

MANUFACTURER / IMPORTER AUTHORISATION

(This English translation is for reference only. It is not part of the official certificate.)

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| 1. Authorisation number/file number | DE_BY_04_MIA_2026_0020/ROB-53Ph-2677.Ph_2-467 |
| 2. Name of authorisation holder | PharmaKorell GmbH
(LOC-100076822) |
| 3. Address(es) of manufacturing site(s) | PharmaKorell GmbH
Schleißheimer Straße 373
80935 München
(LOC-100076822) |
| 4. Legally registered address of authorisation holder | Schleißheimer Straße 373
80935 München |
| 5. Scope of authorisation and dosage forms | ANNEX 1 and ANNEX 2 |
| 6. Legal basis of authorisation | Sect 13 para 1 Arzneimittelgesetz (German Drug Law)
Sect 72 para 1 Arzneimittelgesetz (German Drug Law)
Art. 61 para 1 to 3 of Regulation (EU) No. 536/2014 in conjunction with Sect 13 para 5 AMG
Art. 61 para 1 to 3 of Regulation (EU) No. 536/2014 in conjunction with Sect 72 para 2a AMG |
| 7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation |  |
| 8. Signature | |
| 9. Date | 27/03/2026 |
| 10. Annexes attached | Annex 1 and Annex 2
Annex 4 (Addresses of Contract Laboratories)
Annex 5 (Name of Qualified Person) |

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

PharmaKorell GmbH, Schleißheimer Straße 373, 80935 München

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Importation of Medicinal Products (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

1.1	Sterile Products
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	<i>1.1.3 Batch certification</i>
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1.2	Non-sterile products
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	<i>1.2.2 Batch certification</i>
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1.3	Biological medicinal products
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	<i>1.3.2 Batch certification</i>
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	1.3.2.5 Biotechnology products
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Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

Batch release also includes the release of intermediate products.

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.2	Batch certification of imported medicinal products
	<i>2.2.1 Sterile products</i>
	2.2.1.1 Aseptically prepared
	2.2.1.2 Terminally sterilised
	<i>2.2.2 Non-sterile products</i>
	<i>2.2.3 Biological products</i>
	2.2.3.5 Biotechnology products

Any restrictions or clarifying remarks related to the scope of these Importation operations

Physical import facility is PharmaKorell GmbH, Georges-Köhler-Str. 2, 79539 Lörrach.

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

PharmaKorell GmbH, Schleißheimer Straße 373, 80935 München

Investigational Medicinal Products for Human Use

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Importation of Investigational Medicinal Products (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

1.1	Sterile Products
	<i>1.1.3 Batch certification</i>
1.2	Non-sterile products
	<i>1.2.2 Batch certification</i>
1.3	Biological medicinal products
	<i>1.3.2 Batch certification</i>
	1.3.2.2 Immunological products
	1.3.2.5 Biotechnology products

Part 2 - IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS	
2.2	Batch certification of imported investigational medicinal products
	<i>2.2.1 Sterile products</i>
	2.2.1.1 Aseptically prepared
	2.2.1.2 Terminally sterilised
	<i>2.2.2 Non-sterile products</i>
	<i>2.2.3 Biological products</i>
	2.2.3.2 Immunological products
	2.2.3.5 Biotechnology products

Any restrictions or clarifying remarks related to the scope of these Importation operations

Physical import facility is PharmaKorell GmbH, Georges-Köhler-Str. 2, 79539 Lörrach.

Address(es) of Contract Laboratories

Untersuchungsinstitut Heppeler GmbH
Marie-Curie-Str. 7
79539 Lörrach
Chemical/Physical/Microbiological (non steril)

Labor LS SE & Co. KG
Mangelsfeld 4, 5, 6
97708 Bad Bocklet-Großenbrach
Microbiological (steril and non steril)/endotoxin testing