

MANUFACTURER'S AUTHORISATION^{1, 2}

1. Authorisation Number 5866 F
2. Name of authorisation holder Originalis B.V., AMSTERDAM-DUIVENDRECHT
3. Address(es) of manufacturing site(s) Originalis B.V., Diamantweg 4, ALKMAAR, 1812RC, Netherlands
4. Legally registered address of authorisation holder Joop Geesinkweg 901, AMSTERDAM-DUIVENDRECHT, 1114AB, Netherlands
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 2021-05-11
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 and 44(1) of Directive 2001/82/EC, as amended, 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 Help menu of EudraGMDP database.

³ The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).

SCOPE OF AUTHORISATION

ANNEX 1

Name and address of the site : Originalis B.V., Diamantweg 4, ALKMAAR, 1812RC,
Netherlands

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

1.1	Sterile products
	<i>1.1.3 Batch certification</i>
1.2	Non-sterile products
	<i>1.2.2 Batch certification</i>
1.3	Biological medicinal products (list of product types)
	<i>1.3.2 Batch Certification (list of product types)</i> 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