Botswana Medicines Regulatory Authority

Approved By: _____ _____

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Director – Product Evaluations and Registration

Date of approval (DD/MM/YY)

Revision status sheet

Page	Changes made	Issue No	Process owner's name	Date
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

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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). This guideline excludes all combination products i.e. medical devices with active pharmaceutical ingredients.

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**

Defined as per Medicines and Related Substances Act 2013.

3.2 Abbreviations

None

4. Requirements for Listing of Medical Device(s)

4.1 Kindly refer the Guideline for Application for Exemption from Registration of Medical Devices **BOMRA-ER-MED-P01-G01.** Arrangement for listing through exemption is valid until end of September 2023.

5. Requirements for Changes to Listing Medical Devices Information

5.1 This is mostly based on the changes to device particulars published on the Listed Medical Devices Register **ER-MED-P02-F06**. The following changes are considered un-permissible changes and would require a new exemption application;

5.1.1 Additions of new devices to the listing database after September 2023.

5.1.2 Change to the product name of the listed medical device

5.1.3 Change in model or brand name of the listed medical device

5.2 The following changes are considered permissible changes and would need notification to the Authority using the manufacturer's letter head.

5.2.1 Change to the Manufacturer's details including changes to Manufacturer's name and address.

5.2.2 Changes in GMDN code and term by GMDN agency.

6.0 Removing of Listing Medical Devices Information

6.1 A Manufacturer who wishes to remove the product from the listing register shall provide the Authority on their letter head and in English with;

6.1.1 Information on the decision to removal and

6.1.2 Reasons for removal

6.1.3 Plan of communication to all consignees and

6.1.4 Plan of withdrawal of the product from the Botswana market.

6.2 After the intent to removal of listed medical device has been received , the Authority shall then update the register.

6.3 Updated Listing register will be published on the BOMRA website as and when required.