Health And Youth Care Inspectorate

Certificate No: NL/G 23/2047644

CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

Issued following an inspection in accordance with Art. 111(1) of Directive 2001/83/EC

The competent authority of Nederland confirms the following:

The wholesale distributor (WDA): Orange Pharma B.V.

Site address: Danzigweg 16, Deventer, 7418 EN

OMS Identifiers: (ORG-100024217 / LOC-100056978)

Has been inspected under the national inspection programme in connection with authorisation number 2907 G in accordance with Art. 77 (1) of Directive 2001/83/ EC transposed in the following national legislation: Art. 100 van de Geneesmiddelenwet

Scope of certificate: Human medicinal products

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 2023-02-08, it is considered that it complies with the Good Distribution Practice requirements laid down in Article 84 of Directive 2001/83/EC.

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 the Union database. 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):

due to a technical problem, the WDA number mentioned on this GDP-Certificate is incorrect. This GDP-Certificate is created for WDA 3967 G.

Vanwege technische problemen binnen de EMA is het WDA nummer dat op dit GDP-certificaat staat vermeld incorrect. Dit GDP-certificaat is van toepassing op WDA 3967 G.

2023-06-12

Name and signature of the authorised person of the Competent Authority of Nederland

Certificate No: NL/G 23/2047644

Anouk Boersen Health And Youth Care Inspectorate

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Details of the authorisation can be found in the Union Database.