MANUFACTURER'S AUTHORISATION [1, 2]

1. Authorisation Number	FIMEA/2020/006562
2. Name of authorisation holder	Oy Medfiles Ltd
3. Address(es) of manufacturing site(s)	Oy Medfiles Ltd, Volttikatu 5, Volttikatu 8, Kuopio, 70700, Finland Oy Medfiles Ltd, Neulaniementie 2, Kuopio, 70210, Finland
4. Legally registered address of authorisation holder	PL 1450, Kuopio, 70701, Finland
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. 13 of Directive 2001/20/EC Art. 44 of Directive 2001/82/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2020-11-13
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, 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**
	1.2.2 Batch certification

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : Oy Medfiles Ltd, Volttikatu 5, Volttikatu 8, Kuopio, 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**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 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 1.2.1.13 Tablets 1.2.1.15 Other: Intermediates: liquids and powders for further processing(en)
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packaging 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: Intermediates: liquids and powders for further processing(en)
	1.5.2 Secondary packaging
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
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products

2.3	Other importation activities
	2.3.1 Site of physical importation 2.3.2 Importation of intermediate which undergoes further processing

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

2.2.2: The authorization covers also the batch certification of imported non-sterile comparator products outside EU/EEA. 2.3.2: Intermediates: powders and granules for further processing

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
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non-sterility

SCOPE OF AUTHORISATION **ANNEX 2**

Name and address of the site : Oy Medfiles Ltd, Neulaniementie 2, Kuopio, 70210, 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	
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non-sterility