

MANUFACTURER'S AUTHORISATION

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

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|--|---|
| 1. Authorisation number/file number | DE_NW_05_MIA_2023_0024/24.05.03-079 |
| 2. Name of authorisation holder | Wagener & Co. GmbH
(LOC-100035020) |
| 3. Address(es) of manufacturing site(s) | Wagener & Co. GmbH
Lohesch 48
49525 Lengerich
(LOC-100035021)
Wagener & Co. GmbH
Lohesch 60
49525 Lengerich
(LOC-100035020) |
| 4. Legally registered address of authorisation holder | Lohesch 60
49525 Lengerich |
| 5. Scope of authorisation and dosage forms | ANNEX 1 and ANNEX 2 |
| 6. Legal basis of authorisation | Sect 13 para 1 Arzneimittelgesetz (German Drug Law)
Art. 61 para 1 to 3 of Regulation (EU) No. 536/2014 in conjunction with Sect 13 para 5 AMG |
| 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 | 09/10/2023 |

10. Annexes attached

Annex 1 and Annex 2
Annex 4 (Addresses of Contract Laboratories)

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

Wagener & Co. GmbH, Lohesch 48, 49525 Lengerich

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

1.5	Packaging
	<i>1.5.1 Primary Packing</i>
	1.5.1.1 Capsules, hard shell
	1.5.1.5 Liquids for external use
	1.5.1.6 Liquids for internal use
	1.5.1.11 Semi-solids
	1.5.1.12 Suppositories
	1.5.1.17 Other non-sterile medicinal products powder
	<i>1.5.2 Secondary packing</i>

SCOPE OF AUTHORISATION

Name and address of the site:

Wagener & Co. GmbH, Lohesch 48, 49525 Lengerich

Investigational Medicinal Products for Human Use

AUTHORISED OPERATIONS
Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

1.5	Packaging
	1.5.1 <i>Primary Packing</i>
	1.5.1.11 Semi-solids
	1.5.2 <i>Secondary packing</i>

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

regarding 1.5.1.11: only Infektoscab 5% und 10%
regarding 1.5.2: only Infektoscab 5% und 10%

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

Wagener & Co. GmbH, Lohesch 60, 49525 Lengerich

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS**1.2 Non-sterile products***1.2.1 Non-sterile products (processing operations for the following dosage forms)*

1.2.1.5 Liquids for external use

1.2.1.6 Liquids for internal use

1.2.1.11 Semi-solids

1.2.1.12 Suppositories

1.2.1.17 Other
Powder*1.2.2 Batch certification***1.5 Packaging***1.5.1 Primary Packing*

1.5.1.1 Capsules, hard shell

1.5.1.5 Liquids for external use

1.5.1.6 Liquids for internal use

1.5.1.11 Semi-solids

1.5.1.12 Suppositories

*1.5.2 Secondary packing***1.6 Quality control testing***1.6.2 Microbiological: non-sterility**1.6.3 Chemical/Physical*

SCOPE OF AUTHORISATION

Name and address of the site:

Wagener & Co. GmbH, Lohesch 60, 49525 Lengerich

Investigational Medicinal Products for Human Use

AUTHORISED OPERATIONS
Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i>
	1.2.1.11 Semi-solids
1.6	Quality control testing
	<i>1.6.2 Microbiological: non-sterility</i>
	<i>1.6.3 Chemical/Physical</i>

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

regarding 1.2.1.11: only Infektoscab 5% and 10%
regarding 1.6.2: only Infektoscab 5% und 10%
regarding 1.6.3: only Infektoscab 5% und 10%

Address(es) of Contract Laboratories

Labor für Lebensmitteluntersuchungen und Umweltanalytik
BLS-Analytik GmbH
Columbiastraße 14
97688 Bad Kissingen
Microbiological: non-sterile products
Chemical/Physical