

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



DEPARTMENT OF HEALTH
Republic of South Africa

Licence number: 00000693MD_R1

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

Wena Dental and Kleenex Products Supplier

817 Jacques Street

Moreleta Park

Pretoria East

0167

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.

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

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 28 September 2018

1ST RENEWAL DATE: 23 May 2023

EXPIRY DATE: 23 May 2028

AMENDMENT DATE: N/A

ANNEXURE 1

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AUTHORISED WHOLESALING AND MATERIAL HANDLING ACTIVITIES						
1. SPECIFIC ACTIVITIES						
Locally procured medical devices are stored and handled at this site					YES	NO
"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						
Post						NO
Courier / Van Service						NO
Own Courier / Van Service					YES	
Customer Collection						NO
Other (as specified):						NO
3. CATEGORIES OF MEDICAL DEVICES HANDLED AT THIS SITE						
Class Medical Device		A	B	C	D	RUO
Type Medical Device						
Sterile						
Measuring Medical Device						
Blood storage / transportation product						
Non-Invasive		X	X	X		
Invasive Medical Device	< 60 min					
	>60 min & < 30 days		X	X	X	
	>30 days					
Inactive Medical Device						
Active Medical Device						
Contraceptive						
Combination Medical Device						
IVD						
4. HOLDER OF AN ADDITIONAL SAHPRA LICENCE						
Licence to manufacture / distribute medical devices (as specified): 00001654MD					YES	NO
Licence to manufacture / wholesale medicine (as specified):						NO
5. SITE LISTING ON A SAHPRA LICENCE HELD BY ANOTHER LICENCE HOLDER						
Medical Device Establishment Licence to Manufacture						NO
Medical Device Establishment Licence to Distribute					YES	

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6. PARTICULARS OF THE PERSONNEL RESPONSIBLE FOR OPERATIONS ON THE PREMISES ON BEHALF OF THE LICENCE HOLDER

Authorised Representative
Mr Jasper Booysen
Diploma (Project Management)

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

Name	Contact Details	Address
Mr J Booysen	Tel: 012 997 1035 Cell: N/A Fax: N/A Email: wenab@xsinet.co.za	817 Jacques Street Moreleta Park Pretoria East 0167

8. 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.

9. ADDITIONAL LICENCE SPECIFIC CONDITIONS (IF REQUIRED)