



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_HB_01_MIA_2023_0005/QSI |
| 2. Name of authorisation holder | Quality Services International GmbH
(LOC-100052690) |
| 3. Address(es) of manufacturing site(s) | Quality Services International GmbH
Flughafendamm 9a
28199 Bremen
(LOC-100052690) |
| 4. Legally registered address of authorisation holder | Flughafendamm 9a
28199 Bremen |
| 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 | Katja Ahrens |
| 8. Signature | On behalf |
| 9. Date | 30/05/2023 |
| 10. Annexes attached | Annex 1 and Annex 2
Annex 4 (Addresses of Contract Laboratories)
Annex 7 (Date of inspection on which authorisation granted, scope of last inspection) |

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SCOPE OF AUTHORISATION**Annex 1**

Name and address of the site:

Quality Services International GmbH , Flughafendamm 9a, 28199 Bremen

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS**1.4 Other products or manufacturing activity***1.4.1 Manufacture of:*

1.4.1.1 Herbal products

1.6 Quality control testing*1.6.3 Chemical/Physical*Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

According to § 73, 2a AMG, it is permitted to import investigational medicinal products in small quantities as display samples or for analytical purposes (Quality control testing of imported medicinal products according to Number 2.1.3 chemical/physical).



SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

Quality Services International GmbH , Flughafendamm 9a, 28199 Bremen

Investigational Medicinal Products for Human Use

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

1.6	Quality control testing
	1.6.3 Chemical/Physical

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

Annex 2, Part 1, Clause 1.6.3: refers exclusively to the quality control to be performed. There are no manufacturing activities (also no releases).



Address(es) of Contract Laboratories

BAV Institut für Hygiene und Qualitätssicherung GmbH
Hanns-Martin-Schleyer-Str. 25
77656 Offenburg
Mikrobiological testing according to Ph.Eur.

Indikator GmbH
Wilhelm-Muthmann-Straße 15
42329 Wuppertal
Testing of heavy metals according to Ph. Eur.



Date of Inspection on which
authorisation was granted

21/11/2022

