

Manufacturer/Importer Authorisation^{1, 2}

1. Authorisation Number 16383 F
2. Name of authorisation holder Top-Pharma B.V. (ORG-100017384 / LOC-100096198)
- 2.1. Alternative name of authorisation holder
3. Address(es) of manufacturing site(s) Top-Pharma B.V. (ORG-100017384 / LOC-100096198),
Hagelkruisweg 20, Grubbenvorst, Limburg, 5971 EA, Netherlands
- 3.a Additional details on units inspected of manufacturing site(s) address(es)
4. Legally registered address of authorisation holder Hagelkruisweg 20, Grubbenvorst, Limburg, 5971 EA, Netherlands
- 4.a Additional details on units inspected of legally registered address
5. Scope of authorisation and dosage forms² 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 2025-07-07
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 1

Name and address of the site: Top-Pharma B.V., Hagelkruisweg 20, Grubbenvorst, Limburg,
5971 EA, Netherlands

Additional Details:

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS^(according to part 1)

Part 1 - MANUFACTURING OPERATIONS

1.2 Non-sterile products

1.2.2 Batch certification

1.5 Packaging

1.5.2 Secondary packaging