

South African Health Products Regulatory Authority



Licence number: 000000008MC – v1

LICENCE TO CULTIVATE CANNABIS FOR PURPOSES OF PRODUCING SCHEDULED SUBSTANCES

In terms of section 22C(1)(b) of the Medicines and Related Substances Act, 1965

This licence is granted to:

Licence Holder
Elpasso Farms (Pty) Ltd
Plot 471, Portion 43, Brandbach Cullinan, Gauteng 1000

On the following terms and conditions:

The licence holder and the persons described and named in Annexure 1 of the licence shall at all times ensure that the cultivation and control of cannabis cultivated for purposes of producing scheduled substances complies with relevant provisions of the Medicines and Related Substances Act, 1965, the regulations published in terms of the Act and all relevant SAHPRA Guidelines.

This facility is authorised to perform the cultivation of cannabis for producing scheduled substances as depicted in Annexure 1 to this licence.

DocuSigned by:

Boitumelo Semete-Makokotlala

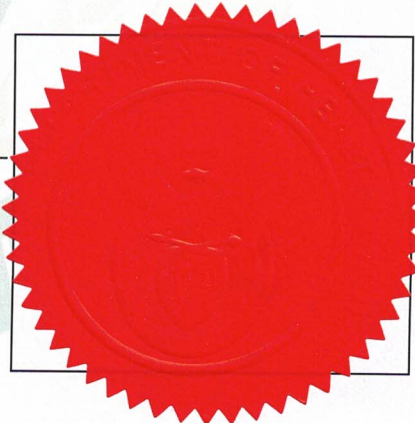
23 October 2020

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CHIEF EXECUTIVE OFFICER

ISSUE DATE: 16 October 2020

EXPIRY DATE: 16 October 2025



ANNEXURE 1

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AUTHORISED CULTIVATION OF CANNABIS FOR PRODUCING SCHEDULED SUBSTANCES
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1. CULTIVATION ACTIVITIES	YES	NO
Cloning / Seedling	YES	
Vegetation	YES	
Flowering	YES	
Harvesting	YES	
Other; specify		NO
2. PROCESSING ACTIVITIES		
Trimming	YES	
Drying	YES	
Packaging – (Bulk only)	YES	
Extraction (For Research Purposes)	YES	
Other; specify		NO
3. TESTING ACTIVITIES		
Analytical testing of cannabis cultivated by the licence holder	YES	
Microbiological testing of cannabis cultivated by the licence holder	YES	
Other Testing Activities: Physical inspection and testing	YES	
4. MATERIALS STORED AT THIS SITE		
Bulk storage of cannabis cultivated by the licence holder	YES	
Bulk cannabis seeds procured or produced by the licence holder	YES	
5. DISTRIBUTION ACTIVITIES		
Bulk distribution of cannabis material cultivated by the licence holder	YES	
6. IMPORT		NO
Specific Material		
7. EXPORT	YES	
Specific Material – Cannabis material cultivated by the licence holder		

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8. PARTICULARS OF THE PERSONNEL RESPONSIBLE FOR OPERATION ON THE PREMISES ON BEHALF OF THE LICENCE HOLDER

Responsible Pharmacist	Head of Production	Quality Control Person
Hendrina Cecilia van Niekerk	Kudzai Brylyne Chitsunge	Almight Maunanidze
B. Pharm, M.Sc. Pharmaceutics	Dr --	Dip. Agriculture

9. PARTICULARS OF THE NATURAL PERSON RESPONSIBLE TO THE MEDICINES CONTROL COUNCIL TO ENSURE COMPLIANCE WITH THE MEDICINES AND RELATED SUBSTANCES ACT, 1965

Responsible Person	Designation	Residential Address
Kudzai Brylyne Chitsunge	Owner	Plot 471, Portion 43, Brandbach Cullinan, Gauteng 1000
Dr --		

10. GENERAL LICENCE CONDITIONS

1. Section 22A(9)(i) and 22A(11)(a) permits shall be required to export any (-)-transdelta-9-tetrahydrocannabinol (THC) containing product that qualifies as Schedule 6; and
2. Cannabinoid-containing products for export for which a registration certificate has not been obtained from the SAHPRA may not be exported without the relevant "Certificate of a Pharmaceutical Product" or alternatively a "Licensing Status of a Pharmaceutical Product" issued by the SAHPRA in terms of the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce.

11. ADDITIONAL LICENCE SPECIFIC CONDITIONS

- The licence authorises cultivation of cannabis for producing scheduled substances.
- The licence prohibits further manipulation of the dry flower (e.g. extraction of cannabinoids) and subsequent production of finished product
- Must comply with cGACP (Good Agricultural and Collection Practice) principles;
- Waste material and rejected material must be destructed as per SAHPRA Guideline for Destruction of Schedule 6 material.
- Must ensure that there will be no critical changes to the site and cultivation area size prior to approval by SAHPRA;
- Must provide the required production reconciliation reports to SAHPRA on a quarterly basis; and
- Must submit the annual reconciliation report on the production yields to SAHPRA which contains the substance THC and CBD.

Enquiries: Jerry Molokwane
Tel: 012 501 0359
Reference: 0000000008MC – v1

The Responsible: Pharmacist/Person
Elpasso Farms
567 (54) LA Quinta Street
Silver Lakes Golf Estate
Pretoria
0081

Tel: 079 038 8786
Email: brylynec@yahoo.com

RE: NEW LICENCE TO CULTIVATE CANNABIS FOR PURPOSES OF PRODUCING SCHEDULED SUBSTANCES IN TERMS OF SECTION 22C (1)(b) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965.

Cultivation and Export Licence **0000000008MC – v1**

Your licence for **Cultivation and Export** in terms of section 22C (1)(b) of the Medicines and Related Substances Act has been approved and is attached herewith. This document replaces any licence document previously issued to you.

This licence authorizes **Cultivation and Export** by the licence holder named; if the business should change hands, the company or person taking over the business will have to obtain a new licence before commencing with **Cultivation and Export of cannabis for purposes of producing scheduled substances**.

This licence is subject to the limitations specified in the licence and to the statutory provisions contained in the Regulations to the Act.

Activities may only be carried out in accordance with the terms of the relevant product licence, unless a specified exemption applies which allows it to take place other than in accordance with the licence.

The licence relates to **Cultivation and Export of cannabis for purposes of producing scheduled substances** on the premises and under the supervision of the persons specified. If any change of premises or of those persons to take place, prior approval must be sought from Licensing Authority. Any proposal to make structural alterations to the premises must also be notified to the Licensing Authority.

The Licensing Authority has power to revoke licences in terms of section 22E should the inspection result in a negative SAHPRA resolution.

Yours faithfully



MANAGER: LICENSING

DATE:

20/10/2020