

MANUFACTURER'S 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_2022_0014/24.05.03-142 |
| 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 | 14/12/2022 |

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 <i>Batch certification</i>
1.2	Non-sterile products
	1.2.2 <i>Batch certification</i>
1.3	Biological medicinal products
	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 biological medicinal products active viral vaccine, DNA vaccine, inactivated vaccine, recombinant antibodies

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.2	Batch certification of imported medicinal products
	<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 biological medicinal products 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 Supply Chain Solutions SE
Gottlieb-Daimler-Straße 1
33428 Harsewinkel

and

Holopack Verpackungstechnik GmbH
Bahnhofstr. 20
73453 Abtsgmuend-Untergroeningen

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 <i>Batch certification</i>
1.2	Non-sterile products
	1.2.2 <i>Batch certification</i>
1.3	Biological medicinal products
	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 biological medicinal products 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
	<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 biological medicinal products 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 Supply Chain Solutions SE Gottlieb-Daimler-Straße 1 33428 Harsewinkel</p> <p>and</p> <p>Holopack Verpackungstechnik GmbH Bahnhofstr. 20 73453 Abtsgmuend-Untergroeningen</p>

Name(s) of Qualified Person(s)

Mr. Dr. Johannes Frings

Mr. Dr. Atila Basoglu

Mr. Dr. Stefan Stromeier

Mr. Gert Wörle