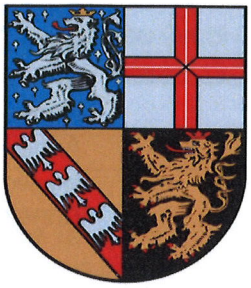

MANUFACTURER / IMPORTER AUTHORISATION

(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_0019/5000-105#002
2. Name of authorisation holder	CBA Chemische Produkte- Beratung und -Analyse GmbH (LOC-100029704)
3. Address(es) of manufacturing site(s)	CBA Chemische Produkte- Beratung und -Analyse GmbH Konrad-Zuse-Straße 10 66459 Kirkel (LOC-100029704)
4. Legally registered address of authorisation holder	Konrad-Zuse-Straße 10 66459 Kirkel-Limbach
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	Vanessa Nguyen
8. Signature	On behalf
9. Date	06/03/2024

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 6 (Name of responsible persons) Annex 7 (Date of inspection on which authorisation granted, scope of last inspection) Annex 8 (Manufactured/ imported products authorised)

SCOPE OF AUTHORISATION **Annex 1**

Name and address of the site:
CBA Chemische Produkte- Beratung und -Analyse GmbH, Konrad-Zuse-Straße 10, 66459 Kirkel

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
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological

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

To 1.3.1. only the medicinal products listet in Annex 8

Examination of pharmaceutical forms according to the European Pharmacopoeia:
Solid forms, semi-solid forms, parenteral, oral fluids

On 1. 6. Examination methods:
- Microbiological tests (pharmacopoeial methods and others)
- Biological tests (endotoxin and pyrogen tests)
- Molecular biological tests (PCR and others)
- Immunological test methods (ELISA and others)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products
	2.2.1.1 Aseptically prepared

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

The import activity is limited to levosimendan carinopharm 12,5 mg powder semi-finished products listed in Appendix 8.

SCOPE OF AUTHORISATION **Annex 2**

Name and address of the site:
CBA Chemische Produkte- Beratung und -Analyse GmbH, Konrad-Zuse-Straße 10, 66459 Kirkel

Investigational Medicinal Products for Human Use

AUTHORISED OPERATIONS Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile Products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical
	1.6.4 Biological

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

The authorisation covers only investigational preparations containing chemical active substances and the following dosage forms: - Solutions for injection and infusion - Tablets

Annex 3

Address(es) of Contract Manufacturing Sites	Baccinex SA Rue de la Source 3 CH-2822 Courroux Schweiz Preparation of Levosimendan Carinopharm, sterile lyophilisate

Annex 4

Address(es) of Contract Laboratories	Haupt Pharma Wülfing GmbH Bethelner Landstraße 18 31028 Gronau/Leine Service laboratory for stability storage according to ICH conditions MoNo chem.-pharm. Produkte GmbH Leystraße 129 1200 Wien Österreich GMP storage at 2-8° C und -20° C (< -15° C) and at room temperature (15-25° C) Eurofins PHAST GmbH Kardinal-Wendel-Straße 16 66424 Homburg Service laboratory for stability storage according to ICH conditions Sykam Chromatographie Vertriebs GmbH Carl-von-Linde-Straße 2 82256 Fürstenfeldbruck Amino acid analysis Eurofins BioPharma Product Testing Munich GmbH Robert-Koch-Str. 3a 82152 Planegg Microbiological service laboratory Testing for sterility and endotoxins according to the European Pharmacopoeia

Annex 5

Name(s) of Qualified Person(s)	Mrs. Dr. Andrea Weiland-Waibel

Name(s) of person(s) responsible for quality control	Mrs. Dr. Madeleine Walter
Name(s) of person(s) responsible for production	Mrs. Dr. Andrea Weiland-Waibel

Date of Inspection on which authorisation was granted	15/11/2023
Scope of last Inspection	look for the inspection report