

MANUFACTURING-IMPORTATION AUTHORISATION

1. Authorisation number/reference number DE_BY_04_MIA_2024_0013/ROB-53Ph-2677.Ph_2-467
2. Name of the holder of the authorisation PharmaKorell GmbH
(LOC-100076822)
3. Address(es) of the manufacturer's / importer's place(s) of operation PharmaKorell GmbH
Schleißheimer Straße 373
80935 München
(LOC-100076822)
4. Registered address of the holder of the authorisation Schleißheimer Straße 373
80935 München
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
9. Date 21/02/2024
10. Attachments Attachment 1 and Attachment 2
Attachment 4 (address(es) of contracting test centres)
Attachment 5 (names of the expert persons)
Attachment 8 (list of products covered by the manufacturing/importation authorisation)

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, 04/03/2024

Ferdinand Kiefer, Dipl.-Übersetzer, sworn translator



SCOPE OF THE AUTHORISATION

Name and address of the place of operation:
PharmaKorell GmbH, Schleißheimer Straße 373, 80935 München/Munich

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

Restrictions or clarifications regarding the manufacturing activities

Batch release also includes the release of intermediate products

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Part 2 – IMPORTATION OF MEDICINAL PRODUCTS	
2.2	Batch release of imported medicinal products
	2.2.1 <i>Sterile products</i>
	2.2.1.1 Aseptically manufactured
	2.2.1.2 Sterilised in the final container
	2.2.2 <i>Non-sterile products</i>
	2.2.3 <i>Biological medicinal products</i>
	2.2.3.1 Blood products Other preparations originating from foreign blood
	2.2.3.5 Biotechnological products

Restrictions or clarifications regarding the importation activities

Place of operation of physical importation is ParmaKorell GmbH, Georges-Köhler-Str. 2, 79539 Lörrach

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SCOPE OF THE AUTHORISATION

Name and address of the place of operation:
PharmaKorell GmbH, Schleißheimer Straße 373, 80935 München/Munich

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
	1.3.2.5 Biotechnological products

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Part 2 – IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS	
2.2	Batch release of imported investigational medicinal products
	2.2.1 <i>Sterile products</i>
	2.2.1.1 Aseptically manufactured
	2.2.1.2 Sterilised in the final container
	2.2.2 <i>Non-sterile products</i>
	2.2.3 <i>Biological medicinal products</i>
	2.2.3.5 Biotechnological products

Restrictions or clarifications regarding the importation activities

Place of operation of physical importation is ParmaKorell GmbH, Georges-Köhler-Str. 2, 79539 Lörrach

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Attachment 4

Address(es) of contracting test centres

Untersuchungsinstitut Heppeler
Marie-Curie-Strasse 7
79539 Lörrach
Chemical/physical /microbiological (non-sterile)

Labor LS SE & Co. KG
Mangelsfeld 4, 5, 6
97708 Bad Bocklet-Großenbrach
Microbiological (sterile and non-sterile)/
Endotoxin test

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