



Health and Youth Care Inspectorate – Pharmaceutical Affairs

Certificate No: NL/G 19/2014133

CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

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

The competent authority of Netherlands confirms the following:

The wholesale distributor: Medcor Pharmaceuticals B.V.

Site address: Artemisweg 232, LELYSTAD, 8239DE, Netherlands

Has been inspected under the national inspection programme in connection with authorisation number 4545 G in accordance with Art. 77 (1) of Directive 2001/83/ EC transposed in the following national legislation: Art. 100 of the Medicines Act

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 2019-07-25, 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.

2019-10-16

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

Dr Florentine Baldee Nieuwmeyer
Health and Youth Care Inspectorate – Pharmaceutical
Affairs
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Details of the authorisation can be found in the [Union Database](#).



Health and Youth Care Inspectorate – Pharmaceutical Products

Certificate No: NL/G 20/2026738

CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

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

The competent authority of Netherlands confirms the following:

The wholesale distributor: Medcor Pharmaceuticals B.V.

Site address: Schutweg 23, LELYSTAD, 8243PC, Netherlands

Has been inspected under the national inspection programme in connection with authorisation number 4545 G in accordance with Art. 77 (1) of Directive 2001/83/ EC transposed in the following national legislation: Art. 100 of the Medicines Act

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 2020-12-11, 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):

This certificate has been created as a result of a change in the WDA (a GMP certificate has been created for a similar change in the MIA). This location will be inspected as part of our regular inspection program. For this change no on-site inspection has been carried out

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

This certificate has been created as a result of a change in the WDA (a GMP certificate has been created for a similar change in the MIA). This location will be inspected as part of our regular inspection program. For this change no on-site inspection has been carried out

2021-02-10

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

Mrs Meggy van Nuenen-Cox
Health and Youth Care Inspectorate – Pharmaceutical
Products
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Details of the authorisation can be found in the Union Database.