

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



Licence number: 00003353MD

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
Ecomed Medical (Pty) Ltd
25 Clew Street, Monuments Ext 1
Krugersdorp
Gauteng
1739

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.

Bisumane Suresh Makokhatfeta

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 08 December 2023

EXPIRY DATE: 08 December 2028

AMENDMENT DATE: N/A



This licence remains the property of the South African Health Products Regulatory Authority. In the event of voluntary withdrawal, recall, suspension or revocation of the licence, the original licence must be returned to the Chief Executive Officer.

[Licence to Wholesale Medical Devices]

ANNEXURE 1

00003353MD

AUTHORISED WHOLESALING AND MATERIAL HANDLING ACTIVITIES

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		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		X	X	X		
Measuring Medical Device		X	X	X		
Blood storage / transportation product		X	X	X		
Non-Invasive		X	X	X		
Invasive Medical Device	< 60 min	X	X	X		
	>60 min & < 30 days	X	X	X		
	>30 days	X	X	X		
Inactive Medical Device		X	X	X		
Active Medical Device		X	X	X		
Contraceptive						
Combination Medical Device		X	X	X		
IVD						
4. HOLDER OF AN ADDITIONAL SAHPRA LICENCE		YES	NO			
Licence to manufacture / distribute medical devices (as specified): Manufacture		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		Yes				
Medical Device Establishment Licence to Distribute		Yes				

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00003353MD

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

Authorised Representative
Madri Small
Basic Ambulance Assistant Certificate

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

Name	Contact Details	Address
Mrs M Small (LH/AR)	Tel: 011 955 5710 Cell: 079 875 8556 Fax: 011 955 6316 Email: sales@ecomед.co.za	25 Clew Street Monuments Ext 1 Krugersdorp, Gauteng 1739

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)