

Certificate of Analysis

Product: **Nobivac DP PLUS 5x1ds+5x1ds dil 443**
Batch: **A205A01**

Country: **Romania**
Sales Order Number: **1111562480 / 10**
Delivery Number: **1214407781 / 900001**



Material Number:
365973
Manufacturing Date/Start date of Shelf Life: **08-Jul-2022** Expiry Date: **Jul-2024**
Storage Conditions:
2-8°C

This Product consists of:

Compound Name: **Nobivac DP Plus 1ds 443** Compound Batch: **A205A01**
Compound Name: **Diluent Nobivac DP Plus 1ml 443** Compound Batch: **P130101**

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. Zuijlen**
Function: 
Date: **25 JUL 2022**
Signature: **Qualified Person**

Certificate of Analysis

Product: Nobivac DP PLUS 5x1ds+5x1ds dil 443
Batch: A205A01

Compound Name: **Nobivac DP Plus 1ds 443**

Compound Batch: **A205A01**

Country: **Romania**

Sales Order Number: **1111562480 / 10**

Delivery Number: **1214407781 / 900001**

Material Number:

368916

Product Type: **Dosage per Container**

Live Vaccines **1 Dose**

Start date of Shelf Life: **Expiry Date**

08-Jul-2022 **Jul-2024**

Storage Conditions:

2-8°C

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



Certificate of Analysis

Product: **Nobivac DP PLUS 5x1ds+5x1ds dil 443**
Batch: **A205A01**

Compound Name: **Nobivac DP Plus 1ds 443**

Compound Batch: **A205A01**

Final Batch Testing Finished Product

<u>Date on</u>	<u>Date off</u>	<u>Test Results</u>
<u>Sterility</u>		
01-Jun-2022	15-Jun-2022	Tested according to: Ph. Eur. 2.6.1 and 0062 Result: No growth Threshold: No growth Conclusion: Passed
<u>Mycoplasma</u>		
01-Jun-2022	15-Jun-2022	Result: No live mycoplasma present Threshold: No live mycoplasma present Conclusion: Passed
<u>Virus content CDV (TCID50)</u>		
16-May-2022	23-May-2022	Result: 5.6 Log10/dose Threshold: $5.4 \leq X \leq 6.5$ Log10/dose Conclusion: Passed
<u>Virus content CPV (TCID50)</u>		
10-Jun-2022	14-Jun-2022	Result: 6.2 Log10/dose Threshold: $5.1 \leq X \leq 6.7$ Log10/dose Conclusion: Passed
<u>Identity CDV</u>		
17-Jun-2022	17-Jun-2022	Result: Identity conform Threshold: Identity conform Conclusion: Passed
<u>Identity CPV</u>		
10-Jun-2022	15-Jun-2022	Result: Identity conform Threshold: Identity conform Conclusion: Passed
<u>Extraneous viruses using cells</u>		
01-Jun-2022	15-Jun-2022	Tested according to: Ph. Eur. 0964 Result: No extraneous agents detected Threshold: No extraneous agents detected Conclusion: Passed
<u>Residual moisture</u>		
01-Jun-2022	01-Jun-2022	Result: 1.3 % Threshold: $0.5 \leq X \leq 4.0$ % Conclusion: Passed

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

