Manufacturer/Importer Authorisation [1, 2]

1. Authorisation Number	DE_BW_01_MIA_2026_0028
2. Name of authorisation holder	PharmaKorell GmbH (ORG-100016018 / LOC-100047338)
2.1. Alternative name of authorisation holder	
3. Address(es) of manufacturing site(s)	PharmaKorell GmbH (ORG-100016018 / LOC-100047338), Georges-Koehler-Strasse 2, Loerrach, Baden-Wuerttemberg, 79539, Germany
3.a Additional details on units inspected of manufacturing site(s) address(es)	
4. Legally registered address of authorisation holder	Georges Koehler Strasse 2, Loerrach, 79539, Germany
4.a Additional details on units inspected of legally registered address	
5. Scope of authorisation and dosage forms[2]	ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation	Art. 40 of Directive 2001/83/EC Art. 61 of Regulation (EU) No 536/2014
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2026-04-24
10. Annexes attached	Annex 1 and/or Annex 2 Optional Annexes as required: Annex 3(Addresses of Contract Manufacturing Site(s)) Annex 4(Addresses of Contract laboratories) Annex 5(Name of Qualified Person) Annex 6(Name of responsible persons) Annex 7(Date of inspection on which authorisation granted, scope of last inspection) Annex 8(Manufactured/ imported products authorised)[3]

[1]*The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC as amended and Article 88(1) of Regulation (EU) 2019/6, shall also be required for imports coming from third countries into a Member State.*

[2]*Guidance on the interpretation of this template can be found in the Interpretation of the Union format for Manufacturer/Importer Authorisation.*

[3]*The Competent Authority is responsible for the appropriate linking of the authorisation with the manufacturer's application (Article 42(3) of Directive 2001/83/EC as amended and Article 90(3) of Regulation (EU) 2019/6).*

SCOPE OF AUTHORISATION ANNEX 1

Name and address of the site: PharmaKorell GmbH, Georges-Koehler-Strasse 2, Loerrach, Baden-Wuerttemberg, 79539, Germany

Additional Details:

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**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.2 Batch Certification (list of product types) 1.3.2.5 Biotechnology products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.17 Other non-sterile medicinal products: Limited to manual primary packaging (also within the context of sampling) of small amounts of non-sterile, solid dosage forms and non-sterile active ingredients(en)
	1.5.2 Secondary packaging

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

ad 1.5.2: manual secondary packaging only This includes the storage of pharmaceuticals,

investigational medicinal products and active ingredients that require authorization at Niedermattenstr. 6, 79238 Ehrenkirchen according to the plans submitted to the authorities.

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products
	2.2.3 Biological medicinal products 2.2.3.1 Blood products 2.2.3.5 Biotechnology products
2.3	**Other importation activities**
	2.3.1 Site of physical importation *2.3.4 Other: Importation of Gentamicin-Sulphate (API of microbiological origin)(en)*

Any restrictions or clarifying remarks related to the scope of these Importation operations (for Public users)

This includes the storage of pharmaceuticals, investigational medicinal products and active ingredients that require authorization at Niedermattenstr. 6, 79238 Ehrenkirchen according to the plans submitted to the authorities. ad 2.3.1: Refers to the storage sites in Lörrach and Ehrenkirchen

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : PharmaKorell GmbH, Georges-Koehler-Strasse 2, Loerrach, Baden-Wuerttemberg, 79539, Germany

Additional Details:

Human Investigational 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**
	1.1.3 Batch certification
1.2	**Non-sterile investigational medicinal products**
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.2 Batch Certification (list of product types) 1.3.2.2 Immunological products 1.3.2.5 Biotechnology products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.15 Other non-sterile medicinal products: Limited to manual primary packaging (also within the context of sampling) of small amounts of non-sterile, solid dosage forms and non-sterile active ingredients.(en)
	1.5.2 Secondary packaging

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

ad 1.5.2: Secondary packing is restricted to (re-)labelling of small batches. This includes the storage of pharmaceuticals, investigational medicinal products and active ingredients that require authorization at Niedermattenstr. 6, 79238 Ehrenkirchen according to the plans submitted to the authorities.

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared

	2.2.1.2 Terminally sterilised
	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 Site of physical importation

Any restrictions or clarifying remarks related to the scope of these Importation operations (for Public users)

This includes the storage of pharmaceuticals, investigational medicinal products and active ingredients that require authorization at Niedermattenstr. 6, 79238 Ehrenkirchen according to the plans submitted to the authorities. ad 2.3.1: Refers to the storage sites in Lörrach and Ehrenkirchen Includes the physical import and storage of biotechnologically manufactured active ingredients for investigational medicinal products at the Lörrach site.