

Landesamt Fuer Soziales Jugend Und Versorgung

Certificate No: DE_RP_01_GDP_2025/3112-0192/250519

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 Germany confirms the following:

The wholesale distributor (WDA): phi Pharma International GmbH & Co. KG

Site address: Carl-Zeiss-Strasse 31, Hechtsheim, Mainz, Rhineland-Palatinate, 55129

OMS Identifiers: (ORG-100038309 / LOC-100060282)

Has been inspected under the national inspection programme in connection with authorisation number DE_RP_01_WDA_2025/3112-0192/250519 in accordance with Art. 77(1) of Directive 2001/83/EC transposed in the following national legislation: Sect. 52a German Medicinal Product Act (wholesale)

Scope of certificate: Human medicinal products

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 2025-01-15, 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):

Archiving is also performed in the 2th upper floor within the building Carl-Zeiss-Strasse 26, 55129 Mainz.

For further information concerning the wholesale distribution see authorisation no.
DE_RP_01_WDA_2025/3112-0192/250519.

2025-05-19

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

EudraGMDP

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Confidential

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