

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



DEPARTMENT OF HEALTH
Republic of South Africa

Licence number: 00000814MD

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

Obsidian Health (Pty) Ltd

Cosmo Business Park

Malibongwe Drive

Randburg

2188

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

00000814MD

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						No
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			
Blood storage / transportation product						
Non-Invasive		X	X			
Invasive Medical Device	< 60 min	X	X	X	X	
	> 60 min & < 30 days	X	X	X	X	
	>30 days			X	X	
Inactive Medical Device		X	X	X	X	
Active Medical Device		X	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): Manufacturer (00000186MD)					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

00000814MD**6. PARTICULARS OF THE PERSONNEL RESPONSIBLE FOR OPERATIONS ON THE PREMISES ON BEHALF OF THE LICENCE HOLDER**

Authorised Representative
Dennis Beech
B.Com in Transport Economics

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

Name	Contact Details	Address
D Beech	Tel: 087 357 5920 /073 316 1045 Fax: 086 687 5384 Email: dennisb@obsidianhealth.co.za	Cosmo Business Park Malibongwe Drive Randburg 2188

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)