State Institute for Drug Control

CERTIFICATE NUMBER: ***sukls10800/2021***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1] [2]

Part 1

Issued following an inspection in accordance with :

The competent authority of Czechia confirms the following:
The manufacturer: ***E&H services a.s., CannabiLab***
Site address: ***Budova VÚHŽ, a.s., Dobrá 240, Dobrá, 739 51, Czechia***

Other
článek 40 Směrnice 2001/83/ES převedeným do národní legislativy jako: § 62 zákona č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů (zákon o léčivech), veznění pozdějších předpisů

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-02-16*** , it is considered that it complies with

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. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2.The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

1 MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical

2021-04-09

Name and signature of the authorised person of the Competent Authority of Czechia

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Confidential
State Institute for Drug Control
Tel:***Confidential***
Fax:***Confidential***

State Institute for Drug Control

CERTIFICATE NUMBER: ***sukls79417/2022***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1] [2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Czechia confirms the following:
The manufacturer: ***E&H Services a.s.***
Site address: ***Dobra 240, Dobra, 739 51, Czechia***
OMS Organisation Id. / OMS Location Id.: ***ORG-100023695*** / ***LOC-100032861***

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-07-29***, it is considered that it complies with:

- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/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. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2.The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Manufacture of active substance. Names of substances subject to inspection:
EXTRACT OF CANNABIS(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES Active Substance:EXTRACT OF CANNABIS	
3.2	**Extraction of Active Substance from Natural Sources**
	3.2.1 Extraction of substance from plant source 3.2.6 Purification of extracted substance Plant 3.2.7 Other: concentration adjustment of active substances
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Clarifying remarks (for public users)

CannabiLab Budova VÚHŽ, a.s

2022-10-10

Name and signature of the authorised person of the Competent Authority of Czechia

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Confidential
State Institute for Drug Control
Tel:***Confidential***
Fax:***Confidential***

State Institute for Drug Control

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

Human medicinal products

1. Authorisation Number	:	sukls132348/2022
2. Name of Authorisation Holder	:	E&H Services a.s. (ORG-100023695 / LOC-100056872)
3. Legally registered address of Authorisation Holder	:	Budejovicka 618/53, Krc, Prague, 140 00
4. Address(es) of Site(s)	:	Dobra 240, Dobra, 739 51, Czechia
5. Scope of authorisation (complete for each site under 4)	:	ANNEX 1
6. Legal basis of authorisation	:	Art. 77(1) of Directive 2001/83/EC
7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation	:	Confidential, Confidential
8. Signature	:	
9. Date	:	2022-08-03
10. Annexes attached	:	Annex 1 Scope of wholesale distribution authorisation Annex 2 (Optional) Address(es) of contract wholesale distribution sites and their authorisation number Annex 3 (Optional) Name(s) of responsible person(s) Annex 4 (Optional) Date of Inspection on which authorisation was granted Annex 5 (Optional) Additional provisions based on national requirements

ANNEX 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site: E&H Services a.s.
(ORG-100023695 / LOC-100032861)
, Dobra 240, Dobra, 739 51, Czechia

Human medicinal products

1. MEDICINAL PRODUCTS

1.1 with a Marketing Authorisation in EEA country(s)

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement
2.2 Holding
2.3 Supply
2.4 Export

*Art 5 of Directive 2001/83/EC or Art 83 of Regulation EC/726/2004
**Without prejudice to further authorisations as may be required according to national legislation