Manufacturer/Importer Authorisation [1, 2]

1. Authorisation Number	DE_SH_01_MIA_2025_0007
2. Name of authorisation holder	Schuelke & Mayr GmbH (ORG-100000981 / LOC-100004861)
3. Address(es) of manufacturing site(s)	Schuelke & Mayr GmbH (ORG-100000981 / LOC-100004861), Robert-Koch-Strasse 2, Norderstedt, Schleswig-Holstein, 22851, Germany
3.a Additional details on units inspected of manufacturing site(s) address(es)	
4. Legally registered address of authorisation holder	Robert-Koch-Strasse 2, Glashuette, Norderstedt, Schleswig-Holstein, 22851, Germany
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 Art. 61 of Regulation (EU) No 536/2014
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2025-06-23
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]

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[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: 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)

Part 1 - MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.5 Liquids for external use 1.2.1.17 Other: Wet wipes for external use(en)
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.5 Liquids for external use
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

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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

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.2	**Non-sterile investigational medicinal products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.5 Liquids for external use
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.5 Liquids for external use
	1.5.2 Secondary packaging
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)

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