

MANUFACTURER / IMPORTER 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_2024_0018/24.05.03-075 |
| 2. Name of authorisation holder | WESSLING GmbH
(LOC-100030855) |
| 3. Address(es) of manufacturing site(s) | WESSLING GmbH
Johann-Krane-Weg 42
48149 Münster
(LOC-100030853)
WESSLING GmbH
Oststraße 7
(gem. Plan vom 03.09.2013)
floor Ebene Dachboden, room GMP-Archiv
48341 Altenberge
(LOC-100030855) |
| 4. Legally registered address of authorisation holder | Oststraße 7
48341 Altenberge |
| 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. Kathrin Rudolph |
| 8. Signature | On behalf |

9. Date

30/09/2024

10. Annexes attached

Annex 1

Annex 5 (Name of Qualified Person)

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

WESSLING GmbH, Johann-Krane-Weg 42, 48149 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
1.4	Other products or manufacturing activity
	1.4.1 Manufacture of:
	1.4.1.1 Herbal products
1.6	Quality control testing
	1.6.1 Microbiological: sterility
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological

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

Regarding point 1.2.2:

Non-sterile products in liquid, semi-solid and solid dosage forms

Regarding point 1.4.1.1:

batch release only

Regarding point 1.6.4: only endotoxin testing

External warehouse for archiving GMP-relevant documents:

Lager 3000 GmbH

Wiesenstr. 5-9

26215 Wiefelstede

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	<i>2.1.1 Microbiological: sterility</i>
	<i>2.1.2 Microbiological: non-sterility</i>
	<i>2.1.3 Chemical/Physical</i>
	<i>2.1.4 Biological</i>
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>

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

Regarding point 2.1.4: only endotoxin testing

Sites of physical importation:

Med-X-Press GmbH
Pracherstieg 1
38644 Goslar

European Pharma Hub Ltd.
Gorcsev Iván str. 5
2360 Gyál
Hungary

PS Pharma Service GmbH
Lise-Meitner-Straße 10
40670 Meerbusch

External warehouse for archiving GMP-relevant documents:

Lager 3000 GmbH
Wiesenstr. 5-9
26215 Wiefelstede

SCOPE OF AUTHORISATION**Annex 1**

Name and address of the site:

WESSLING GmbH, Oststraße 7, (gem. Plan vom 03.09.2013), floor Ebene Dachboden, room
GMP-Archiv , 48341 Altenberge

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS**1.1 Sterile Products***1.1.3 Batch certification***1.2 Non-sterile products***1.2.2 Batch certification***1.6 Quality control testing***1.6.1 Microbiological: sterility**1.6.2 Microbiological: non-sterility**1.6.3 Chemical/Physical*

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

No analytical operations, only archiving of documents of the activities
regarding points 1.1.3, 1.2.2, 1.6.1, 1.6.2 and 1.6.3

Annex 5

Name(s) of Qualified Person(s)

Mr. Dr. Maik Siebelmann

Mr. Dr. Ludger Josef Wedy

Mrs. Carolin Redecker

Mrs. Claudine Malyszek-Wantia