

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



DEPARTMENT OF HEALTH
Republic of South Africa

Licence number: 00001070MD

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

Miba Snips T/A Medequip

Eden-Greene Office Park

14 Boeing Road East

Dunvegan

1609

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.

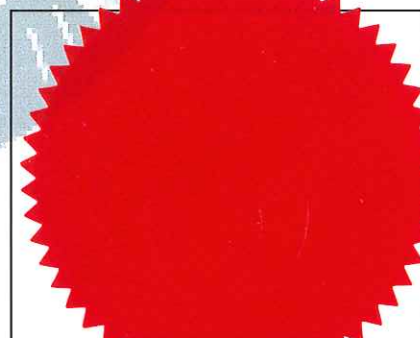
This facility is authorised to perform the activities listed in Annexure 1 to this licence.

ACTING CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 05 July 2019

EXPIRY DATE: 05 July 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			No			
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		Yes				
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		X	X	X	X	
Blood storage / transportation product						
Non-Invasive		X	X	X	X	
Invasive Medical Device	< 60 min	X	X	X	X	
	> 60 min & < 30 days	X	X	X	X	
	>30 days					
Inactive Medical Device		X	X	X	X	
Active Medical Device		X	X	X	X	
Contraceptive						
Combination Medical Device		X	X	X	X	
IVD						
4. HOLDER OF AN ADDITIONAL SAHPRA LICENCE		YES	NO			
Licence to manufacture / distribute medical devices (as specified): Manufacture (00000849MD)		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
Quenton Greene
BAC-Emergency Medicine

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

Name	Contact Details	Address
Quenton Greene	Tel: 011 454 2610 Cell: N/A Fax: 011 454 2626 Email: quenton@medequip.co.za	PO Box 1708 Bedfordview 1708

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)