

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



Licence number: 00002733MD

LICENCE TO DISTRIBUTE MEDICAL DEVICES

**In terms of section 22C(1)(b) of the Medicines and Related Substances Act, 1965
To act as a Distributor and Importer**

This licence is granted to:

Licence Holder
Prime Dental (Pty) Ltd
57 Douglas Avenue, Craighall
Randburg
Johannesburg
2196

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 its 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.

Digitally Signed by:
Boitumelo Semete-Makokotlela
Chief Executive Officer
53e72d92-3391-4cd7-8da3-b6116e65c520

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 17 March 2023

EXPIRY DATE: 17 March 2028

AMENDMENT DATE: N/A

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

[Licence to Distribute Medical Devices_v2]