

## Manufacturer/Importer Authorisation <sup>1, 2</sup>

1. Authorisation Number DE\_SH\_01\_MIA\_2025\_0005
2. Name of authorisation holder Lichtenheldt GmbH Pharmazeutische Fabrik (ORG-100011704 / LOC-100020595)
3. Address(es) of manufacturing site(s) Lichtenheldt GmbH Pharmazeutische Fabrik (ORG-100011704 / LOC-100020595), Industriestrasse 7 - 11, Wahlstedt, Schleswig-Holstein, 23812, Germany  
Lichtenheldt GmbH Pharmazeutische Fabrik (ORG-100011704 / LOC-100020699), Justus-Liebig-Weg 1, Wahlstedt, Schleswig-Holstein, 23812, Germany
- 3.a Additional details on units inspected of manufacturing site(s) address(es)
4. Legally registered address of authorisation holder Industriestrasse 7 - 11, Wahlstedt, Schleswig-Holstein, 23812, Germany
- 4.a Additional details on units inspected of legally registered address
5. Scope of authorisation and dosage forms<sup>2</sup> 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 2025-03-14
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)<sup>3</sup>

<sup>1</sup>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.

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

<sup>3</sup>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: Lichtenheldt GmbH Pharmazeutische Fabrik, Industriestrasse 7 - 11, Wahlstedt, Schleswig-Holstein, 23812, Germany

Additional Details:

Human Medicinal Products
Veterinary Medicinal Products

### Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

### Part 1 - MANUFACTURING OPERATIONS

<b>1.2</b>	<b>Non-sterile products</b>
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.5 Liquids for external use Special Requirements : 7 Other: Hormones or substances with hormonal activity(en) 1.2.1.6 Liquids for internal use Special Requirements : 7 Other: Hormones or substances with hormonal activity(en) 1.2.1.11 Semi-solids Special Requirements : 7 Other: Hormones or substances with hormonal activity(en)
	<i>1.2.2 Batch certification</i>
<b>1.3</b>	<b>Biological medicinal products (list of product types)</b>
	<i>1.3.1 Biological medicinal products (list of product types)</i> 1.3.1.6 Human or animal extracted products Special Requirements : 7 Other: Human Medicinal Products with heparin or bee venom(en)
<b>1.4</b>	<b>Other products or manufacturing activity</b>

	<i>1.4.1 Manufacture of</i> 1.4.1.1 Herbal products 1.4.1.2 Homoeopathic products
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.1 Primary Packaging</i> 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.11 Semi-solids
	<i>1.5.2 Secondary packaging</i>
<b>1.6</b>	<b>Quality control testing</b>
	<i>1.6.3 Chemical/Physical</i>

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

To 1.2.1.5 Also Veterinary Investigational Medicinal Products in the dosage forms liquids for external use. Also Veterinary Investigational Products as placebos in the dosage forms liquids for external use.

## SCOPE OF AUTHORISATION

## ANNEX 2

Name and address of the site : Lichtenheldt GmbH Pharmazeutische Fabrik, Industriestrasse 7 - 11, Wahlstedt, Schleswig-Holstein, 23812, Germany

Additional Details:

Human Investigational Medicinal Products
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<b>Authorised Operations</b> MANUFACTURING OPERATIONS (according to part 1)
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<b>Part 1 - MANUFACTURING OPERATIONS</b>	
<b>1.2</b>	<b>Non-sterile investigational medicinal products</b>
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.11 Semi-solids
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.1 Primary Packaging</i> 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.11 Semi-solids
	<i>1.5.2 Secondary packaging</i>
<b>1.6</b>	<b>Quality control testing</b>
	1.6.3 Chemical/Physical

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

To 1.5.1.5, 1.5.1.6 and 1.5.1.11 The manufacturing steps blinding and randomization are excluded from the scope of production.

## SCOPE OF AUTHORISATION

## ANNEX 1

Name and address of the site: Lichtenheldt GmbH Pharmazeutische Fabrik,  
Justus-Liebig-Weg 1, Wahlstedt, Schleswig-Holstein, 23812,  
Germany

Additional Details:

Human Medicinal Products Veterinary Medicinal Products
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<b>Authorised Operations</b> MANUFACTURING OPERATIONS (according to part 1)
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<b>Part 1 - MANUFACTURING OPERATIONS</b>	
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.1 Primary Packaging</i> 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.11 Semi-solids
	<i>1.5.2 Secondary packaging</i>
<b>1.6</b>	<b>Quality control testing</b>
	<i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>

## SCOPE OF AUTHORISATION

## ANNEX 2

Name and address of the site : Lichtenheldt GmbH Pharmazeutische Fabrik,  
Justus-Liebig-Weg 1, Wahlstedt, Schleswig-Holstein, 23812,  
Germany

Additional Details:

Human Investigational Medicinal Products
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<b>Authorised Operations</b> MANUFACTURING OPERATIONS (according to part 1)
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<b>Part 1 - MANUFACTURING OPERATIONS</b>	
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.1 Primary Packaging</i> 1.5.1.5 Liquids for external use
	<i>1.5.2 Secondary packaging</i>
<b>1.6</b>	<b>Quality control testing</b>
	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)**

To 1.5.1.5 The manufacturing steps blinding and randomization are excluded from the scope of production.