Botswana Medicines Regulatory Authority

Approved By: _____ _____

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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 including in vitro diagnostics establishments.

2. Scope

This guideline is only applicable to listing of Medical devices including in vitro diagnostics establishments.

3. Definitions and Abbreviations

3.1 Definitions

The following definitions shall apply:

3.1.1 Authorized Representative

Any natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on their behalf for specified tasks with regard to their obligations under that country or jurisdiction's legislation.

3.1.2 Distributor

Any natural or legal person in the supply chain who, on their own behalf, furthers the availability of a medical device to the end user.

3.1.3 Importer

A person or institution licensed and/or authorized to import medical devices into the country.

3.1.4 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.

3.1.6 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.

3.1.7 Manufacture (manufacturing)

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

3.1.8 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).

3.1.9 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.

3.1.10 Retailer

A person or business that sells goods to the public in relatively small quantities for use or consumption rather than for resale.

3.1.11 Responsible/Key Person

The Responsible/Key Person is responsible for ensuring product manufactured is not harmful to the users and prevent potential harm arising from the methods and the materials used to produce the product. The responsibilities also include:

a. To ensure that the provisions of the license are observed
b. To ensure that the operations do not compromise the quality of medical devices
c. To ensure that an adequate quality system is established and maintained
d. To oversee audit of the quality system and to carry out independent audits
e. To ensure that adequate records are maintained
f. To ensure that all personnel are trained
g. To ensure that all processes and methods are validated and approved for use.
h. To ensure full and prompt cooperation with product licence holders in the event of recalls.
i. To be the liaison person with the regulatory authority on issues of compliance

3.1.12 Wholesaler

Means a dealer who purchases medical devices and/or IVDs from a manufacturer or distributor and sells them to a retailer.

3.1.13 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

3.2.1 **IVD** - In Vitro Diagnostic

3.2.2 **BoMRA**- Botswana Medicines Regulatory Authority

4. Requirements for Listing of Medical Device Establishments

4.1 Filled Form for Listing of Medical devices establishment. Manufacturer or retailers/distributors/importers/exporters/wholesalers shall use the Application Form for Listing of Medical Device Establishment **BOMRA/ER//P07/F01.**

4.2 Copy of the business license of the establishment, copy of trade license of the medical devices establishment

4.3 Copy of professional practice certificate for the key personnel issued by the professional body.

4.4 Copy of official professional and academic certificates for the key personnel

4.5 Filled the form on the BoMRA website "**www.bomra.co.bw**"and email supporting documents to **medicaldevices.services@bomra.co.bw and rmu@bomra.co.bw.**

5. Processing of Applications

5.1 The Authority shall conduct assessment of the application submitted by the applicant to completeness of the submissions.

5.2 If an application is found to be incomplete, the applicant would be required to provide the requested information within five (05) working days after the receipt of the query communication.

5.3 If applicant failed to submit query response within five(5) working days, application will be closed. Applicant need to resubmit the application.

6 Listed Medical Device Establishments

6.1 Listed Medical Device Establishments Database **BOMRA/ER/MED/P07/F03** shall be published on the BoMRA website or any media as may be determined by the Authority.