Veterinary Medicines Directorate

Certificate No: VMDGMP/M186/2023

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Non-UK Manufacturer

Part 1

Issued following an inspection in accordance with Schedule 2 of the Veterinary Medicines Regulations 2013 as it has effect in Northern Ireland and Great Britain.

The competent authority of: UNITED KINGDOM (***Veterinary***) confirms the following:

The manufacturer: **Merck Animal Health (also known as Intervet Inc.)**

Site address: 375 South Lake Street
PO Box 775
Worthington
Minnesota MN56187
USA

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the United Kingdom in accordance with Good Manufacturing Practice (GMP).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **12th to 14th September**, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice as required by the Veterinary Medicines Regulations 2013.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified on GOV.UK. If it does not appear, please contact the issuing authority.

Signature: CONFIDENTIAL

Name: CONFIDENTIAL

Date: 7th December 2023

Veterinary Medicines Directorate
Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911
Search for VMD on GOV.UK

Part 2

Veterinary Medicinal Products

1.	**MANUFACTURING OPERATIONS**
1.1	Sterile Products: 1.1.1.2 Lyophilisates
1.2	Non-sterile products: N/A
1.3	Biological medicinal products: 1.3.1.2 Immunological products
1.4	Other products or manufacturing activity: 1.4.1.3 Active biological starting substances
1.5	Packaging: N/A
1.6	Quality Control testing: 1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of this certificate:

The manufacturing areas inspected and covered by this certificate are as follows:-

- Production (Bacterial and Viral Production, Building 1)
- Quality Control (Building 5)
- Warehousing (Buildings 23 and 24)

Dedicated domestic manufacturing areas such as rooms 102, 103, 105, 106, 109, 110, 112, 113, 115 and 116 in Building 1, and other manufacturing buildings are not covered by this certificate.

Name and signature of the authorised person of the Competent Authority of the UK:

CONFIDENTIAL

Signature: _____

Date: 7th December 2023

Name: CONFIDENTIAL