

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



Licence number: 00000924MD

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

Prestige Laboratory Supplies (Pty) Ltd

9 Marshall Drive, Old Mill Industrial Park

Mount Edgecombe

Durban

4302

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.


ACTING CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 31 May 2019

EXPIRY DATE: 31 May 2024

AMENDMENT DATE: N/A



This licence remains the property of the National Department of Health and 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.
[Licence to Wholesale Medical Devices]

ANNEXURE 1

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AUTHORISED WHOLESALING AND MATERIAL HANDLING ACTIVITIES
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1. SPECIFIC ACTIVITIES						YES	NO
Locally procured medical devices are store 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						Yes	
Customer Collection							No
Other (as specified): Designated driver						Yes	
3. CATEGORIES OF MEDICAL DEVICES HANDLED AT THIS SITE							
Class Medical Device							
Type Medical Device						A	B
Sterile							C
Measuring Medical Device							D
Blood storage / transportation product							RUO
Non-Invasive						X	
Invasive Medical Device						< 60 min	X
						> 60 min & < 30 days	
						>30 days	
inactive Medical Device							
Active Medical Device							
Contraceptive							
Combination Medical Device							
IVD							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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6. PARTICULARS OF THE PERSONNEL RESPONSIBLE FOR OPERATIONS ON THE PREMISES ON BEHALF OF THE LICENCE HOLDER

Authorised Representative
Nevon Naidoo
Diploma in Business and Computer Studies

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

Name	Contact Details	Address
Nevon Naidoo	Tel: 031 539 3266 Fax: 031 539 1831 Email: nevon@prestigelab.co.za	PO Box 417 Mount Edgecombe Durban 4300

8. 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.

9. ADDITIONAL LICENCE SPECIFIC CONDITIONS (IF REQUIRED)