REPUBLIC OF MACEDONIA
AGENCY FOR MEDICINES AND MEDICAL DEVICES

MALMED
MACEDONIAN AGENCY FOR MEDICINES AND MEDICAL DEVICES

Certificate No: UP1 20-23

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(1) and article 111(5) of Directive 2001/83/EC

The competent authority AGENCY FOR MEDICINES AND MEDICAL DEVICES OF THE REPUBLIC OF MACEDONIA confirms the following:

The manufacturer **NYSK HOLDING DOO Skopje**
Company for manufacturing, trade and services

Site address: Bul. „Boris Trajkovski " 73, 1000 Skopje

Quality control address: PHI INSTITUT OF PUBLIC HEALTH of the Republic of Macedonia

Has been inspected under the national inspection programme in connection with manufacturing authorization and in accordance with Art.111 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) and Law on narcotic drugs and psychotropic substances (Official gazette of the RM No. 103/08, 124/10, 164/13, 149/15, 37/16 и 193/17).

From the knowledge gainedduring inspection of this manufacturer, the latest of which was conducted on 18.04.2018 it is considered thatit 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 all three parts: Parts 1, 2 and 3.
The authenticity of this certificate may be verified with the issuing authority.

REPUBLIC OF MACEDONIA
AGENCY FOR MEDICINES AND MEDICAL DEVICES

MALMED
MACEDONIAN AGENCY FOR MEDICINES AND MEDICAL DEVICES

Part 2

1.	**Manufacturing operations- Production of Cannabis extracts**

1.2	**Production of Cannabis extracts**
	1.2.1 Extraction of substance from plant source **(extraction from dried Cannabis floss or another herbal part)**

1.3	***General Finishing Steps***
	3.5.2 Primary packaging

1.4	***Quality control testing***
	3.6.1 Chemical/Physical
	3.6.2 Microbiological: non-sterility

Agency for medicines and medical devices
Director,
M-r ph. Robert Bekiroski

АГЕНЦИЈА ЗА ЛЕКОВИ И МЕДИЦИНСКИ СРЕДСТВА • СКОПЈЕ •

Certificate No: UP1 20-23
Date: 02 -05- 2018
Skopje