

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



Licence number: 00003475MD

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

Access Dental Coastal CC

Unit 6, The Reserve 1

Cnr Kruispad and Capricorn Way

Cape Town, Western Cape

7560

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.

Bontumelo Semete-Makokotela

SAHPRA

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 23 February 2024

EXPIRY DATE: 23 February 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

00003475MD

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	
Measuring Medical Device						
Blood storage / transportation product						
Non-Invasive		X	X	X		
Invasive Medical Device	< 60 min	X	X			
	>60 min & < 30 days	X	X		X	
	>30 days		X		X	
Inactive Medical Device		X	X	X	X	
Active Medical Device						
Contraceptive						
Combination Medical Device						
IVD						
4. HOLDER OF AN ADDITIONAL SAHPRA LICENCE					YES	NO
Licence to manufacture / distribute medical devices (as specified): 00000278_R1					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