Manufacturer/Importer Authorisation [1], [2]

1. Authorisation Number	sukls123199/2024
2. Name of authorisation holder	Eurofins BioPharma Product Testing Czech Republic s.r.o. (ORG-100005361 / LOC-100010303)
3. Address(es) of manufacturing site(s)	Eurofins BioPharma Product Testing Czech Republic s.r.o. (ORG-100005361 / LOC-100010303), Videnska 204/125, Prizrenice, Brno, 619 00, CZECHIA
4. Legally registered address of authorisation holder	Videnska 204/125, Prizrenice, Brno, 619 00, CZECHIA
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
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2024-08-28
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: Eurofins BioPharma Product Testing Czech Republic s.r.o., Videnska 204/125, Prizrenice, Brno, 619 00, CZECHIA

Additional Details:

DUNS Number : 49-578-2570

Human Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS(according to part 1)
IMPORTATION OF MEDICINAL PRODUCTS(according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.4	**Other products or manufacturing activity**
	1.4.3 Other: Confirmation(en)
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
2.3	**Other importation activities**
	2.3.4 Other: Confirmation(en)