

LICENCE NUMBER:

DL01-708bbb

LICENCE TO MANUFACTURE, IMPORT OR EXPORT COMPLEMENTARY MEDICINES (CATEGORY D)

This licence is issued in terms of section 22C(1)(b) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), and regulation 23 of General Regulations made in terms of the same Act, to the Licence Holder indicated herein and licenses this party to manufacture, import or export Complementary medicines (Category D), inclusive of the activities stipulated herein.

Licence Holder

Address

Sastel Packaging CC 292 Burger st

Pretoria North, Pretoria, Gauteng 0116

LICENSED ACTIVITIES

Contract Manufacturing

Packaging

Secondary Packaging

Testing / Laboratory Analysis

Storage

Labelling

This licence consists of one page in addition to the letter of granting and the complete product list and is issued in terms of section 22C(1)(b) on the following conditions:

- 1. The licence holder and the persons described and named in this licence must:
 - a. at all times ensure that all Complementary Medicines (Category D) associated with this licence, irrespective of registration status, comply with the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended and the General Regulations made in terms of this Act;
 - b. be inspected at least once within a period of FIVE (5) years for verification of compliance with the minimum requirements as attested to; and
 - c. pay annual licence retention fees.
- 2. Verification of appropriate standards and certification thereof will only be undertaken after successful inspection of the
- 3. Only products listed or attached to this licence will be permitted association with this licence as Category D medicines and continued rights of sale, provided that an application is submitted for their registration by the prescribed deadlines of the applicable notice issued in terms of section 14 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).
- 4. This licence is issued to the licence holder based on SAHPRA's acceptance of the applicant's attestation of compliance with minimum requirements relevant to Category D medicines at the time of application and the payment of the required licence application and desktop evaluation fees.
- 5. This licence is not a confirmation of applicable GMP standards, unless presented together with a valid SAHPRA GMP certificate.

The validity and content of this licence as the appended product list may be verified at www.sahpracm.org.za - Registers - Category D Licences.

rela Senreja Makakaffeta

CHIEF EXECUTIVE OFFICER

DATE OF ISSUE:

01 February 2024

EXPIRY DATE:

31 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 ecutive Officer. Licence to manufacture, import or export Complementary Medicines (Category D)]