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_0002/24.05.03-231
2. Name of authorisation holder	Hälsa Pharma GmbH
3. Address(es) of manufacturing site(s)	Hälsa Pharma GmbH Hafenweg 18-20 48155 Münster
4. Legally registered address of authorisation holder	Maria-Goeppert-Straße 5 23562 Lübeck
5. Scope of authorisation and dosage forms	ANNEX 1 and ANNEX 2
6. Legal basis of authorisation	Sect 13 para 1 and sect 72 para 1 Arzneimittelgesetz (AMG, German Drug Law)
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	07/02/2022
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:
Hälsa Pharma GmbH, Hafenweg 18-20, 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 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**
	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 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:
Hälsa Pharma GmbH, Hafenweg 18-20, 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 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**
	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 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

Name(s) of Qualified Person(s)	Mr. Dr. Johannes Frings
	Mr. Dr. Atila Basoglu
	Mr. Dr. Stefan Stromeier
	Mr. Gert Wörle