

Health And Youth Care Inspectorate

Certificate No: NL/G 22/2043601

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): Orly Pharma B.V.

Site address: Sint Jansweg 15, Venlo, 5928 RC

OMS Identifiers: (ORG-100024316 / LOC-100067014)

Has been inspected under the national inspection programme in connection with authorisation number 6559 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 2022-10-25, 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.

2023-11-02

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

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