Ministry of Agriculture, Nature and Food Quality of the Netherlands

Certificate No: NL/V/20/0001

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 PROXY Laboratories B.V.

Site address : Archimedesweg 25
2333 CM Leiden

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. 2767-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 30th of April and 1th of May 2019, 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.

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

Issue date: 11-02-2020	Name: ir. F. Verheijen
Signature :	

Certificate No: NL/V/20/0001

Part 2

Veterinary Medicinal Products

1. MANUFACTURING OPERATIONS	
1.6	**Quality control testing**
	1.6.1. Microbiological: sterility 1.6.2 Microbiological: non-sterility 1.6.3. Chemical/Physical 1.6.4. Biological
2. IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility 2.1.2 Microbiological: non-sterility 2.1.3 Chemical/Physical 2.1.4 Biological

Any restrictions or clarifying remarks related to the scope of this certificate *: **Import activities related to veterinary medicinal products have not taking place yet.**

Competent Authority of the Netherlands.

The Minister of Agriculture, Nature and Food Quality,

per pro:
Utrecht, 11-02-2020

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

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