

Manufacturer/Importer Authorisation^{1, 2}

1. Authorisation Number BG/MIA-0503
2. Name of authorisation holder Kevaro Group EOOD (ORG-100034005 / LOC-100053703)
3. Address(es) of manufacturing site(s) Kevaro Group EOOD (ORG-100034005 / LOC-100053703), Floor 5, Ulitsa Tsaritsa Eleonora 9 Office 23, Sofia, 1618, Bulgaria
Kevaro Group EOOD (ORG-100034005 / LOC-100096028), Floor 8, Ulitsa Nedelcho Bonchev 8, Sofiya, 1528, Bulgaria
4. Legally registered address of authorisation holder Floor 5, Ulitsa Tsaritsa Eleonora 9 Office 23, Sofia, 1618, Bulgaria
5. Scope of authorisation and dosage forms² ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation Art. 40 of Directive 2001/83/EC
Art. 61 of Regulation (EU) No 536/2014
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation confidential
8. Signature
9. Date 2025-04-10
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

¹The 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.

²Guidance on the interpretation of this template can be found in the Interpretation of the Union format for Manufacturer/Importer Authorisation.

³The 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: Kevaro Group EOOD, Floor 5, Ulitsa Tsaritsa Eleonora 9 Office
23, Sofia, 1618, Bulgaria

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	
1.1	Sterile products
	1.1.3 Batch certification
1.2	Non-sterile products
	1.2.2 Batch certification
1.3	Biological medicinal products (list of product types)
	1.3.2 Batch Certification (list of product types) 1.3.2.5 Biotechnology products
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 2.2.3.5 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 (for Public users)

KeVaRo GROUP Ltd doesn't possess any storage premises. Medicinal products storage operations are performed under contract Quality control of the imported batches of medicinal products is performed by companies listed in Annex 4.

SCOPE OF AUTHORISATION

ANNEX 2

Name and address of the site : Kevaro Group EOOD, Floor 5, Ulitsa Tsaritsa Eleonora 9 Office
23, Sofia, 1618, Bulgaria

Additional Details:

Human Investigational Medicinal Products
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Authorised Operations

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.2	Batch certification of imported medicinal products
	<i>2.2.1 Sterile products</i> 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	<i>2.2.2 Non-sterile products</i>
	<i>2.2.3 Biological medicinal products</i> 2.2.3.3 Cell therapy 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 (for Public users)

KeVaRo GROUP Ltd doesn't possess any storage premises. Storage operations of investigational medicinal products are performed under contract at address: 425 Tsarigradsko Shose Blvd., Sofia 1137.

SCOPE OF AUTHORISATION

ANNEX 1

Name and address of the site: Kevaro Group EOOD, Floor 8, Ulitsa Nedelcho Bonchev 8,
Sofiya, 1528, Bulgaria

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

1.6	Quality control testing
	1.6.3 Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

2.1	Quality control testing of imported medicinal products
	2.1.3 Chemical/Physical