

Manufacturer/Importer Authorisation ^{1, 2}

1. Authorisation Number DE_SH_01_MIA_2019_0029
2. Name of authorisation holder Schuelke & Mayr GmbH
3. Address(es) of manufacturing site(s) Schuelke & Mayr GmbH (ORG-100000981 / LOC-100004861), Robert-Koch-Strasse 2, Norderstedt, Schleswig-Holstein, 22851, Germany
4. Legally registered address of authorisation holder Robert-Koch-Strasse 2, Norderstedt, Schleswig-Holstein, 22851, Germany
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
Art. 44 of Directive 2001/82/EC
Art. 13 of Directive 2001/20/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation confidential
8. Signature
9. Date 2019-12-18
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

¹The 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.

²Guidance on the interpretation of this template can be found in the Interpretation of the Union format for Manufacturer/Importer Authorisation.

³The 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: Schuelke & Mayr GmbH, Robert-Koch-Strasse 2, Norderstedt, Schleswig-Holstein, 22851, Germany

Additional Details:

Human Medicinal Products
Veterinary Medicinal Products

Authorised Operations MANUFACTURING OPERATIONS (according to part 1)
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Part 1 - MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.5 Liquids for external use 1.2.1.17 Other: Wet wipes for external use(en)
	<i>1.2.2 Batch certification</i>
1.6	Quality control testing
	<i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>

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

SCOPE OF AUTHORISATION

ANNEX 2

Name and address of the site : Schuelke & Mayr GmbH, Robert-Koch-Strasse 2, Norderstedt, Schleswig-Holstein, 22851, Germany

Additional Details:

Human Investigational Medicinal Products
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Authorised Operations MANUFACTURING OPERATIONS (according to part 1)
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Part 1 - MANUFACTURING OPERATIONS	
1.2	Non-sterile investigational medicinal products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.5 Liquids for external use
	<i>1.2.2 Batch certification</i>
1.6	Quality control testing
	1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical

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

Veterinary or Human Investigational Medicinal Products (Clinical trials to phase III)