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

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1. Purpose

The intention and purpose of these 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 requirement are in compliance with the laws and regulation in force in Botswana.

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 stakeholder 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

3.1.7 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

3.2 Abbreviations

None

4. Requirements for Listing of Medical Device(s)

4.1 Filled Form for Listing of Medical device(s). Manufacturer or Authorized representative shall use Form 1 for listing of medical devices **BOMRA/ER/MED/P02/F01** along with Annexure I of Listing of Medical Devices **BOMRA/ER/MED/P02/F05.**

4.2 Filled Form for Listing of Medical device(s). Stakeholders other than Manufacturer or Authorized representative shall use Form 2 for listing of medical devices **BOMRA/ER/MED/P02/F02** along with Annexure I of Listing of Medical Devices **BOMRA/ER/MED/P02/F05.**

4.3 Copy of labeling of the medical device(s) as Annexure II. Mandatory for manufacturer and authorized representative.

4.4 Signed and dated Declaration of conformity by the manufacturer as Annexure III. Mandatory for manufacturer and authorized representative.

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

4.6 Filled form and relevant documents should be emailed to **rmu@bomra.co.bw and medicaldevices.services@bomra.co.bw.**