

# South African Health Products Regulatory Authority



Licence number: 0000000019MC – v2

## 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
<b>Farma Growers (Pty) Ltd</b>
Portion 1075 of Farm Haartebeespoort, C419JQ, District Brits, Brits, North West, 0250

### 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.

A handwritten signature in black ink, appearing to be 'S. S.', is located to the left of the date.

20/08/2022

CHIEF EXECUTIVE OFFICER

ORIGINAL ISSUE DATE: 30 November 2020  
RENEWAL DATE: N/A  
FIRST AMENDMENT DATE: 10 August 2022  
EXPIRY DATE: 30 November 2025



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



**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
Helena Johanna Voges	York Rose	Ananri Werner
MSc (Med) Pharm, B. Pharm	NQF-4 Agriseta	B. Pharm

**9. PARTICULARS OF THE NATURAL PERSON RESPONSIBLE TO THE SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY TO ENSURE COMPLIANCE WITH THE MEDICINES AND RELATED SUBSTANCES ACT, 1965**

Responsible Person	Designation	Residential Address
Helena Johanna Voges	Responsible Pharmacist	Portion 1075 of Farm Haartebeespoort, C419JQ, District Brits, Brits, North West, 0250
MSc (Med) Pharm, B. Pharm		

**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 destroyed 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.

**12. GENERAL LICENCE CONDITIONS**

- The site to comply with cGMP principles for cultivation activities;
- The cultivation area size is limited to the area inspected;
- This is limited to cultivation activities with the harvest material as the end product (no processing of the harvest material to produce finished or intermediate products is allowed);
- Farma Growers (Pty) Ltd must provide on a quarterly basis, the production reconciliation reports;
- Farma Growers (Pty) Ltd must submit the annual reconciliation report on the production yields which contains the substance Delta-9-THC and CBD;
- That any critical changes (Refer to S.A. Guideline Amendments) to the facility be approved by SAHPRA prior to implementation; and
- The licence is restricted to activities listed only; any additional activities must be approved by SAHPRA prior to implementation.

**SITE SPECIFIC CONDITIONS**

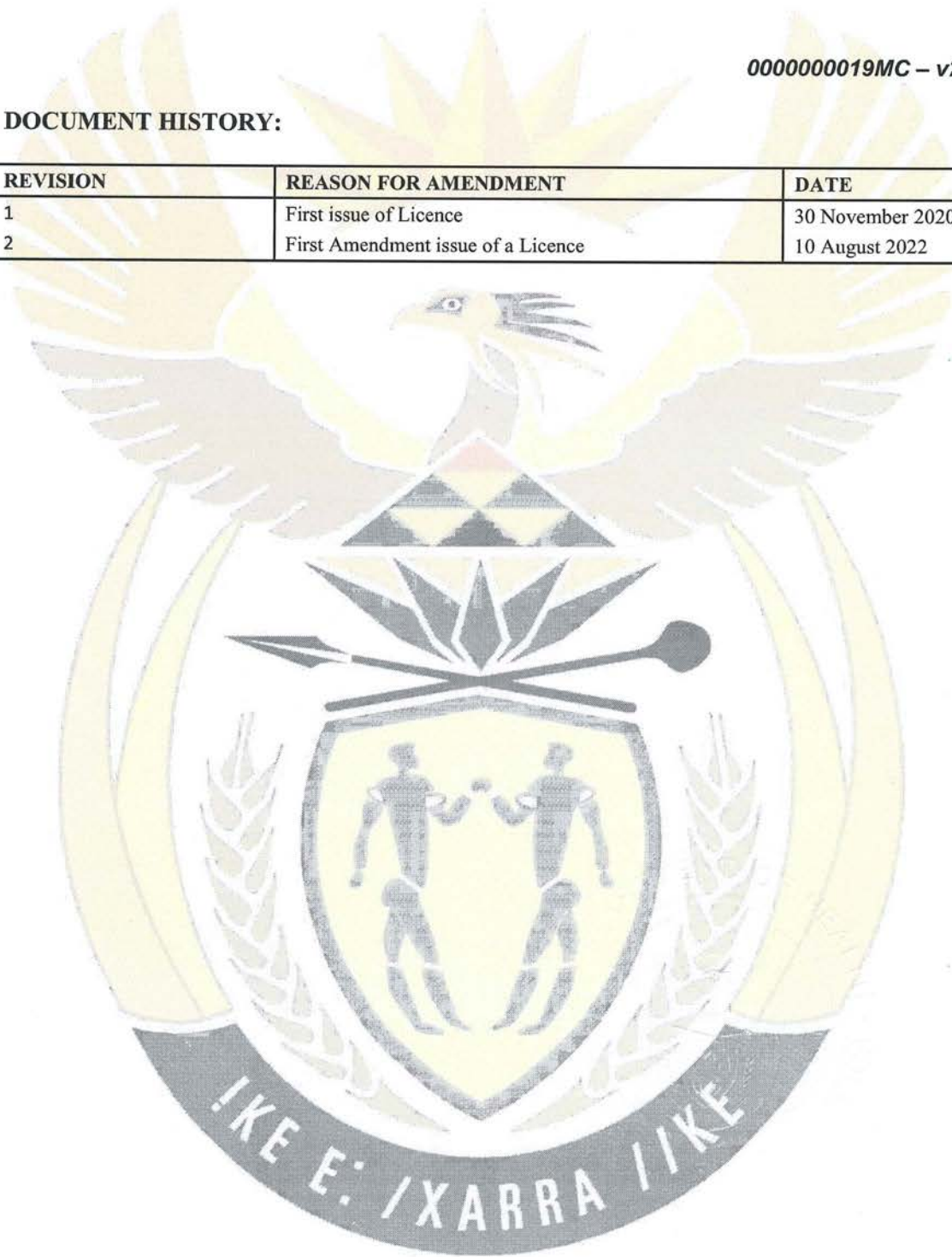
- The inspectors recommend that the Applicant be fully inspected as routine follow up within the next 3 years.
- Applicant to respond on the defined time commitments of outstanding deficiencies.
- Effective implementation of several corrective actions to be verified during the next inspection.



0000000019MC – v2

**DOCUMENT HISTORY:**

REVISION	REASON FOR AMENDMENT	DATE
1	First issue of Licence	30 November 2020
2	First Amendment issue of a Licence	10 August 2022



Enquiries: Jerry Molokwane  
Tel: 012 501 0359  
Reference: 000000019MC – v2

The Responsible Pharmacist  
**Farma Growers (Pty) Ltd**  
Portion 1075 of Farm Haartebeespoort, C419JQ  
District Brits  
Brits  
North West  
0250

Tel: 082 854 5110  
Email: [info@farmagrowers.co.za](mailto:info@farmagrowers.co.za)

**RE: LICENCE AMENDMENT 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 **000000019MC – v2**

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



**Khotso Bokaba**  
**ACTING MANAGER: LICENSING**

Date: 17/08/2022