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

8. Signature

Entry d) Company number 9e) Detect of business, domestic

a) General regulation of represent2tix002/2024

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business address, branches
16). Attasos of the enterprise

b) Owners, general partners, managing difectors, was a fide Attachment 2

managers Attalogrished 4 (address(es) of contracting test centres)
representatives and special power
of representation
Attachment 8 (list of products covered by the manufacturing/

importation authorisation) Dr. Tymister, Ulrike, Essen, *19-09-1962

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*21-04-1964

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Ferdinand Kiefer, Dipl.-Übersetzer, sworn translator



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Other legal relation Limited partners, m

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Attachment 1

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

Entry number

- d) Company
- Place of business, domestic e)
- business address, branches Purpose of the enterprise

2 1

representation

Owners, general partners, managing directors, board of managers, authorised

representatives and special power of representation

a) General regulation of

Dr. Tymister, Ulrike, Essen, *19-09-1962

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Legal form, beginni articles of associat

Other legal relation

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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	
		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

Entry Company number Place of business, domestic

23

business address, branches Purpose of the enterprise

1 2

a) General regulation of representation b) Owners, general partners,

managing directors, board of managers, authorised representatives and special power

of representation

Dr. Tymister, Ulrike, Essen, *19-09-1962

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Attachment 2

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		

Entry number

1

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- d) Company Place of business, domestic
- business address, branches
- Purpose of the enterprise

a) General regulation of representation Owners, general partners, managing directors, board of managers, authorised representatives and special power of representation

Dr. Tymister, Ulrike, Essen, *19-09-1962

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d) Legal form, beginning and articles of association

Other legal relationships

Limited partners, members

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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				
		2.2.3.5 Biotechnological products				

Restrictions or clarifications regarding the importation activities

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

Entry number	d) Company e) Place of business, domestic business address, branches f) Purpose of the enterprise	a) General regulation of representation b) Owners, general partners, managing directors, board of managers, authorised representatives and special power of representation	Proxy	d) Legal form, beginning and articles of association e) Other legal relationships f) Limited partners, members
1	2	3	4	5
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Address(es) of contracting test centres

Attachment 4

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

Entry number

- d) Company
 e) Place of business, domestic business address, branches
- Purpose of the enterprise

a) General regulation of representation

b) Owners, general partners, managing directors, board of managers, authorised representatives and special power of representation

Proxy

- Legal form, beginning and articles of association Other legal relationships
- Limited partners, members

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