MANUFACTURER'S AUTHORISATION [1, 2]

1. Authorisation Number	DE_RP_01_MIA_2023_0004
2. Name of authorisation holder	Mikle-Pharm GmbH (ORG-100008670 / LOC-100016628)
3. Address(es) of manufacturing site(s)	Mikle-Pharm GmbH (ORG-100008670 / LOC-100016628), Sandgasse 17, Queichheim, Landau In Der Pfalz, Rhineland-Palatinate, 76829, Germany
3.a Additional details on units inspected of manufacturing site(s) address(es)	
4. Legally registered address of authorisation holder	Sandgasse 17, Queichheim, Landau In Der Pfalz, Rhineland-Palatinate, 76829, 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	2023-02-27
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 and 44(1) of Directive 2001/82/EC, as amended, 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 Help menu of EudraGMDP database.*

[3]*The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).*

SCOPE OF AUTHORISATION — ANNEX 1

Name and address of the site: Mikle-Pharm GmbH, Sandgasse 17, Queichheim, Landau In Der Pfalz, Rhineland-Palatinate, 76829, 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

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

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : Mikle-Pharm GmbH, Sandgasse 17, Queichheim, Landau In Der Pfalz, Rhineland-Palatinate, 76829, Germany

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 products**
	1.2.2 Batch certification

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