

Republic of North Macedonia
Agency for Drugs and Medical assets

/Seal/
Company for production and trade
BUL-BILDING DOO (LLC)
No. 03-560/1
23.09.2021 Strumica

The Agency for Drugs and Medical assets based on Article 65 paragraph 5 line 4 and Article 69 paragraph 3 of the Law on Medicines and Medical assets ("Official Gazette of the Republic of Macedonia", No. 106/ 07, 88/10, 36/11, 53/11, 136/11 , 11/12, 147/13, 164/13, 27/14, 43/14, 88/15, 154/15 228/15, 7/16, 53/16, 83/18, 113/18, 245 / 18 and the Official Gazette of the Republic of Macedonia (§ 28/21), Article 31 paragraph 1, Article 32, Article 33 and Article 34 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), concerning Lists for the classification of substances and plants in the lists of international conventions on narcotic drugs and psychotropic substances in the category of narcotic drugs and psychotropic substances ("Official Gazette of RM" no. 112/09, 56/14, 87/16 and "Official Gazette of RM" 104/21), acting upon the request No. 18-7503 / 1 dated 26.07.2021 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 st. Agro exchange f. 32 in Strumica, meets the conditions regarding the space, equipment and staff for performing the activity of production and trade of active substance in herbal form - flower fruiting tops of the cannabis plant, in the production capacity located at the address of the same name.
2. The Company for production and trade BUL-BILDING LLC Strumica, with headquarters at st. Agro exchange f. 32 in Strumica is given approval for production and trade of active substance from item 1 of the enacting clause of this decision, with a validity period of five years from the day of adoption of this decision
3. The quality control (physical-chemical and microbiological examination) of the produced active substance from item 1 of the dispositive of this solution will be performed in the laboratory for testing and control of drugs in the Institute of Public Health of the Republic of Northern Macedonia.

Explanation

The company for production and trade BUL - BUILDING LLC Strumica, with headquarters on Agroberza street no. 32 in Strumica and with PIN 7285108 to the Agency for Drugs and Medical Devices submitted a request no. 18-7503 / 2 dated 26.07.2021 and supplement of the request no. 18-7503 / 2 dated 03.08.2021 for obtaining an approval for production and trade of active substance in herbal form - flower fruiting tops of the cannabis plant in the production capacity located at the eponymous address st. Agricultural Exchange no. 32 in Strumica



the lists of international conventions on narcotic drugs and psychotropic substances in the category of narcotic drugs and psychotropic substances. The company for production and trade BUL-BILDING DOO Strumica, meets the requirements regarding the required space. (1158 equipment and staff) responsible for production Tatjana Chatalova Petrovska B.Sc. Farm. Specialist in Pharmaceutical Technology, person responsible for quality control Mirela Ilic B.Sc. Farm. Specialist in drug testing and control and person responsible for placing a batch Ana Zafirovska Gapkovska B.Sc. Pharmacy Specialist in Pharmaceutical Technology) for production and trade of active substance in herbal form - flower fruiting tops of the cannabis plant in the building located on st. Agro exchange f. 32 in 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. 17/93, 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. 18-7503 / 4 dated 11.08.2021

Director
Mr. farm. Spec Lirim Shabani
/signature/

/Seal/

The Agency for Drugs and Medical assets
Skopje

Prepared by: J.A Shakjiri, advisor
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Submitted to:
- Applicant
Archive

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Потврдувам дека преводот е веродостоен на оригиналот.
Постојан Судски Преведувач во Основен Суд Струмица, Р.С. Македонија од македонски на англиски јазик.

Васко Андонов

I confirm that the translation is true to the original.
Official Judicial Translator under the Primary Court in Strumica, R.N Macedonia from Macedonian into English language.

Vasko Andonov

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