SAHPRA
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

DEPARTMENT OF HEALTH

Licence number: 00000046MD_R1

LICENCE TO MANUFACTURE MEDICAL DEVICES

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

This licence is granted to:

Licence Holder

Pharmaceuticals Enterprises (Pty)Ltd
49 Morningside Road
Ndabeni
Cape Town
7405

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 South African Health Products Regulatory Authority Guidelines.

This licence consists of 4 pages.
This facility is authorised to perform the manufacturing activities listed in Annexure 1 to this licence.

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 31 July 2017

1ST RENEWAL DATE: 30 August 2022

EXPIRY DATE: 30 August 2027

AMENDMENT DATE: N/A

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ANNEXURE 1

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AUTHORISED MANUFACTURING AND MATERIAL HANDLING ACTIVITIES

1. MANUFACTURING ACTIVITIES	YES	NO
Sterile Medical Device Manufacture (includes primary packing, but not secondary packing such as cartooning or labelling)		
Single use	Yes	
Measuring medical devices		No
Non-invasive medical device		No
Invasive medical devices	Yes	
Active medical devices		No
Inactive medical devices		No
Contraceptive medical devices		No
Combination medical devices		No
Other sterile medical devices (as specified):		No
Non-sterile Manufacture		
Measuring medical devices		No
Non-invasive medical devices		No
Invasive medical devices		No
Active medical devices		No
Inactive medical devices		No
Contraceptive medical devices		No
Combination medical devices		No
Other non-sterile medical devices (as specified):		No
Manufacture of *In Vitro* Devices (IVDs)		
Class A IVD		No
Class B IVD		No
Class C IVD		No
Class D IVD		No
End point Sterilisation of Medical Devices		No
Manufacture of Radioactive Medical Devices		No
Servicing and Refurbishment of Medical Devices		No
2. PACKAGING ACTIVITIES		
Packaging of bulk product and labelling	Yes	
Re-labelling or redressing	Yes	
Cartoning or secondary packaging	Yes	
Assembly or "kits" / procedure packs		No
3. TESTING ACTIVITIES		
Analytical		No
Microbiological	Yes	
Sterility	Yes	
Stability		No
Animal		No
Other Testing Activities (as specified):		No
4. DISTRIBUTION ACTIVITIES		
Distribution to hospitals and retail pharmacies and other clients: Class A	Yes	
Distribution to hospitals and retail pharmacies and other clients: Class B		No
Distribution to hospitals and retail pharmacies and other clients: Class C		No
Distribution to hospitals and retail pharmacies and other clients: Class D		No

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	YES	NO
5. 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
6. IMPORT		
Import Class A medical device	Yes	
Import Class B medical device		No
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
7. 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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8. 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
Annerie Tiedt	Ian Lindsay	Annerie Tiedt
B.Pharm	B.Pharm	B.Pharm

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

Name	Contact Details	Address
Ms A Bisnath	Tel: (021) 531 1341 Cell: (+27) 730699551 Fax: N/A Email: avlika@pharm.co.za	Unit 7, Howard Studios, Howard Drive Pinelands Cape Town 7405

10. 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

11. ADDITIONAL LICENCE SPECIFIC CONDITIONS (IF REQUIRED)

SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
Kirkness Road
Arcadia
0083

Enquiries: Jerry Molokwane
Email: jerry.molokwane@sahpra.org.za
Tel: 076 422 4934
Reference: 0000000552.-.11

The Responsible Pharmacist
Pharmaceutical Enterprises (Pty) Ltd
49 Morningside Road
N'Dabeni, Cape Town
Western Cape
7405

Tel: 021 531 7850
Email: elmari@pharm.co.za

Dear Sir/Madam

RE: **Renewal and Amendment (Change in Key Personnel and Deletion of Manufacturing Activities)** to LICENCE TO ACT AS a **Packer & Importer & Exporter (HCR)** IN TERMS OF SECTION 22C (1)(b) OF THE MEDICINES AND RELATED SUBSTANCES ACT,1965

Manufacturer Licence ***0000000552.-.11***

Your licence to act as **Packer & Importer & Exporter (HCR)** 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 previously issued to you.

This licence authorizes the acting as **Packer & Importer & Exporter (HCR)** by the licence holder named; if the business should change hands, the company or person taking over the business will have to obtain a new licence before commencing acting as a **Packer & Importer & Exporter (HCR)** of products.

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.

The licence relates to the acting as a **Packer & Importer & Exporter (HCR)** of products on the premises and under the supervision of the persons specified. If any change of premises or of those persons to take place, prior approval must be sought from Licensing Authority. Any proposal to make structural alterations to the premises must also be notified to the Licensing Authority.

The Licensing Authority has power to revoke licences in terms of section 22E should the inspection result in a negative SAHPRA resolution.

Yours faithfully

Jerry Molokwane

Jerry Molokwane
UNIT MANAGER: PHARMA LICENSING

Date: 07 May 2024

South African Health Products Regulatory Authority

Licence number: 0000000552.-.11

LICENCE TO MANUFACTURE MEDICINES – Packaging. Import & Export (HCR)

In terms of section 22C(1)(b) of the Medicines and Related Substances Act, 1965

This licence is granted to:

Licence Holder
Pharmaceutical Enterprises (Pty) Ltd
49 Morningside Road, N'Dabeni, Cape Town, Western Cape, 7405

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 medicines manufactured in this facility, 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, 22G, 33, Regulations 7, 10, 11, 12, 13, 14, 15, 40, 42, 53 and all relevant SAHPRA Guidelines.

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

Boitumelo Semete-Makokotlela

07 May 2024

CHIEF EXECUTIVE OFFICER

ORIGINAL ISSUE DATE:	**11 September 2009**
FIRST RENEWAL DATE:	10 September 2014
SECOND RENEWAL DATE:	25 October 2019
THIRD RENEWAL DATE:	**30 April 2024**
AMENDMENT DATE:	**30 April 2024**
EXPIRY DATE:	**30 April 2029**