



AGENCY FOR MEDICINES AND MEDICAL DEVICES
Skopje

No. 18-695/3

Date: 04-02-2025

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) and 111(5) of Directive 2001/83/EC
The competent authority AGENCY FOR MEDICINES AND MEDICAL DEVICES OF THE REPUBLIC
OF NORTH MACEDONIA confirms the following

BUL- BILDING DOOEL STRUMICA
Company for production and trade

Site address and company Head quarter address: Str. Agroberza No. 32 Strumica, Republic of
North Macedonia

Has been inspected under the national inspection program in connection with manufacturing au-
thorization No.18-7176/4 dated 03.08.2021 year and No. 18-1131/2 од 27.03.2023 year in accord-
ance with 111(5) and 111(5) of Directive 2001/83/EC transposed in the national legislation Law on
medicines and medical devices (Official gazette of the RM No. 106/07,88/2010, 36/11, 53/11, 136/11,
11/12, 147/13, 27/14, 43/14, 88/15, 154/15, 228/15, 7/16, 53/16, 83/18, 113/18, 245/18 and Official ga-
zette of the RNM 28/21, 122/21) and Law on control of narcotic drugs and psychotropic substances
(Official gazette of the RM No.103/08, 124/10,164/13, 149/15, 37/16 and 193/17).

From the knowledge gained during inspection of this manufacturer, the latest of which was
conducted on 09-10.01.2025 it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice requirements laid down in
Directive 2003/94/EC

This certificate reflects the status of the manufacturing site at the time of the inspection noted
above and should not be relied upon to reflect the compliance status if more than three years have
elapsed since the date of that inspection, after which time the issuing authority should be consult-
ed.

This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity
of this certificate may be verified with the issuing authority.



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Part 2

ACTIVE SUBSTANCES

1. Manufacturing operations- Production of Cannabis extracts for medicinal use	
1.1	Extraction from dried Cannabis flower or another herbal part
	1.1.1 Extraction of a substance from a plant (extraction of dried cannabis flower and/or other parts of the plant)
	1.1.2 Production of crude and purified cannabis extract for medical purposes
1.2	Finishing steps
	1.2.1 Primary packaging
	1.2.2 Secondary packaging



Agency for medicines and medical devices
Director,
Sefedin JONUZI