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Botswana Medicines Regulatory Authority




Approved By: _____

Dr Innocent Ravengai

**Ag. 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's name	Date
4	2 Added "This guideline excludes all combination products i.e. medical devices with active pharmaceutical ingredients" under Scope	2.0	Director, DPER	19/05/2020
4	Replaced local representative with Applicant	2.0	Director, DPER	19/05/2020
5	3.1.3 Added Definition of In Vitro Diagnostic under Definitions	2.0	Director, DPER	19/05/2020
5	3.2.1 Added Abbreviations of IVD under Abbreviations	2.0	Director, DPER	19/05/2020
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	2.0	Director, DPER	19/05/2020
5	Added "A copy of a manufacturing license"	2.0	Director, DPER	19/05/2020
5	4.3 Added "or Singapore Health Sciences Authority or China National Medical Products Administration" under Requirements	2.0	Director, DPER	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.	2.0	Director, DPER	19/05/2020
5	Deleted requirement for local representative agreement	2.0	Director, DPER	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	2.0	Director, DPER	19/05/2020
6	5 Added Annexure A	2.0	Director, DPER	19/05/2020
5	3.2.4 Added Abbreviation of CE under Abbreviations	3.0	Director, DPER	22/07/2020

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5	4.5 “by European notified bodies (Except Class A)”	3.0	Director, DPER	22/07/2020
5	4.7 Added “Clear Pictures/Photographs of a sample”.	3.0	Director, DPER	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.”	3.0	Director, DPER	22/07/2020
6	4.10 Changed 48 hours to 24 hours	3.0	Director, DPER	08/06/2020
6	5.5 Added “Medical Gown: Certificate of analysis from an accredited laboratory”	3.0	Director, DPER	22/07/2020
6	2. Added “Covid -19 related medical devices” and “excludes rapid Covid-19 antibody test kit” under Scope	4.0	Director, DPER	10/03/2021
6	3.1.7 Added Definition of Classification of Medical Devices” under Definitions	4.0	Director, DPER	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	4.0	Director, DPER	10/03/2021
7	4.4 Added “or proof”, “(Only for Class A & B medical devices)”and “or South African Health Products Regulatory Authority (Only for Class A & B medical devices)” under Requirements	4.0	Director, DPER	10/03/2021
7	4.5 Replaced “Except Class A” with “As per MDD/IVDMD” under Requirements	4.0	Director, DPER	10/03/2021
7	4.6 Added “For Rapid Covid-19 antigen test kit WHO Emergency Use Listing is required” under Requirements	4.0	Director, DPER	10/03/2021
7	4.7 with manufacturer’s instruction for use of the device” under Requirements	4.0	Director, DPER	10/03/2021
7	4.10 Replaced “24” hours to “48” hours under Requirements	4.0	Director, DPER	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 –	4.0	Director, DPER	10/03/2021

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	95, EMC reports or equivalent” under Annexure A			
8	5.3.2 Removed “Copy of user manual/ Manufacturer’s instruction for use” under Annexure A	4.0	Director, DPER	10/03/2021
8	5.4 Removed “manufactured locally” under Annexure A	4.0	Director, DPER	10/03/2021
8	5.5.1 Removed “For all risk class” and “for risk class B,C, D) Annexure A	4.0	Director, DPER	10/03/2021
8	5.5.1 Replaced “For class D” to “For surgical gown” Annexure A	4.0	Director, DPER	10/03/2021
8	4.6 Added that an existence of the product applied for on the WHO prequalified product list is necessary	5.0	Director, DPER	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	5.0	Director, DPER	13/07/2021
6	2 Added “as per WHO Priority Medical Device List for Covid-19”	6.0	Director, DPER	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”	6.0	Director, DPER	21/01/2021
8	5.1 Added “as per applicable national or International standards”	6.0	Director, DPER	21/01/2021
8	5.1.1 Removed “Tests shall include breathability, particle penetration and water absorption rate”	6.0	Director, DPER	21/01/2021
8	5.2 Added “as per applicable national or International standards”	6.0	Director, DPER	21/01/2021
8	5.2.1 Removed “Tests shall include leakage (freedom from holes), tensile strength and elongation tests”	6.0	Director, DPER	21/01/2021
9	5.4.1 Added “for Local Manufacturer only”	6.0	Director, DPER	21/01/2021
9	5.4.2 Added “Validation”	6.0	Director, DPER	21/01/2021

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9	5.5 Added “as per applicable national or International standards”	6.0	Director, DPER	21/01/2021
9	5.5.1 Removed “Tests shall include Impact penetration, hydrostatic pressure, and Viral penetration (For surgical gown)”	6.0	Director, DPER	21/01/2021



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1. Purpose

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

2. Scope

This guideline is only applicable to exemptions from registration of covid-19 related medical devices as per WHO Priority Medical Device List for Covid-19. This guideline excludes rapid Covid-19 antibody test kit and 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 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.

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3.1.6 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. disinfection 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.


3.1.7 Classification of Medical Devices:

- a) Class A – Low Risk
- b) Class B – Low-Moderate Risk
- c) Class C – Moderate-High Risk
- d) Class D – High Risk

3.2 Abbreviations

The following abbreviations shall apply:

- 3.2.1 **IVD** - In Vitro Diagnostic.
- 3.2.2 **CE**- European Conformity
- 3.2.3 **SRA** - Stringent Regulatory Authority as per WHO definition prior to 23 Oct 2015.
- 3.2.4 **WHO** - World Health Organization.

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4. Requirements of Exemption from Registration of Medical Devices

- 4.1 Application Form for Exemption from Registration of Medical Devices, **BOMRA/ER/MED/P01/F01**, shall be used.
- 4.2 Proof of payment of application fee BWP 350 (Non-refundable).
- 4.3 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 .
- 4.4 A copy or proof of the Marketing Authorization and/or Free Sale Certificate issued by the relevant SRA 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
- 4.5 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 SRA, and/or
- 4.6 In the case of WHO Prequalification-accepted products, a copy of a final acceptance letter. For Rapid Covid-19 antigen test kit WHO Emergency Use Listing is required
- 4.7 Clear Pictures/Photographs of a sample with manufacturer's instruction for use of the device.
- 4.8 For specific products, see Annexure A.
- 4.9 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.
- 4.10 If an application is found to be incomplete, the applicant would be required to provide the requested information within 48 hours after the receipt of the communication.
- 4.11 For medical devices and IVDs manufactured in Botswana, clauses 4.4 – 4.6 do not apply. For exemption from registration of these products the manufacturer is required to submit declaration of conformity, provide validation report from an accredited laboratory, relevant standards, or proof of conforming to the relevant standards and compliance to the WHO specifications as per the link below:


[Priority medical devices list for the COVID-19 response and associated technical specifications \(who.int\)](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-specifications)

5. Annexure A

The following are specific requirements for specific products:

- 5.1 Masks: Certificate of analysis from an accredited laboratory as per applicable national or International standards.
- 5.2 Gloves: Certificate of analysis from an accredited laboratory as per applicable national or International standards

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5.3 Thermometers:

5.3.1 Provide certificate against standards like ASTM E1965-1998, EN12470-5:2003, IEC 62942-1 TS, ASTM E 1256 – 95, EMC reports or equivalent.

5.4 IVDs

5.4.1 Declaration of conformity (for Local Manufacturer only), and

5.4.2 Clinical Evaluation and/or Validation report.

5.5 Medical Gown: Certificate of analysis from an accredited laboratory as per applicable national or International standards