

Certificate No: NL/V 24/0025

Medicines Evaluation Board - Veterinary Medicinal Products Unit

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 94 (1) of Regulation (EU) 2019/6.

The competent authority of **the Netherlands** confirms the following:

The manufacturer : **Prionics Lelystad B.V.**

Site address : **Platinastraat 33
8211 AR Lelystad**

Has been inspected under the national inspection program in connection with manufacturing authorization no. **2647-F** in accordance with art. 88 of Regulation (EU) 2019/6 transposed in the following national legislation: Art. 3.1 of the Decree on Veterinary Medicinal Products 2022.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2024/05/23**, 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 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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Part 2

Veterinary Medicinal Products

1. MANUFACTURING OPERATIONS - VETERINARY MEDICINAL PRODUCTS	
1.1	Sterile Products
	<i>1.1.3 Batch certification</i>
1.3	Biological medicinal products
	<i>1.3.2 Batch certification (list of product types)</i> 1.3.2.2 Immunological products 1.3.2.8 Other biological medicinal products < <i>in vivo diagnostics</i> >

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

Competent Authority of the Netherlands.

Ministry of Agriculture, Fisheries, Food Security and Nature,
per pro:

Utrecht, 25.9.2024



Dhr. Drs. P. Salomons
Medicines Evaluation Board
Head of the Veterinary Medicinal Products Unit



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