

Certificate of Analysis

Product: **Nobivac Tricat Trio 10x1ds 720**
Batch: **A424E01**

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



Country: **Romania**
Sales Order Number: **1110955093 / 10**
Delivery Number: **1214624632 / 900003**

Material Number:
157286

Product Type: **Dosage per Container**
Live Vaccines **1 Dose**

Start date of Shelf Life: **Expiry Date:**
19-May-2022 **Feb-2025**

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: **M. de Klein**
Function:
Date: **26 AUG 2022**
Signature: **Qualified Person**

A handwritten signature in black ink, appearing to read "M. de Klein", with a horizontal line drawn underneath it.

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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>
05-May-2022	19-May-2022	<u>Sterility</u> Tested according to: Ph. Eur. 2.6.1 and 0062 Result: No growth Threshold: No growth Conclusion: Passed
23-May-2022	07-Jun-2022	<u>Mycoplasma</u> Tested according to: Ph. Eur. 2.6.7 Result: No live mycoplasma present Threshold: No live mycoplasma present Conclusion: Passed
20-May-2022	24-May-2022	<u>Virus content FPLV (TCID50)</u> Result: 5.3 Log10/VL Threshold: 4.3-6.4 Log 10/dose Conclusion: Passed
19-May-2022	23-May-2022	<u>Virus content FCV (PFU)</u> Result: 5.7 Log10/VL Threshold: 4.6-6.4 Log 10/dose Conclusion: Passed
19-May-2022	23-May-2022	<u>Virus content FRV (PFU)</u> Result: 6.2 Log10/VL Threshold: 5.9-7.0 Log 10/dose Conclusion: Passed
13-Jun-2022	27-Jun-2022	<u>Extraneous viruses using cells</u> Result: No extraneous agents detected Threshold: No extraneous agents detected Conclusion: Passed
		<u>Identity FRV</u> Result: Identity conform Threshold: Identity conform Conclusion: Passed
		<u>Identity FCV</u> Result: Identity conform Threshold: Identity conform Conclusion: Passed
03-Jun-2022	08-Jun-2022	<u>Identity FPL</u> Result: Identity conform Threshold: Identity conform Conclusion: Passed
11-May-2022	11-May-2022	<u>Residual moisture</u> Result: 1 % Threshold: ≤ 5 % Conclusion: Passed