

Medicines and Healthcare products Regulatory Agency

Certificate No: UK WDA(H) 59766 Insp GDP 59766/37415707-0001

CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

Issued following an inspection in accordance with Regulation 331 (4) (b) of the Human Medicines Regulations 2012

The wholesale distributor : BIOSIMILARS NEWCO LIMITED

Site address : BIOSIMILARS NEWCO LIMITED, 52 GROSVENOR GARDENS, LONDON, SW1W 0AU, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with authorisation number UK WDA(H) 59766 Insp GDP 59766/37415707-0001 in accordance with regulation 18 of the Human Medicines Regulations 2012

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 17/09/2024, it is considered that it complies with the principles of good distribution practice requirements referred to in regulation C17 of the Human Medicines Regulations 2012

This certificate reflects the status of the premises at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of that inspection. However this period of validity may be reduced 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.

The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear please contact the issuing authority.

Any restrictions or clarifying remarks related to the scope of this certificate(For All Users):

In accordance with the MHRA risk based inspection procedures this site, which was the subject of a new wholesale distribution authorisation application, will be re-inspected within 24 months of the initial inspection. This certificate should not be relied upon to reflect the compliance status if more than 24 months have elapsed since the date of that initial inspection. This certificate is issued based on a remote inspection of GDP compliance as part of a risk-based site inspection programme.

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| 07/11/2024 | Name and signature of the authorised person of the Competent Authority of United Kingdom |
| | Confidential |
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