Ministry of Health, Welfare and Sport

Office of Medicinal Cannabis



## **Release certificate**

Product:		variety Bedroca				
Country:		to be sold on the pharmaceutical market				
Strength:	tetrahydrocannabinol: ca. 22%			cannabidiol: < 1.0%		
Dosage form:	flowers					
Package size:	5 grams in container, 400 grams in bags					
Batch:	24F24EY24G17					
Order numbers:	containers: 386600 to 386608					
	bags: 38	6612				
Grower/drier:	Bedrocan Nederland B.V P.O. Box 2009		harvest date/period: 24 Jun. 2024			
	NL- 9640 CA Ve	10 CA Veendam				
Gamma	Synergy Health Ede B.V.		dat	e:	dose:	
irradiation:	Soevereinstraat 2 NL-4879 NN Etten-Leur		17	Jul. 2024	≥ 10,0 kGy	
Packager:	Packager: Fagron Nederland B.V.		date:			
	Venkelbaan 10	baan 101		02 Oct. 2024 to 16 Oct. 2024		
	NL-2908 KE Ca	pelle a/d IJssel				
Laboratory:	Laboratorium (	Ofichem B.V.	1.	General analysis		
	Heembadweg	5		Analysis number: 4973	2	
	NL-9561 CZ Te	r Apel		Report date: 22 Jul. 20	024	
			2.	Microbiology of end pr	oduct in container	
				Analysis number: 5091	3	
				Report date: 15 Oct. 20	)24	
Testing method:	OMC Monogra	ph Cannabis Flo	ower /	Version 8.0 / November	01, 2021	
	Method	k	Specif	ication	Result	
Characters	Monog	graph	Odou	r characteristic for	Conform	
				abis flower. Leaves		
			shoot	t out no more than		
			20% (	of the length of the		
			flowe	er and stalks are		
			most	ly cut off directly		
			unde	r the bottom site of		
			the fl	owers		
Identification					Conform	
Macroscopic bota	<i>nical</i> Visual			n, green clustered		
characters				owers of about 1.5 to		
			3.0 cr	n length		
Microscopic bota characters	nical Monog	graph	Gland	d hairs are mainly rved	Conform	
Thin-layer chromat	ography Ph. Fu	r. (current ed.)		Comparable with	Conform	
in a for on on on a		Monograph		reference		
	/					

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Internet address: www.minvws.nl www.cannabisbureau.nl e-mail: info@cannabisbureau.nl Ministry of Health, Welfare and Sport

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Our reference

24F24EY24G17 Foreign material Visual Free from insects and Conform other vermin Microbial contamination Ph. Eur. (current ed.) Total aerobic microbial 2.6.12, 2.6.13 ≤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 yeasts/moulds count (TYMC) S. aureus, P. aeruginosa, Absent (1 gram) Conform bile-tolerant gramnegative bacteria Aflatoxins Monograph  $< 2.0 \mu g/kg$ Aflatoxin B1  $\leq 2 \mu g/kg$ Sum of aflatoxins B1, B2, ≤ 4 µg/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 max. 0.5 ppm < 0.125 ppm Cadmium < 0.125 ppm Mercury max. 0.5 ppm Ph. Eur. (current ed.) ≤ 10.0 % 9.7 % Loss on drying 2.2.32 Assay (HPLC) Ph. Eur. (current ed.) 2.2.29, Monograph 22 % [17.6 - 26.4] Tetrahydrocannabinol 22.2 % (THC, total equivalent) Cannabidiol (CBD, total <1.0 % 0.1 % equivalent) Related substances (HPLC) Ph. Eur. (current ed.) ≤ 1.0 % < 0.1 % Cannabinol (CBN, total 2.2.29, Monograph equivalent) 5 gram Content of container BMC-SWV 455 ± 5.15 gram Expiry date 31 May 2025

\*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, 22 October 2024

Amorsch

K. Amponsah / M. Mennens QA, Office of Medicinal Cannabis