SAHPRA
South African
Health Products
Regulatory Authority

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

LINDASENGANI Trading (Pty) Ltd
1734 Kokomere Crescent. Teanong Ext 5, Tembisa
Gauteng
1632

Enquiries: Dr D Mathibe

Tel: N/A

Dear Sir/Madam,

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

Licence Number 00004451MD

Your licence to wholesale 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 wholesaling 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 wholesaling 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 wholesaling 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.

Kindly note that the **Annual retention fee** come into effect the year after the said licence was approved by the Authority in terms of Section 22C(1)(b) on or before the last working day of June that year.

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

Dr Dimakatso (Theresa) Mathibe, PhD, MBL
Senior Manager Medical Device Unit
Date: 25 March 2025

Chairperson: Prof Helen Rees • Vice-Chairperson: Dr Obakeng Khaole • Prof Joyce Tsoka-Gwegweni
Prof Patrick Demana • Dr Xolani Khayelihle Ngobese • Adv Hasina Cassim • Ms Ditaba Lucy Maraka
Mr Itani Elias Mashau • Ms Lerato Mothae • Mr Norman Baloyi • Dr Afred Kgasi • Prof Johanna Meyer
• Ms Mandisa Skhosana • Prof Yahya Choonara • Dr Zinhle Makatini
CEO: Dr Boitumelo Semete-Makokotlela

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

DEPARTMENT OF HEALTH

Licence number: 00004451MD

LICENCE TO WHOLESALE MEDICAL DEVICES

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

This licence is granted to:

Licence Holder

LINDASENGANI Trading (Pty) Ltd
1734 Kokomere Crescent
Teanong Ext 5, Tembisa
Gauteng
1632

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 product 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.

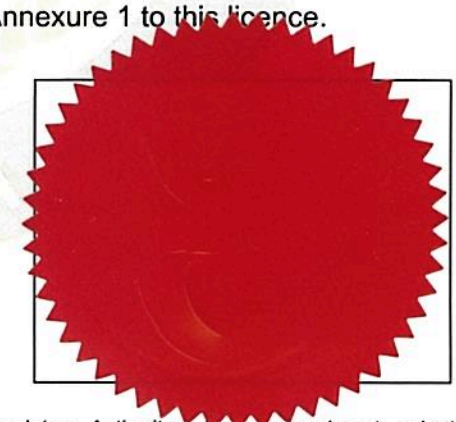
Bafumeli Semete Makaketeta

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 11 March 2025

EXPIRY DATE: 11 March 2030

AMENDMENT DATE: N/A



This licence remains the property of the 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 Chief Executive Officer.

ANNEXURE 1 **00004451MD**

AUTHORISED WHOLESALING AND MATERIAL HANDLING ACTIVITIES

1. SPECIFIC ACTIVITIES	YES	NO
Imported medical devices are stored and handled at this site		No
Locally procured medical devices are stored and handled at this site	Yes	
"Special" manufactured products are handled at this site		No
Medical devices are exported from this site on behalf of SAHPRA licensed manufacturers or distributors of medical devices		No

2. METHOD OF ONWARD DISPATCH	YES	NO
Post		No
Courier / Van Service	Yes	
Own Courier / Van Service		No
Customer Collection		No
Other (as specified):		No

3. CATEGORIES OF MEDICAL DEVICES HANDLED AT THIS SITE

Class Medical Device / Type Medical Device		A	B	C	D	RUO
Sterile		X	X	X	X	
Measuring Medical Device		X	X	X	X	
Blood storage / transportation product				X		
Non-Invasive		X	X	X		
Invasive Medical Device	< 60 min					
	>60 min & < 30 days	X	X	X	X	
	>30 days					
Inactive Medical Device		X	X	X	X	
Active Medical Device		X	X	X	X	
Contraceptive		X	X	X	X	
Combination Medical Device		X	X	X	X	
IVD		X	X	X		

4. HOLDER OF AN ADDITIONAL SAHPRA LICENCE	YES	NO
Licence to manufacture / distribute medical devices (as specified):		No
Licence to manufacture / wholesale medicine (as specified):		No

5. SITE LISTING ON A SAHPRA LICENCE HELD BY ANOTHER LICENCE HOLDER	YES	NO
Medical Device Establishment Licence to Manufacture		No
Medical Device Establishment Licence to Distribute		No

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00004451MD

6. PARTICULARS OF THE PERSONNEL RESPONSIBLE FOR OPERATIONS ON THE PREMISES ON BEHALF OF THE LICENCE HOLDER

Authorised Representative
Themeli Lawrence Matodzi
National Certificate

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

Name	Contact Details	Address
Mr T.L Matodzi (AR/LH)	Tel: N/A Cell: 061 420 0206 Fax: N/A Email: lindasengani@gmail.com	1734 Kokomere Crescent Teanong Ext 5, Tembisa Gauteng 1632

8. 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.

9. ADDITIONAL LICENCE SPECIFIC CONDITIONS (IF REQUIRED)

This licence remains the property of the 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 Chief Executive Officer.