# 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_NW_03_MIA_2023_0035/24.05.05.01-Paesel & Lorei |
| 2. Name of authorisation holder | Paesel & Lorei GmbH & Co. KG<br>Biochemika, Diagnostika und Pharmazeutika<br>(LOC-100016612) |
| 3. Address(es) of manufacturing site(s) | Paesel & Lorei GmbH & Co. KG Biochemika,<br>Diagnostika und Pharmazeutika<br>Nordring 11<br>47495 Rheinberg<br>(LOC-100016612) |
| 4. Legally registered address of authorisation holder | Nordring 11<br>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)<br>Sect 72 para 1 Arzneimittelgesetz (German Drug Law)<br>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 | Sven Herdmann |
| 8. Signature | On behalf |
| 9. Date | 05/02/2024 |

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| 10. Annexes attached | Annex 1 and Annex 2<br>Annex 4 (Addresses of Contract Laboratories)<br>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 |
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| **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:<br>- excludes radioactive medicinal products |
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| Part 2 - IMPORTATION OF MEDICINAL PRODUCTS | |
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| **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** |
| | *2.2.2 Non-sterile 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. 2.2.2:
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. 2.3.1:
The authorisation refers to the site of physical importation of medicinal products (see annex 8). There are no further manufacturing activities.

The authorisation refers to the site of physical importation of medicinal products (see annex 8) and ref. 2.2.2. 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

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| Investigational Medicinal Products for Human Use |

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| **AUTHORISED OPERATIONS**<br>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

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| ref. 1.5.2:<br>- excludes radioactive medicinal products,<br>- 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**

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| 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).

Nachfolgende Produkte beziehen sich auf die Anlage 1, Teil 2, Ziffer 2.3.1 (Betriebsstätte der physischen Einfuhr) dieser Erlaubnis: