

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



Licence number: 00000981MD_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

Medi-Clave (Pty) Ltd

Portion 69, Melvic

Schurveberg

Pretoria

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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.

Bontwanele Senete Makokotlota

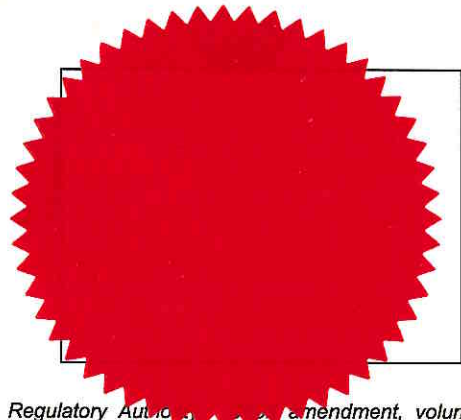
CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 31 May 2019

1ST RENEWAL DATE: 20 February 2024

EXPIRY DATE: 20 February 2029

AMENDMENT DATE: N/A



This licence remains the property of the South African Health Products Regulatory Authority. In the event of 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 WHOLESALING AND MATERIAL HANDLING ACTIVITIES
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1. SPECIFIC ACTIVITIES						YES	NO
Locally procured medical devices are stored and handled at this site						Yes	
"Special" manufactured products are handled at this site						Yes	
Medical devices are exported from this site on behalf of SAHPRA licensed manufacturers or distributors of medical devices						Yes	
2. METHOD OF ONWARD DISPATCH						YES	NO
Post							No
Courier / Van Service						Yes	
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						
	>30 days						
Inactive Medical Device		X	X	X			
Active Medical Device				X			
Contraceptive							
Combination Medical Device							
IVD							
4. HOLDER OF AN ADDITIONAL SAHPRA LICENCE						YES	NO
Licence to manufacture / distribute medical devices (as specified): (00000676MD)						Yes	
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
Johann Bosman Hoffman
N5 (Engineering)

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

Name	Contact Details	Address
Mr. B. J. Hoffman (LH/AR)	Tel: 012 379 1983 Cell: 082 450 4080 Fax: N/A Email: johann@medi-clave.co.za	Portion 69, Melvic Schurveberg Pretoria 0001

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)

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