

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



DEPARTMENT OF HEALTH
Republic of South Africa

Licence number: 00000981MD

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, Ext 488

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.


ACTING CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 31 May 2019

EXPIRY DATE: 31 May 2024

AMENDMENT DATE: N/A



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		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): Road Freight			No			
3. CATEGORIES OF MEDICAL DEVICES HANDLED AT THIS SITE		A	B	C	D	RUO
Class Medical Device						
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): Manufacture (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			

0000981MD

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

Authorised Representative
Johann Bosman Hoffman
N4 National Certificate in Electronics, Industrial Electronics, Mechanotechnics and Mathematics

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

Name	Contact Details	Address
J Hoffmann	Tel: 012 379 1983 Fax: 086 551 6700 Email: admin@medi-clave.co.za	Portion 69, Melvic Schurveberg, Ext 488 Pretoria 0001

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)

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Republic of South Africa
Private Bag X828
PRETORIA
0001



Republiek van Suid-Afrika
Privaatsak X828
PRETORIA
0001

Medi-Clave (Pty) Ltd
Portion 69, Melvic
Schurveberg, Ext 488
Pretoria
0001

Dear Sir/Madam,

LICENCE TO WHOLESALE IN TERMS OF SECTION 22C(1)(b) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

Licence Number 00000981MD

Your licence to act as a wholesaler in terms of section 22C(1)(b) of the Medicines and Related Substances Act, 1965 has been approved and is attached herewith. This document replaces any wholesale licence document, for a medical device establishment, previously issued to you.

This licence authorises the wholesale of medical devices by the licence holder named; if the business should change hands, the company or person taking over the business will have to obtain a new licence before commencing the wholesale of medical devices.

This licence is subject to the limitations specified in the licence and to the statutory provisions contained in the Regulations to Act 101 of 1965.

Activities may only be carried out in accordance with the terms of the relevant product licence, unless a specified exemption applies, which allows it to take place other than in accordance with the licence.

This licence relates to the wholesale of medical devices on the premises and under the supervision of the persons specified. If any change of premises or of those persons takes place, prior approval must be sought from the South African Health Products Regulatory Authority. Any proposal to make structural alterations to the premises must also be notified to the South African Health Products Regulatory Authority.

The South African Health Products Regulatory Authority has the power to revoke, suspend or amend licences in terms of Section 22E of Act 101 of 1965.

Yours faithfully,

ACTING CHIEF EXECUTIVE OFFICER

Date: 31 May 2019

Navrae/Enquiries: Mrs A.A Keyter

Telefoon/Telephone: (012) 842 7585/ 7580