

[Coat of Arms]

District Government Cologne

Wholesale Permit for Medicinal Products

1. Number of the permit/file number	DE_NW_04_WDA_2019_0068
2. Name of the permit holder	ToRa Pharmahandel GmbH
3. Registered address(es) of the permit holder	Landbaughstr. 20a 53842 Troisdorf
4. Address(es) of the business premises of the permit holder	Landbaughstr. 20a 53842 Troisdorf
5. Scope of the permit (Please indicate for each of the business premises listed under number 4)	Appendix 1
6. Legal basis of the permit	Article 52 a Section 1 of the law on trade in medicinal products (<i>Arzneimittelgesetz - AMG</i>) in the applicable version
7. Name of the person in charge of processing at the applicable authority of the member state issuing the permit	ORPhR'in Anna Schäferhoff
8. Signature	<i>[round stamp: District Government Cologne 144; Coat of arms Cologne] [handwritten signature]</i>
9. Date	05.04.2019

[Certified Translation from German]

10. Attached Appendices:

- | | |
|--|--|
| <input checked="" type="checkbox"/> Appendix 1 | Scope of the permit |
| <input type="checkbox"/> Appendix 2 | (Optional) Address(es) and number(s) of the permit of the business premises of the hired wholesalers |
| <input type="checkbox"/> Appendix 3 | (Optional) Name of the person(s) in charge |
| <input type="checkbox"/> Appendix 4 | (Optional) Date of inspection on the basis of which the permit was granted |
| <input type="checkbox"/> Appendix 5 | (Optional) Further regulations based on the national legislation |

APPENDIX 1

SCOPE OF THE PERMIT

Name and address of the business premises:

ToRa Pharmahandel GmbH

Landbaughstr. 20a

53842 Troisdorf

1. MEDICINAL PRODUCTS

Medicinal products for human use Veterinary medicinal products

1.1 with the permit to place on the market in a state of the European Economic Area

1.2 without the permit to place on the market in a state of the European Economic Area (EEA) that are placed on the market in the EEA (exemption from the obligation of registration)*

1.3 without permission to place on the market in a state of the European Economic Area that are NOT placed on the market in the EEA (medicinal products for third countries)

2. PERMITTED ACTIVITIES

2.1 Acquisition

2.2 Storage

2.3 Distribution (sale)

2.4 Export

2.5 Other activities: (please state)

3. MEDICINAL PRODUCTS WITH SPECIFIC REQUIREMENTS

3.1 Medicinal products equating to article 83 of the directive 2001/83/EG¹

Medicinal products equating to article 67 of the directive 2001/82/EG

3.1.1 anaesthetics or psychotropic substances

3.1.2 medicinal products made from blood

3.1.3 immunological medicinal products

3.1.4 radioactive medicinal products (including radionuclide kits)

3.2 [] Medical gases

3.3 [X] Medicinal products requiring a temperature-controlled supply chain (storage and transport at low temperatures)

3.4 [] Other activities: (please state or refer to attachment 5)

Restrictions or clarifications concerning the scope of the permit (publicly accessible)

None.

*article 5 of the directive 2001/83/EG or article 83 of the regulation 726/2004/EG

¹Irrespective of further permits based on the national legislation

*[round stamp:
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Source: 151107_F01_01

Stamp/signature

This is to certify that the above is a correct and complete translation from German into English made on the grounds of the copy presented.

Rostock, 26 April 2019

Dr. Thomas R. Seeliger
Generally sworn and publicly appointed interpreter for English & French
at the Rostock Regional Court

[Certified Translation from German]

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Restrictions or clarifications concerning the scope of the permit (publicly accessible)

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*article 5 of the directive 2001/83/EG or article 83 of the regulation 726/2004/EG

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