



IMPORTER'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_2021_0022
2. Name of authorisation holder	Midas Pharma GmbH
3. Address(es) of manufacturing site(s)	Midas Pharma GmbH Rheinstraße 49, 63 und 64 55218 Ingelheim
4. Legally registered address of authorisation holder	Rheinstraße 49, 63 und 64 55218 Ingelheim
5. Scope of authorisation and dosage forms	ANNEX 1
6. Legal basis of authorisation	Sect 72 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	17/06/2021
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 und 64, 55218 Ingelheim

Human Medicinal Products

AUTHORISED OPERATIONS
Importation of Medicinal Products (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	2.1.1 <i>Microbiological: sterility</i>
	2.1.3 <i>Chemical/Physical</i>
2.2	Batch certification of imported medicinal products
	2.2.1 <i>Sterile products</i>
	2.2.1.1 Aseptically prepared
	2.2.2 <i>Non-sterile products</i>
	2.2.3 <i>Biological products</i>
	2.2.3.6 Human or animal extracted products
2.3	Other importation activities
	2.3.4 <i>Other</i> Import and Release of Active Pharmaceutical Ingredients microbiological and animal origin





Address(es) of Contract Laboratories

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

WESSLING Laboratorien GmbH
Johann-Krane-Weg 42
48149 Münster

Haupt Pharma Wolfratshausen GmbH
Pfaffenrieder Straße 5
82515 Wolfratshausen

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





Date of Inspection on which
authorisation was granted

08/11/2018

