MANUFACTURER / IMPORTER AUTHORISATION

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

1. Authorisation number/file number	DE_NW_05_MIA_2025_0005/24.05.03-142
2. Name of authorisation holder	Diapharm GmbH & Co.KG (LOC-100074110)
3. Address(es) of manufacturing site(s)	Diapharm GmbH & Co.KG Am Mittelhafen 56 48155 Münster (LOC-100074110)
4. Legally registered address of authorisation holder	Am Mittelhafen 56 48155 Münster
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	Dr. Petra Rempe
8. Signature	On behalf
9. Date	17/03/2025

10. Annexes attached	Annex 1 and Annex 2 Annex 5 (Name of Qualified Person)

SCOPE OF AUTHORISATION **Annex 1**

Name and address of the site:
Diapharm GmbH & Co.KG, Am Mittelhafen 56, 48155 Münster

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**
	1.3.2 Batch certification
	1.3.2.4 Gene therapy products
	1.3.2.5 Biotechnology products
	1.3.2.8 Other active viral vaccine, DNA vaccine, inactivated vaccine, recombinant antibodies

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 products
	2.2.3.2 Immunological products
	2.2.3.5 Biotechnology products
	2.2.3.8 Other active viral vaccine, DNA vaccine, inactivated vaccine, recombinant antibodies

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

Site of physical importation:

SK Pharma Logistics GmbH
Remusweg 8
33729 Bielefeld

SCOPE OF AUTHORISATION **Annex 2**

Name and address of the site:
Diapharm GmbH & Co.KG, Am Mittelhafen 56, 48155 Münster

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**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.3	**Biological medicinal products**
	1.3.2 Batch certification
	1.3.2.4 Gene therapy products
	1.3.2.5 Biotechnology products
	1.3.2.8 Other active viral vaccine, DNA vaccine, inactivated vaccine, recombinant antibodies

Part 2 - IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS	
2.2	**Batch certification of imported investigational 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 products
	2.2.3.8 Other active viral vaccine, DNA vaccine, inactivated vaccine, recombinant antibodies

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

Site of physical importation: SK Pharma Logistics GmbH Remusweg 8 33729 Bielefeld

Annex 5

Name(s) of Qualified Person(s)	Mr. Dr. Atila Basoglu
	Mr. Dr. Lars Lüllwitz