

Certificate No: NL/V 14/0029

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: INTOS

Site address

: De Groote Heeze 41

6598 AV Heijen

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. 2191-F 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 October 29, 2014, 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: 20-11-2014

Name: ir. F. Verheijen

Page 1 of 2



Certificate No: NL/V 14/0029

Part 2

Veterinary Medicinal Products

1. MANUFACTURING OPERATIONS		
1.1	Sterile Products N.A.	
1.2	Non-sterile products N.A.	
1.3	Biological medicinal products N.A.	
1.4	Other products or manufacturing activity N.A.	
1.5	Packaging	
	1.5.2 Secondary packing	
1.6	Quality control testing N.A.	

2. IMPORTATION OF MEDICINAL PRODUCTS*		
2.1	Quality control testing of imported medicinal products N.A.	
2.2	Batch certification of imported medicinal products N.A.	

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

The State secretary of Economic Affairs,

per pro:

Utrecht, 20-11-2014

Dhr. Jr. F. Verheijen

Head of the Veterinary Medicinal Products Unit

Issue date: 20-11-2014 Name: ir. F. Verheijen

Signature: Page 2 of 2

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