Veterinary Medicines Directorate

Certificate No: VMDGMP/M156/2022

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: **Syngene International Limited**

Site address: Plot No. 2 & 3, Bommasandra IV Phase
Jigani Link Road
Bangalore – 560 099
Karnataka
India

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 **26th to 30th September 2022**, 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 in EudraGMP or on GOV.UK. If it does not appear, please contact the issuing authority.

Signature: _____

Date: 21 December 2022

Name: CONFIDENTIAL

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: N/A
1.2	Non-sterile products: N/A
1.3	Biological medicinal products: N/A
1.4	Other products or manufacturing activity: 1.4.1 Manufacture of: 1.4.1.3 Other - *manufacture of biological / immunological active substance* 1.4.2 Sterilisation of active substances / excipients / finished product 1.4.2.1 Filtration
1.5	Packaging: N/A
1.6	Quality Control testing: 1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical 1.6.4 Biological

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

The scope of the inspection and thus this certificate is limited to the manufacture of a biological active substance (a monoclonal antibody) in the mammalian cell culture suite – bedinvetmab. However, this statement of GMP compliance is on the basis that only manufacture of mammalian cells or mammalian cell based products is performed in the facilities at the same time as bedinvetmab manufacture.

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

Signature: _____

Date: 21 December 2022

Name: CONFIDENTIAL