Manufacturer/Importer Authorisation [1], [2]

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 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	2023-12-11
10. Annexes attached	Annex 1 and/or Annex 2 Optional Annexes as required: 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)[3]

[1] *The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC as amended and Article 88(1) of Regulation (EU) 2019/6, 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 Interpretation of the Union format for Manufacturer/Importer Authorisation.*

[3] *The Competent Authority is responsible for the appropriate linking of the authorisation with the manufacturer's application (Article 42(3) of Directive 2001/83/EC as amended and Article 90(3) of Regulation (EU) 2019/6).*

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:

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

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products
	2.2.3 Biological medicinal products 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

Additional Details:

Human Investigational 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 2.2.1.1 Aseptically prepared
	2.2.2 Non-sterile products
	2.2.3 Biological medicinal products 2.2.3.5 Biotechnology products
2.3	**Other importation activities**
	2.3.4 Other: distribution(en)