Botswana Medicines Regulatory Authority

BOMRA
MEDICINES REGULATORY AUTHORITY

Approved By: _____ 04/04/23

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Date of approval (DD/MM/YY)

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Revision status sheet

Page	Changes made	Issue No	Process owner's name	Date
12	4.9 (iii)List of approved/exempted medical devices along with applicant details will be published on the BoMRA website or any public domain on a monthly basis or as and when necessary.	6.0	Director, Product Evaluation and Registration	13/03/2023
1	Change in the name of the Director for Department of Product Evaluation and Registration	6.0	Director, Product Evaluation and Registration	13/03/2023
7	1.2 Added "The Medicines and Related Substance Act, 2013, section 23 (3), (4) and (5) provides for the Authority to exempt medical devices from registration, under special circumstances.	6.0	Director, Product Evaluation and Registration	13/03/2023
13-15	Clause 8 table: Categories of Medical Devices according to GMDN and table added	6.0	Director, Product Evaluation and Registration	13/03/2023
10	Annexure A removed	6.0	Director, Product Evaluation and Registration	13/03/2023
6	2 Added "as per WHO Priority Medical Device List for Covid-19"	5.0	Director, Product Evaluation and Registration	21/01/2021
8	4.5 Replaced " As per MDD/IVDMD" to "As per Medical Device Directive 92/42/EEC or In-Vitro Diagnostics Medical Device Directive 98/79/EC or Medical Devices Regulation (EU) 2017/745 or In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746"	5.0	Director, Product Evaluation and Registration	21/01/2021
8	5.1 Added "as per applicable national or International standards"	5.0	Director, Product Evaluation and Registration	21/01/2021
8	5.1.1 Removed "Tests shall include breathability, particle penetration and water absorption rate"	5.0	Director, Product Evaluation and Registration	21/01/2021

8	5.2 Added "as per applicable national or International standards"	5.0	Director, Product Evaluation and Registration	21/01/2021
8	5.2.1 Removed "Tests shall include leakage (freedom from holes), tensile strength and elongation tests"	5.0	Director, Product Evaluation and Registration	21/01/2021
9	5.4.1Added "for Local Manufacturer only"	5.0	Director, Product Evaluation and Registration	21/01/2021
9	5.4.2 Added "Validation"	5.0	Director, Product Evaluation and Registration	21/01/2021
9	5.5 Added "as per applicable national or International standards"	5.0	Director, Product Evaluation and Registration	21/01/2021
9	5.5.1 Removed "Tests shall include Impact penetration, hydrostatic pressure, and Viral penetration (For surgical gown)"	5.0	Director, Product Evaluation and Registration	21/01/2021
8	4.6 Added that an existence of the product applied for on the WHO prequalified product list is necessary	4.0	Director, Product Evaluation and Registration	13/07/2021
8	4.7 Added that for Rapid Covid-19 antigen test kit WHO Emergency Use Listing is required. Proof of an existence of the product applied for on WHO emergency list is needed	4.0	Director, Product Evaluation and Registration	13/07/2021
6	2. Added "Covid -19 related medical devices" and "excludes rapid Covid-19 antibody test kit" under Scope	3.0	Director, Product Evaluation and Registration	10/03/2021
6	3.1.7 Added Definition of Classification of Medical Devices" under Definitions	3.0	Director, Product Evaluation and Registration	10/03/2021
7	4.3 Added "ISO 13485 certification or Business License any proof of manufacturer's registration in the respective authorities" under Requirements	3.0	Director, Product Evaluation and Registration	10/03/2021
7	4.4 Added "or proof", "(Only for Class A & B medical devices)"and "or South African Health Products Regulatory	3.0	Director, Product Evaluation and Registration	10/03/2021

	Authority (Only for Class A & B medical devices)" under Requirements			
7	4.5 Replaced "Except Class A" with "As per MDD/IVDMD" under Requirements	3.0	Director, Product Evaluation and Registration	10/03/2021
7	4.6 Added "For Rapid Covid-19 antigen test kit WHO Emergency Use Listing is required" under Requirements	3.0	Director, Product Evaluation and Registration	10/03/2021
7	4.7 with manufacturer's instruction for use of the device" under Requirements	3.0	Director, Product Evaluation and Registration	10/03/2021
7	4.10 Replaced "24" hours to "48" hours under Requirements	3.0	Director, Product Evaluation and Registration	10/03/2021
8	5.3.1 Replaced "Calibration certificate from an accredited service provider" to "Provide certificate against standards like ASTM E1965-1998, EN12470-5:2003, IEC 62942-1 TS, ASTM E 1256 – 95, EMC reports or equivalent" under Annexure A	3.0	Director, Product Evaluation and Registration	10/03/2021
8	5.3.2 Removed "Copy of user manual/ Manufacturer's instruction for use" under Annexure A	3.0	Director, Product Evaluation and Registration	10/03/2021
8	5.4 Removed "manufactured locally" under Annexure A	3.0	Director, Product Evaluation and Registration	10/03/2021
8	5.5.1 Removed "For all risk class" and "for risk class B,C, D) Annexure A	3.0	Director, Product Evaluation and Registration	10/03/2021
8	5.5.1 Replaced "For class D" to "For surgical gown" Annexure A	3.0	Director, Product Evaluation and Registration	10/03/2021
5	3.2.4 Added Abbreviation of CE under Abbreviations	2.0	Director, Product Evaluation and Registration	22/07/2020
5	4.5 "by European notified bodies (Except Class A)"	2.0	Director, Product Evaluation and Registration	22/07/2020
5	4.7 Added "Clear Pictures/Photographs of a sample".	2.0	Director, Product Evaluation and Registration	08/06/2020

6	4.9 Added "If any document is not written in English, a verified translation to English should be provided along with the original."	2.0	Director, Product Evaluation and Registration	22/07/2020
6	4.10 Changed 48 hours to 24 hours	2.0	Director, Product Evaluation and Registration	08/06/2020
6	5.5 Added "Medical Gown: Certificate of analysis from an accredited laboratory"	2.0	Director, Product Evaluation and Registration	22/07/2020
5	4.2 Replaced "A duly signed and stamped covering letter indicating the intended purpose of the device" with "Proof of payment (BWP 350)" under Requirements	1.0	Director, Product Evaluation and Registration	19/05/2020
5	Added "A copy of a manufacturing license"	1.0	Director, Product Evaluation and Registration	19/05/2020
5	4.3 Added "or Singapore Health Sciences Authority or China National Medical Products Administration" under Requirements	1.0	Director, Product Evaluation and Registration	19/05/2020
5	4.6 Replaced "Evidence of a minimum of two (2) years of current and continuous manufacturing experience" with "For specific products, see Annexure A" under requirements.	1.0	Director, Product Evaluation and Registration	19/05/2020
5	Deleted requirement for local representative agreement	1.0	Director, Product Evaluation and Registration	19/05/2020
6	4.9 Added "If application found incomplete, the applicant needs to provide the requested information within 48 hours after the receipt of the communication" under requirements	1.0	Director, Product Evaluation and Registration	19/05/2020
6	5 Added Annexure A	1.0	Director, Product Evaluation and Registration	19/05/2020

1. Purpose

1.1 The intention and purpose of these guidelines is to provide guidance to those submitting applications for exemption from registration of Medical devices including IVDs.

1.2 The Medicines and Related Substance Act, 2013, section 23 (3), (4) and (5) provides for the Authority to exempt medical devices from registration, under special circumstances.

2. Scope

2.1 This guideline is applicable to exemptions from registration of medical devices including IVDs which are not included in the interim register/listed.

2.2 The guidelines will be revised regularly to respond to any new requirements addressing the challenges for exemption process as may arise from time to time in line with legal framework for exemptions of medical devices including IVDs.

3. Definitions and Abbreviations

3.1 Definitions

The following definitions shall apply:

3.1.1 Act

The Medicines and Related Substances Act, 2013 and as subsequently amended.

3.12 Applicant

Any entity requesting for service and taking responsibility for ensuring the medical device's requirement are in compliance with the laws and regulation in force in Botswana.

3.1.2 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.

3.1.3 In Vitro Diagnostic

Means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimen derived from the human or animal; solely or principally to provide information for diagnostic, monitoring or compatibility purposes which includes but not limited to – reagents used for IVD purposes, calibrators, control chemicals, specimen receptacles, software and related instruments or apparatus or other articles and are used for the following test purposes; diagnosis; aid to diagnosis; screening; monitoring; predisposition; prognosis; prediction; determination of physiological status.

3.1.4 Manufacturer

A 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).

3.1.5 Manufacture (manufacturing)

All operations of generating a medical device, including purchase of materials and components, production, quality control, packing, labelling, release, storage, and shipment.

3.1.6 Manufacturing Site

Means an authorized space where designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device take place.

3.1.7 Medical device

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

reagent for in vitro use, software, material or other similar or related article, intended by

the manufacturer to be used, alone or in combination, for human beings or animals, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury,
- investigation, replacement, modification, or support of the anatomy, or of a physiological process,
- supporting or sustaining life,
- control of conception,
- cleaning, disinfection or sterilization of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body;

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

3.1.8 Listed Medical device

Medical devices including IVDs appearing in Listed Medical Device Register.

3.1.9 Non-Listed Medical device

Medical devices including IVDs not appearing in Listed Medical Device Register.

3.1.10 Medical device family

A group of medical devices that are made by the same manufacturer, that differ only in shape, color, flavor or size, that have the same design and manufacturing process and that have the same intended use.

3.1.11 **Medical device group** - means medical devices comprising a collection of medical devices, such as a procedure pack or tray, that is sold under a single name.

3.1.12 **Medical Device System**: Means a number of components or parts intended to be used together to fulfil some or the entire device's intended functions and that is sold under a single name.

3.1.13 **Software**: Software is a medical devices if it purpose fits the definition of a medical device e.g. Software intended to enhance images from x-ray or ultrasound

3.1.14 **Medical Device Accessories** :Are classified as a medical device and do not take the classification of the device intended to be used.

3.1.15 **Medical Device Spare parts/Components** : Are supplied for the replacement of existing components of a medical device that has already been registered and are not considered to be medical devices

3.1.16 **Label** - Means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embosed or impressed on or attached to a container of any medical devices;

3.1.17 **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.

3.1.18 **Recognized Standards** - Means national or international standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.

3.1.19 **Classification of Other Medical Devices**:

a) Class A – Low Risk

b) Class B – Low-Moderate Risk

c) Class C – Moderate-High Risk

d) Class D – High Risk

3.1.20 **Classification of IVD Medical Devices**:

a) Class A – Low Individual Risk and Low Public Health Risk

b) Class B – Moderate Individual Risk and/or Low Public Health Risk

c) Class C – High Individual Risk and/or Moderate Public Health Risk

d) Class D – High Individual Risk and High Public Health Risk

3.2 Abbreviations

The following abbreviations shall apply:

3.2.1 **CE**- European Conformity.

3.2.2 **DoC**- Declaration of Conformity

3.2.3 **EUL**- Emergency Use Listing.

3.2.4 **GHTF** - Global Harmonization Task Force

3.2.5 **GMDN**- Global Medical Device Nomenclature

3.2.6 **IMDRF** – International Medical Devices Regulatory Forum

3.2.7 **ICH** - International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use

3.2.8 **IFU** – Instructions for Use

3.2.9 **ISO** – International Organization for Standardization

3.2.10 **IVD** - In Vitro Diagnostic

3.2.11 **NRA**- National Regulatory Authority

3.2.12 **QMS** – Quality Management System

3.2.13 **WHO** - World Health Organization.

4. Each submitted application shall contain only one of the following

4.1 A single medical device

4.2 One medical device family

4.3 One medical device system

4.4 One medical device group

5. Documentation Requirements of Exemption from Registration

5.1 Completed application Form for Exemption from Registration of Medical Devices, **BOMRA/ER/MED/P01/F01,** should be provided with the application. The form should be signed and dated by the applicant. Applications for exemptions must be emailed to: medicaldevices.services@bomra.co.bw

5.2 Payment

5.2.1 For applicable fees applicants should refer to BoMRA_Fees_2019 found on the BOMRA website.

5.3 Product details

Product description including accessories, intended use and users should be indicated as follows;

5.3.1 Device category (Medical Devices or IVD). Need to declare that device comes under general medical device or IVD medical device category

5.3.2 Provide Generic name of the product (e.g. Mask, Ventilator etc.) and there brand name.

5.3.3 The intended use of the product should be specified.

5.3.4 Intended users should be indicated (Healthcare professional or general users).

5.3.5 Any associated products that work together with the product to be indicated (e.g. controls, reagents, accessories etc)

5.3.6 Number of unit products in a commercial park should be indicated.

5.3.7 Pictures of label of the product should be provided with the application.

5.3.8 Manufacturer's instruction for use of the device should be provided with the application.

5.3.9 Specify country of origin and software version (if applicable) for the device applied.

5.4 Manufacturer Information

5.4.1 A copy of a manufacturing license and/or ISO 13485 certificate or Business license or any proof of manufacturer's registration in the respective authorities . Certificate should be issue by recognized Conformity Assessment Body.

5.4.2 Used product which have been refurbished by a third party who is not the original manufacturer of the devices, then, that third party shall bear the responsibility of the manufacturer described in this guideline.

5.5 Independent Reference Regulatory Agencies

5.5.1 A copy or proof of the Marketing Authorization issued by the relevant RRAs or Singapore Health Sciences Authority or China National Medical Products (Only for Class A & B medical devices) Administration or South African Health Products Regulatory Authority (Only for Class A & B medical devices) and/or

5.5.2 CE certificate issued by European notified bodies (As per Medical Device Directive 92/42/EEC or In-Vitro Diagnostics Medical Device Directive 98/79/EC or Medical Devices Regulation (EU) 2017/745 or In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746) for a product marketed in the European member states can be used as evidence for a marketing authorization in an RRA, and/or

5.5.3 In the case of WHO EUL / Prequalification-accepted products, a copy of a final acceptance letter.

5.5.4 For a Public Health Emergency product, a valid Registration Certificate/Approval/Emergency Use Authorization for the product issued by ICH member countries as defined prior to 23 October 2013 or WHO must be provided.

5.5.5 Points from 5.5.1 to 5.5.4 are not applicable to Local Manufacturer.

5.6 Other Requirements

5.6.1 Declaration of Conformity (DoC) to BoMRA Medical Devices Regulations. The declaration form should follow the format below. The DoC should be signed and stamped by the manufacturer.

5.6.2 **DoC should include;**

a. Name and Address of Product Owner:
b. Detail of Medical Device(s):
c. Risk Classification (As per IMDRF/GHTF classification or equivalent)
d. Quality Management System Certificate: (Certification Body and Certificate Number, issue date, expiry date) (if available)
e. Standards Applied (BoBS Standard Or International standards)
f. Declaration of conformity validity (Day Month Year)

5.6.3 Copy of Medical Devices Specifications certificate of standards that the product complied with.

5.6.4 Concerning donations, unregistered/listed medical devices that have been deemed unacceptable in the donor country for safety, quality, and efficacy-related reasons will not be eligible for exemption.

5.7 Language

All documents must be in English. If any document is not written in English, a verified translation to English should be provided along with the original.

6 Processing of Applications

6.1 The Authority shall conduct assessment of the dossier submitted by the applicant to completeness of the submissions.

6.2 Once application has been accepted and appropriate fees paid, the processing of application will be within three (3) working days.

6.3 If an application is found to be incomplete, the applicant would be required to provide the requested information within two (2) working days after the receipt of the communication.

6.4 Once a query or a request has been raised, the processing shall halt until after the response to the query has been received.

6.5 For amendment requests, on issued exemption letters the following applies:

6.5.1 If the amendment is as a result of errors by the Authority, the applicant may provide a letter or email detailing the nature of the amendment.

6.5.2 If the amendments is as a result of errors in the information submitted to the Authority prior to approval or to changes post approval, a new exemption from registration application must be lodged (including accompanying fees where applicable).

6.5.3 Amendment on an expired exemption letter will not be considered. Applicants must lodge a new application

7 Exemption Approval

7.1 If a product has been found to comply with all the requirements for safety, quality and performance, it will be exempted, listed and approval letter will be issued to the applicant.

7.2 The validity period of the approved products will be Six (6) months unless revoked by Authority or terminated by the applicant.

7.3 The list of approved/exempted medical devices along with applicant details will be published on the BoMRA website or any public domain on a monthly basis or as and when necessary.

8 Categories of Medical Devices according to GMDN

Category	Examples
Active implantable medical devices	• Implantable cardiac pacemakers Implantable defibrillators • Leads, electrodes • adaptors for implantable cardiac pacemakers and defibrillators • Implantable neuro stimulator systems • Brachytherapy • Hemodynamic support • Cochlear implants • Implantable infusion pumps and accessories • Implantable glucose monitors • Micro Electro-Mechanical Systems (MEMS)
Anesthetic and respiratory devices	Ventilators, breathing circuits, endotracheal tubing's Anesthesia machines , nebulizers, humidifiers
Dental devices	Craniofacial fixation plate, dental unit , amalgamator, impressions materials, dental laboratory items

Electro mechanical medical devices	Monitors, resuscitators, defibrillators, syringe pumps, infusion pumps, suction pumps, ultrasound machines, Electrical surgical units, Incubators
Hospital hardware	Patient Beds, cabinets, wheelchair, stool, examination couches
In vitro diagnostic devices	Reagent , controls , immunoassays, calibrators, blood testing strips, kits, solutions
Non-active implantable devices	Stents, vascular grafts, orthopaedic implants, artificial teeth, orthopaedic screws
Ophthalmic and optical devices	Ophthalmic, Lamps (Ophthalmic Examination) ,Fundus Cameras/ Keratometer/Slit Lamp Microscopes and Associated Software, Low Vision Aids ,Operating Room Microscopes / Magnification Systems F 5 Ophthalmoscopes/ Retinoscopes , Spectacle Lenses , Spectacle Frames , Ready-Made Spectacles (Non-Prescribed) , Sight Testing Devices , (Ophthalmic and Optical Devices) , Tonometer(Reusable, Eye Speculums(Ophthalmic and Optical Devices) , Contact Lens accessories (Ophthalmic and Optical Devices) , Eye Baths/Irrigation Systems And Eyewash Solutions(Ophthalmic and Optical Devices) System and Procedure Packs
Reusable devices	surgical forceps, endoscopes and stethoscopes, bronchoscopes, arthroscopes, laparoscopes
Single-use devices	Hypodermic needles, syringes, applicators, bandages and wraps, drug tests, exam gowns, face masks, gloves, suction catheters, and surgical sponges
Assistive products for persons with disability	Aids to mobility (e.g. wheelchairs, pushchairs, ramps, rollators, walkers, sticks/canes/crutches)
Diagnostic and therapeutic radiation devices	• Cabinet X-Ray Systems (Closed X-Ray Systems) • Dental Cone-beam Computed Tomography • Fluoroscopy • Laser Products and Instruments Mammography • Medical Lasers • Ultraviolet Phototherapy Equipment • Medical X-ray Imaging

	• MRI (Magnetic Resonance Imaging) • Radiofrequency and Microwave Products for medical use • Radiography • Ultrasound Imaging • Ultrasonic Therapy Product or Ultrasonic Diathermy
Complementary therapy devices	Acupuncture device, cupping therapy device, foot bath, eye heat therapy pads
Biologically derived devices	Patches, meshes , grafts
Healthcare facility products and adaptations	Autoclave, hair laser removal device, antimicrobial shower curtains, assistive devices, bariatric transport wheelchairs, blood bank refrigerator, blanket warming cabinets, blood plasma freezers, chairs, stools, chemical fume hoods, safety cabinets
Laboratory equipment	Centrifuges, incubators, collection rubes, media, pipettes, cryogenic devices, class1,2,3 safety cabinets
Medical software	All software used for medical applications such as CT software, Oncology applications
Procedure packs	Packs and sets
Other categories	For which not included in any of the above categories