Ministry of Agriculture, Nature and Food Quality of the Netherlands

Certificate No: NL/V 19/0012

Medicines Evaluation Board - Veterinary Medicinal Products Unit

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

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

The competent authority of the Netherlands confirms the following:

The manufacturer : Eurofins Spinnovation Analytical B.V.

Site address : Kloosterstraat 9
5349 AB Oss

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. 3004-FI in accordance with art. 44 of Directive 2001/82/EC transposed in the following national legislation: Art. 2.19 of the Act Animals and art. 5.1 of the Decree on Veterinary Medicinal Products.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on May 31, 2018, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EEC.

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 en 2.
The authenticity of this certificate may be verified in EudraGMP. If it does not appear, please contact the issuing authority.

Issue date: 05-12-2019	Name: ir. F. Verheijen
Signature :	Page 1 of 2

MINISTRY OF AGRICULTURE, NATURE AND FOOD QUALITY
CHIEF VETERINARY OFFICER OF THE NETHERLANDS
THE HAGUE

Certificate No: NL/V 19/0012

Part 2

Veterinary Medicinal Products

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

2. IMPORTATION OF MEDICINAL PRODUCTS	
2.3	**Other importation activities**
	2.3.1. Site of physical importation

Any restrictions or clarifying remarks related to the scope of this certificate :

"The validity period of this certificate has been extended until December 31 2021. Due to the restraints of the Dutch Government related to the occurrence of the Corona-virus the initially planned inspection has been postponed. A novel inspection date will be set as soon as the restraints are lifted".

Competent Authority of the Netherlands.

THE MINISTER OF STATE FOR AGRICULTURE, NATURE and FOOD QUALITY,

per pro:

Utrecht, 05-12-2019

Dhr. Ir. F. Verheijen
Medicines Evaluation Board
Head of the Veterinary Medicinal Products Unit

Issue date: 05-12-2019	Name: ir. F. Verheijen
Signature :	Page 2 of 2

MINISTRY OF AGRICULTURE, NATURE AND FOOD QUALITY
THE HAGUE