

# MANUFACTURER'S AUTHORISATION<sup>1, 2</sup>

1. Authorisation Number 0000012546/21/1
2. Name of authorisation holder QUALIMETRIX ΕΡΓΑΣΤΗΡΙΑ ΑΝΑΛΥΣΗΣ – ΕΛΕΓΧΟΥ ΠΟΙΟΤΗΤΑΣ Α.Ε./ QUALIMETRIX S.A.
3. Address(es) of manufacturing site(s) QUALIMETRIX ΕΡΓΑΣΤΗΡΙΑ ΑΝΑΛΥΣΗΣ – ΕΛΕΓΧΟΥ ΠΟΙΟΤΗΤΑΣ Α.Ε./ QUALIMETRIX S.A., ΛΕΩΦΟΡΟΣ ΜΕΣΟΓΕΙΩΝ 579/ 579 MESOGEION AVENUE, ΑΓΙΑ ΠΑΡΑΣΚΕΥΗ/ AGIA PARASKEVI, Αθήνα / Athens, 15343, Greece
4. Legally registered address of authorisation holder ΛΕΩΦΟΡΟΣ ΜΕΣΟΓΕΙΩΝ 579/ 579 MESOGEION AVENUE, ΑΓΙΑ ΠΑΡΑΣΚΕΥΗ/ AGIA PARASKEVI, Αθήνα / Athens, 15343, Greece
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. 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 2021-08-23
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)<sup>3</sup>

<sup>1</sup> 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.

<sup>2</sup> Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

<sup>3</sup> 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 : QUALIMETRIX ΕΡΓΑΣΤΗΡΙΑ ΑΝΑΛΥΣΗΣ – ΕΛΕΓΧΟΥ ΠΟΙΟΤΗΤΑΣ Α.Ε./ QUALIMETRIX S.A., ΛΕΩΦΟΡΟΣ ΜΕΣΟΓΕΙΩΝ 579/ 579 MESOGEION AVENUE, ΑΓΙΑ ΠΑΡΑΣΚΕΥΗ/ AGIA PARASKEVI, Αθήνα / Athens, 15343, Greece

Human Medicinal Products
Veterinary Medicinal Products

<b>Authorised Operations</b> MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
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<b>Part 1 - MANUFACTURING OPERATIONS</b>	
<b>1.1</b>	<b>Sterile products</b>
	<i>1.1.3 Batch certification</i>
<b>1.2</b>	<b>Non-sterile products</b>
	<i>1.2.2 Batch certification</i>
<b>1.3</b>	<b>Biological medicinal products (list of product types)</b>
	<i>1.3.2 Batch Certification (list of product types)</i> <i>1.3.2.6 Human or animal extracted products</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> <i>1.6.4 Biological</i>

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

1. The microbiological and biological testings are carried out in the microbiological laboratory of the site, located at 36 Marathonos Avenue, 15354, Glyka Nera, Attica. 2. Under Biological controls LAL test is also included.

<b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b>	
<b>2.1</b>	<b>Quality control testing of imported medicinal products</b>
	<i>2.1.2 Microbiological: non-sterility</i> <i>2.1.3 Chemical/Physical</i> <i>2.1.4 Biological</i>
<b>2.2</b>	<b>Batch certification of imported medicinal products</b>

	<p>2.2.1 <i>Sterile products</i></p> <p>2.2.1.1 Aseptically prepared</p> <p>2.2.1.2 Terminally sterilised</p>
	<p>2.2.2 <i>Non-sterile products</i></p>
	<p>2.2.3 <i>Biological medicinal products</i></p> <p>2.2.3.6 Human or animal extracted products</p>

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

1. The microbiological and biological testings are carried out in the microbiological laboratory of the site, located at 36 Marathonos Avenue, 15354, Glyka Nera, Attica. 2. Under Biological controls LAL test is also included.

## SCOPE OF AUTHORISATION

## ANNEX 2

Name and address of the site : QUALIMETRIX ΕΡΓΑΣΤΗΡΙΑ ΑΝΑΛΥΣΗΣ – ΕΛΕΓΧΟΥ  
ΠΟΙΟΤΗΤΑΣ Α.Ε./ QUALIMETRIX S.A., ΛΕΩΦΟΡΟΣ  
ΜΕΣΟΓΕΙΩΝ 579/ 579 MESOGEION AVENUE, ΑΓΙΑ  
ΠΑΡΑΣΚΕΥΗ/ AGIA PARASKEVI, Αθήνα / Athens, 15343,  
Greece

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

<b>1.1</b>	<b>Sterile products</b>
	<i>1.1.3 Batch certification</i>
<b>1.2</b>	<b>Non-sterile products</b>
	<i>1.2.2 Batch certification</i>
<b>1.3</b>	<b>Biological medicinal products (list of product types)</b>
	<i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.6 Human or animal extracted products
<b>1.6</b>	<b>Quality control testing</b>
	1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical 1.6.4 Biological

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

1. The microbiological and biological testings are carried out in the microbiological laboratory of the site, located at 36 Marathonos Avenue, 15354, Glyka Nera, Attica. 2. Under Biological controls LAL test is also included.

### Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

<b>2.1</b>	<b>Quality control testing of imported medicinal products</b>
	2.1.2 Microbiological: non-sterility 2.1.3 Chemical/Physical 2.1.4 Biological
<b>2.2</b>	<b>Batch certification of imported medicinal products</b>
	<i>2.2.1 Sterile products</i>

	2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 <i>Non-sterile products</i>
	2.2.3 <i>Biological medicinal products</i> 2.2.3.6 Human or animal extracted products

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

1. The microbiological and biological testings are carried out in the microbiological laboratory of the site, located at 36 Marathonos Avenue, 15354, Glyka Nera, Attica. 2. Under Biological controls LAL test is also included.