Manufacturer/Importer Authorisation [1, 2]

1. Authorisation Number	104622
2. Name of authorisation holder	Vepidan ApS (ORG-100014276 / LOC-100020135)
2.1. Alternative name of authorisation holder	
3. Address(es) of manufacturing site(s)	Vepidan ApS (ORG-100014276 / LOC-100020135), Oesterbrogade 23, Loegstoer, Nordjylland, 9670, Denmark Vepidan ApS (ORG-100014276 / LOC-100020136), Limfjordsvej 9/11, Loegstoer, 9670, Denmark
3.a Additional details on units inspected of manufacturing site(s) address(es)	
4. Legally registered address of authorisation holder	Oesterbrogade 23, Loegstoer, Nordjylland, 9670, Denmark
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 Art. 88 of Regulation (EU) 2019/6
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2025-08-15
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: Vepidan ApS, Oesterbrogade 23, Loegstoer, Nordjylland, 9670, Denmark

Additional Details:

Human Medicinal Products Veterinary Medicinal Products

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

Part 1 - MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.2 Secondary packaging

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation *2.3.4 Other: Medicinal products for compassionate use for delivery in Denmark and other EEA countries(en)*

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

2.3.4: Export of pharmaceutical products for compassionate use are on the condition that the authorities of each respective country accept and continues to accept that products without a

Marketing Authorisation are distributed from Denmark. It is a further condition that the authorities of each respective country are informed that the imported pharmaceutical products are not analysed in Denmark.

SCOPE OF AUTHORISATION **ANNEX 1**

Name and address of the site: Vepidan ApS, Limfjordsvej 9/11, Loegstoer, 9670, Denmark

Additional Details:

Human Medicinal Products Veterinary Medicinal Products

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

Part 1 - MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.2 Batch certification

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation *2.3.4 Other: Medicinal products for compassionate use for delivery in Denmark and other EEA countries(en)*

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

2.3.4: Export of pharmaceutical products for compassionate use are on the condition that the authorities of each respective country accept and continues to accept that products without a Marketing Authorisation are distributed from Denmark. It is a further condition that the authorities of each respective country are informed that the imported pharmaceutical products are not analysed in Denmark.