

# SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY



Licence number: 00001990MD\_v1

## 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 amended licence replaces the licence issued on the 15<sup>th</sup> of June 2021

This licence is granted to:

Licence Holder

**ICA International Chemicals (Pty) Ltd**  
ICA Administrative Building, Planken Street  
Plankenbrug Industrial, Stellenbosch  
7600

### 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.

Boitumelo Semete-Makokotela

**CHIEF EXECUTIVE OFFICER**

**ORIGINAL DATE OF ISSUE: 15 June 2021**

**EXPIRY DATE: 15 June 2026**

**AMENDMENT DATE: 19 April 2024**

*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.*