

# Certificate of Analysis

Product: **Porcilis PCV 1x100ds (200ml) 575**  
Batch: **B604A05**

Country: **Romania**  
Sales Order Number: **1112133890 / 10**  
Delivery Number: **1214815519 / 900004**



Material Number:  
**028857**  
Product Type: **Inactivated Vaccines** Dosage per Container: **100 Doses**  
Start date of Shelf Life: **18-Oct-2021** Expiry Date: **31-Oct-2024**  
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 Regulation (EU) 2019/6. 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: **H. van. Zijlen**  
Function:  
Date: **26 SEP 2022**  
Signature: **Qualified Person**



# Certificate of Analysis

Product: *Porcilis PCV 1x100ds (200ml) 575*  
Batch: **B604A05**

## Final Batch Testing Finished Product

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



<u>Date on</u>	<u>Date off</u>	<u>Test Results</u>
22-Oct-2021	12-Nov-2021	<b><u>Sterility</u></b> Tested according to: Ph. Eur. 2.6.1 and 0062 Result: No growth Threshold: No growth Conclusion: Passed
02-Feb-2022	03-Feb-2022	<b><u>Antigenic mass AlphaLISA</u></b> Result: 2495 AU/mL Threshold: $\geq 1860$ AU/mL Conclusion: Passed
		<b><u>Identity</u></b> Result: Identity conform Threshold: Identity conform Conclusion: Passed
29-Oct-2021	29-Oct-2021	<b><u>pH</u></b> Tested according to: Ph. Eur. 2.2.3 Result: 6.4 Threshold: $6.0 \leq X \leq 7.5$ Conclusion: Passed
08-Dec-2021	08-Dec-2021	<b><u>D,L alpha Tocopherol Acetate</u></b> Result: 12.4 mg/mL Threshold: $11.8 \leq X \leq 13.2$ mg/mL Conclusion: Passed
10-Nov-2021	10-Nov-2021	<b><u>Mineral oil assay</u></b> Result: 179 mg/mL Threshold: $155 \leq X \leq 191$ mg/mL Conclusion: Passed
19-Oct-2021	19-Oct-2021	<b><u>Appearance</u></b> Result: Conform Threshold: Conform Conclusion: Passed