

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



Licence number: 00000504MD 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

Sourcelink Healthcare (Pty) Ltd

Factory 11, Techno Complex, 51 Venturi Crescent, Hennopspark Centurion

0157

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 4 pages.

This 1	facility	is	authorised	to	perform	the	manufacturing	activities	listed in	Annexure	1	to t	his
licenc	e.												

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

CHIEF EXECUTIVE OFFICER ORIGINAL DATE OF ISSUE:

1ST RENEWAL DATE: 28 March 2023

EXPIRY DATE: 28 March 2028

AMENDMENT DATE: N/A



ANNEXURE 1 00000504MD_R1

AUTHORISED MANUFACTURING AND MATERIAL HANDLING ACTIVITIES

packing such as cartoning or labelling) Single use Measuring medical devices Mon-invasive medical devices Active medical devices NO Active medical devices Combination medical devices NO Non-sterile Manufacture Measuring medical devices Mon-invasive medical devices No Non-invasive medical devices No Non-invasive medical devices No Active medical devices No Contraceptive medical devices No Contraceptive medical devices No Contraceptive medical devices No Combination medical devices No Manufacture of in Vitro Devices (IVDs) Class B IVD Class B IVD Class B IVD Class D IVD No Anufacture of Radioactive Medical Devices No Monufacture of Radioactive Medical Devices No Servicing and Refurbishment of Medical Devices No Monufacture of Radioactive medical Devices No Monufacture medical devices No Monufacture medical de	1. MANUFACTURING ACTIVITIES	YES	NO
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	Distribution to hospitals and retail pharmacies and other clients: Class D		NO





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5. MATERIALS HANDLED OR STORED AT THIS SITE					
Medical devices stored at licence holder site		NO			
Combination medical devices with Penicillins		NO			
Combination medical devices with Cephalosporins					
Combination medical devices with (other) Antibiotics (as specified):					
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	YES	NO			
Import Class A medical device		NO			
Import Class B medical device		NO			
Import Class C medical device					
Import Class D medical device					
Import Class A IVD					
Import Class B IVD					
Import Class C IVD		NO			
Import Class D IVD					
Import RUO IVDs		NO			
7. EXPORT	YES	NO			
Export Class A medical device		NO			
Export Class B medical device					
Export Class C medical device					
Export Class D medical device					
Export Class A IVD					
Export Class B IVD					
Export Class C IVD					
Export Class D IVD					
Export RUO IVDs	V	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			
Almirie Maraz	Willem Adolph Botha	Almirie Maraz			
N. Dip Clinical Technology (Pulmonology)	Project Manager	N. Dip Clinical Technology (Pulmonology)			

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

Name	Contact Details	Address
Mr W.A. Botha	Tel: 012 653 2704	Factory 11, Techno
	Cell: 0828054139	Complex,
	Fax: N/A	51 V <mark>ent</mark> uri Crescent
	Email: willem@slhealthcare.co.za	Henno <mark>ps</mark> park
		Pretoria <mark>, 15</mark> 7

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)

