

Certificate No: NL/V 23/0016

**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 : Bodinco B.V.

Site address : Hazenkoog 35B  
1822BS Alkmaar

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. 1668-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 2023/07/12, 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 EudraGMP. If it does not appear, please contact the issuing authority.

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**Part 2**

**Veterinary Medicinal Products\***

<b>2. IMPORTATION OF VETERINARY MEDICINAL PRODUCTS*</b>	
<b>2.2</b>	<b>Batch certification of imported medicinal products</b>
	<i>2.2.1. Sterile Products</i>
	2.2.1.1 Aseptically prepared
<b>2.3</b>	<b>Other importation activities</b>
	<i>2.3.1 Site of physical importation</i>

Any restrictions or clarifying remarks related to the scope of this certificate: only for importation of REG NL 7831 Ovagen.

Competent Authority of the Netherlands.

Ministry of Agriculture, Nature and Food Quality,

per pro:

Utrecht, 07-11-2023



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

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