Baden-Württemberg

THE GOVERNMENT OF THE DISTRICT OF TÜBINGEN
PHARMACOVIGILANCE COORDINATING OFFICE

MANUFACTURING-IMPORTATION AUTHORISATION

1. Authorisation number/reference number	DE_BW_01_MIA_2023_0059/DE_BW_01_PharmaKorell
2. Name of the holder of the authorisation	PharmaKorell GmbH (LOC-100047338
3. Address(es) of the manufacturer's / importer's place(s) of operation	PharmaKorell GmbH (LOC-100047338 Georges-Köhler-Str. 2 79539 Lörrach
4. Registered address of the holder of the authorisation	Georges-Köhler-Str. 2 79539 Lörrach
5. Scope of the authorisation and dosage forms	ATTACHMENT 1 and ATTACHMENT 2
6. Legal basis of the grant of the authorisation	Article 13 section 1 German Medicines Law (AMG) Article 72 section 1 German Medicines Law (AMG) Article 61 sections 1 to 3 of Regulation EU No. 536/2014 in connection with Article 13 section 5 German Medicines Law (AMG) Article 61 sections 1 to 3 of Regulation EU No. 536/2014 in connection with Article 72 section 2a German Medicines Law (AMG)
7. Name of the responsible officer of the responsible authority of the Member State granting the authorisation	
8. Signature	(Signature, Stamp of the Government of the District of Tübingen)
9. Date	27/06/2023
10. Attachments	Attachment 1 and Attachment 2 Attachment 4 (address(es) of contracting test centres) Attachment 8 (list of products covered by the manufacturing/ importation authorisation)

Office building Konrad-Adenauer-Str. 20 · 72072 Tübingen · Telephone 07071 757-0 · Telefax 07071 757-3190

This is to certify that the above translation is a true and complete translation of an original Manufacturing-Importation Authorisation issued in German language by the Government of the District of Tübingen for the company PharmaKorell GmbH (Page 1 of 8).
Schönau, 17-07-2023
Ferdinand Kiefer, Dipl.-Übersetzer, sworn translator

Baden-Württemberg
THE GOVERNMENT OF THE DISTRICT OF TÜBINGEN
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Attachment 8 (List of the products covered by the manufacturing/importation authority)

(Stamp of the Government of the District of Tübingen)

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Attachment 1

SCOPE OF THE AUTHORISATION
Name and address of the place of operation:
PharmaKorell GmbH, Georges-Köhler-Str. 2, 79539 Lörrach

Medicinal products for human use

PERMITTED ACTIVITIES
Manufacturing activities (according to part 1)
Importation of medicinal products (according to part 2)

Part 1 – MANUFACTURING ACTIVITIES	
1.1	**Sterile products**
	1.1.3 Batch release
1.2	**Non-sterile products**
	1.2.2 Batch release
1.3	**Biological medicinal products**
	1.3.2 Batch release
	1.3.2.5 Biotechnological products
1.5	**Packaging**
	1.5.1 Primary packaging
	1.5.1.17 Other non-sterile products Restricted to manual primary packing (also in the framework of sampling) of small quantities in case of non-sterile, solid dosage forms and non-sterile active pharmaceutical ingredients

Restrictions or clarifications regarding the manufacturing activities

Included is the storage of medicinal products, investigational medicinal products and active pharmaceutical ingredients requiring a license in Niedermattenstr. 6, 79238 Ehrenkirchen according to the plans submitted to the authority.

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Part 2 – IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch release of imported medicinal products**
	2.2.1 Sterile products
	2.2.1.1 Aseptically manufactured
	2.2.1.2 Sterilised in the final container
	2.2.2 Non-sterile products
	2.2.3 Biological medicinal products
	2.2.3.1 Blood products Other preparations originating from foreign blood (Preparation with human coagulation factor X)
	2.2.3.5 Biotechnological products
2.3	**Other importation activities**
	2.3.1 Place of operation of physical importation
	2.3.4 Other Importation of gentamicin sulfate Ph. Eur. (Active pharmaceutical ingredient of microbiological origin)

Restrictions or clarifications regarding the importation activities

Included is the storage of medicinal products, investigational medicinal products and active pharmaceutical ingredients requiring a license in Niedermattenstr. 6, 79238 Ehrenkirchen according to the plans submitted to the authority.

Re 2.3.1: Refers to the storage locations in Lörrach and Ehrenkirchen

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Schönau, 17-07-2023

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THE GOVERNMENT OF THE DISTRICT OF TÜBINGEN
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Attachment 2

SCOPE OF THE AUTHORISATION
Name and address of the place of operation:
PharmaKorell GmbH, Georges-Köhler-Str. 2, 79539 Lörrach

Investigational medicinal products for human use

PERMITTED ACTIVITIES
Manufacturing activities (according to part 1)
Importation of investigational medicinal products (according to part 2)

Part 1 – MANUFACTURING ACTIVITIES	
1.1	**Sterile products**
	1.1.3 Batch release
1.2	**Non-sterile products**
	1.2.2 Batch release
1.3	**Biological medicinal products**
	1.3.2 Batch release
	1.3.2.2 Immunological products
	1.3.2.5 Biotechnological products
1.5	**Packaging**
	1.5.1 Primary packaging
	1.5.1.15 Other non-sterile products Restricted to manual primary packing (also in the framework of sampling) of small quantities in case of non-sterile, solid dosage forms and non-sterile active pharmaceutical ingredients
	1.5.2 Secondary packaging

Limitations or clarifications regarding the manufacturing activities

Re 1.5.2: Secondary packaging is limited to the (re-)labelling of small batches.

External permanent establishments according to Article 14 (4) no. 2 German Medicinal Products Act (AMG): Test centres may be used for the purpose of changing the expiration date of clinical investigational preparations. PharmaKorell provides the Pharmacovigilance Coordinating Office with an up-to-date list of the test centres used.

Included is the storage of medicinal products, investigational medicinal products and active pharmaceutical ingredients requiring a license in Niedermattenstr. 6, 79238 Ehrenkirchen according to the plans submitted to the authority.

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Part 2 – IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS	
2.2	**Batch release of imported investigational medicinal products**
	2.2.1 Sterile products
	2.2.1.1 Aseptically manufactured
	2.2.1.2 Sterilised in the final container
	2.2.2 Non-sterile products
	2.2.3 Biological medicinal products
	2.2.3.2 Immunological products
2.3	**Other importation activities**
	2.3.1 Place of operation of physical importation

Limitations or clarifications regarding the importation activities

External permanent establishments according to Article 14 (4) no. 2 German Medicinal Products Act (AMG): Test centres may be used for the purpose of changing the expiration date of clinical investigational preparations. PharmaKorell provides the Pharmacovigilance Coordinating Office with an up-to-date list of the test centres used.

Included is the storage of medicinal products, investigational medicinal products and active pharmaceutical ingredients requiring a license in Niedermattenstr. 6, 79238 Ehrenkirchen according to the plans submitted to the authority.

Re 2.3.1: Refers to the storage locations in Lörrach and Ehrenkirchen

Included is the physical importation and storage of the active substance [redacted] for the storage location in Lörrach.

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Schönau, Schönau, 17-07-2023
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Attachment 4

Address(es) of contracting test centres	Untersuchungsinstitut Heppeler Marie-Curie-Strasse 7 79539 Lörrach - Chemical/physical tests - Microbiological tests (non-sterile products) Labor LS SE & Co. KG Mangelsfeld 4, 5, 6 97708 Bad Bocklet-Großenbrach - Microbiological tests (sterile and non-sterile products) - Endotoxin test

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PHARMACOVIGILANCE COORDINATING OFFICE

Attachment 8

List of the products covered by the manufacturing/importation authority (in accordance with sections 41 and 42 of the Directive 2001/83/EC or sections 89 and 90 of the Regulation (EU) 2019/6), respectively.

Re item 2.2.3.1:
Coagadex 250 I.U. Powder and solvent intended for the manufacture of an injection solution
Re item 2.2.3.1:
Coagadex 500 I.U. Powder and solvent intended for the manufacture of an injection solution

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