

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



DEPARTMENT OF HEALTH
Republic of South Africa

Licence number: 00000767MD

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
Unit B Factoria Industrial Park
Louis Friedman Street
Factoria
Krugersdorp
1740

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: 20 March 2019

EXPIRY DATE: 20 March 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							
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	X	X	X	X		
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 00000528MD						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

00000767MD

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

Authorised Representative
Gregory Mark De Freitas
MBA Business

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

Name	Contact Details	Address
Gregory Mark De Freitas	Tel: 011 955 5710 Fax: 011 955 6316 Email: sales@ecomед.co.za	25 Clew Street, Monument Ext 1 Krugersdorp 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)