Botswana Medicines Regulatory Authority

Approved By: _____ _____

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Director – Product Evaluations and Registration

Date of approval (DD/MM/YY)

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Revision status sheet

Page	Changes made	Issue No	Process owner (Title)	Reviewer's name	Date
5	3.1.6 Changed the definition of medical devices	3.0	Director, DPER	Batlegang Mosweu	13/11/2023
5	3.2 Adding Abbreviation of BOMRA and GMDN	3.0	Director, DPER	Batlegang Mosweu	13/11/2023
5	4. Update the requirements for listing of medical devices.	3.0	Director, DPER	Batlegang Mosweu	13/11/2023
5	5. Update the requirements for changes in listed medical devices information	3.0	Director, DPER	Batlegang Mosweu	13/11/2023
5	6. Adding requirements for removal of listing medical devices information	3.0	Director, DPER	Batlegang Mosweu	13/11/2023
5	Replaced 4.1 & 4.2 with "Kindly refer the Guideline for Application for Exemption from Registration of Medical Devices **BOMRA-ER-MED-P01-G01.** Arrangement for listing through exemption will valid till September 2023"	2.0	Director, DPER		29/05/2023
5	Added clause 5 : Requirements for Changes to Listing Medical Devices Information	2.0	Director, DPER		29/05/2023
5	Adde clause 6 : Removing of Listing Medical Devices Information	2.0	Director, DPER		29/05/2023
5	4.3 Changed " Mandatory for Manufacturer and authorized representative" to "Optional for all Stakeholder"	1.0	Director, DPER		15/11/2021

1. Purpose

The intention and purpose of this guidelines is to provide guidance to those submitting documents for listing of Medical devices.

2. Scope

This guideline is only applicable to listing of medical device(s).

3. Definitions and Abbreviations

3.1 Definitions

The following definitions shall apply:

3.1.1 **Authorized Representative** - Any entity requesting for service and taking responsibility for ensuring the medical device's requirements are in compliance with the laws and regulation in force in Botswana.

3.1.2 **Device Risk Classification;**

a) Class A – Low Risk

b) Class B – Low-Moderate Risk

c) Class C – Moderate-High Risk

d) Class D – High Risk

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 **Listing -** The process whereby a stakeholder(s) submits information to the regulatory authority, for purposes of identification of a medical device that is or will be allowed into Botswana.

3.1.5 **Manufacturer** - A company that carries out at least one step of the manufacturer 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).

3.1.6 **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.

3.2 Abbreviations

3.2.1 **BOMRA-** Botswana Medicines Regulatory Authority

3.2.2 **GMDN**- Global Medical Device Nomenclature

4. Requirements for Listing of Medical Device(s)

4.1 Listing of medical devices process has been closed. New Medical devices can be imported through registration or exemption process only. Please refer to the Guideline for application for Registration of Medical Devices including In Vitro Diagnostics (**BOMRA/ER/MED/P04/G01**) for registration applications. For exemptions application please refer to Guideline for Application for Exemption from Registration of Medical Devices (**BOMRA/ER/MED/P01/G01**).

5. Requirements for Changes to Listed Medical Devices Information

5.1 Changes in GMDN code and term by GMDN agency are considered permissible changes and manufacturer needs to notify the Authority using their letter head.

5.2 For all changes except above mentioned, please refer to the Guidelines on Submission of Application for Variation to Registered/Listed Medical Devices **(BOMRA-ER-MED-P09-G01)**.

6. Removing of Listing Medical Devices Information

6.1 For all the removal of information from Listed Medical Devices Register **(BOMRA/ER/MED/P02/F06)**, please refer to the Guideline on Withdrawal of market authorization and/or registered/listed medical devices including IVDs **(BOMRA-ER-MED-P08-G01)**.