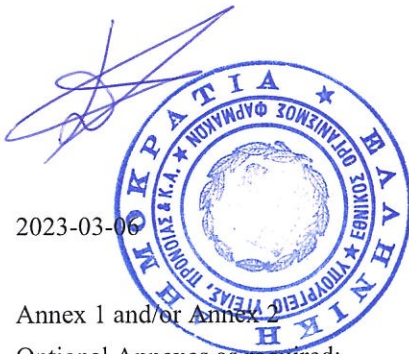


MANUFACTURER'S AUTHORISATION^{1, 2}

1. Authorisation Number 0000008934/23/1
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 forms² 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 2023-03-06
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

¹The 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.

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

³The 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: 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
	<i>1.1.3 Batch certification</i>
1.2	Non-sterile products
	<i>1.2.2 Batch certification</i>
1.6	Quality control testing
	<i>1.6.2 Microbiological: non-sterility</i>
	<i>1.6.3 Chemical/Physical</i>

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

QACS ΕΠΕ/ QACS LTD, Αντιγόνης 1 / 1, Antigonis str., Μεταμόρφωση Αττικής / 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 Αττικής / 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

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 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 Decision: 18322/24-02-2022)

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

QUALITY CONTROL 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

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 acetone), 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 acetone), 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

MEDICAL DEVICES

MICROBIOLOGICAL & CHEMICAL QUALITY CONTROL TESTING:

Creams, Emulsions (lotions), Gels, Foambaths, Aerosols

MICROBIOLOGICAL TESTING:

Incontinence diapers (children / infants, adults)

Medical face masks (according to EN 14683, FFP2 / KN95)

Bed sheets

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 Deputy Head of
Inspection Department**

Dr D. Dimas





National Organization For Medicines

CERTIFICATE NUMBER: 107498/11-10--2022

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

The competent authority of Greece confirms the following:

The manufacturer: **QACS Ltd.**

Site address: **Antigonis Str. 1, Metamorfossi, 144 51, Greece**

Additional details on units inspected: **QACS ΕΠΕ/ QACS LTD, Αντιγόνης 1 / 1, Antigonis str., Μεταμόρφωση Αττικής / Metamorfossi Attiki, 14451**

OMS Organisation Id. / OMS Location Id.: **ORG-100012500 / LOC-100022505**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **0000008934/23/1** in accordance with Art. 13 of Directive 2001/20/EC, Art. 40 of Directive 2001/83/EC and Art. 88 of Regulation (EU) 2019/6 transposed in the following national legislation:

ΔΥΤ 3/89292/03, Art. 12

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 **2021-07-09**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569³
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EC³

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. 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.

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/EC, 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 These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products
Veterinary Medicinal Products
Human Investigational 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:

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

2023-03-06

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


Dimitrios Dimas

Tel: +30 213 2040373

Fax: +30 213 2040563

