Manufacturer/Importer Authorisation [1, 2]

1. Authorisation Number	IMP12181/00001
2. Name of authorisation holder	Almac Clinical Services (Ireland) Limited (ORG-100033336 / LOC-100052086)
3. Address(es) of manufacturing site(s)	Almac Clinical Services (Ireland) Limited (ORG-100033336 / LOC-100052086), Finnabair Industrial Estate, Dundalk, A91 P9KD, Ireland
3.a Additional details on units inspected of manufacturing site(s) address(es)	
4. Legally registered address of authorisation holder	Finnabair Industrial Estate, Dundalk, A91 P9KD, Ireland
4.a Additional details on units inspected of legally registered address	
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	2023-12-07
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 : Almac Clinical Services (Ireland) Limited, Finnabair Industrial Estate, Dundalk, A91 P9KD, Ireland

Additional Details:

Human Investigational 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) 1.3.2.1 Blood products 1.3.2.2 Immunological products 1.3.2.3 Cell therapy products 1.3.2.4 Gene therapy products 1.3.2.5 Biotechnology products 1.3.2.6 Human or animal extracted products
1.5	**Packaging**
	1.5.2 Secondary packaging

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

This site is authorised to supply medicinal products in accordance with the provisions of Article 5 of Directive 2001/83/EC providing that it would normally conduct a manufacturing activity, as listed above, for the product concernedAuthorisation to carry out Secondary Packaging and labelling, and Just In Time (JIT) labelling i.e. labelling immediately prior to despatchAuthorised operations include remote batch certification by a Qualified Person when operating within the EEA or Northern Ireland

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 2.2.3.1 Blood products 2.2.3.2 Immunological products 2.2.3.3 Cell therapy products 2.2.3.4 Gene therapy products 2.2.3.5 Biotechnology products 2.2.3.6 Human or animal extracted 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)

This site is authorised to supply medicinal products in accordance with the provisions of Article 5 of Directive 2001/83/EC providing that it would normally conduct an importation activity, as listed above, for the product concerned.Authorised operations include remote batch certification by a Qualified Person when operating within the EEA or Northern Ireland