REPUBLIC OF BULGARIA
MINISTRY OF AGRICULTURE, FOOD AND FORESTRY
BULGARIAN FOOD SAFETY AGENCY

Certificate No 97/2019/GMP

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER
Part 1

Issued following an inspection in accordance with Art. 80(5) of Directive 2001/82/EC as amended

The competent authority of Republic of Bulgaria confirms the following:
The manufacturer: **OOO AleksAnn**
Site address: **13 Vinogradnaya Str., Dolgoprudniy, Moscow region 141700, Russia**
Has been inspected in connection with the procedure for issuing a Manufacturing Authorisation to **Bionox LTD** company, situated at the address: ap. 3, vh. A, 86, Alexander Dondukov-Korsakov blvd, 1504 Sofia, Bulgaria, in accordance with Art. 44 of Directive 2001/82/EC/, transposed in the national legislation by Art. 343 and 355 of the Veterinary Act, enforced on 2-nd May, 2006 and promulgated in the SG 87 on 1st November, 2005

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **17. 01. 2019**, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in 51 of Directive 2001/82/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 EudraGMP. If it does not appear, please contact the issuing authority.

Done in Sofia on 8th of March, 2019

Dr. DAMYAN ILIEV
EXECUTIVE DIRECTOR
Bulgarian Food Safety Agency
Ministry of Agriculture and Food
Sofia, Bulgaria

BULGARIAN FOOD SAFETY AGENCY

1 The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.
2 These requirements fulfil the GMP recommendations of WHO.

Part 2

☐ Human Medicinal Products
☒ Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up,packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to thecontrary.
- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;
- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form.

1.1	**Sterile products**
	1.1.1 Aseptically prepared 1.1.1.4 Small volume liquids *1.1.2 Terminally sterilized* 1.1.2.3 Small volume liquids *1.1.3 Batch certification*
1.2	**Non-sterile products**
	1.2.1 Non-sterile products 1.2.1.6 Liquids for internal use 1.2.1.11 Semi-solids *1.2.2 Batch certification*
1.4	**Other products or processing activity**
	1.4.1 Manufacture of: 1.4.1.2 Homoeopathic products
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility 1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of this certificate:
This certificate applies to veterinary medicinal products as specified in Manufacturing Authorisation N 37 of 08.03.2019 issued to Bionox LTD

Done in Sofia on 8th of March, 2019

Dr. DAMYAN ILIEV
EXECUTIVE DIRECTOR
Bulgarian Food Safety Agency
Ministry of Agriculture and Food
Sofia, Bulgaria

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