

Certificate of Analysis

Product: **NOBIVAC PARVO-C, 10X1 D**
Batch: **A123A04**

Country: **Romania**
Sales Order Number: **1112269905 / 10**
Delivery Number: **1214959017 / 900003**

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



MSD
Animal Health

Material Number:
017240
Product Type: **Live Vaccines**
Dosage per Container: **1 Dose**
Start date of Shelf Life: **30-Sep-2022**
Expiry Date: **Sep-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: **D. de Crom**
Function: **18 OCT 2022**
Date: **18 OCT 2022**
Signature: **Qualified Person**

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Final Batch Testing Finished Product

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| <u>Date on</u> | <u>Date off</u> | <u>Test Results</u> |
|----------------|-----------------|---|
| 13-Apr-2022 | 27-Apr-2022 | <u>Sterility</u> Tested according to: Ph. Eur. 2.6.1 and 0062 Result: No growth Threshold: No growth Conclusion: Passed |
| 13-Apr-2022 | 28-Apr-2022 | <u>Mycoplasma</u> Tested according to: Ph. Eur. 2.6.7 Result: No live mycoplasma present Threshold: No live mycoplasma present Conclusion: Passed |
| 05-Apr-2022 | 15-Apr-2022 | <u>Virus content CPV (TCID50)</u> Result: 7.7 Log10/VL Threshold: 7.0 - 8.4 Log 10/dose Conclusion: Passed |
| 30-Mar-2022 | 13-Apr-2022 | <u>Extraneous viruses using cells</u> Tested according to: Ph. Eur. 0964 Result: No extraneous agents detected Threshold: No extraneous agents detected Conclusion: Passed |
| 08-Apr-2022 | 13-Apr-2022 | <u>Identity CPV</u> Result: Identity conform Threshold: Identity conform Conclusion: Passed |
| 30-Mar-2022 | 30-Mar-2022 | <u>Residual moisture</u> Tested according to: Ph. Eur. 2.5.32 Result: 1 % Threshold: ≤ 4 % Conclusion: Passed |