Certified translation from German to English



Ministry of Labour, Social Affairs, Health and Women's Affairs

SAARLAND

Ministry of Labour, Social Affairs, Health and Women's Affairs

WHOLESALER LICENCE FOR MEDICINAL PRODUCTS

1. Licence/File number

DE_SL_01_GDP_2016_001; G5/2-5040 - ortscheit

2. Name of licence holder

Lucien Ortscheit GmbH

3. Registered address of licence holder

Stromstr. 6-8

66115 Saarbrücken

4. Address(es) of licence holder's business premises

See Annex 1

5. Licence scope (please indicate for each business premises listed in 4. above)

Wholesaler for medicinal products

6. Legal basis for granting the licence

§ 52 a, section 1 of the German Medicines Act (Arzneimittelgesetz - AMG), as amended

7. Name of person responsible at the respective authority in the member state granting the licence

Stefan Stein

8. Signature

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9. Date

Saarbrücken, 22 May 2018

[Stamp]

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ANNEX 1

Scope of licence

Name and address of business premises:
Stromstr. 6-8
66115 Saarbrücken
1. MEDICINAL PRODUCTS [X] Medicinal products for human use [X] Veterinary medicinal products 1.1 [X] with a licence to place on the market in a state of the European Economic Area 1.2 [X] without a licence to place on the market in a state of the European Economic Area (EEA) which are circulated in the EEA (exemption from mandatory authorisation)* 1.3 [X] without a permit to place on the market in a state of the European Economic Area (EEA) which are NOT circulated in the EEA (medicinal products for third countries)
2. AUTHORISED ACTIVITIES 2.1 [X] Procurement 2.2 [X] Storage 2.3 [X] Delivery (release) 2.4 [X] Export 2.5 [] Other activities:
3. MEDICINAL PRODUCTS WITH SPECIAL REQUIREMENTS 3.1 [X] Medicinal products in accordance with Art. 83 of Guideline 2001/83/EC¹ [X] Medicinal products in accordance with Art. 67 of Guideline 2001/82/EC 3.1.1 [] Narcotics or psychotropic substances 3.1.2 [X] Medicinal products derived from blood 3.1.3 [X] Immunological medicinal products 3.1.4 [] Radioactive medicinal products (including radionuclide kits) 3.2 [] Medical gases 3.3 [X] Cold-chain medicinal products (storage and transport at low temperatures) 3.4 [] Other activities:
Restrictions or clarifications concerning the licence scope (publicly accessible)
*Art. 5 of Guideline 2001/83/EC or Art. 83 of Directive 726/2004/EC



