Bezirksregierung Düsseldorf

MANUFACTURER / IMPORTER AUTHORISATION

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

1. Authorisation number/file number	DE_NW_03_MIA_2024_0038/24.05.05.01-Paesel & Lorei
2. Name of authorisation holder	Paesel & Lorei GmbH & Co. KG Biochemika, Diagnostika und Pharmazeutika (LOC-100016612)
3. Address(es) of manufacturing site(s)	Paesel & Lorei GmbH & Co. KG Biochemika, Diagnostika und Pharmazeutika Nordring 11 47495 Rheinberg (LOC-100016612)
4. Legally registered address of authorisation holder	Nordring 11 47495 Rheinberg
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	Sonja Grüterich
8. Signature	On behalf
9. Date	30/09/2024

10. Annexes attached	Annex 1 and Annex 2 Annex 4 (Addresses of Contract Laboratories) Annex 8 (Manufactured/ imported products authorised)

SCOPE OF AUTHORISATION **Annex 1**

Name and address of the site:
Paesel & Lorei GmbH & Co. KG Biochemika, Diagnostika und Pharmazeutika, Nordring 11, 47495 Rheinberg

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
1.5	**Packaging**
	1.5.2 Secondary packing

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

ref. 1.5.2: - excludes radioactive medicinal products

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non-sterility
	2.1.3 Chemical/Physical
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
2.3	**Other importation activities**
	2.3.1 Site of physical importation

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

ref. 2.2:
The authorisation refers to the batch certification of imported medicinal products and to the site of physical importation of medicinal products (see annex 8). The EU-retest is carried out by a contract laboratory (see annex 4).

ref. 2.2.2:
The EU reanalysis is carried out by a commissioned test laboratory (see Annex 4).

ref. 2.3.1:
The authorisation refers to the site of physical importation of medicinal products (see annex 8). There are no further manufacturing activities.

SCOPE OF AUTHORISATION **Annex 2**

Name and address of the site:
Paesel & Lorei GmbH & Co. KG Biochemika, Diagnostika und Pharmazeutika, Nordring 11, 47495 Rheinberg

Investigational Medicinal Products for Human Use

AUTHORISED OPERATIONS Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.2 Secondary packing

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

ref. 1.5.2:
- excludes radioactive medicinal products,
- the manufacture of investigational medicinal products is restricted to repackaging (incl. packaging) without opening of the primary packaging, relabelling and storage of retention samples under room temperature as well as under controlled conditions (2°-8°C).

Annex 4

Address(es) of Contract Laboratories

Annex 8

Products authorised to be manufactured/imported (in accordance with Article 41 and 42 of Directive 2001/83/EC and/or Article 89 and 90 of Regulation (EU) 2019/6, as amended).