

SAARLAND Ministerium für Arbeit, Soziales, Frauen und Gesundheit

MANUFACTURER'S AUTHORISATION

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

1. Authorisation number/file number DE_SL_01_MIA_2023_0009/5010-108#002

2. Name of authorisation holder Quasaar GmbH (LOC-100070273)

3. Address(es) of manufacturing site(s)

Quasaar GmbH

Lichtenkopfer Weg 1
66450 Bexbach
(LOC-100070273)

4. Legally registered address of authorisation holder Lichtenkopfer Weg 1 66450 Bexbach

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

8. Signature On behalf

9. Date 12/06/2023

10. Annexes attached

Annex 1

Annex 5 (Name of Qualified Person)

Annex 7 (Date of inspection on which authorisation

granted, scope of last inspection)

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

Quasaar GmbH, Lichtenkopfer Weg 1, 66450 Bexbach

Veterinary Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS 1.4 Other products or manufacturing activity

1.4.3 Other

Sterile and non-sterile starting materials, active ingredients, medicinal products and packaging materials

1.6 Quality control testing

1.6.3 Chemical/Physical

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

To number 1.4.3:

Carrying out stability studies to determine the shelf life of starting materials, active ingredients and medicinal products.

To number 1.6.3:

Pharmaceutical-chemical analysis (customer specification/pharmacopoeial methods)

Pharmaceutical-technological analysis (pharmacopoeial methods)

Chromatographic Studies

Spectroscopic investigations

Electrochemical investigations

Biopharmaceutical investigations

There are no batch releases.

The manufacturing license is limited to quality control testing of veterinary medicinal products.

Name(s) of Qualified Person(s)

Mr. Dr. Christoph Jacobs

Date of Inspection on which authorisation was granted

18/02/2022