

SOUTH AFRICAN HEALTH PRODUCTS

REGULATORY AUTHORITY



DEPARTMENT OF HEALTH
Republic of South Africa

Licence number: 00001127MD_R1

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

Ambasaam (Pty) Ltd

9 Galaxy Avenue

Fresenius Medical Care, Buiding A, Linbro Park

Frankenwald

Sandton, Gauteng

2090

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.

Boitumelo Seemole-Makoketjane

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 26 July 2019

1ST RENEWAL DATE: 12 April 2024

EXPIRY DATE: 12 April 2029

AMENDMENT DATE: N/A

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.

ANNEXURE 1

00001127MD_R1

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						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		X	X	X	X	X
Measuring Medical Device		X	X	X	X	X
Blood storage / transportation product		X	X	X	X	X
Non-Invasive		X	X	X	X	X
Invasive Medical Device	< 60 min	X	X	X	X	X
	>60 min & < 30 days	X	X	X	X	X
	>30 days	X	X	X	X	X
Inactive Medical Device		X	X	X	X	X
Active Medical Device		X	X	X	X	X
Contraceptive		X	X	X	X	X
Combination Medical Device		X	X	X	X	X
IVD		X	X	X	X	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): 0000001146.-.7					Yes	
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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