

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



Licence number: 00003378MD

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

OFAM Investments (Pty) Ltd

27 Nansen Place

Tulisa Park

Johannesburg South

Gauteng

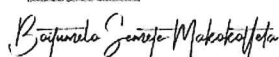
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On the following terms and conditions:

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, 22H, 23, 26, 28, 33 and the Regulations relating to Medical Devices 2, 3, 4, 5, 6, 13, 14, 17, 18, 19, 20, 21, 22, 23, 24, 25, 27, 28 and all relevant South African Health Products Regulatory Authority Guidelines.

This licence consists of 3 pages.

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



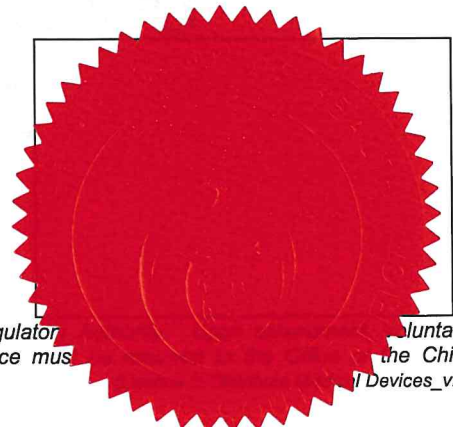
CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 19 December 2023

EXPIRY DATE: 19 December 2028

AMENDMENT DATE: N/A

This licence remains the property of the South African Health Products Regulatory Authority. In the event of voluntary withdrawal, recall, suspension or revocation of the licence, the original licence must be returned to the Chief Executive Officer.



Voluntary
the Chief
[Devices_v2]

ANNEXURE 1

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AUTHORISED DISTRIBUTION AND MATERIAL HANDLING ACTIVITIES

1. DISTRIBUTION ACTIVITIES	YES	NO
Distribution to hospitals and retail pharmacies and other clients: Class A	Yes	
Distribution to hospitals and retail pharmacies and other clients: Class B	Yes	
Distribution to hospitals and retail pharmacies and other clients: Class C	Yes	
Distribution to hospitals and retail pharmacies and other clients: Class D		No
2. MATERIALS HANDLED OR STORED AT THIS SITE		
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	Yes	
Import Class B medical device	Yes	
Import Class C medical device	Yes	
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
Gilbert Sibusiso Ovana	Gilbert Sibusiso Ovana	Gilbert Sibusiso Ovana
Diploma (Mechanical Engineering)	Diploma (Mechanical Engineering)	Diploma (Mechanical Engineering)

6. PARTICULARS OF THE LICENCE HOLDER CONTACT (AND AUTHORISED REPRESENTATIVE, if not the same person)

Name	Contact Details	Address
Mr S G Ovana (LH/AR)	Tel: 010 745 0679 Cell: 061 429 4046 Fax: N/A Email: gee@ofaminvest.com	27 Nansen Place Tulisa Park Johannesburg South Gauteng 2197

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.

8. ADDITIONAL LICENCE SPECIFIC CONDITIONS (IF REQUIRED)

OFAM Investments (Pty) Ltd
27 Nansen Place
Tulisa Park
Johannesburg South, Gauteng
2197

Enquiries: Dr D Mathibe

Tel: N/A

Dear Sir/Madam,

LICENCE TO DISTRIBUTE IN TERMS OF SECTION 22C(1)(b) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965

Licence Number 00003378MD

Your licence to distribute in terms of section 22C (1)(b) of the Medicines and Related Substances Act has been approved and is attached herewith. This document replaces any licence document, for a medical device establishment, previously issued to you.

This licence authorises distribution by the licence holder; if the business should change hands, the company or person taking over the business will have to obtain a new licence before commencing the distribution of medical devices.

This licence is subject to the limitations specified in the licence and to the statutory provisions contained in the Regulations to the Act.

Activities may only be carried out in accordance with the terms of the relevant product licence, unless a specified exemption applies, which allows it to take place other than in accordance with the licence.

This licence relates to the distribution of medical devices on the premises and under the supervision of the persons specified. If any change of premises or of those persons takes place, prior approval must be sought from the South African Health Products Regulatory Authority. Any proposal to make structural alterations to the premises must also be notified to the South African Health Products Regulatory Authority.

The South African Health Products Regulatory Authority has the power to revoke, suspend or amend licences in terms of Section 22E of Act 101 of 1965.

Yours faithfully,

Dimakatso Mathibe

Dimakatso Mathibe

Dr Dimakatso (Theresa) Mathibe, PhD, MBL
Senior Manager Medical Device Unit

Date: 16 January 2024