

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



Licence number: 00000672MD_v1R1

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, Importer and Exporter**

This amended licence replaces the licence issued on the 20th of June 2023

This licence is granted to:

Licence Holder

Neomedic (Pty) Ltd

90 Corobrik Road

Unit 5, Bella Vista Estate

Riverhorse Valley East

4017

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.

Boitumelo Semete-Makoketela

CHIEF EXECUTIVE OFFICER

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 28 September 2018

1ST RENEWAL DATE: 20 June 2023

EXPIRY DATE: 20 June 2028

AMENDMENT DATE: 12 November 2024

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

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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	YES	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
3. IMPORT	YES	NO
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	Yes	
Import Class C IVD		No
Import Class D IVD		No
Import RUO IVDs		No
4. EXPORT	YES	NO
Export Class A medical device	Yes	
Export Class B medical device	Yes	
Export Class C medical device	Yes	
Export Class D medical device		No
Export Class A IVD		No
Export Class B IVD	Yes	
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
Mohamed Hoosen Patel	Mohamed Hoosen Patel	Shameera Allie
None	None	Bcom (Accounting) Hons

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

Name	Contact Details	Address
Ms S. Allie (LH)	Tel: 031 533 9680 Cell: 072 252 2280 Fax: 031 569 6679 Email: shameera@neomedic.net	90 Corobrik Road Unit 5, Bella Vista Estate Riverhorse Valley East 4017
Mr M. H Patel (AR)	Tel: 031 533 9680 Cell: 083 786 7313 Fax: 031 596 6679 Email: mohamed@neomedic.net	90 Corobrik Road Unit 5, Bella Vista Estate Riverhorse Valley East 4017

7. LICENCE SPECIFIC CONDITIONS

- 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)

See amended sections (v1R1)

- Section 4.3
- Section 17.1
- Section 18.4