MANUFACTURER'S AUTHORISATION

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

1. Authorisation number/file number

DE_HB_02_MIA_2024_0006/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

6. Legal basis of authorisation

Art. 88 of Regulation (EU) 2019/6 and Sect 28 para 1 German Veterinary Medicinal Products Law

7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

Lena Engeländer

8. Signature

On behalf

9. Date

18/10/2024

10. Annexes attached

Annex 1

Annex 4 (Addresses of Contract Laboratories)
Annex 7 (Date of inspection on which authorisation

granted, scope of last inspection)

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

Quality Services International GmbH, Flughafendamm 9a, 28199 Bremen

Veterinary Medicinal Products

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

Pursuant to §25 (2) Nr. 3 Tierarzneimittelgesetz it is permitted to import investigational medicinal products in small quantities as reference samples or for analytical purposes.

Address(es) of Contract Laboratories

BAV Institut für Hygiene und Qualitätssicherung GmbH Hanns-Martin-Schleyer-Str. 25 77656 Offenburg

Indikator GmbH Wilhelm-Muthmann-Straße 15 42329 Wuppertal Date of Inspection on which authorisation was granted

21/11/2022