SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Licence number: 00000422MD_R1

LICENCE TO DISTRIBUTE MEDICAL DEVICES

In terms of section 22C(1)(b) of the Medicines and Related Substances Act, 1965
To act as a Distributor and Importer

This licence is granted to:

Licence Holder

Africa Healthcare Holdings (Pty) Ltd

The Cube Workspace

Cnr The Straight and Forest Drive

Fourways

2191

On the following terms and conditions:

The licence holder and the persons described and named in Annexure 1 shall at all times ensure that all medical devices distributed, irrespective of its registration status, comply with all the provisions of the Medicines and Related Substances Act, 1965, as amended and in particular with sections 14, 18, 18A, 18B, 18C, 19, 20, 22A, 22C,22D 22G, 23, 26, 28, 33 and the Regulations relating to Medical Device and *In Vitro Diagnostic* Medical Devices (IVDs) 2, 3, 4, 5, 6, 13, 14, 17, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28 and all relevant Medicines Control Council Guidelines.

This licence consists of 3 pages.

This facility is authorised to perform the activities listed in Annexure 1 to this licence.

Digitally Signed by:
Boitumelo Semete-Makokotlela
Chief Executive Officer
53e72d92-3391-4cd7-8da3-b6116e65c520

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 22 March 2018

1ST RENEWAL DATE: 22 December 2022

EXPIRY DATE: 22 December 2027

AMENDMENT DATE: N/A

This licence remains the property of South African Health Products Regulatory Authority. Upon amendment, voluntary withdrawal, recall, suspension or revocation of the licence, the original licence must be returned to the Office of the Registrar.

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ANNEXURE 1 **00000422MD_R1**

AUTHORISED DISTRIBUTION AND MATERIAL HANDLING ACTIVITIES

1. DISTRIBUTION ACTIVITIES	YES	NO
Distribution to hospitals and retail pharmacies and other clients: Class A		No
Distribution to hospitals and retail pharmacies and other clients: Class B	Yes	
Distribution to hospitals and retail pharmacies and other clients: Class C		No
Distribution to hospitals and retail pharmacies and other clients: Class D		No
2. MATERIALS HANDLED OR STORED AT THIS SITE		No
Combination medical devices with Penicillins		No
Combination medical devices with Cephalosporins		No
Combination medical devices with (other) Antibiotics (as specified):		No
Combination medical devices with Hormones		No
Combination medical devices with Cytostatics/Cytotoxics		No
Bulk Pesticides, Herbicides or Rodenticides		No
Radioactive material or Radioactive medical devices		No
Other potent, toxic, sensitising or hazardous materials (as specified):		No
3. IMPORT		
Import Class A medical device		No
Import Class B medical device	Yes	
Import Class C medical device		No
Import Class D medical device		No
Import Class A IVD		No
Import Class B IVD		No
Import Class C IVD		No
Import Class D IVD		No
Import RUO IVDs		No
4. EXPORT		
Export Class A medical device		No
Export Class B medical device		No
Export Class C medical device		No
Export Class D medical device		No
Export Class A IVD		No
Export Class B IVD		No
Export Class C IVD		No
Export Class D IVD		No
Export RUO IVDs		No

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5. PARTICULARS OF THE PERSONNEL RESPONSIBLE FOR OPERATION ON THE PREMISES ON BEHALF OF THE LICENCE HOLDER

Authorised Representative	Manufacture / Import / Distribution / Export Control Person	Quality Control Person
Belinda Banfield	Belinda Banfield	Mark Banfield
None	None	MBA

6. PARTICULARS OF THE LICENCE HOLDER CONTACT (Other than the Authorised Representative)

Name	Contact Details	Address
Mr. M. Banfield	Tel: 011 467 6673 Cell: 083 407 2222 Fax: 086 684 2410 Email: mark@afrihealth.co.za	PO Box 145 Magaliessig 2067

7. LICENCE SPECIFIC CONDITIONS

1. The holder of the licence shall conduct all manufacturing, distribution or wholesaling operations in respect of those medical devices for which a registration certificate has been obtained, so as to ensure that the medical devices shall conform to the standards of quality, safety and performance applicable to them in accordance with the specifications made by the person to whose order they are manufactured, distributed or wholesaled or the specifications under which the medical devices are sold or supplied.
2. Once the renewed license is issued to the applicant the current existing license becomes invalid.

8. ADDITIONAL LICENCE SPECIFIC CONDITIONS (IF REQUIRED)