MEDICONZERT
Zertifizierung von
Qualitäts-Management-Systemen

DIN EN ISO 9001:2015 Qualitätsmanagement MEDICONZERT seit 2005 ZERTIFIZIERUNG

Hamburg, 12/20/2023

ZERTIFIKAT

CERTIFICATE OF CONFORMITY

We hereby certify, that

Cert.No. 226.1-R2

ANDENEX-CHEMIE ENGELHARD + PARTNER GMBH
in 22761 Hamburg, Albert-Einstein-Ring 11-13

has successfully established a

Quality-Management-System according DIN EN ISO 9001:2015

and keeps it working since 2010. All management-, distribution-, and storage-processes have been evaluated by a validated System Audit in Hamburg on 12/5/2023. This Certification has been approved by the Certification Council of MediConZert.

Scope:

Trade with Pharmaceutical Raw Materials

This Certification is valid until 12/19/2026 and will be validated once a year.

ANDENEX-CHEMIE is allowed to use the MediConZert sign for certified quality management systems in all their paperwork and documents as long as this certification is valid.

Dipl.- Kfm. Jens Wegner
Managing Director
IRCA Lead-Auditor

DIN EN ISO 9001:2015 MEDICONZERT ZERTIFIZIERT

MEDICONZERT
Zertifizierung von
Qualitäts-Management-Systemen

DIN EN ISO 9001:2015 Qualitätsmanagement MEDICONZERT seit 2005 ZERTIFIZIERUNG

ZERTIFIKAT

Hamburg, den 20.12.2023

Hiermit wird bescheinigt, daß die

Zert.Nr. 226.1-R2

ANDENEX-CHEMIE ENGELHARD + PARTNER GMBH

in 22761 Hamburg, Albert-Einstein-Ring 11-13

ein Qualitäts-Management-System nach DIN EN ISO 9001:2015

erfolgreich betreibt und in allen Handlungsabläufen wirksam anwendet. Dies wurde in einem System-Audit am 5.12.2023 festgestellt und in der Zertifizierungsprüfung der MediConZert bestätigt. Diese Zertifizierung umfasst folgenden Geltungsbereich:

Handel mit pharmazeutischen Rohstoffen und Wirkstoffen

Die Aufrechterhaltung der Zertifizierung wird durch die Zertifizierungsstelle im Rahmen externer Audits überwacht. ANDENEX-CHEMIE GMBH ist berechtigt, während der Gültigkeit dieses Zertifikates das MediConZert-Siegel für geprüfte QM-Systeme zu führen.

Dieses Zertifikat ist gültig bis zum 19.12.2026

DIN EN ISO 9001:2015 MEDICONZERT ZERTIFIZIERT

Dipl.- Kfm. Jens Wegner
Leiter der Zertifizierungsstelle
IRCA Lead-Auditor

MediConZert GmbH
- Zertifizierungsstelle für QM-Systeme gem. ISO 9001:2008 und 9001:2015
zugelassen für Scope 13, 29.1, 38.1 und 38.3
(Pharmazie, Humanmedizin und Handel)
- Konformitätsbewertungsstelle für normgebundene Systeme
Corthumstr. 2, D-21029 Hamburg

NORM-CHECK
Geprüft nach ISO 17021

Konformitätsbescheinigung

Hiermit wird bescheinigt, daß die

ANDENEX-CHEMIE ENGELHARD + PARTNER GMBH

in 22761 Hamburg, Albert-Einstein-Ring 11-13

die EU-Leitlinie 2015/C95/01 („GDP-Guideline")
für die Gute Vertriebspraxis für Wirkstoffe von Humanarzneimitteln
(beruhend auf Art. 47 Abs. 4 der Richtlinie 2001/83/EG)

umgesetzt hat und in allen Handlungsabläufen wirksam und angemessen anwendet. Dies wurde in einem Audit am 5.12.2023 festgestellt und durch die Zertifizierungsstelle validiert.

Diese Bestätigung umfasst besonders folgende Prozesse der ANDENEX-CHEMIE GmbH:

- ***Temperaturgesicherte und überwachte Lagerung von Wirkstoffen***
- ***Qualitätsmanagement und Qualitätsrisikomanagement***
- ***Transportmanagement***
- ***Abweichungskontrolle („Change Control")***
- ***Kontroll- und Verbesserungsmaßnahmen („CAPA")***

Diese Bescheinigung wird von der Zertifizierungsstelle jährlich durch ein Wiederholungsaudit überwacht und behält ihre Gültigkeit im Zusammenhang mit der ISO 9001:2015-Zertifizierung der ANDENEX-CHEMIE GmbH durch MediConZert.

Hamburg, den 20.12.2023

Dipl.- Kfm. Jens Wegner
Leiter der Zertifizierungsstelle
IRCA-Lead Auditor

GOOD DISTRIBUTION PRACTICE
QM-PRÜFUNGEN
MEDICONZERT
SEIT 2005
GDP-ZERTIFIZIERT

KBS-Nr. 226.1-R2-GDP

MediConZert GmbH
Certification Body for QM-systems acc. ISO 9001:2015
Scope 13, 29.1, 38.1 und 38.3
- Pharmacy, Human Medicine und Wholesale –
Corthumstr. 2, D-21029 Hamburg, Germany

NORM-CHECK
Geprüft nach ISO 17021

Certificate of Conformity

We hereby certify that

ANDENEX-CHEMIE ENGELHARD + PARTNER GMBH

in 22761 Hamburg, Albert-Einstein-Ring 11-13

runs successfully the

Good Distribution Practice
of active substances for medicinal products for human use

as per EU-Guideline 2015/C95/01
based on Art. 47, 4 of EU-Directive 2001/83/EG

All concerning management-, distribution-, and storage processes have been evaluated by a validated System Audit in Hamburg on Dec. 2, 2023. This Certification has been approved by the Certification Council of MediConZert.

This certification is valid for all services including the following procedures:

- ***Temperature monitored storage***
- ***Quality Management and Quality Risk Management***
- ***Transportation Management***
- ***Change Control***
- ***CAPA***

This certification is valid without expiry date and will be validated once a year in combination with the external control visits of the established Quality management System according ISO 9001.

Hamburg, December 20, 2023

Dipl.- Kfm. Jens Wegner
Managing Director
IRCA-Lead Auditor

GOOD DISTRIBUTION PRACTICE
QM-AUDITS
MEDICONZERT
SINCE 2005
GDP-CERTIFIED

Reg.Nr. 226.1-R2-GDP

Freie und Hansestadt Hamburg, Ministry of Health and Consumer Protection

Union Format for Registration of Manufacturer, Importer or Distributor of Active Substances to be used as Starting Materials in Medicinal Products for Human Use

1. Registration Number	:	DE_HH_01_Reg_2018_0065
2. Name or corporate name of registrant	:	Andenex - Chemie Engelhard + Partner GmbH
3. Permanent or legal address of registrant	:	Albert-Einstein-Ring 11, Hamburg, Hamburg, 22761, Germany
4. Address(es) of site(s) where registered activities take place	:	Albert-Einstein-Ring 11, Hamburg, Hamburg, 22761, Germany
5. National legal basis of registration	:	Sect. 64 (3g) of German Drug Law
6. Name of responsible officer of the competent authority of the member state validating the registration	:	Confidential
7. Signature	:	
8. Date	:	2018-10-18

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in the Union database or with the validating authority.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

EudraGMDP

SCOPE OF REGISTRATION

Name and address of the site: Andenex-Chemie Engelhard + Partner GmbH, Albert-Einstein-Ring 11, Hamburg, Hamburg, 22761, Germany

Any restrictions or clarifying remarks to the scope of these registered operations (for all users) : Registered activities comprise the import and the distribution of APIs. A list of relevant APIs is maintained by supervisory authority
Die registrierte Tätigkeit umfasst die Einfuhr bzw. den Handel mit Wirkstoffen. Um welche Wirkstoffe es sich handelt, ist der Behörde bekannt. Die Auflistung der Wirkstoffe unterbleibt.

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Behoerde Fuer Gesundheit Und Verbraucherschutz Der Freien Und Hansestadt Hamburg

Union Format for Registration of Manufacturer, Importer or Distributor of Active Substances to be used as Starting Materials in Human Active Substances and Veterinary Active Substances

1. Registration Number	:	DE_HH_01_Reg_2018_0065
2. Name or corporate name of registrant	:	Andenex-Chemie Engelhard + Partner GmbH (ORG-100020223/LOC-100028979)
3.Permanent or legal address of registrant	:	Albert-Einstein-Ring 11, Bahrenfeld, Hamburg, 22761, Germany
4. Address(es) of site(s) where registered activities take place	:	Albert-Einstein-Ring 11, Hamburg, Hamburg, 22761, Germany
5. National legal basis of registration	:	Sect. 64 (3g) of German Drug Law, Art. 95 (6) of Regulation (EU) 2019/6
6. Name of responsible officer of the competent authority of the member state validating the registration	:	Confidential
7. Signature	:	
8. Date	:	2023-04-13

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This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in the Union database or with the validating authority.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

SCOPE OF REGISTRATION

Name and address of the site: Andenex-Chemie Engelhard + Partner GmbH, (/), Albert-Einstein-Ring 11, Hamburg, Hamburg, 22761, Germany

Human Active Substances
Veterinary Active Substances

Any restrictions or clarifying remarks to the scope of these registered operations (for all users) :
Registered activities comprise the import and the distribution of APIs. A list of relevant APIs is maintained by supervisory authority
Die registrierte Tätigkeit umfasst die Einfuhr bzw. den Handel mit Wirkstoffen. Um welche Wirkstoffe es sich handelt, ist der Behörde bekannt. Die Auflistung der Wirkstoffe unterbleibt.

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Freie und Hansestadt Hamburg, Ministry of Justice and Consumer Protection

Certificate No: DE_HH_01_GDP/517-02.13/01,0091-1

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): Andenex - Chemie Engelhard + Partner GmbH

Site address: Albert-Einstein-Ring 11, Hamburg, Hamburg, 22761, Germany

Has been inspected under the national inspection programme in connection with authorisation number DE_HH_01_WDA/517-02.13/01,0091 in accordance with Art. 77(1) of Directive 2001/83/EC.

Scope of certificate:

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 2021-04-16, 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):

- see Annex 1 of the Wholesale Distribution Authorisation
- Distant Assessment

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

2021-06-04

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

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Confidential

Freie und Hansestadt Hamburg, Ministry of Justice and Consumer Protection

Confidential

Confidential

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

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Freie und Hansestadt Hamburg, Ministry of Health and Consumer Protection

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

1. Authorisation Number	:	DE_HH_01_WDA/517-02.13/01,0091
2. Name of Authorisation Holder	:	Andenex-Chemie Engelhard + Partner GmbH
3. Address(es) of Site(s)	:	Albert-Einstein-Ring 11, Hamburg, Hamburg, 22761, Germany
4. Legally registered address of Authorisation Holder	:	Albert-Einstein-Ring 11, Hamburg, Hamburg, 22761, Germany
5. Scope of authorisation (complete for each site under 4)	:	ANNEX 1
6. Legal basis of authorisation	:	Art. 77(1) of Directive 2001/83/EC
7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation	:	Confidential, Confidential
8. Signature	:	
9. Date	:	2018-12-21
10. Annexes attached	:	Annex 1 Scope of wholesale distribution authorisation Annex 2 (Optional) Address(es) of contract wholesale distribution sites and their authorisation number Annex 3 (Optional) Name(s) of responsible person(s) Annex 4 (Optional) Date of Inspection on which authorisation was granted Annex 5 (Optional) Additional provisions based on national requirements

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ANNEX 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site: Andenex - Chemie Engelhard + Partner GmbH
, Albert-Einstein-Ring 11, Hamburg, Hamburg, 22761, Germany

1. MEDICINAL PRODUCTS

1.2. without a Marketing Authorisation in the EEA and intended for EEA market
1.3. without a Marketing Authorisation in the EEA and intended for exportation

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1. Procurement
2.3. Supply
2.4. Export
2.5. Other activities(s): Holding is outsourced, see Annex 5 of the official documentLagerung bei einem beauftragten Betrieb, siehe Anlage 5 der Urkunde

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1.1. Narcotic or psychotropic products
3.3. Cold chain products(requiring low temperature handling)

Any restrictions or clarifying remarks (for all users): ref. 3.1.1: subject to authorisation according to section 3 German Narcotic Drug Law
zu 3.1.1: vorbehaltlich einer entsprechenden Erlaubnis nach § 3 Betäubungsmittelgesetz (BtMG)

*Art 5 of Directive 2001/83/EC or Art 83 of Regulation EC/726/2004
**Without prejudice to further authorisations as may be required according to national legislation

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