SAARLAND
Ministerium für Arbeit, Soziales, Frauen und Gesundheit

MANUFACTURER / IMPORTER 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_2024_0014/5000-120#002
2. Name of authorisation holder	Eurofins PHAST GmbH (LOC-100022643)
3. Address(es) of manufacturing site(s)	Eurofins PHAST GmbH Kardinal-Wendel-Straße 16 66424 Homburg (LOC-100022643) Eurofins PHAST GmbH Entenmühlstraße 48 66424 Homburg (LOC-100067022)
4. Legally registered address of authorisation holder	Kardinal-Wendel-Straße 16 66424 Homburg
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) Sect 72 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 Art. 61 para 1 to 3 of Regulation (EU) No. 536/2014 in conjunction with Sect 72 para 2a AMG
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Dr. Thomas Rohn
8. Signature	On behalf [redacted]

9. Date	20/02/2024
10. Annexes attached	Annex 1 and Annex 2 Annex 3 (Addresses of Contract Manufacturing Site(s)) Annex 4 (Addresses of Contract Laboratories) 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:
Eurofins PHAST GmbH, Kardinal-Wendel-Straße 16, 66424 Homburg

Human Medicinal Products

AUTHORISED OPERATIONS Manufacturing Operations (according to part 1) Importation of Medicinal Products (according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile Products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.3	**Biological medicinal products**
	1.3.2 Batch certification
	1.3.2.5 Biotechnology products
1.6	**Quality control testing**
	1.6.3 Chemical/Physical
	1.6.4 Biological

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical
	2.1.4 Biological
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products
	2.2.1.1 Aseptically prepared
	2.2.2 Non-sterile products
	2.2.3 Biological products
	2.2.3.5 Biotechnology products

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

Import of patches with the active ingredient Rivastigmine
Import of lyophilisate the drug metreleptin (MYALEPTA),
powder for solution for Injection
Zulassungs-Nummern: Myalepta
EU/1/18/1276/001, 11,3 mg 1 Vial,
EU/1/18/1276/002, 11,3 mg 30 vials,
EU/1/18/1276/003, 3 mg 1 vial,
EU/1/18/1276/004, 3 mg, 30 vials,
EU/1/18/1276/005, 5,8 mg 1 vial,
EU/1/18/1276/006, 5,8 mg 30 vials

SCOPE OF AUTHORISATION **Annex 2**

Name and address of the site:
Eurofins PHAST GmbH, Kardinal-Wendel-Straße 16, 66424 Homburg

Investigational Medicinal Products for Human Use

AUTHORISED OPERATIONS Manufacturing Operations (according to part 1) Importation of Investigational Medicinal Products (according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile Products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.3	**Biological medicinal products**
	1.3.2 Batch certification
	1.3.2.5 Biotechnology products
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.3 Chemical/Physical
	1.6.4 Biological

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

Secondary packaging of clinical test samples by Clinigen Clinical Supplies Management GmbH in D-65824 Schwalbach

Part 2 - IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported investigational medicinal products**
	2.1.3 Chemical/Physical
	2.1.4 Biological
2.2	**Batch certification of imported investigational medicinal products**
	2.2.2 Non-sterile products
	2.2.3 Biological products
	2.2.3.5 Biotechnology products

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

Import of patches with the active pharmaceutical ingredient Rivastigmin

SCOPE OF AUTHORISATION **Annex 1**

Name and address of the site:
Eurofins PHAST GmbH, Entenmühlstraße 48, 66424 Homburg

Human Medicinal Products

AUTHORISED OPERATIONS
Manufacturing Operations (according to part 1)
Importation of Medicinal Products (according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile Products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.3	**Biological medicinal products**
	1.3.2 Batch certification
	1.3.2.5 Biotechnology products
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.3 Chemical/Physical
	1.6.4 Biological

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

Priority methods in redundancy to Kardinal-Wendel-Straße 16 are available at Entenmühlstraße 48

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical
	2.1.4 Biological
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products
	2.2.1.1 Aseptically prepared
	2.2.2 Non-sterile products
	2.2.3 Biological products
	2.2.3.5 Biotechnology products

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

Import of patches with the active ingredient Rivastigmine
Import of lyophilisate the drug metreleptin (MYALEPTA),
powder for solution for Injection
Zulassungs-Nummern: Myalepta
EU/1/18/1276/001, 11,3 mg 1 Vial,
EU/1/18/1276/002, 11,3 mg 30 vials,
EU/1/18/1276/003, 3 mg 1 vial,
EU/1/18/1276/004, 3 mg, 30 vials,
EU/1/18/1276/005, 5,8 mg 1 vial,
EU/1/18/1276/006, 5,8 mg 30 vials

SCOPE OF AUTHORISATION **Annex 2**

Name and address of the site:
Eurofins PHAST GmbH, Entenmühlstraße 48, 66424 Homburg

Investigational Medicinal Products for Human Use

AUTHORISED OPERATIONS Manufacturing Operations (according to part 1) Importation of Investigational Medicinal Products (according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile Products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.3	**Biological medicinal products**
	1.3.1 Biological medicinal products
	1.3.1.5 Biotechnology products
1.6	**Quality control testing**
	1.6.3 Chemical/Physical
	1.6.4 Biological

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

Secondary packaging of clinical test samples by Clinigen Clinical Supplies Management GmbH in D-65824 Schwalbach

Part 2 - IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported investigational medicinal products**
	2.1.3 Chemical/Physical
	2.1.4 Biological
2.2	**Batch certification of imported investigational medicinal products**
	2.2.2 Non-sterile products
	2.2.3 Biological products
	2.2.3.5 Biotechnology products

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

Import of patches with the active pharmaceutical ingredient Rivastigmin

Address(es) of Contract Manufacturing Sites	Rhenus Archiv Services GmbH Schmickstraße 14 60314 Frankfurt am Main Storage of documents Movianto Deutschland GmbH In der Vogelsbach 1 66540 Neunkirchen Storage of retained samples Clinigen Clinical Supplies Management GmbH Am Kronberger Hang 3 65824 Schwalbach a. Ts. Secondary packaging and distribution of investigational medicinal products Millmount Healthcare Limited (PCI-Gruppe) Block 7, City North Business Campus K32 YD60 Stamullen, Co. Meath Ireland Irland Place of import, secondary packaging

Address(es) of Contract Laboratories	BioChem Labor für biologische und chemische Analytik GmbH Daimlerstr. 5b 76185 Karlsruhe Microbiological tests: Testing for sterility and adequate preservation of sterile products and testing according to Ph. Eur. 5.1.4 for non-sterile products Physicochemical studies (e.g., loss of drying, sulphated ash, melting point determination)
	Eurofins BioPharma Product Testing Munich GmbH Robert-Koch-Str. 3a 82152 Planegg Testing for sterility endotoxin test
	MikroBiologie Krämer GmbH Primsaue 7 66809 Nalbach Microbial Testing: Sterility testing and testing for efficacy of antimicrobial preservation of sterile products as well as testing according to Ph. Eur. 5.1.4 of non-sterile products
	Labor LS SE & Co. KG Mangelsfeld 4, 5, 6 97708 Bad Bocklet-Großenbrach Microbiological tests: Sterility testing and adequate preservation of sterile products and Ph. Eur. 5.1.4 for non-sterile products
	Eurofins Biolab S.r.l. Milan Via Bruno Buozzi 2 20090 Vimodrone Italien test for mycoplasma qualification of reference standard substances using chromatographic and mass spectrometric methods
	Eurofins PROXY Laboratories B.V. Darwinweg 24 2333CR LEIDEN

test for mycoplasma

Eurofins Spinnovation Analytical B.V.
Kloosterstraat 9 PP, RK, OSS
5349AB Netherlands
Qualification of reference standard substances using DSC, DVS, XRD und NMR

Eurofins IDmyk SAS
1 Rue des Vergers Batiment 4 Hall B
69760 Limonest, Frankreich
Frankreich
Testing of starting material, method development and validation,
Release analytics

Eurofins PHAST Development GmbH & Co. KG
Byk-Gulden-Strasse 2
78467 Konstanz
Physico-chemical determination, e.g. content, purity and/or identity by HPLC and GC with mass spectroscopy,
Water determination by Karl Fischer titrations,
Content determination by titrations and ion chromatography,
Particulate determination by Helos, Sprayview and micro flow imaging
Biological determination
HCP-determination by Sprayblott,
Identity determination by SDS-PAGE,
Protein activity by elisa
Storage of stability samples

Eurofins Amatsi Analytics SAS
Parc de Génibrat
31470 Fontenilles
Frankreich
Stability storage and testing

Eurofins Analytics & Services Austria GmbH
Sankt-Peter-Straße 25
A-4020 Linz
Österreich
Purity tests and raw material testing

Eurofins BioPharma Product Testing Hamburg GmbH
Am Neuländer Gewerbepark 2
21079 Hamburg

Raw material testing and microbiological testing

Eurofins BioPharma Product Testing Switzerland AG
Parkstraße 10
5012 Schönenwerd
Schweiz
Microbiological tests

Eurofins Biopharma Product Testing Spain S.L.U.
Calle de Josep Argemi 13-15
08950 Esplugues de Llobregat, Barcelona
Spanien
Test for nitrosamines

Eurofins Pharma Quality Control (EPQC)
rue Clément Ader 16
68127 SAINTE CROIX EN PLAINE
Frankreich
Stability storage and testing

Eurofins Pharma Quality Control
9 Avenue de Laponie
91978 Les Ulis
Frankreich
Stability storage and testing

Name(s) of Qualified Person(s)	Mr. Dr. Denis Theobald Mr. Dr. Denis Theobald is responsible for the batch release pursuant to § 16 AMWHV: - of the finished pharmaceutical products with the active pharmaceutical ingredients Rivastigmin - of the investigational medicinal products with the active pharmaceutical ingredient Rimeporide (Verum and Placebo) - of the finished pharmaceutical products Alfuzosin 5mg and Alfuzosin 10mg - in the event of vacation and illness, as well as other absences as a substitute for Dr. Caspar the finished pharmaceutical products with the active pharmaceutical ingredients Metreleptin Mr. Patrick Klein Mr. Patrick Klein is responsible for the batch release pursuant to § 16 AMWHV: Representation of Mr. Dr. Denis Theobald as a knowledgeable Person in the vacation and illness case - in the Project Rivastigmin transdermal patches - of the finished pharmaceutical products Alfuzosin 5mg and Alfuzosin 10mg Mr. Dr. Achim Caspar Mr. Dr. Achim Caspar is responsible for the batch release pursuant to § 16 AMWHV: - of the finished pharmaceutical products with the active pharmaceutical ingredients Metreleptin - in the event of vacation and illness, as well as other absences as a substitute for Dr. Theobald the finished pharmaceutical products with the active pharmaceutical ingredients Rivastigmin Mrs. Dr. Franziska Krebs Mrs. Dr. Franziska Krebs is responsible for the batch release pursuant to § 16 AMWHV: Representation of Dr. Theobald as an expert person in

case of leave and sickness, as well as other absences
- Rivastigmine transdermal patch
Representation of Dr. Caspar as a qualified person in case of leave and sickness, as well as other absences
- in the project Metreleptin

Date of Inspection on which authorisation was granted	13/12/2023