii. 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.

iv. If the applicant experiences difficulty in responding in full or within the specified

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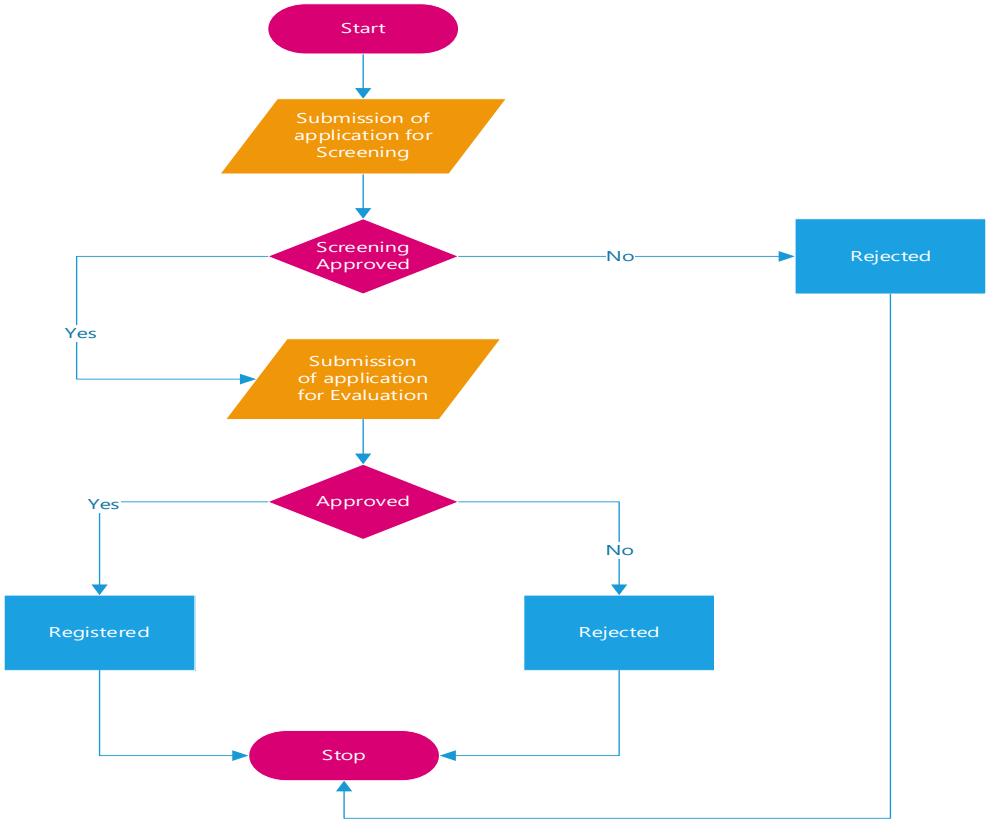
timeframe, he should contact the Authority to discuss the queries as soon as possible after receipt of the input request for information/clarification.

v. 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.

vi. Once the evaluation application has been accepted and evaluation fees are paid, the application for class B, C and D will take (8, 10 and 12 months respectively). Note that for WHO PQ medical devices the manufacturer has to submit a filled form 2 and form 3 along with the application.

vii. A summary of processing Class B, C and D 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 of that effect. A certificate of registration together with such conditions as may determine by the Authority shall be issued. Registration of a device shall be site 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: -

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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.

d) And any other conditions will be set in the registration certificate.

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 or withdraw the marketing authorization 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 and follow the appeal's process as stipulated in the MRS Act of 2023 or the regulations.

4.13 Changes to a registered medical device

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

b) MAH are required to submit a "Variation" application. Please refer to **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 six (6) months before the expiry of existing registration by submitting all the applicable requirements indicated in the renewal guidelines. If the registration certificate is not renewed after the expiry date, the certificate will become invalid hence the marketing authorization terminated. Further information on retention can be found on the: **Guideline for the Retentions of Listed and Registered Medical Devices including In Vitro Diagnostics - BOMRA/ER/MED/P10/G01**.

4.15 Registration Timelines in months

Registration Route	Notification	Class A & B	Class C	Class D
Screening	Within 3 months	Within 1 month	Within 2 months	Within 2 months
Abridged	NA	Within 4 months	Within 6 months	Within 8 months

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Full Evaluation (for local manufacturers)	NA	Within 6 months	Within 8 months	Within 10 months
Full Evaluation (for foreign manufacturer)	NA	Within 8 months	Within 10 months	Within 12 months
Expedited	NA	Within 4 months	Within 6 months	Within 8 months
WHO CRP	Within 3 months			
Query Response	Within 1 Month			
Exemptions	Within 72 Hours			
Major Variations	Within 3 months			
Minor Variations	Within 3 months			
Notification variations	Within 1 Month			

4.16 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 and model of the medical 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 systems, 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

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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 and the stability studies report should be provided.

5.12 Recommended shelf-life

State the recommended shelf-life of the device and provide a study report to substantiate the shelf life.

5.13 UDI

State the UDI number such GS1 or any other UDI relevant to the device (if applicable).

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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 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 with other medical devices, systems or units should be identified. Variants of the device must be identified, as well as the parameter ranges of variants [for example (e.g.), hip implants with varying coatings].

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: -

a) Compliance with a recognized or other standard(s)

b) Internal industry methods

c) Comparison to another similar marketed device

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 Materials

Details of material identifications and specifications including raw materials and components should be provided. The description of the materials of the device and their physical properties should be sufficient to demonstrate the conformity with the relevant Essential Principles. The information shall include

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complete chemical, biological and physical characterization of the materials of the device especially for materials contacting the patient or when the material chosen is considered critical for the design or function of that component. Reference to applicable material standards may be useful in this description.

6.4 Device Specification

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.

Note: A list of the features, dimensions and performance attributes of the medical device, its variants and accessories that would typically appear in the product specification should be made available to the end user e.g. in brochures and catalogues.

6.5 Device Verification and Validation

Summarize the results of verification and validation studies undertaken to demonstrate compliance of the device with Essential Principles that apply.

The following documentation should be submitted.

i. Declarations/ certificates of conformity to the recognized standards listed as applied by the manufacturer; and

ii. Summaries or reports of tests and evaluations based on other standards, manufacturer methods and tests or alternative ways of demonstrating compliance.

Whenever applicable the information should cover:

(a) Engineering tests

(b) Laboratory tests

(c) Biocompatibility tests

(d) Animal tests

(e) Simulated use

(f) Software validation

6.5.1 For sterile medical devices the following information should be provided in this section:

i. Detailed information of the initial sterilization validation including bio- burden testing, pyrogen testing, testing for sterilant residues (if applicable) and packaging validation. If initial sterilization validation is not performed, adequate justification must be provided. For example, if reference to the sterilization validation conducted for another medical device is made for the medical device in the application, the justification for the applicability of the previously conducted validation to the current medical device must be provided. In addition, the initial sterilization validation report for the reference medical device must be provided.

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ii. Evidence of the ongoing revalidation of the process; typically, this would consist of arrangements for, or evidence of, revalidation of the packaging and sterilization processes.

iii. Detailed validation information should include the method used, sterility assurance level attained, standards applied, the sterilization protocol developed in accordance with those standards, and a summary of results.

iv. Post-sterilization functional test on the medical device;

v. If the sterilant is toxic or produces toxic residuals (e.g. ethylene oxide residues), test data and methods that demonstrate that post-process sterilant and/or residuals are within acceptable limits must be presented.

6.5.2 Shelf life of the device

For medical devices with a shelf-life, data demonstrating that the relevant performances and characteristics of the medical device are maintained throughout the claimed shelf-life which the "expiry" date reflects is to be provided under this section. This may include:

i. Prospective studies using accelerated aging, validated with real time degradation correlation;

ii. Retrospective studies using real time experience, involving e.g. testing of stored samples, review of the complaint's history or published literature etc.; OR

iii. A combination of (i) and (ii)

6.5.3 If real time shelf-life data is not available, shelf-life data collected from accelerated studies can be used to support the initial shelf-life claim. The rationale for the parameters selected for the accelerated studies must be provided. Shelf-life data collected from accelerated studies must be supported by real time testing to confirm the initial shelf-life claim. The final real time study report must be submitted when completed.

6.5.4 As the absence of an "expiry" date constitutes an implicit claim of an infinite shelf-life, evidence demonstrating the following shall be provided:

i. That there are no safety-related performances or characteristics which are likely to deteriorate over time; OR

ii. That the extent of any likely deterioration does not represent an unacceptable risk; OR

iii. That the period over which unacceptable deterioration occurs is far beyond the likely time of the first use of the medical device e.g. 30 years.

6.5.5 For devices that do not have expiry dates (e.g. infusion pump, digital thermometer), the projected useful life of the medical device must be provided. Manufacturers may refer to the current TS/ISO 14969 (Medical devices – Quality Management Systems – Guidance on the application of ISO 13485) for information on how to determine the projected useful life.

6.5.6 For medical devices with a measuring function where inaccuracy could have a significant adverse effect on the patient, studies demonstrating conformity with metrological requirements shall be provided.

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6.5.7 If the device requires special packaging (e.g. considerations related to sterility, humidity, light sensitivity, pressure or oxidative reaction under irradiation), evidence should be provided that this has been addressed. Likewise, evidence should be provided to demonstrate that the integrity of the device and the internal environment can be maintained by the device packaging during handling, transport and storage (i.e., for claimed shelf life). In the case of sterility, ensure that the test methods address both seal integrity and sterility (e.g., bubble tests, dye penetration test, etc.).

6.6 Biocompatibility (if applicable)

i. Biocompatibility testing characterizes the biological response to the material. If the device comes in contact with the patient then the biocompatibility of all materials which are potentially patient contacting is required. Tests should be conducted on samples from the final product after all manufacturing and processing have been completed (e.g., sterilization). Deviations from this should be justified; generic claims from the raw material supplier are generally insufficient.

ii. Reports describing the tests, the results and the analyses of data should be presented. For each test, the predefined acceptance criteria and the results should be clearly provided (e.g., tabular form). In general, ISO 10993 standards are taken as the gold standards for biocompatibility. If testing was not conducted from a currently recognized standard, the validated alternative method should be provided along with a justification for its use (e.g., devices incorporating nanotechnology). Any deviations from a standard method should also be specified.

6.7 Software Verification and Validation (if applicable)

Provide 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 verifications, validation protocols and report and testing performed both in-house and in a simulated or actual user environment prior to final release. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the labeling.

6.8 Devices containing Biological Material (if applicable)

Provide results of studies substantiating the adequacy of the measures taken with regards to the risks associated with transmissible agents. This will include viral clearance results for known hazards. Donor screening concerns must be fully addressed, and methods of harvesting must also be fully described. Process validation results are required to substantiate that manufacturing procedures are in place to minimize biological risks.

To fulfill the requirements under this section, the following information shall be submitted:

i. A list of all materials of animal, human, microbial and/or recombinant origin used in the medical device and in the manufacturing process of the medical device. This includes animal or human cells, tissues and/or derivatives rendered non-viable and cells, tissues and/or derivatives of microbial or recombinant origin;

ii. Detailed information concerning the selection of sources/donors;

iii. Detailed information on the harvesting, processing, preservation, testing and handling of tissues, cells and substances;

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iv. Process validation results to substantiate that manufacturing procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents;

v. Full description of the system for record keeping allowing traceability from sources to the finished medical device; and

vi. Evidence that demonstrates a system is in place for animals and tissue traceability; and quality control processes and procedures are in place to prevent contamination with potential infectious/transmissible agents, including Transmissible Spongiform Encephalopathies (TSEs) should be provided. Disinfection/decontamination procedures in the event of contamination should also be outlined along with appropriate validation.

6.9 Pre – clinical Studies (if applicable)

I. Provide detailed information on pre-clinical animal studies conducted to justify the probability of effectiveness in humans. These studies must follow Good Laboratory Practices. The objective, methodology, results, analysis and manufacturers conclusions must be presented. The conclusion of the study should address the device's interactions with animal fluids and tissues and the functional effectiveness of the device in the experimental animal model(s). The rationale (and limitations) of selecting the particular animal model should be discussed.

II. If a clinical history has been well established with a given device technology, evidence may be provided in the form of a literature review of relevant publications in the peer-reviewed scientific literature. Reference to devices other than the subject device in support of safety or effectiveness requires a thorough comparison to the subject device design, features and performance capabilities to demonstrate relevance. This may be provided in a table format. The clinical evaluation report should be summarized as per the current IMDRF guidance documents.

6.10 Risk Analysis

i. A risk assessment should be based on an analysis and an evaluation of the risks inherent in the use of the device, as well as the risk reduction measures adopted to satisfy safety and effectiveness requirements. The manufacturer should identify the individual or organization that carried out the risk analysis and it should be conducted on the version of the device under review. The risk analysis report should be as per the ISO 14971 Medical devices - Application of risk management to medical devices.

ii. The information provided should include a description and identification of the devices and accessories under consideration in a risk assessment. Design aspects should be evaluated. The method of risk analysis must be appropriate for the device and the level of risk involved. A brief description of the technique used to perform the risk assessment, definitions of risk and any standards used in this process should be stated. A list of critical hazards should be provided, which includes how the risks associated with these hazards have been evaluated and what risk reduction measures have been taken. An evaluation of the risks as compared with the claimed benefits of the device and steps taken to reduce the risks to acceptable levels should also be presented.

6.11 Manufacturing Information

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A. Provide details of the manufacturing process for the device in the form of a list of resources and activities that transform inputs into the desired output. The manufacturing process should include the appropriate manufacturing methods and procedures, manufacturing environment or conditions and the facilities and controls used for the manufacturing, processing, packaging, labeling and storage of the device. A manufacturing process flow chart should be submitted.

B. Sufficient details must be provided to enable a person generally familiar with quality systems to judge the appropriateness of the controls in place. If multiple facilities are involved in the manufacture of the device, the physical address of the manufacturing site and manufacturing activities for each facility should be provided. The sites where design and manufacturing activities are performed shall be identified. For example:

   (i) if the manufacturing process of a product consists of a number of subassembly processes, the manufacturing sites where each of these subassembly processes are carried out must be identified, and the relationship between these processes must be shown; or

   (ii) If multiple sites manufacture the same product, each of these sites must be identified.

C. The sites (including contract manufacturers) where design and manufacturing activities are performed shall be identified. Quality Management System certificates are to be provided for the design and manufacturing sites (including contract manufacturers as Annexes to the submission).

D. For those multiple facilities involved in the manufacture of medical devices, the applicable information (e.g. quality assurance certificates issued by an accredited third-party inspection body) for each facility must be submitted. Firms that manufacture or process the medical device under contract to the manufacturer may elect to submit all or a portion of the manufacturing information applicable to their facility directly to the Regulatory Authority in the form of a master file

E. The manufacturer should inform these contractors of the need to supply detailed information on the medical device. However, it is not the intent of this section to capture information relating to the supply of sub-components (i.e. unfinished medical devices) that contributes to the manufacture of the finished medical device itself.

F. Details of the sterilization method and processing should be included, if the device is sold sterile or is to be sterilized, process validation data should include sterility test data, reference to a standardized test method, and attestation or evidence of successful validation under real-life conditions under which the product is to be sterilized. Bioburden determination, culture media used, time and temperature of incubation, controls, number of samples examined and frequency of testing should also be presented. A Sterility Assurance Level (SAL) of 10-6 is generally required

G. If a biological indicator was used, its placement needs to be described and rationalized (e.g., most difficult to sterilize location). If a group of devices are to be sterilized together, the worst-case scenario or most difficult to sterilize product should be validated. Attestation of validation may be used. The manufacturer should also demonstrate that they have a process in place to monitor bioburden levels on a regular basis to confirm that the sterilization method remains valid.

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H. Alternatively, a method of parametric release may be proposed and validated. If a process challenge device was used to assess the sterilization process it must be shown to have comparative resistance or a greater challenge to sterilization than the biological indicators placed inside the product/packaging.

I. If the product is to be re-sterilized by the end-user, a description of the recommended sterilization process for the end-user should be provided, and evidence of validation provided. Validation should be for sterility and also to confirm that the process does not compromise integrity or performance of the product. The recommended, validated sterilization method should be stated in the device labeling information.

7.0 LABELLING REQUIREMENTS

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

7.2 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 Agreement between Product owner/ Manufacturer and 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.

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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 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) or equivalent should be provided about the manufacturer of the product. An Authentic ISO 13485 certificate needs to be provided.

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/Policy1**

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, any novel features and a synopsis of the content of the STED.

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8.7.2 Commercial marketing history-the list of countries from SRA/RRA regulatory agency jurisdictions where the medical device 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 devices since their 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**

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(c) if the medical device contains one or more of the following, a description of the following must be provided;

(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 Registration of Medical Devices Incorporating Medicinal Product`

(i) By the design and intent of the product owner, a medical device may be incorporated with a therapeutic/medicinal product in an ancillary role (chemical drug or biologic), to achieve its intended purpose. The regulatory controls applicable (i.e. medical device or therapeutic/medicinal product) to such products including both medical device and therapeutic/medicinal product components is determined based on their primary mode of action (PMOA). "Primary mode of action (PMOA)" means the mode of action that makes the greatest contribution to the overall intended therapeutic purpose of the combined product.

(ii) A product that does not achieve its PMOA in or on the human body by pharmacological, immunological, or metabolic means will be regulated as a medical device under the Act.

Examples of medical devices incorporating a therapeutic/medicinal product that are regulated as medical device include:

(a) Drug eluting stents

(b) Condoms incorporating medicines and lubricants

(c) Dermal fillers incorporating analgesic

(iii) Medical devices incorporating registrable therapeutic/medicinal products are classified as Class D medical devices. Such devices would qualify for the abridged evaluation route if the product is approved as a medical device in at least two of RRA (with one SRA) agencies and the chemical or biological component has been evaluated and approved by at least one competent drug regulatory agency, as defined by the WHO.

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9.2 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 be returned to its owner.

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

9.3 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. second hand medical devices imported should be registered if they are not registered before.

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.

9.4 Medical Devices That Require Final Processing

Some devices may not be supplied in their final state (i.e. may not be immediately available for use) once placed on the market. They may require some further processing prior to being "usable", for example processing, preparation, installation, assembly or fitting. These activities are not usually undertaken by the manufacturer but are carried out by the healthcare professional or the final user.

Examples of such activities are:

a. sterilization of medical devices supplied non-sterile;

b. configuration of electronic equipment;

c. preparation of dental fillings

d. fitting of contact lenses;

e. adaptation of a prosthesis to the needs of the individual patient.

9.5 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

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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**."

For example:

a) Software intended to enhance images from x-ray or ultrasound would be considered to be medical devices.

b) Software that is simply a patient management system or a records storage system would not, however, be considered to be a medical device.

9.6 Medical / Cosmetic / Toiletry Purpose

Where there is a specific intended medical purpose, products may be considered to be medical devices. For example:

a. breast pumps for treatment of inverted nipples;

b. feminine hygiene products (sanitary towels, tampons).

c. Medical lubricant with specific intended medical purpose.

9.7 Assistive technology products (aids for daily living)

Equipment intended for alleviation of, or compensation for a disability may or may not be considered as medical devices. The determining factor will be whether or not there is a direct link between the corrective function of the equipment and the individual concerned and that there is a stated medical purpose. The following products are considered to be medical devices as there is such a direct link:

a. baths with integral hoists;

b. external limb prostheses and accessories;

c. hearing aids;

d. mobility aids for the visually impaired;

e. orthopedic footwear;

f. orthoses (lower/upper limb, spinal, abdominal, neck, head);

g. patient hoists;

h. rehabilitation tricycles / mobility carts;

i. walking / standing frames, walking sticks / crutches;

j. wheel chairs

10 Accessories

Accessories should be classified in their own right as a medical device and do not necessarily

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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. Accessories can be registered as a group with the parent medical devices or registered alone win cases where they are manufacturers and sold as standalone accessories to medical devices The registration of accessories will follow the requirements of these guidelines.

Examples of such potential accessories are:

a. sterilizer for use with medical equipment;

b. pouches for packaging re-sterilized medical devices;

c. specific battery chargers for battery-driven electro-medical devices

d. contact lens care product

e. disinfectants specifically intended for medical devices;

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.

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Template 1
Letter of Authorization 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 Authorization for [LTR (Company Name)]

We, [name of Product Owner (Company Name)], as the Product Owner, hereby authorize (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 authorization shall apply to the following medical devices:
[List containing product names of medical devices]

We also authorize [(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 authorization shall remain in effect until our notification to the Botswana Medicines Regulatory Authority in writing (either by postal mail or facsimile transmission) that the authorization 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]

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Template II
Safety Declaration Template

[To be printed on Company Letterhead of local 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]

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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)

Authorized Signatory:

_____ _____

Name, Position Date

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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

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