SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

DEPARTMENT OF HEALTH
Republic of South Africa

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 facility is authorised to perform the manufacturing 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:

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

1. MANUFACTURING ACTIVITIES	**YES**	**NO**
Sterile Medical Device Manufacture (includes primary packing, but not secondary packing such as cartoning or labelling)		
Single use	YES	
Measuring medical devices		NO
Non-invasive medical device	YES	
Invasive medical devices		NO
Active medical devices		NO
Inactive medical devices	YES	
Contraceptive medical devices		NO
Combination medical devices		NO
Other sterile medical devices (as specified): Disposable Surgical Drapes	YES	
Non-sterile Manufacture		
Measuring medical devices		NO
Non-invasive medical devices	YES	
Invasive medical devices		NO
Active medical devices		NO
Inactive medical devices	YES	
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	**YES**	**NO**
Packaging of bulk product and labelling	YES	
Re-labelling or redressing	YES	
Cartoning or secondary packaging	YES	
Assembly or “kits” / procedure packs	YES	
3. TESTING ACTIVITIES	**YES**	**NO**
Analytical		NO
Microbiological		NO
Sterility		NO
Stability		NO
Animal		NO
Other Testing Activities (as specified): Visual, Equipment Calibration		NO
4. 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		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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5. MATERIALS HANDLED OR STORED AT THIS SITE	**YES**	**NO**
Medical devices stored at licence holder 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
6. IMPORT	**YES**	**NO**
Import Class A medical device		NO
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	**YES**	**NO**
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

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 Cell: 0828054139 Fax: N/A Email: willem@slhealthcare.co.za	Factory 11, Techno Complex, 51 Venturi Crescent Hennopspark Pretoria, 157

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)