

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



Licence number: 00004823MD

LICENCE TO MANUFACTURE MEDICAL DEVICES

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

This licence is granted to:

Licence Holder
Ngasolinye (Pty) Ltd
Plot 114, Road 2
Wheatlands, Randfontein
Gauteng
1759

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 4 pages.

This facility is authorised to perform the manufacturing activities listed in Annexure 1 to this licence.

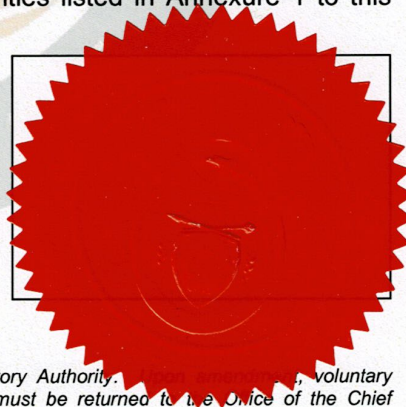
Bobumelo Semete-Makokotela

CHIEF EXECUTIVE OFFICER

ORIGINAL DATE OF ISSUE: 22 July 2025

EXPIRY DATE: 22 July 2030

AMENDMENT DATE: N/A



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