

## MANUFACTURER'S AUTHORISATION

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

1. Authorisation number/file number	DE_RP_01_MIA_2023_0033/54.3/GMP/Midas/20230725
2. Name of authorisation holder	Midas Pharma GmbH (LOC-100004656)
3. Address(es) of manufacturing site(s)	Midas Pharma GmbH Rheinstraße 49 55218 Ingelheim am Rhein (LOC-100004656)
4. Legally registered address of authorisation holder	Rheinstraße 49 55218 Ingelheim am Rhein
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. Ilka Petry
8. Signature	On behalf
9. Date	25/07/2023
10. Annexes attached	Annex 1 Annex 3 (Addresses of Contract Manufacturing Site(s)) Annex 4 (Addresses of Contract Laboratories) Annex 7 (Date of inspection on which authorisation granted, scope of last inspection)

Annex 8 (Manufactured/ imported products authorised)

**SCOPE OF AUTHORISATION**

Name and address of the site:

Midas Pharma GmbH, Rheinstraße 49, 55218 Ingelheim am Rhein

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>
	<i>1.1.3 Batch certification</i>
<b>1.2</b>	<b>Non-sterile products</b>
	<i>1.2.2 Batch certification</i>

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

To 1.1.3 und 1.2.2: The manufacturing authorisation is also valid for the permitted activities in the buildings with the addresses Rheinstraße 63 und Dietrich-Bonhoeffer-Straße 2-4.
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<b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b>	
<b>2.1</b>	<b>Quality control testing of imported medicinal products</b>
	<i>2.1.3 Chemical/Physical</i>
<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
	<i>2.2.2 Non-sterile products</i>
	<i>2.2.3 Biological products</i>
	2.2.3.5 Biotechnology products
<b>2.3</b>	<b>Other importation activities</b>
	<i>2.3.4 Other</i> Active pharmaceutical ingredients

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

The importation authorisation is also valid for the permitted activities in the buildings with the addresses Rheinstraße 63 and Dietrich-Bonhoeffer-Straße 2-4.

Amendment 2.2.1.1: Meropenem sterile mixture and vial

Amendment 2.2.2: Paracetamol DC blend

Amendment 2.2.3.5: Ranibizumab vial, Adalimumab (API and pre-filled syringes with and without needle guard and pre-filled pens) and Infliximab (API and vials, pre-filled syringes with and without needle guard and pre-filled pens)

Amendment 2.3.4: Acetylcystein Ph.Eur., Carbocistein Ph. Eur., Heparin Sodium Ph.Eur./non steril, Spironolacton Ph.Eur.

Medicinal products, Active pharmaceutical ingredients and manufacturing sites see Annex 8



Address(es) of Contract  
Manufacturing Sites

Popack Logistik GmbH  
Achardstraße 1  
55127 Mainz

The company Popack is a service provider.  
Scope of the service: Storage of drug products and active  
pharmaceutical ingredients.

Address(es) of Contract Laboratories

BioChem Labor für biologische und chemische Analytik  
GmbH  
Daimlerstr. 5b  
76185 Karlsruhe  
1.6.1 Microbiological Testing: Sterility  
1.6.2 Microbiological Testing: non steril Products  
1.6.3 Chemical/Physical Testing  
1.6.4 Biological Testing

WESSLING Laboratorien GmbH  
Johann-Krane-Weg 42  
48149 Münster  
1.6.1 Microbiological Testing: Sterility  
1.6.2 Microbiological Testing: non steril Products  
1.6.3 Chemical/Physical Testing  
1.6.4 Biological Testing

Famar Italia S.p.A.  
Via Zambelletti 25  
20021 Baranzate (MI)  
Italien  
1.6.2 Microbiological Testing: non steril Products  
1.6.3 Chemical/Physical Testing

Hikma Farmaceutica (Portugal) S.A.  
Estrada Do Rio Da Mo No 8 8-A E 8-B  
2705-906 Fervenca Terrugem Snt Lisbon  
Portugal  
1.6.1 Microbiological Testing: Sterility  
1.6.3 Chemical/Physical Testing  
1.6.4 Biological Testing  
EU release testing

Egis Pharmaceuticals Plc.  
Bokenyfoldi Ut 118-120  
1165 Budapest  
Ungarn  
1.6.1 Microbiological Testing: Sterility  
1.6.3 Chemical/Physical Testing  
1.6.4 Biological Testing  
EU release testing

Kymos Pharma Services S.L.  
Ronda De Can Fatjo 7b

08290 Cerdanyola Del Valles, Barcelona  
Spanien  
1.6.1 Microbiological Testing: Sterility  
1.6.3 Chemical/Physical Testing  
1.6.4 Biological Testing  
EU release testing

Catalent Pharma Solutions  
Font Saint Landry 10  
1120 Brussels  
Belgien  
1.6.1 Microbiological Testing: Sterility  
1.6.3 Chemical/Physical Testing  
1.6.4 Biological Testing  
EU release testing

Date of Inspection on which  
authorisation was granted

28/10/2021

Products authorised to be manufactured/imported (in accordance with Article 41 and 42 of Directive 2001/83/EC and/or Article 89 and 90 of Regulation (EU) 2019/6, as amended).

Ranibizumab vial  
Vial filling:

Ajinomoto Biopharma Services  
11040 Roselle Street  
San Diego CA 92121, US

Packaging:

PCI Pharma Services  
3001 Red Lion Rd.  
Philadelphia PA 19114, US

Acetylcystein Ph.Eur. + Carbocistein Ph.Eur  
Wuhan Grand Hoyo Co., Ltd  
Gedian Economy Development Zone, No. 1  
Industrial Park  
436030 Ezhou City, Hubei Provinz, China

Heparin Natrium/sodium Ph.Eur./nicht steril/non steril  
Shenzhen Hepalink Pharmaceutical Group Co., Ltd.  
21 Langshan Road, Songpingshan, Nanshan District,  
Shenzhen 518057, China

Spirolacton Ph.Eur.  
Zhejiang Shenzhou Pharmaceutical Co., Ltd.  
No 9 Hongyun Road, Xiandai Industrial Zone  
Fuying Subdistrict, Xianju, 317300 Taizhou  
Zhejiang, China

Paracetamol DC Mischung/blend  
Atabay Kimya Sanayi ve Ticaret A.S.  
Acibadem, Köftünci Sodak No. 1  
34718 Kadiköy, Istanbul, Turkey

Meropenem Trihydrat E.P./Natriumcarbonat  
sterile mixture + drug products + bulk drug products (1,141 g à 30 ml vial 0,57 g à 20 ml vial)  
Shenzhen Haibin Pharmaceutical Co., Ltd.  
Shenyan Road Yantian District No. 2003  
518081 Shenzhen City Guangdong Province, China

Heparin sodium Ph.Eur./non sterile  
Shenzhen Hepalink Pharmaceutical Group Co., Ltd.  
No. 1 Rongtian South, Kengzi Sub-district, Pingshan New District, Shenzhen 518122, China

Diethylenetriaminepentaacetic acid (DTPA)

Sionc Pharmaceuticals Pvt. Ltd.

Plot No. 34A, Roas No. 1, JN Pharma City, Thanam (Village), IDA Parwada, Visakhapatnam - 531021  
Andhra Pradesh, Indien

Adalimumab

- CELLTRION, Inc. (CLT2)

20, Academy-ro 51 beon-gil, Yeonsu-gu,  
Incheon, 22014, Republic of Korea

Production of drug substance

Release testing of drug substance

Secondary Packaging of drug product

- CELLTRION Pharm, Inc.

82, 2 Sandan-ro, Ochang-eup, Cheongwon-gu,  
Cheongju-si, Chungcheongbuk-do, 28117, Republic of Korea

Manufacturing of drug product

Secondary Packaging of drug product

Infliximab

- CELLTRION, Inc. (CLT1)

23, Academy-ro, Yeonsu-gu, Incheon, 22014, Republic of Korea

Production of drug substance

Release testing of drug substance

- CELLTRION, Inc. (CLT2)

20, Academy-ro 51 beon-gil, Yeonsu-gu, Incheon, 22014, Republic of Korea

Production of drug substance

Release testing of drug substance

Manufacturing of drug product

Secondary Packaging of drug product

- Gensenta İlaç Sanayi ve Ticaret Anonim Sirketi

Other Product Plant

Yenibosna Cobancesme Mahallesi

Sanayi Caddesi No:13, 34196 Yenibosna-Istanbul, Turkey

Manufacturing of drug product

-CELLTRION Pharm, Inc.

82, 2 Sandan-ro, Ochang-eup, Cheongwon-gu,

Cheongju-si, Chungcheongbuk-do, 28117, Republic of Korea

Secondary Packaging of drug product

- Anderson Brecon (UK) Ltd

Units 2-7, Wye Valley Business Park,

Brecon Road, Hay-On-Wye, Hereford,HR3 5PG, United Kingdom

Secondary Packaging of drug product