

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



Licence number: 00001772MD

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 licence is granted to:

Licence Holder

Specmed Medical Services (Pty) Ltd

Unit 27 midline business park

Cnr richards drive and le roux

Midrand

1685

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.

DocuSigned by:

Boitumelo Semele Makokotlala

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 19 January 2021

EXPIRY DATE: 19 January 2026

AMENDMENT DATE: N/A

ANNEXURE 1**00001772MD****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	Yes	
2. 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
3. IMPORT		
Import Class A medical device	Yes	
Import Class B medical device	Yes	
Import Class C medical device	Yes	
Import Class D medical device	Yes	
Import Class A IVD		No
Import Class B IVD		No
Import Class C IVD		No
Import Class D IVD		No
Import RUO IVDs		No
4. EXPORT		
Export Class A medical device	Yes	
Export Class B medical device	Yes	
Export Class C medical device	Yes	
Export Class D medical device	Yes	
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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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
Cheryl Denise McCormick	Royden Anton Peirone	Ramolwetsi Ruth Kekana
Supervisory and management	National higher diploma electronics	Matric

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

Name	Contact Details	Address
DA PEIRONE	Tel: 011 805 5891 Cell: 061 981 1234 Fax: 010 446 3041 Email: specmed@mweb.co.za	PO BOX 5040 HALWAY HOUSE MIDRAND JOHANNESBURG 1685

7. 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.

8. ADDITIONAL LICENCE SPECIFIC CONDITIONS (IF REQUIRED)