AGENCY FOR MEDICINES AND MEDICAL DEVICES
Skopje

No. 18-7966/6
02 -11- 2021
Date: ----------. 2021

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 DOO- Strumica
Company for production and trade

Site address and company Head quarter address: Str. Agroberza No. 32 Strumica, Republic of North Macedonia
Quality control address: PHI Institut of Public Health of the Republic of North Macedonia, ul.50 Division No.6, Skopje

Has been inspected under the national inspection program in connection with manufacturing authorization 18-7176/4 од 03.08.2021 year in accordance 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 gazette 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 18.10.2021 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 consulted.
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.

Agency for medicines and medical devices Skopje
street St. Cyril and Methodius, no. 54, first floor
1000, Skopje, Republic of North Macedonia
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Part 2

ACTIVE SUBSTANCES

1. Manufacturing operations- Production of Cannabis extracts for medicinal use	
1.1	Extraction from dried Cannabis floss or another herbal part
1.2	Crude and purified extracts of cannabis for medicinal use packed in glass container of 500ml and 1000 ml
1.3	Finishing steps
	1.3.1 Primary packaging
	1.3.2 Secondary packaging
1.4	Quality control testing
	1.4.1 Chemical/Physical (Institut of Public health)
	1.4.2Microbiological: non-sterility (Institut of Public health)

Agency for medicines and medical devices
Director,
Mr.farm.spec Lirim Shabani

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