# MANUFACTURER'S AUTHORISATION [1] , [2]

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|---|---|
| 1. Authorisation Number | 271/0637/22 |
| 2. Name of authorisation holder | Sciencepharma Sp. z o.o. (ORG-100001975 / LOC-100002407) |
| 3. Address(es) of manufacturing site(s) | Sciencepharma Sp. z o.o. (ORG-100001975 / LOC-100002407), Ul. Chelmska 30/34, Warsaw, 00-725, Poland |
| 3.a Additional details on units inspected of manufacturing site(s) address(es) | |
| 4. Legally registered address of authorisation holder | Ul. Chelmska 30/34, Warsaw, 00-725, Poland |
| 5. Scope of authorisation and dosage forms[2] | ANNEX 1 and/ or ANNEX 2 |
| 6. Legal Basis of authorisation | Art. 40 of Directive 2001/83/EC<br>Art. 13 of Directive 2001/20/EC |
| 7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation | confidential |
| 8. Signature | |
| 9. Date | 2023-02-06 |
| 10. Annexes attached | Annex 1 and/or Annex 2<br>Optional Annexes as required:<br>Annex 3(Addresses of Contract Manufacturing Site(s))<br>Annex 4(Addresses of Contract laboratories)<br>Annex 5(Name of Qualified Person)<br>Annex 6(Name of responsible persons)<br>Annex 7(Date of inspection on which authorisation granted, scope of last inspection)<br>Annex 8(Manufactured/ imported products authorised)[3] |

[1] *The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC and 44(1) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).*

**SCOPE OF AUTHORISATION** **ANNEX 1**

Name and address of the site: Sciencepharma Sp. z o.o., Ul. Chelmska 30/34, Warsaw, 00-725, Poland

Additional Details:

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|---|
| Human Medicinal Products |

| **Authorised Operations** |
|---|
| IMPORTATION OF MEDICINAL PRODUCTS(according to part 2) |

| **Part 2 - IMPORTATION OF MEDICINAL PRODUCTS** | |
|---|---|
| **2.2** | **Batch certification of imported medicinal products** |
| | *2.2.1 Sterile products*<br>2.2.1.1 Aseptically prepared<br>2.2.1.2 Terminally sterilised |
| | *2.2.2 Non-sterile products* |
| | *2.2.3 Biological medicinal products*<br>2.2.3.6 Human or animal extracted products |
| **2.3** | **Other importation activities** |
| | *2.3.4 Other: distribution(en)* |

**SCOPE OF AUTHORISATION** **ANNEX 2**

Name and address of the site : Sciencepharma Sp. z o.o., Ul. Chelmska 30/34, Warsaw, 00-725, Poland

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| Human Investigational Medicinal Products |

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| **Authorised Operations**<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2) |

| **Part 2 - IMPORTATION OF MEDICINAL PRODUCTS** | |
|---|---|
| **2.2** | **Batch certification of imported medicinal products** |
| | *2.2.1 Sterile products*<br>2.2.1.1 Aseptically prepared |
| | *2.2.2 Non-sterile products* |
| | *2.2.3 Biological medicinal products*<br>2.2.3.5 Biotechnology products |
| **2.3** | **Other importation activities** |
| | 2.3.4 Other: distribution(en) |