

MANUFACTURER / IMPORTER AUTHORISATION

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

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| 1. Authorisation number/file number | DE_SL_01_MIA_2026_0002/5000-120#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) |
| 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 |
| 7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation |  |
| 8. Signature | On behalf |
| 9. Date | 19/01/2026 |
| 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**1.2 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*Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

to 1.2.2 batch certification of non-sterile products:
transdermal patches with the active ingredient rivastigmine

to 1.3.2.5: batch certification of biotechnology products
concentrate for solution for infusion with the active ingredient catumaxomab, sterile
- KORJUNY 10 micrograms concentrate for solution for infusion - marketing authorisation number
EU/1/24/1826/001
- KORJUNY 50 micrograms concentrate for solution for infusion - marketing authorisation number
EU/1/24/1826/002

concentrate for solution for infusion with the active ingredient toripalimab, sterile
-LOQTORZI 240 mg concentrate for solution for infusion - marketing authorisation number
EU/1/24/1853/001

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	<i>2.1.3 Chemical/Physical</i>
	<i>2.1.4 Biological</i>
2.2	Batch certification of imported medicinal products
	<i>2.2.2 Non-sterile products</i>
	<i>2.2.3 Biological products</i>
	2.2.3.5 Biotechnology products
2.3	Other importation activities
	<i>2.3.1 Site of physical importation</i>

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

Import of patches with the active ingredient rivastigmine

Import of LOQTORZI 240 mg concentrate for solution for infusion - marketing authorisation number EU/1/24/1853/001 (Active ingredient: toripalimab)

Site of physical importation for LOQTORZI:
 Movianto Deutschland GmbH
 In der Vogelsbach 1
 66540 Neunkirchen

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
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AUTHORISED OPERATIONS Manufacturing Operations (according to part 1)
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Part 1 - MANUFACTURING OPERATIONS	
1.6	Quality control testing
	<i>1.6.3 Chemical/Physical</i>
	<i>1.6.4 Biological</i>

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
Site of physical importation (LOQTORZI 240 mg
concentrate for solution for infusion - marketing
authorisation number EU/1/24/1853/001)

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)

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 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 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 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 BioPharma Product Testing Czech Republic s.r.o
Videnska 204/125, Prizrenice
61900 Brno
Tschechische Republik
Analytical tests (e.g. chromatographic analyses)

Eurofins Biopharma Product Testing Biologics, Zone
Industrielle Du Charpenay
12 Rue du Parc d'Activités
69210 Lentilly
Frankreich

Stability storage of raw materials
Analytical testing (e.g. release testing of raw materials)

Henkel AG & Co. KGaA, Department Corporate Scientific
Solutions
Henkelstraße 67
40589 Düsseldorf
Analytical testing for nitrosamines and residues of cleaning
agents

Microcoat Biotechnologie GmbH
Am Neuland 3
82347 Bernried am Starnberger See
Microbiological testing, (e.g. endotoxins)

Eurofins Pharma Quality Control, ZI de Courtaboeuf
9 avenue de Laponie
91940 Les Ulis
Frankreich
Physical and chemical testing
Stability storage and testing

Eurofins BioPharma Product Testing Munich GmbH
Robert-Koch-Str. 3a
82152 Planegg
Sterility testing
Test for endotoxins
Analytical tests (e.g. bioassay, chromatographic methods)

Eurofins Biolab S. r. l.
Via Bruno Buozzi 2
20055 Vimodrone
Italien
Testing for mycoplasma
Qualification of reference standard substances using
chromatographic and mass spectrometric methods
Microbiological testing (e.g. sterility, CCIT, endotoxins)
Analytical testing (e.g. titration, GC, nitrosamines, lubricity)

Name(s) of Qualified Person(s)

Mrs. Dr. Franziska Krebs

Mr. Patrick Klein

Deputy

Date of Inspection on which
authorisation was granted

13/12/2023