Baden-Württemberg
REGIERUNGSPRÄSIDIUM TÜBINGEN
LEITSTELLE ARZNEIMITTELÜBERWACHUNG

MANUFACTURING-IMPORTATION AUTHORISATION

1.	Authorisation number/reference number	DE_BW_01_MIA_2024_0070/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 Georges-Köhler-Str. 2 79539 Lörrach (LOC-100047338)
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	Paragraph 13 section 1 German Medicines Law (AMG) Paragraph 72 section 1 German Medicines Law (AMG) Article 61 sections 1 to 3 of Regulation EU No. 536/2014 in connection with Paragraph 13 section 5 German Medicines Law (AMG) Article 61 sections 1 to 3 of Regulation EU No. 536/2014 in connection with Paragraph 72 section 2a German Medicines Law (AMG)
7.	Name of the responsible officer of the responsible authority of the Member State granting the authorisation	[redacted]
8.	Signature	Under the authority of the Regional Council Tübingen REGIERUNGSPRÄSIDIUM TÜBINGEN (Signature)
9.	Date	10/07/2024
10.	Attachments	Attachment 1 and Attachment 2 Attachment 4 (address(es) of contracting test centres)

This is to certify that the above translation is a true and complete translation of an original Manufacturing-Importation Authorisation issued in German language for the company PharmaKorell GmbH
Schönau, 24/07/2024
Ferdinand Kiefer, Dipl.-Übersetzer, sworn translator

FERDINAND KIEFER Dipl.-Übersetzer

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Attachment 8 (list of products covered
by the manufacturing/ importation authorisation)

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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 Others Restricted to the manual primary packaging (also in the framework of sampling) of small quantities in case of non-sterile solid dosage forms and non-sterile active ingredients.

Restrictions or clarifications regarding the manufacturing activities

Included is the storage of medicinal products, investigational medicinal products and active ingredients which are subject to authorisation at Niedermattenstr. 6, 79238 Ehrenkirchen in accordance with 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 humane coagulation factor)
	2.2.3.5 Biotechnological products
2.3	**Other importation activities**
	2.2.1 Operating site of physical importation
	2.3.4 Others Importation of gentamicin sulphate Ph. Eur. (active ingredient of microbiological origin)

Restrictions or clarifications regarding the importation activities

Included is the storage of medicinal products, investigational medicinal products and active ingredients which are subject to authorisation at Niedermattenstr. 6, 79238 Ehrenkirchen in accordance with the plans submitted to the authority.

Re 2.3.1 Refers to the storage sites in Lörrach and Ehrenkirchen

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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 Others Restricted to the manual primary packaging (also in the framework of sampling) of small quantities in case of non-sterile solid dosage forms and non-sterile active ingredients.
	1.5.2 Secondary packaging

Restrictions or clarifications regarding the manufacturing activities

Re 1.5.2: Secondary packaging is restricted to the (re)labelling of small lots

External sites in accordance with § 14 (4) No. 2 AMG: Test centres can be used to change the expiry date of clin. investigational medicinal products. PharmaKorell provides the Control centre of Pharmacovigilance with a current list of the trial sites/test centres used.

Included is the storage of medicinal products, investigational medicinal products and active substances which are subject to authorisation at Niedermattenstr. 6, 79238 Ehrenkirchen in accordance with 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 Operation site of physical importation

Restrictions or clarifications regarding the importation activities

External sites in accordance with § 14 (4) No. 2 AMG: Test centres can be used to change the expiry date of clin. investigational medicinal products. PharmaKorell provides the Control centre of Pharmacovigilance with a current list of the trial sites/test centres used.

Included is the storage of medicinal products, investigational medicinal products and active substances which are subject to authorisation at Niedermattenstr. 6, 79238 Ehrenkirchen in accordance with the plans submitted to the authority.

Re 2.3.1: Refers to the storage facilities in Lörrach and Ehrenkirchen.

Included is the physical importation and storage of biotechnologically manufactured active substances for investigational medicinal products at the Lörrach operation site.

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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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