



MANUFACTURER'S AUTHORISATION

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

- | | |
|--|--|
| 1. Authorisation number/file number | DE_RP_01_MIA_2020_0003 |
| 2. Name of authorisation holder | Midas Pharma GmbH |
| 3. Address(es) of manufacturing site(s) | Midas Pharma GmbH
Rheinstrasse 49, 63, 64 und Dietrich Bonhoefer
Strasse 2-4
55218 Ingelheim |
| 4. Legally registered address of authorisation holder | Rheinstraße 49
55218 Ingelheim |
| 5. Scope of authorisation and dosage forms | ANNEX 1 |
| 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 | Dr. Burkhard Trapp |
| 8. Signature | On behalf |
| 9. Date | 05/03/2020 |
| 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

Name and address of the site:

Midas Pharma GmbH, Rheinstrasse 49, 63, 64 und Dietrich Bonhoefer Strasse 2-4 , 55218 Ingelheim

Human Medicinal Products
Veterinary Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

1.1	Sterile Products
	<i>1.1.3 Batch certification</i>
1.2	Non-sterile products
	<i>1.2.2 Batch certification</i>
1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i>
	<i>1.6.3 Chemical/Physical</i>





Address(es) of Contract Laboratories

BioChem Labor für biologische und chemische Analytik
GmbH
Daimlerstr. 5b
76185 Karlsruhe

Haupt Pharma Wolfratshausen GmbH
Pfaffenrieder Straße 5
82515 Wolfratshausen

WESSLING Laboratorien GmbH
Johann-Krane-Weg 42
48149 Münster

Famar Italia S.p.A.
Via Zambelletti 25
20021 Baranzate (MI)
Italien





Date of Inspection on which
authorisation was granted

08/11/2018

