

Medicines and Healthcare products Regulatory Agency

Certificate No: UK WDA(H) 15720 Insp GDP 15720/19196149-0001

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 : RECORDATI RARE DISEASES UK LIMITED

Site address : RECORDATI RARE DISEASES UK LIMITED, ORIGIN, WESTERN ROAD, BRACKNELL, RG12 1US, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with authorisation number UK WDA(H) 15720 Insp GDP 15720/19196149-0001 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 13/06/2019, 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 the GDP certificate has been re-issued for this new site that is authorised for administrative functions only. The expiry date of the certificate is unchanged.

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| 18/02/2020 | Name and signature of the authorised person of the Competent Authority of United Kingdom |
| | Confidential |
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