

MANUFACTURER / IMPORTER 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_2024_0030/54.3/GMP/Midas/20241010
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	Katharina Habel
8. Signature	On behalf
9. Date	10/10/2024
10. Annexes attached	Annex 1 Annex 3 (Addresses of Contract Manufacturing Site(s)) Annex 4 (Addresses of Contract Laboratories) Annex 8 (Manufactured/ imported products authorised)

SCOPE OF AUTHORISATION**Annex 1**

Name and address of the site:

Midas Pharma GmbH, Rheinstraße 49, 55218 Ingelheim am Rhein

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

To 1.1.3:

To apply for an authorisation.

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	<i>2.1.3 Chemical/Physical</i>
2.2	Batch certification of imported medicinal products
	<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
2.3	Other importation activities
	<i>2.3.4 Other</i> Active pharmaceutical ingredients

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

<p>The importation authorisation is also valid for the permitted activities in the buildings with the addresses Rheinstrasse 63 and Dietrich-Bonhoeffer-Strasse 2-4.</p> <p>Amendment 2.2.1.1: Meropenem sterile mixture and vial (bulk) Amendment 2.2.2: Paracetamol DC blend (bulk) Amendment 2.2.3.5: -Ranibizumab vial (market goods) -Adalimumab (API; bulk: pre-filled syringes with and without needle guard and pre-filled pens) -Infliximab (API; bulk: vials, pre-filled syringes with and without needle guard and pre-filled pens) -Ustekinumab (API; bulk: vial and pre-filled syringes with and without needle guard and their market goods) -Omalizumab (API, bulk: pre-filled syringes with and without needle guards and their market goods) Amendment 2.3.4: Acetylcystein Ph.Eur., Carbocistein Ph. Eur., Heparin Sodium Ph.Eur./non steril</p> <p>Medicinal products, Active pharmaceutical ingredients and manufacturing sites: see Annex 8</p>
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Address(es) of Contract
Manufacturing Sites

Popack Logistik GmbH
Achardstraße 1
55127 Mainz

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

Next Pharma Logistics GmbH
Eichenbusch 1
59368 Werne

Scope of service: Labeling of medical samples and storage
of drug products

Lichtenheldt GmbH - Werk I -
Industriestraße 7 - 11
23812 Wahlstedt

manufacturing, packaging and quality control of drug
products

Lichtenheldt GmbH - Werk II -
Justus-Liebig-Weg 1
23812 Wahlstedt

packaging and quality control of drug products

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

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 Province, China

Acetylcystein Ph.Eur. + Carbocistein Ph.Eur.
Wuhan Grand Hoyo Co., Ltd.
Dingliu Village, Longhuashan Street
433000 Xiantao, 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.
Shenyang 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

Adalimumab
- CELLTRION, Inc. (CLT2)
20, Academy-ro 51 beon-gil, Yeonsu-gu,
Incheon, 22014, Republic of Korea
Manufacturing of drug substance
Release testing of drug substance

Secondary Packaging

- 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

Infliximab

- CELLTRION, Inc. (CLT1)
23, Academy-ro, Yeonsu-gu, Incheon, 22014, Republic of Korea
Manufacturing of drug substance
Release testing of drug substance

-CELLTRION, Inc. (CLT2)
20, Academy-ro 51 beon-gil, Yeonsu-gu, Incheon, 22014, Republic of Korea
Manufacturing of drug substance
Release testing of drug substance
Manufacturing of drug product
Secondary Packaging

-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

-Anderson Brecon (UK) Ltd
Units 2-7, Wye Valley Business Park,
Brecon Road, Hay-On-Wye, Hereford,HR3 5PG, United Kingdom
Secondary Packaging

Ustekinumab

- CELLTRION, Inc. (CLT 2)
20, Academy-ro 51 beon-gil, Yeonsu-gu, Incheon, 22014, Republic of Korea
Release testing of drug substance
Manufacturing of drug substance
Secondary Packaging (vial)

- CELLTRION, Inc. (CLT 1)
23, Academy-ro, Yeonsu-gu, Incheon, 22014, Republic of Korea
Release testing of drug substance

- Gensenta İlaç Sanayi ve Ticaret Anonim Sirketi

Yenibosna Cobancesme Mahallesi
Sanayi Caddesi No:13, 34196 Yenibosna-Istanbul, Turkey
Manufacturing of drug product (vial)

- CELLTRION Pharm, Inc.
82, 2 Sandan-ro, Ochang-eup, Cheongwon-gu,
Cheongju-si, Chungcheongbuk-do, 28117, Republic of Korea
Manufacturing of drug product (pre-filled syringe)
Secondary Packaging (vial and pre-filled syringe)

Omalizumab
-CELLTRION, Inc. (CLT 1)
23, Academy-ro, Yeonsu-gu, Incheon, 22014, Republic of Korea
Manufacturing of drug substance
Release testing of drug substance

- CELLTRION Pharm, Inc.
82, 2 Sandan-ro, Ochang-eup, Cheongwon-gu,
Cheongju-si, Chungcheongbuk-do, 28117, Republic of Korea
Manufacturing of drug product (pre-filled syringe)
Secondary Packaging

-CELLTRION, Inc., Plant II (CLT2) 20, Academy-ro 51 beon-gil, Yeonsu-gu, Incheon, 22014, Republic of Korea
Release testing of drug substance