Manufacturer/Importer Authorisation [1, 2]

1. Authorisation Number	800-17/2024-15
2. Name of authorisation holder	GaiaCell d.o.o. (ORG-100052201 / LOC-100091894)
3. Address(es) of manufacturing site(s)	GaiaCell d.o.o. (ORG-100052201 / LOC-100091894), Prevale 9, Trzin, 1236, Slovenia, GPS: 46.122370, 14.548149
4. Legally registered address of authorisation holder	Prevale 9, Trzin, 1236, Slovenia, GPS: 46.122370, 14.548149
5. Scope of authorisation and dosage forms[2]	ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation	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	2024-11-05
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 2**

Name and address of the site : GaiaCell d.o.o., Prevale 9, Trzin, 1236, Slovenia, GPS: 46.122370, 14.548149

Additional Details:

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.6 Other: (cell) dispersion for injection/infusion(en) Special Requirements : 3 Live Cells
	1.1.3 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.3 Cell therapy products Special Requirements : 3 Live Cells
	1.3.2 Batch Certification (list of product types) 1.3.2.3 Cell therapy products Special Requirements : 3 Live Cells
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility 1.6.4 Biological