

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



Licence number: 00000935MD

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

Iziko Medical & Surgical 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: 14 June 2019

EXPIRY DATE: 14 June 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). Driver Specific to customer		Yes				
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				
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
Saraswathi Ranjit
Diploma in Cost & Management

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

Name	Contact Details	Address
S Ranjit	Tel: 031 502 1611 Cell: N/A Fax: 031 502 1669 Email: rita@izimed.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)

