

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



Licence number: 00004755MD

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

Glenmed Healthcare Solutions (Pty) Ltd

6 Barham Road,
Surrey Park, Office Block B
Westville
Durban
3629

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.

Batimela Sente-Makoketjela
eSHPRA

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 04 July 2025

EXPIRY DATE: 04 July 2030

AMENDMENT DATE: N/A



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

ANNEXURE 1

00004755MD

AUTHORISED WHOLESALING AND MATERIAL HANDLING ACTIVITIES

1. SPECIFIC ACTIVITIES		YES	NO			
Imported medical devices are stored and handled at this site		Yes				
Locally procured medical devices are stored 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		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		
Blood storage / transportation product						
Non-Invasive		X	X	X		
Invasive Medical Device	< 60 min					
	>60 min & < 30 days					
	>30 days					
Inactive Medical Device						
Active Medical Device		X	X	X		
Contraceptive						
Combination Medical Device						
IVD						
4. HOLDER OF AN ADDITIONAL SAHPRA LICENCE		YES	NO			
Licence to manufacture / distribute medical devices (as specified): 00000673MD		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			

This licence remains the property of 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.

00004755MD

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

Authorised Representative
Glen Walter Strike
Diploma (Light Current Electronic Engineering)

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

Name	Contact Details	Address
Mrs Y. Chetty (LH)	Tel: (031) 202 4115 Cell: 083 464 1445 Fax: 086 666 5710 Email: sales@glenmed.co.za	6 Barham Road, Surrey Park, Office Block B Westville Durban 3629
MR G.W. Strike (AR)	Tel: (031) 202 4115 Cell: 083 456 5511 Fax: N/A Email: sales@glenmed.co.za	6 Barham Road, Surrey Park, Office Block B Westville Durban 3629

8. LICENCE SPECIFIC CONDITIONS

1. 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)

This licence remains the property of 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.