

MANUFACTURER'S AUTHORISATION^{1, 2}

1. Authorisation Number 003181/06.08.00.04/2018
2. Name of authorisation holder Oy Medfiles Ltd
3. Address(es) of manufacturing site(s) Oy Medfiles Ltd, Volttikatu 5, Volttikatu 8, Kuopio, FI-70700, Finland
Oy Medfiles Ltd, Neulaniementie 2, Kuopio, 70210, Finland
4. Legally registered address of authorisation holder PL 1450, Kuopio, FI-70701, Finland
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 2018-05-18
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

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 : Oy Medfiles Ltd, Volttikatu 5, Volttikatu 8, Kuopio, FI-70700, Finland

Human Medicinal Products
Veterinary Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

1.2	Non-sterile products
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	<i>1.2.2 Batch certification</i>
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1.6	Quality control testing
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	<i>1.6.3 Chemical/Physical</i>
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Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

2.1	Quality control testing of imported medicinal products
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	<i>2.1.3 Chemical/Physical</i>
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SCOPE OF AUTHORISATION

ANNEX 2

Name and address of the site : Oy Medfiles Ltd, Volttikatu 5, Volttikatu 8, Kuopio, FI-70700, Finland

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.8 Other solid dosage forms 1.2.1.15 Other: Intermediates: liquids and powders for further processing(en)
	<i>1.2.2 Batch certification</i>
1.5	Packaging
	<i>1.5.1 Primary Packing</i> 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms 1.5.1.13 Tablets 1.5.1.15 Other non-sterile medicinal products
	<i>1.5.2 Secondary packing</i>
1.6	Quality control testing
	1.6.3 Chemical/Physical
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	2.1.3 Chemical/Physical

SCOPE OF AUTHORISATION**ANNEX 1**

Name and address of the site : Oy Medfiles Ltd, Neulaniementie 2, Kuopio, 70210, Finland

Human Medicinal Products
Veterinary Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS**1.6 Quality control testing***1.6.2 Microbiological: non-sterility**1.6.4 Biological***Part 2 - IMPORTATION OF MEDICINAL PRODUCTS****2.1 Quality control testing of imported medicinal products***2.1.2 Microbiological: non-sterility**2.1.4 Biological*

SCOPE OF AUTHORISATION**ANNEX 2**

Name and address of the site : Oy Medfiles Ltd, Neulaniementie 2, Kuopio, 70210, Finland

Human Investigational Medicinal Products
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Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS**1.6 Quality control testing**

1.6.2 Microbiological: non-sterility

1.6.4 Biological

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**2.1 Quality control testing of imported medicinal products**

2.1.2 Microbiological: non-sterility

2.1.4 Biological