

Ministerie van Volksgezondheid Welzijn en Sport

UNION FORMAT FOR A WHOLESale DISTRIBUTION AUTHORISATION

Human medicinal products

1. Authorisation Number : 109574 G
2. Name of Authorisation Holder : Mosadex B.V.
(ORG-100053529 / LOC-100094612)
3. Address(es) of Site(s) : Nieuwenhuizenweg 19, Leiden, 2314 XP, Netherlands

Business Park Stein 192, Elsloo LK 5181 MA,
Netherlands
4. Legally registered address of Authorisation Holder : De Weegschaal 14, 'S-Hertogenbosch 5215 M
5. Scope of authorisation : ANNEX 1
6. Legal basis of authorisation : Art. 77(1) of Directive 2001/83
7. Name of responsible officer of the competent authority of the member state granting the wholesale distribution authorisation : Confidential, Confidential
8. Signature :
9. Date : 2016-07-21
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

ANNEX 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site: Mosadex B.V.
(ORG-100053529 / LOC-100094870)
, Nieuwenhuizenweg 19, Leiden, 2314 XP, Netherlands

Human medicinal products

<p>1. MEDICINAL PRODUCTS</p> <p>1.1. with a Marketing Authorisation or registration in EEA country(s) 1.2. without a Marketing Authorisation or registration in the EEA and intended for EEA market*</p>
<p>2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS</p> <p>2.1. Procurement 2.2. Holding 2.3. Supply</p>
<p>3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS</p> <p>3.1. Narcotic or psychotropic products** 3.2. Products requiring low temperature handling 3.2.1. Temperatures between 2 to 8 °C</p>

Name and address of the site: Mosadex B.V.
(ORG-100053529 / LOC-100094869)
, Business Park Stein 192, Elsloo Lb, 6181 MA, Netherland

Human medicinal products

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*Art. 5 of Directive 2001/83/EC, Art. 83 of Regulation (EC) 726/2004 and Art. 110 of Regulation 2019/6.

**Without prejudice to further authorisations as may be required according to national legislation.

EudraGMDP