Manufacturer/Importer Authorisation [1, 2]

1. Authorisation Number	0000008934/25/1
2. Name of authorisation holder	QACS Ltd. (ORG-100012500 / LOC-100022505)
3. Address(es) of manufacturing site(s)	QACS Ltd. (ORG-100012500 / LOC-100022505), Antigonis Str. 1, Metamorfossi, 144 51, Greece
4. Legally registered address of authorisation holder	Antigonis Str. 1, Metamorfossi, 144 51, Greece
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. 88 of Regulation (EU) 2019/6
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Dimitrios Dimas
8. Signature	 
9. Date	2025-01-10
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 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: QACS Ltd., Antigonis Str. 1, Metamorfossi, 144 51, Greece

Additional Details:

Human Medicinal Products Veterinary Medicinal Products

Authorised Operations MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
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

QACS ΕΠΕ/ QACS LTD, Αντιγόνης 1 / 1, Antigonis str., Μεταμόρφωση Αττική / Metamorfossi Attiki, 14451 The laboratory also performs the above Quality Control Testing at the facilities of 25-27 (OMS Location ID: LOC-100070512), Aristotelous street, Metamorfossi Attiki, 14451

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

QACS ΕΠΕ/ QACS LTD, Αντιγόνης 1 / 1, Antigonis str., Μεταμόρφωση Αττική / Metamorfossi Attiki, 14451 The laboratory also performs the above Quality Control Testing at the facilities of 25-27 (OMS Location ID: LOC-100070512), Aristotelous street, Metamorfossi Attiki, 14451

SCOPE OF AUTHORISATION

ANNEX 2

Name and address of the site : QACS Ltd., Antigonis Str. 1, Metamorfossi, 144 51, Greece

Additional Details:

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.3 Batch certification
1.2	**Non-sterile investigational medicinal products**
	1.2.2 Batch certification
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

QACS ΕΠΕ/ QACS LTD, Αντιγόνης 1 / 1, Antigonis str., Μεταμόρφωση Αττική / Metamorfossi Attiki, 14451 The laboratory also performs the above Quality Control Testing at the facilities of 25-27 (OMS Location ID: LOC-100070512), Aristotelous street, Metamorfossi Attiki, 14451

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

QACS ΕΠΕ/ QACS LTD, Αντιγόνης 1 / 1, Antigonis str., Μεταμόρφωση Αττική / Metamorfossi Attiki, 14451 The laboratory also performs the above Quality Control Testing at the facilities of 25-27 (OMS Location ID: LOC-100070512), Aristotelous street, Metamorfossi Attiki, 14451

NATIONAL ANNEX
QACS Ltd.
(EOF Decisions: 133543/ 06-12-2024, 116484/ 21-10-2024, 87014/ 12-08-2024)

MANUFACTURING ACTIVITIES

MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE

MICROBIOLOGICAL QUALITY CONTROL TESTING:
Tablets, capsules, creams, ointments, oral suspensions, syrups, oral ampoules, solutions
Solutions for external use, Solutions for internal use, Ophthalmic solutions, Gels, Nasal solutions, Liquids for Injections, Suppositories, Pharmaceutical shampoos, Powders

CHEMICAL TESTING & STABILITY TESTING:
Creams for external use, oral suspensions, syrups, suppositories, eye drops (solution), nasal solutions, gels external, external use solutions (lacquers).
Tablets, capsules, ointments, pharmaceutical shampoos, Liquid injectable Solutions for external use, Creams, Solutions for internal use, Oral ampoules, Gels, Powders

RELEASE OF MEDICINAL PRODUCTS FRO HUMAN AND VETERINARY USE
Tablets, Capsules, Creams, Ointments, Oral Suspensions, Syrups, Oral Ampoules, Solutions for internal use, Suppositories, Ophthalmic Solutions, Gels, Solutions for external use, Nasal Solutions, Pharmaceutical Shampoos, Liquids for Injections, Powders

CHEMICAL/ PHYSICAL TESTING and MICROBIOLOGICAL QUALITY CONTROL TESTING:
Dried flower of medicinal cannabis
Oral solution of medicinal cannabis oil

INVESTIGATIONAL MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE

MICROBIOLOGICAL QUALITY CONTROL TESTING, QUALITY CONTROL TESTING & STABILITY TESTING:
Tablets, Capsules, Creams, Ointments, Oral Suspensions, Syrups, Oral Ampoules, Suppositories, Ophthalmic Solutions, Nasal Solutions, Gels, Solutions for external use, Pharmaceutical Shampoos, Liquids for Injections, Powders Solutions for internal use, Powders

PHARMACEUTICAL STARTING MATERIALS

CHEMICAL QUALITY CONTROL TESTING:
Solid and liquid starting materials

MICROBIOLOGICAL QUALITY CONTROL TESTING:
Solid and liquid starting materials

COSMETIC PRODUCTS
MICROBIOLOGICAL QUALITY CONTROL TESTING: **Foambaths, creamsoaps, shampoos, soaps, creams (and sunscreens), masks, emulsions (and sunscreens), lotions with low concentration of ethanol, toothpastes, body oils, mouthwashes, colognes, lotions containing alcohol, wet tissues, hair foams, shaving foams, deodorants (with or without propellant), products for nail care (mixtures containing aceton), lipsticks, cotton (for pharmaceutical use, demake up, cotton batonettes)** **CHEMICAL QUALITY CONTROL TESTING:** **Foambaths, creamsoaps, shampoos, soaps, creams (and sunscreens), masks, emulsions (and sunscreens), lotions with low concentration of ethanol, toothpastes, body oils, mouthwashes, colognes, lotions containing alcohol, wet tissues, hair foams, shaving foams, deodorants (with or without propellant), products for nail care (mixtures containing aceton), lipsticks, cotton (for pharmaceutical use, demake up, cotton batonettes)** **TESTING OF ALLERGENICS** **STARTING MATERIALS**
MICROBIOLOGICAL QUALITY CONTROL TESTING OF WATER
DISINFECTANTS
CHEMICAL QUALITY CONTROL TESTING: **Liquids, Powders, Gels, Antiseptics - Disinfectant wipes** **MICROBIOLOGICAL QUALITY CONTROL TESTING:** **Liquid form** **EFFICACY OF DISINFECTANTS**
FOOD SUPPLEMENTS
MICROBIOLOGICAL & CHEMICAL QUALITY CONTROL TESTING: **Tablets, Capsules, Syrups, Oils, Oral solutions**
MEDICAL DEVICES
MICROBIOLOGICAL & CHEMICAL QUALITY CONTROL TESTING: **Creams, Emulsions (lotions), Gels, Foambaths, Aerosols, Vaginal suppositories, Examination rolls** **Incontinence diapers (children / infants, adults)** **Medical face masks (according to EN 14683, FFP2 / KN95)** **Bed sheets**

Molecular Laboratory for the analysis-identification of microorganisms:

i. In pharmaceutical products for human and veterinary use in the following forms:

Tablets, capsules, creams, ointments, ointments, oral suspensions, syrups, oral ampoules, solutions, external solutions, internal solutions, ophthalmic solutions, gels, nasal solutions, liquid injectables, suppositories, medicated shampoos, powders.

ii. In pharmaceutical raw materials in the forms:

Solid, Liquid

iii. In water

The laboratory also performs the above Quality Control Testing at the facilities of 25-27 (OMS Location ID: LOC-100070512), Aristotelous street, Metamorfossi Attiki, 14451

The Head of Division
of Production and Distribution Control

Dr D. Dimas

National Organization For Medicines

CERTIFICATE NUMBER: ***133543/ 06-12-2024***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended
Art. 94(1) of Regulation (EU) 2019/6 as amended
Art. 15 of Directive 2001/20/EC as amended

The competent authority of Greece confirms the following:
The manufacturer: ***QACS Ltd.***
Site address: ***Antigonis Str. 1, Metamorfossi, 144 51, Greece***
OMS Organisation Id. / OMS Location Id.: ***ORG-100012500 / LOC-100022505***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***0000008934/25/1*** in accordance with Art. 88 of Regulation (EU) 2019/6, Art. 13 of Directive 2001/20/EC and Art. 40 of Directive 2001/83/EC, transposed in the following national legislation:ΔΥΓ 3/89292/03, Art. 12 and Δ.ΥΓ 3(α)/Γ.Π. 32221/29-4-2013, art. 57.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-07-03***, it is considered that it complies with::

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572. [3]
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EEC. [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC, Art. 80(5) of Directive 2001/82/EC and Art. 15 of Directive 2001/20/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products
Human Investigational Medicinal Products
Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Any restrictions related to the scope of this certificate:

Clarifying remarks (for registered users)

The laboratory also performs the above Quality Control Testing at the facilities of 25-27 (OMS Location ID: LOC-100070512), Aristotelous street, Metamorfossi Attiki, 14451

Clarifying remarks (for public users)

The laboratory also performs the above Quality Control Testing at the facilities of 25-27 (OMS Location ID: LOC-100070512), Aristotelous street, Metamorfossi Attiki, 14451

2025-01-10

Name and signature of the authorised person of the Competent Authority of Greece

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Dimitrios Dimas
National Organization For Medicines
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