

Certificate of Analysis

Product: Porcilis PRRS 1x25ds 296
Batch: A213DD01

INTERVET INTERNATIONAL BV
Wim de Körverstraat 35
P.O. Box 31, 5830 AA BOXMEER
NETHERLANDS



Country: **Russian Fed.**

Sales Order Number: **1105644140 / 10**

Delivery Number: **1206980106 / 900004**

Material Number:
107081

Product Type: **Live Vaccines** Dosage per Container: **25 Doses**

Start date of Shelf Life: **05-Jan-2018** Expiry Date: **Jan-2019**

Storage Conditions:
2-8°C

CERTIFICATION BY THE MANUFACTURER

I herewith certify that the presented information is authentic and accurate. All measures have been taken to demonstrate compliance with Directive 2001/82/EC as amended. This batch has been manufactured /fabricated (incl. APIs and intermediates if applicable) including packaging and quality control, in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Name:

Function: **A. van Drunen**

Date:

Signature: **22 JAN 2018** 

Qualified Person

Certificate of Analysis

Product: *Porcilis PRRS 1x25ds 296*

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Final Batch Testing Finished Product



<u>Date on</u>	<u>Date off</u>	<u>Test Results</u>
01-Feb-2017	15-Feb-2017	<u>Sterility</u> Tested according to: Ph. Eur. 2.6.1 and 0062 Result: No growth Threshold: No growth Conclusion: Passed
19-Apr-2016	17-May-2016	<u>Mycoplasmas</u> Tested according to: Ph. Eur. 2.6.7 Result: No growth Threshold: No growth Conclusion: Passed
25-Jan-2017	01-Feb-2017	<u>Virus content (TCID50)</u> Result: 6.7 Log10/VL Threshold: ≥ 4.0 Log10/dose Conclusion: Passed
13-May-2016	27-May-2016	<u>Extraneous viruses using cells</u> Result: No extraneous agents detected Threshold: No extraneous agents detected Conclusion: Passed
19-Jan-2017	19-Jan-2017	<u>Residual moisture</u> Tested according to: Ph. Eur. 2.5.32. Result: 1 % Threshold: ≤ 5 % Conclusion: Passed