Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



## **Release certificate**

Product:	Cannabis flos, variety Bedro		
Country:	to be sold on the pharmace		00/
Strength:	tetrahydrocannabinol: ca. 2. flowers		.070
Dosage form: Package size:	5 grams in container, 400 gr	rame in bage	
Batch:	22112EY22L07	ans in bays	
Order numbers:		33758	
order numbers.	bags: 383760		
Grower/drier:	Bedrocan Nederland B.V. P.O. Box 2009 NL- 9640 CA Veendam	harvest date/period: 12 September 2022	
Gamma	Synergy Health Ede B.V.	date:	dose:
irradiation:	Soevereinstraat 2	07 December 2022	≥ 10,0 kGy
in adiation.	NL-4879 NN Etten-Leur		_ 10/0 ((0))
Packager:	Fagron B.V.	date:	
-	Venkelbaan 101	24 January 2023 – 31 January 2023	
	NL-2908 KE Capelle a/d IJss	el	
Laboratory:	Laboratorium Ofichem B.V.	1. General analysis	
	Heembadweg 5	Analysis number: 3971	6
	NL-9561 CZ Ter Apel	Report date: 24 Octobe	
		2. Microbiology of end pr	
		Analysis number: 4185	
T	OMC Management Canaakia	Report date: 06 Februar	
Testing method:	ONC Monograph Cannadis	Flower / Version 8.0 / November	01, 2021
	Method	Specification	Result
Characters	Monograph	Odour characteristic for	conform
	0 1	Cannabis flower. Leaves	
		shoot out no more than	
		20% of the length of the	
		flower and stalks are	
		mostly cut off directly	
		under the bottom site of	
		the flowers	
Identification		D	
Macroscopic bota	<i>nical</i> Visual	Brown, green clustered flowers of about 1.5 to	conform
characters		3.0 cm length	comonn
Microscopic botai	nical Monograph	Gland hairs are mainly	conform
characters	nour wonograph	observed	comonn
Thin-layer chromat	ography Ph. Eur. (current ed		conform
,	2.2.27, Monograph	reference	

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All correspondence addressed to the postal address quoting date and NL-2515 XP THE HAGUE reference of this letter.

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Our reference 22I12EY22L07 Foreign material Visual Free from insects and conform other vermin Microbial contamination Ph. Eur. (current ed.) 2.6.12, 2.6.13 Total aerobic microbial ≤10<sup>2</sup> cfu/gram <10<sup>2</sup> cfu/gram count (TAMC) Total combined ≤10<sup>1</sup> cfu/gram <10<sup>1</sup> cfu/gram veasts/moulds count (TYMC) S. aureus, P. aeruginosa, bile-tolerant gram-Absent (1 gram) conform negative bacteria Aflatoxins Monograph Aflatoxin B1 ≤ 2 µg/kg  $< 2.0 \mu g/kg$ Sum of aflatoxins B1, B2,  $\leq 4 \mu g/kg$ < 4.0 µg/kg G1 and G2 Pesticides Ph. Eur. (current ed.) ≤ Limits Ph. Eur. 2.8.13\* conform 2.8.13 Heavy metals Ph. Eur. (current ed.) Lead 2.4.27, 2.2.58 max. 20.0 ppm < 5 ppm Cadmium max. 0.5 ppm < 0.125 ppm Mercury < 0.125 ppm max. 0.5 ppm Loss on drying Ph. Eur. (current ed.) ≤ 10.0 % 8.0 % 2.2.32 Assay (HPLC) Ph. Eur. (current ed.) Tetrahydrocannabinol 2.2.29, Monograph 22 % [17.6 - 26.4] 19.7 % (THC, total equivalent) Cannabidiol (CBD, total <1.0 % 0.1 % equivalent) Related substances (HPLC) Ph. Eur. (current ed.) Cannabinol (CBN, total 2.2.29, Monograph ≤ 1.0 % < 0.1 % equivalent) Content of container BMC-SWV 360 5 gram ± 5.15 gram Expiry date 31 Dec 2023

\*The following pesticides are not analysed: dithiocarbamates (expressed as CS2), methoxychlor, paraoxonmethyl and tetradifon. The limit of detection is increased for fenpropathrin to 0.1 mg/kg and azinphos-ethyl to 1 mg/kg.

I hereby certify that the above information is authentic and accurate. This batch of product has been cultivated and manufactured, including packaging and quality control at the above mentioned sites in full compliance with the GAP requirements as published in the Dutch State Gazette (Staatscourant) as the annex to the Regulation of the Minister of Health, Welfare and Sport of 9 January 2003, GMT/BMC 2340685, and with the specifications as stated in this document. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GAP and GMP.

The Hague, the Netherlands, 23 February 2023

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D.M.Mande Vada de Velde Head, Office of Medicinal Cannabis