MANUFACTURING-IMPORTATION AUTHORISATION

1. Authorisation number/reference number	DE_BY_04_MIA_2023_0029/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	15/03/2023
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, 27/03/2023
Ferdinand Kiefer, Dipl.-Übersetzer, sworn translator

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

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, 27/03/2023
Ferdinand Kiefer, Dipl.-Übersetzer, sworn translator

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
	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

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, 27/03/2023
Ferdinand Kiefer, Dipl.-Übersetzer, sworn translator

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

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, 27/03/2023
Ferdinand Kiefer, Dipl.-Übersetzer, sworn translator

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

Restrictions or clarifications regarding the importation activities

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

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, 27/03/2023
Ferdinand Kiefer, Dipl.-Übersetzer, sworn translator

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

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, 27/03/2023
Ferdinand Kiefer, Dipl.-Übersetzer, sworn translator