

Republic of North Macedonia
Agency for Drugs and Medical assets

/Seal/
Company for production and trade
BUL-BILDING DOO (LLC)
No. 03-472/1
04.08.2021 Strumica

The Agency for Drugs and Medical assets based on Article 32 paragraphs 5 of the Law on Control of Narcotic Drugs and Psychotropic Substances ("Official Gazette of RM" no. 103/08, 124/10, 164/13, 149/15, 37 / 16 and 193/17), acting upon the request No. 18-7176 / 1 dated 16.07.2021 of the Company for production and trade BUL - BILDING DOO Strumica for obtaining a license for production of cannabis extracts for medical purposes, issued :

DECISION

1. It is determined that the Company for production and trade BUL - BILDING LLC Strumica, with headquarters at ul. Agroberza no. 32 in Strumica meets the conditions regarding the space, equipment and staff for performing the activity of production of cannabis extracts for medical purposes in the form of raw (unrefined) and purified extract packed in glass bottles of 500 ml and 1000 ml, in the facility located at st.Agroberza No. 32 in Strumica, municipality of Strumica.
2. The Company for production and trade BUL - BILDING LLC Strumica, with headquarters on Agroberza street no. 32 in Strumica, is given a license for production of cannabis extracts for medical purposes, in the building located on st. Agroberza No. 32 in Strumica, municipality of Strumica with a validity period of five years from the date of adoption of this decision.
3. The Company for production and trade BUL - BUILDING LLC Strumica, with headquarters on Agroberza street no. 32 Strumica, is given a permit for the equipment and premises in the building located on Agroberza street no. production of cannabis extracts for medical purposes.

Explanation

The company for production and trade BUL - BUILDING LLC Strumica, with headquarters on Agroberza street no. 32 in Strumica and with EMBS 7285108 to the Agency for Drugs and Medical Devices submitted a request no. 18-7176 / 1 dated 16.07.2021 and supplemented on request no. 18-7176 / 2 dated 21.07.2021 for obtaining a license for production of cannabis extracts for medical purposes in the form of raw (untreated) and purified extract packed in glass bottles of 500 ml and 1000 ml, in the facility located at str. Agroberza No. 32 in Strumica, municipality of Strumica.

To the request submitted: proof of paid administrative costs, property list, notification for the correct address no. RSM, technical-technological report for the cannabis extract production facility (Site Master File), list of standard operating procedures for the technological process, list and documentation for the equipment in production, documentation for calibration and qualification of equipment, types of extracts that will be produced, agreement for performing services with PHI - Institute of Public Health of the Republic of Northern Macedonia no.0Z-140b / 1 from 02.07.2021, agreement for quality and performance of services with the University of St. Cyril and Methodius, Faculty of Pharmacy, Center for Natural Products in Skopje No. 14-279 / 1 from 15.06.2021, certificates for non-conviction of professionals, documents for employees responsible for production and placement on a series of



substances and plants in the lists of the international conventions for narcotic drugs and psychotropic substances in the category of narcotic drugs and psychotropic substances (" Official Gazette of the Republic of Macedonia "no. 112 / 09, 56/14 and 87/16), the Company for PRODUCTION and Trade BUL BILDING DOO Strumica, with headquarters at Agroberza No. 32 in Strumica, meets the requirements regarding the required space, equipment and staff for production of extracts from cannabis for medical purposes in the production premises and equipment in a facility located on st. Agroberza No. 32 in Strumica, municipality of Strumica.

Based on the above, a decision was made as in the enacting clause.

The fee for this decision was collected according to tariff number Z of the Law on Administrative Fees ("Official Gazette of RM", No. 7/9Z, 20/96, 7/98, 13/01 and 23/16).

INSTRUCTIONS FOR LEGAL ADVICE: An administrative dispute may be initiated against this decision before the Administrative Court in Skopje within 30 days from the day of receipt of this decision.

Resolved in the Agency for Drugs and Medical Devices no. 18-7176 / 4 dated 03.08.2021

Director
Mr. farm. Spec Lirim Shabani
/signature/

/Seal/

The Agency for Drugs and Medical assets
Skopje

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- Applicant
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Васко Андонов

I confirm that the translation is true to the
original.
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