Bezirksregierung Detmold
Leopoldstr. 15
32756 Detmold

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_02_MIA_2023_0020/24.05.01-010
2. Name of authorisation holder	SK Pharma Logistics GmbH (LOC-100050390)
3. Address(es) of manufacturing site(s)	SK Pharma Logistics GmbH Remusweg 8 33729 Bielefeld (LOC-100050390) SK Pharma Logistics GmbH Schnatweg 16 32051 Herford (LOC-100067868)
4. Legally registered address of authorisation holder	Remusweg 8 33729 Bielefeld
5. Scope of authorisation and dosage forms	ANNEX 1
6. Legal basis of authorisation	Sect 13 para 1 Arzneimittelgesetz (German Drug Law) Sect 72 para 1 Arzneimittelgesetz (German Drug Law)
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Dr. Stephanie Kottmann
8. Signature	On behalf
9. Date	09/11/2023

Bezirksregierung 163 Detmold

10. Annexes attached

Annex 1

Bezirksregierung
163
Detmold

SCOPE OF AUTHORISATION **Annex 1**

Name and address of the site:
SK Pharma Logistics GmbH, Remusweg 8, 33729 Bielefeld

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
1.5	**Packaging**
	1.5.2 Secondary packing

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

sampling of medicinal products, which are not released

Bezirksregierung 163 Detmold

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
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

Bezirksregierung 163 Detmold

SCOPE OF AUTHORISATION **Annex 1**

Name and address of the site:
SK Pharma Logistics GmbH, Schnatweg 16, 32051 Herford

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

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

sampling of medicinal products, which are not released

Bezirksregierung 163 Detmold

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.3	**Other importation activities**
	2.3.1 Site of physical importation