Manufacturer/Importer Authorisation [1, 2]

1. Authorisation Number	4491 F
2. Name of authorisation holder	Medcor Pharmaceuticals B.V. (ORG-100013485 / LOC-100019037)
3. Address(es) of manufacturing site(s)	Medcor Pharmaceuticals B.V. (ORG-100013485 / LOC-100019037), Artemisweg 232, Lelystad, 8239 DE, Netherlands Medcor Pharmaceuticals B.V. (ORG-100013485 / LOC-100051066), Schutweg 23, Lelystad, 8243 PC, Netherlands
3.a Additional details on units inspected of manufacturing site(s) address(es)	
4. Legally registered address of authorisation holder	Artemisweg 232, Lelystad, 8239 DE, Netherlands
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. 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	2022-10-05
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 1

Name and address of the site: Medcor Pharmaceuticals B.V., Artemisweg 232, Lelystad, 8239 DE, Netherlands

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) 1.3.2.1 Blood products 1.3.2.2 Immunological products 1.3.2.5 Biotechnology products
1.5	**Packaging**
	1.5.2 Secondary packaging

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.3	**Other importation activities**
	2.3.1 Site of physical importation

SCOPE OF AUTHORISATION **ANNEX 1**

Name and address of the site: Medcor Pharmaceuticals B.V., Schutweg 23, Lelystad, 8243 PC, Netherlands

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) 1.3.2.1 Blood products 1.3.2.2 Immunological products 1.3.2.5 Biotechnology products
1.5	**Packaging**
	1.5.2 Secondary packaging
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.3	**Other importation activities**
	2.3.1 Site of physical importation