Bezirksregierung Detmold
Leopoldstr. 15
32756 Detmold

# 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_02_MIA_2021_0016/24.05.01-50 |
| 2. Name of authorisation holder | C. Hedenkamp GmbH & Co.KG |
| 3. Address(es) of manufacturing site(s) | C.Hedenkamp GmbH & Co.KG<br>Schierbusch 1<br>33161 Hövelhof |
| 4. Legally registered address of authorisation holder | Schierbusch 1<br>33161 Hövelhof |
| 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) |
| 7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation | Martin Sieling |
| 8. Signature | On behalf |
| 9. Date | 29/09/2021 |
| 10. Annexes attached | Annex 1 and Annex 2<br>Annex 4 (Addresses of Contract Laboratories) |

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**SCOPE OF AUTHORISATION** **Annex 1**

Name and address of the site:
C.Hedenkamp GmbH & Co.KG, Schierbusch 1, 33161 Hövelhof

| Human Medicinal Products |
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**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)* |
| | 1.2.1.1 Capsules, hard shell |
| | 1.2.1.8 Other solid dosage forms |
| | 1.2.1.13 Tablets |
| **1.4** | **Other products or manufacturing activity** |
| | *1.4.3 Other*<br>batch release for non-sterile products |
| **1.5** | **Packaging** |
| | *1.5.1 Primary Packing* |
| | 1.5.1.1 Capsules, hard shell |
| | 1.5.1.2 Capsules, soft shell |
| | 1.5.1.8 Other solid dosage forms |
| | 1.5.1.13 Tablets |
| | *1.5.2 Secondary packing* |
| **1.6** | **Quality control testing** |
| | *1.6.3 Chemical/Physical* |

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

| to 1.2.1.8 and 1.5.1.8<br>Production and Filling of powder in sticks<br>to 1.6.3<br>only tests by HPLC, wet chemistry, physical tests (only determination loss of drying, ash und sulphated ash) |
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**SCOPE OF AUTHORISATION** **Annex 2**

Name and address of the site:
C.Hedenkamp GmbH & Co.KG, Schierbusch 1, 33161 Hövelhof

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| Investigational Medicinal Products for Human Use |

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| **AUTHORISED OPERATIONS**<br>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)* |
| | 1.2.1.1 Capsules, hard shell |
| | 1.2.1.8 Other solid dosage forms |
| | 1.2.1.13 Tablets |
| **1.4** | **Other products or manufacturing activity** |
| | *1.4.3 Other*<br>batch release for non-sterile products |
| **1.5** | **Packaging** |
| | *1.5.1 Primary Packing* |
| | 1.5.1.1 Capsules, hard shell |
| | 1.5.1.2 Capsules, soft shell |
| | 1.5.1.8 Other solid dosage forms |
| | 1.5.1.13 Tablets |
| | *1.5.2 Secondary packing* |
| **1.6** | **Quality control testing** |
| | *1.6.3 Chemical/Physical* |

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

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| to 1.2.1.8 and 1.5.1.8<br>Production and Filling of powder in sticks<br>to 1.6.3<br>only tests by HPLC, wet chemistry, physical tests (only determination loss of drying, ash und sulphated ash) |

**Annex 4**

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| Address(es) of Contract Laboratories | BAV Institut für Hygiene und Qualitätssicherung GmbH<br>Hanns-Martin-Schleyer-Str. 25<br>77656 Offenburg<br>microbiological testing according Ph.Eur.<br><br>Dr. Graner & Partner GmbH<br>Lochhausener Straße 205<br>81249 München<br>Quality control testing of excipients/active ingredients/medicinal products<br>- pharmaceutical-chemical analysis<br>- pharmaceutical-chemical analysis (compendial methods)<br>- chromatographic assays<br>- microbiological assays of non-sterile products<br>- |

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