

## 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_NW_05_MIA_2024_0003/24.05.03-142   |
| 2. Name of authorisation holder  | Diapharm GmbH & Co.KG<br>(LOC-100074110)  |
| 3. Address(es) of manufacturing site(s)  | Diapharm GmbH & Co.KG<br>Am Mittelhafen 56<br>48155 Münster<br>(LOC-100074110)  |
| 4. Legally registered address of authorisation holder  | Am Mittelhafen 56<br>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)<br>Sect 72 para 1 Arzneimittelgesetz (German Drug Law)<br>Art. 61 para 1 to 3 of Regulation (EU) No. 536/2014 in conjunction with Sect 13 para 5 AMG<br>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  | 22/01/2024  |

10. Annexes attached

Annex 1 and Annex 2  
Annex 5 (Name of Qualified Person)

**SCOPE OF AUTHORISATION**

Name and address of the site:

Diapharm GmbH & Co.KG, Am Mittelhafen 56, 48155 Münster

Human Medicinal Products
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<b>AUTHORISED OPERATIONS</b> Manufacturing Operations (according to part 1) Importation of Medicinal Products (according to part 2)
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<b>Part 1 - MANUFACTURING OPERATIONS</b>	
<b>1.1</b>	<b>Sterile Products</b>
	1.1.3 <i>Batch certification</i>
<b>1.2</b>	<b>Non-sterile products</b>
	1.2.2 <i>Batch certification</i>
<b>1.3</b>	<b>Biological medicinal products</b>
	1.3.2 <i>Batch certification</i>
	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

<b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b>	
<b>2.2</b>	<b>Batch certification of imported medicinal products</b>
	<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
	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

<p>Site of physical importation:</p> <p>SK Pharma Logistics GmbH Remusweg 8 33729 Bielefeld</p> <p>and</p> <p>Arvato SE Gottlieb-Daimler-Straße 1 33428 Harsewinkel</p> <p>and</p> <p>Holopack Verpackungstechnik GmbH Bahnhofstr. 20 73453 Abtsgmuend-Untergroeningen</p>
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**SCOPE OF AUTHORISATION**

Annex 2

Name and address of the site:

Diapharm GmbH &amp; Co.KG, Am Mittelhafen 56, 48155 Münster

Investigational Medicinal Products for Human Use
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**AUTHORISED OPERATIONS**

Manufacturing Operations (according to part 1)

Importation of Investigational Medicinal Products (according to part 2)

**Part 1 - MANUFACTURING OPERATIONS**

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

<b>Part 2 - IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS</b>	
<b>2.2</b>	<b>Batch certification of imported investigational medicinal products</b>
	<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>
	2.2.3.8 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

and

Arvato SE  
Gottlieb-Daimler-Straße 1  
33428 Harsewinkel

and

Holopack Verpackungstechnik GmbH  
Bahnhofstr. 20  
73453 Abtsgmuend-Untergroeningen

Name(s) of Qualified Person(s)

Mr. Dr. Atila Basoglu

Mr. Dr. Stefan Stromeier

Mr. Dr. Lars Lüllwitz