G. Samaras S.A.
MEDICAL GAS SYSTEMS

Thermi industrial area
57001 Thessaloniki
Greece
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Digitally signed by Cârstocea Ioan-Răzvan
Date: 2022.07.25 12:37:23 EEST
Reason: MoldSign Signature
Location: Moldova

DECLARATION

To: *CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SANATATE*

Name of project: *"Medical devices (Medical oxygen production station) according to the needs of IMSP Clinical Hospital for Traumatology and Orthopedics for 2022 (repeated)"*

We *G. SAMARAS SA,* who are official manufacturers of *complete medical gas systems,* having factories at *Thermi industrial area, Thermi, Greece* do hereby confirm that the *Medical O_2 Generator* conforms the below listed specifications:

Model	*20C6-3*
Method of obtaining oxygen	Pressure Swing Adsorbtion (PSA)
Oxygen purity	93% - 95%
Oxygen flow at a concentration of 93 %	≥ 16 m3 / hour
Oxygen tank outlet pressure reducer (pressure adjustment)	min. 6.0 bar
Power supply	220 V / 50 Hz
Compressed air inlet pressure,	≥ 5 bar
The installation must not affect the environment and the ozone layer	yes
Operating temperature, with values between	+5°C - +45°C, ±5°C
Central control-panel touch screen	3"
Continuous monitoring of the compressed air inlet pressure in the oxygen generator	yes
Continuous monitoring of the oxygen outlet pressure of the oxygen generator	yes
Permanent monitoring of the purity of the oxygen produced by the generator - double display	yes, via a zirconium sensor
Monitoring the air temperature at the generator inlet-dew point sensor	yes
Continuous monitoring of the loading pressure of the separation tanks	yes
Remote monitoring via TCP / IP interface of basic parameters	yes
Soft PC- no licenses required	
Permanent monitoring of instantaneous oxygen flow in the network (liters / minute or m3 / hour)	yes
Permanent monitoring of oxygen pressure in the hospital network	yes
Permanent monitoring of the operating time of the generator	yes
Acoustic and visual alarm when oxygen purity drops below 90%	yes
Acoustic and visual alarm when the compressed air inlet pressure decreases in the generator	yes
Acoustic alarm when the temperature inside the generator rises above the permissible limit	yes
Internal storage of data and operating parameters	yes
Internal storage of alarms with the date and time that occurred	yes
USB / SD port for collecting data and operating parameters and storing them in the PC	
Inlet and outlet pressure sensor	yes
UPS with voltage stabilization system- min. 30 minutes of operation after switching off the light	Not included in price
ISO 13485 Quality Certificate, CE and Declaration of Conformity **93/42 EEC**	yes
All components of the system are new (unused) Year of production of the oxygen production station is after 2021	yes
The unit *Medical O_2 Generator 20C6-3*, qty. 1, will be made available for shipment in a time **not exceeding 75 (seventy-five) days** from Order Confirmation and the receipt of the contractual down payment (notified by your bank).	

Name: *Menelaos Samaras*
Title: *General Manager*

G. SAMARAS S.A.
MEDICAL GAS SYSTEMS
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VAT NUMBER EL094575861

ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ ΣΤΗΝ ΥΓΕΙΑ Α.Ε.

NATIONAL EVALUATION CENTER OF QUALITY & TECHNOLOGY IN HEALTH S.A.

ΠΙΣΤΟΠΟΙΗΤΙΚΟ / CERTIFICATE

EN ISO 9001:2015

Πιστοποιείται ότι ο παρακάτω αναφερόμενος οργανισμός έχει καθιερώσει και εφαρμόζει για τις αναγραφόμενες δραστηριότητες σύστημα διαχείρισης της ποιότητας το οποίο συμμορφώνεται με τις απαιτήσεις του προτύπου.
Η ισχύς του πιστοποιητικού συνδέεται με την επιτυχή ολοκλήρωση των επιθεωρήσεων επιτήρησης.

We hereby certify that the under mentioned organization has established and maintains for the listed activities a quality management system that complies with the requirements of the standard.
Validity of the certificate is based upon the successful completion of surveillance audits.

Αριθμός Πιστοποιητικού / Certificate Number: 302051047RE

Οργανισμός:	**Γ. ΣΑΜΑΡΑΣ Α.Β.Ε.Ε.**
Organization:	**G. SAMARAS S.A.**
Διεύθυνση:	**ΒΙ.ΠΕ. ΘΕΡΜΗΣ, ΘΕΣΣΑΛΟΝΙΚΗΣ.**
Address:	**THERMI INDUSTRIAL AREA, THESSALONIKI GREECE.**
Δραστηριότητες:	• **ΣΧΕΔΙΑΣΜΟΣ, ΠΑΡΑΓΩΓΗ, ΠΟΙΟΤΙΚΟΣ ΕΛΕΓΧΟΣ ΚΑΙ ΕΓΚΑΤΑΣΤΑΣΗ ΣΥΣΤΗΜΑΤΩΝ ΠΑΡΟΧΗΣ ΙΑΤΡΙΚΩΝ ΑΕΡΙΩΝ, ΜΟΝΑΔΩΝ ΠΑΡΑΓΩΓΗΣ ΟΞΥΓΟΝΟΥ, ΣΥΣΤΗΜΑΤΩΝ ΠΑΡΑΓΩΓΗΣ - ΔΙΑΝΟΜΗΣ ΚΕΝΟΥ ΚΑΙ ΝΟΣΟΚΟΜΕΙΑΚΟΥ ΕΞΟΠΛΙΣΜΟΥ.** • **ΣΧΕΔΙΑΣΜΟΣ, ΕΓΚΑΤΑΣΤΑΣΗ, ΕΛΕΓΧΟΣ ΚΑΙ ΠΙΣΤΟΠΟΙΗΣΗ ΔΙΚΤΥΩΝ ΙΑΤΡΙΚΩΝ ΑΕΡΙΩΝ ΚΑΙ ΜΟΝΑΔΩΝ ΠΑΡΑΓΩΓΗΣ ΟΞΥΓΟΝΟΥ.** • **ΣΧΕΔΙΑΣΜΟΣ, ΚΑΤΑΣΚΕΥΗ, ΕΛΕΓΧΟΣ ΚΑΙ ΠΙΣΤΟΠΟΙΗΣΗ ΚΕΝΤΡΩΝ ΔΙΑΝΟΜΗΣ ΙΑΤΡΙΚΩΝ ΑΕΡΙΩΝ.** • **ΣΥΝΤΗΡΗΣΗ ΚΑΙ ΕΠΙΣΚΕΥΗ ΕΓΚΑΤΑΣΤΑΣΕΩΝ ΙΑΤΡΙΚΩΝ ΑΕΡΙΩΝ ΚΑΙ ΜΟΝΑΔΩΝ ΠΑΡΑΓΩΓΗΣ ΟΞΥΓΟΝΟΥ.** • **ΕΜΠΟΡΙΑ ΚΑΙ ΔΙΑΚΙΝΗΣΗ ΙΑΤΡΟΤΕΧΝΟΛΟΓΙΚΩΝ ΠΡΟΪΟΝΤΩΝ.**
Activities:	• **DESIGN, PRODUCTION, QUALITY CONTROL AND INSTALLATION OF MEDICAL GASES AND VACUUM SUPPLY SYSTEMS, OXYGEN GENERATORS AND HOSPITAL EQUIPMENT.** • **DESIGN, INSTALLATION, COMMISSIONING AND CERTIFICATION OF MEDICAL GAS PIPELINE SYSTEMS AND OXYGEN GENERATORS.** • **DESIGN, PRODUCTION, COMMISSIONING AND CERTIFICATION OF MEDICAL GAS CENTRAL DISTRIBUTION SYSTEMS.** • **SERVICE AND MAINTENANCE OF MEDICAL GAS PIPELINE SYSTEMS AND OXYGEN GENERATORS.** • **TRADING AND DISTRIBUTION OF MEDICAL DEVICES.**
Ημερομηνία αρχικής έκδοσης: First issue date:	**23/12/2015**
Ημερομηνία τρέχουσας έκδοσης: Current issue date:	**23/12/2020**
Ισχύει μέχρι: Valid until:	**22/12/2023**
Έκθεση επιθεώρησης: Audit report:	**200061047**

ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
PIKROU - MORAITAKI ELEFTHERIA, President & Managing Director

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ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ ΣΤΗΝ ΥΓΕΙΑ Α.Ε.

NATIONAL EVALUATION CENTER OF QUALITY & TECHNOLOGY IN HEALTH S.A.

ΠΙΣΤΟΠΟΙΗΤΙΚΟ / CERTIFICATE

EN ISO 13485:2016

Πιστοποιείται ότι ο παρακάτω αναφερόμενος οργανισμός έχει καθιερώσει και εφαρμόζει για τις αναγραφόμενες δραστηριότητες σύστημα διαχείρισης της ποιότητας το οποίο συμμορφώνεται με τις απαιτήσεις του προτύπου.
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We hereby certify that the under mentioned organization has established and maintains for the listed activities a quality management system that complies with the requirements of the standard.
Validity of the certificate is based upon the successful completion of surveillance audits.

Αριθμός Πιστοποιητικού / Certificate Number: 303041047RE

Οργανισμός:	**Γ. ΣΑΜΑΡΑΣ Α.Β.Ε.Ε.**
Organization:	**G. SAMARAS S.A.**
Διεύθυνση:	**ΒΙ.ΠΕ. ΘΕΡΜΗΣ, ΘΕΣΣΑΛΟΝΙΚΗΣ.**
Address:	**THERMI INDUSTRIAL AREA, THESSALONIKI GREECE.**
Δραστηριότητες:	• **ΣΧΕΔΙΑΣΜΟΣ, ΠΑΡΑΓΩΓΗ, ΠΟΙΟΤΙΚΟΣ ΕΛΕΓΧΟΣ ΚΑΙ ΕΓΚΑΤΑΣΤΑΣΗ ΣΥΣΤΗΜΑΤΩΝ ΠΑΡΟΧΗΣ ΙΑΤΡΙΚΩΝ ΑΕΡΙΩΝ, ΜΟΝΑΔΩΝ ΠΑΡΑΓΩΓΗΣ ΟΞΥΓΟΝΟΥ, ΣΥΣΤΗΜΑΤΩΝ ΠΑΡΑΓΩΓΗΣ - ΔΙΑΝΟΜΗΣ ΚΕΝΟΥ ΚΑΙ ΝΟΣΟΚΟΜΕΙΑΚΟΥ ΕΞΟΠΛΙΣΜΟΥ.** • **ΣΧΕΔΙΑΣΜΟΣ, ΕΓΚΑΤΑΣΤΑΣΗ, ΕΛΕΓΧΟΣ ΚΑΙ ΠΙΣΤΟΠΟΙΗΣΗ ΔΙΚΤΥΩΝ ΙΑΤΡΙΚΩΝ ΑΕΡΙΩΝ ΚΑΙ ΜΟΝΑΔΩΝ ΠΑΡΑΓΩΓΗΣ ΟΞΥΓΟΝΟΥ.** • **ΣΧΕΔΙΑΣΜΟΣ, ΚΑΤΑΣΚΕΥΗ, ΕΛΕΓΧΟΣ ΚΑΙ ΠΙΣΤΟΠΟΙΗΣΗ ΚΕΝΤΡΩΝ ΔΙΑΝΟΜΗΣ ΙΑΤΡΙΚΩΝ ΑΕΡΙΩΝ.** • **ΣΥΝΤΗΡΗΣΗ ΚΑΙ ΕΠΙΣΚΕΥΗ ΕΓΚΑΤΑΣΤΑΣΕΩΝ ΙΑΤΡΙΚΩΝ ΑΕΡΙΩΝ ΚΑΙ ΜΟΝΑΔΩΝ ΠΑΡΑΓΩΓΗΣ ΟΞΥΓΟΝΟΥ.** • **ΕΜΠΟΡΙΑ ΚΑΙ ΔΙΑΚΙΝΗΣΗ ΙΑΤΡΟΤΕΧΝΟΛΟΓΙΚΩΝ ΠΡΟΪΟΝΤΩΝ.**
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Ημερομηνία αρχικής έκδοσης: First issue date:	**23/12/2015**
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Έκθεση επιθεώρησης: Audit report:	**200061047**

ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
PIKROU - MORAITAKI ELEFTHERIA, President & Managing Director

ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ ΣΤΗΝ ΥΓΕΙΑ Α.Ε.
NATIONAL EVALUATION CENTER OF QUALITY & TECHNOLOGY IN HEALTH S.A.

ΠΙΣΤΟΠΟΙΗΤΙΚΟ ΕΚ / EC CERTIFICATE

ΠΛΗΡΕΣ ΣΥΣΤΗΜΑ ΔΙΑΣΦΑΛΙΣΗΣ ΠΟΙΟΤΗΤΑΣ / FULL QUALITY ASSURANCE SYSTEM

Πιστοποιείται ότι ο παρακάτω αναφερόμενος κατασκευαστής έχει καθιερώσει και εφαρμόζει πλήρες σύστημα διασφάλισης της ποιότητας σύμφωνα με τις απαιτήσεις της Οδηγίας 93/42/ΕΟΚ, Παράρτημα ΙΙ (εξαιρουμένου του σημείου 4) και της ενσωμάτωσης της στην ελληνική νομοθεσία, για το σχεδιασμό, την κατασκευή και τον τελικό έλεγχο των προϊόντων που αναφέρονται στο παρόν πιστοποιητικό.
Το πιστοποιητικό υπόκειται στους όρους και τις προϋποθέσεις που αναγράφονται στην επόμενη σελίδα.
Οποιεσδήποτε σημαντικές αλλαγές στο σχεδιασμό ή την κατασκευή μπορεί να καταστήσουν το πιστοποιητικό άκυρο.

We hereby certify that the under mentioned manufacturer has established and maintains a full quality assurance system according to the requirements of Directive 93/42/EEC, Annex II (with the exemption of section 4) and its transposition in Greek legislation, for the design, manufacture and final inspection of the products mentioned in this certificate.
The certificate is subject to terms and conditions overleaf.
Any significant changes in design or manufacture may render this certificate invalid.

Αριθμός Πιστοποιητικού / Certificate Number: 304021047RE

Κατασκευαστής:	**Γ. ΣΑΜΑΡΑΣ Α.Β.Ε.Ε.**
Manufacturer:	**G. SAMARAS S.A.**
Εγκατάσταση:	**ΒΙ.ΠΕ. ΘΕΡΜΗΣ, ΘΕΣΣΑΛΟΝΙΚΗ.**
Facility:	**THERMI INDUSTRIAL AREA, THESSALONIKI GREECE.**
Προϊόντα:	**ΩΣ ΕΧΟΥΝ ΣΤΟ ΠΑΡΑΡΤΗΜΑ**
Products:	**AS LISTED IN ANNEX**
Κατηγοριοποίηση Προϊόντων/ Devices Classification:	**1/ 2/ 3/ 4/ 5/ 6/ 7/ 8/ 9/ 10/ 11: IIb 12: IIa.**
Ημερομηνία πρώτης έκδοσης: First issue date:	**23/12/2015**
Ημερομηνία τρέχουσας έκδοσης: Current issue date:	**23/12/2020**
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Εκθέσεις επιθεώρησης: Audit reports:	**200061047**

ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
PIKROU - MORAITAKI ELEFTHERIA, President & Managing Director

Το Εθνικό Κέντρο Αξιολόγησης της Ποιότητας και Τεχνολογίας στην Υγεία (ΕΚΑΠΤΥ) είναι Κοινοποιημένος Οργανισμός σύμφωνα με την Οδηγία 93/42/ΕΟΚ περί των ιατροτεχνολογικών προϊόντων, με αριθμό αναγνώρισης 0653.
National Evaluation Center of Quality & Technology in Health S.A. (EKAPTY) is a Notified body according to Council Directive 93/42/EEC concerning medical devices, with identification number 0653.

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T: +30 2132026200 | F: +30 210 9615464 | e-mail: info@ekapty.gr | www.ekapty.gr

ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.
NATIONAL EVALUATION CENTER
OF QUALITY & TECHNOLOGY
IN HEALTH S.A.

ΠΑΡΑΡΤΗΜΑ ΤΟΥ ΥΠ. ΑΡΙΘΜ. 304021047RE ΠΙΣΤΟΠΟΙΗΤΙΚΟΥ /
ANNEX No. 304021047RE CERTIFICATE

Προϊόντα:

1. **ΛΗΨΕΙΣ ΙΑΤΡΙΚΩΝ ΑΕΡΙΩΝ.**
2. **ΜΟΝΑΔΕΣ ΚΕΦΑΛΗΣ ΚΛΙΝΗΣ ΑΣΘΕΝΩΝ.**
3. **ΣΤΗΛΕΣ ΟΡΟΦΗΣ.**
4. **ΚΕΝΤΡΟ ΑΠΑΓΩΓΗΣ ΑΝΑΙΣΘΗΤΙΚΩΝ ΑΕΡΙΩΝ.**
5. **ΚΕΝΤΡΟ ΠΑΡΑΓΩΓΗΣ ΚΕΝΟΥ ΙΑΤΡΙΚΗΣ ΧΡΗΣΗΣ.**
6. **ΚΕΝΤΡΟ ΦΙΑΛΩΝ ΙΑΤΡΙΚΩΝ ΑΕΡΙΩΝ.**
7. **ΚΕΝΤΡΟ ΠΑΡΑΓΩΓΗΣ ΠΕΠΙΕΣΜΕΝΟΥ ΑΕΡΑ ΙΑΤΡΙΚΗΣ ΧΡΗΣΗΣ.**
8. **ΣΥΣΤΗΜΑΤΑ ΠΑΡΑΚΟΛΟΥΘΗΣΗΣ ΚΑΙ ΣΥΝΑΓΕΡΜΟΥ ΙΑΤΡΙΚΩΝ ΑΕΡΙΩΝ.**
9. **ΜΕΙΩΤΗΡΑΣ ΠΙΕΣΗΣ ΓΡΑΜΜΗΣ ΙΑΤΡΙΚΩΝ ΑΕΡΙΩΝ.**
10. **ΣΥΓΚΡΟΤΗΜΑΤΑ ΕΛΕΓΧΟΥ ΠΙΕΣΗΣ.**
11. **ΣΥΣΤΗΜΑΤΑ ΠΑΡΟΧΗΣ ΜΕ ΣΥΓΚΕΝΤΡΩΤΕΣ ΟΞΥΓΟΝΟΥ ΙΑΤΡΙΚΗΣ ΧΡΗΣΗΣ.**
12. **ΔΙΚΤΥΟ, ΣΩΛΗΝΕΣ ΚΑΙ ΕΞΑΡΤΗΜΑΤΑ ΔΙΚΤΥΟΥ ΔΙΑΝΟΜΗΣ ΙΑΤΡΙΚΩΝ ΑΕΡΙΩΝ - ΚΕΝΟΥ - ΑΑΑ.**

Products:

1. **TERMINAL UNITS FOR COMPRESSED MEDICAL GASES - VACUUM - ANAESTHETIC GAS SCAVENGING DISPOSAL SYSTEMS.**
2. **BED HEAD UNITS.**
3. **PENDANT ARMS.**
4. **ANESTHETIC GASES SCAVENGING SYSTEM.**
5. **MEDICAL VACUUM CENTRAL STATION.**
6. **CYLINDER STATION FOR MEDICAL GASES.**
7. **AIR COMPRESSORS SYSTEM FOR BREATHING AIR.**
8. **MEDICAL ALARM PANELS.**
9. **MEDICAL GASES LINE REDUCER.**
10. **CONTROL AND REDUCER PANELS.**
11. **MEDICAL OXYGEN CONCENTRATORS SUPPLY SYSTEM.**
12. **NETWORK, PIPELINES AND COMPONENTS FOR DISTRIBUTION SYSTEMS OF MEDICAL GASES - VACUUM - AGSS.**

ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
PIKROU - MORAITAKI ELEFTHERIA, President & Managing Director

1 ΜΥΡΝΗΣ 13-15 | 165 62 ΓΛΥΦΑΔΑ • 13-15 SMYRNIS | 165 62 GLYFADA - GREECE
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ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.
NATIONAL EVALUATION CENTER
OF QUALITY & TECHNOLOGY
IN HEALTH S.A.

ΟΡΟΙ & ΠΡΟΫΠΟΘΕΣΕΙΣ / TERMS & CONDITIONS

1. Για αποστειρωμένα προϊόντα κατηγορίας Ι, η πιστοποίηση αφορά μόνο τα θέματα επίτευξης και διατήρησης της αποστείρωσης.
   For class I sterile products, the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions.
2. Για προϊόντα κατηγορίας Ι με λειτουργία μέτρησης, η πιστοποίηση αφορά μόνο τα θέματα συμμόρφωσης των προϊόντων προς τις μετρολογικές απαιτήσεις.
   For Class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.
3. Για προϊόντα κατηγορίας ΙΙΙ, είναι απαραίτητο ένα συμπληρωματικό πιστοποιητικό Εξέτασης Σχεδιασμού σύμφωνα με τις απαιτήσεις της Οδηγίας 93/42/ΕΟΚ, Παράρτημα ΙΙ (σημείο 4).
   For class III products an additional Design Examination certificate is required according to the requirements of Annex II 93/42/EEC (section 4).
4. Το πιστοποιητικό ισχύει μόνα για τα προϊόντα και τις εγκαταστάσεις που αναφέρονται.
   The certificate is valid only for the products and the facilities mentioned.
5. Θα πραγματοποιούνται περιοδικές επιθεωρήσεις επιτήρησης όπως αναφέρεται στην Οδηγία 93/42/ΕΟΚ, με σκοπό να επαληθεύεται ότι ο κατασκευαστής διατηρεί και εφαρμόζει το σύστημα ποιότητας.
   Periodical surveillance as referred in 93/42/EEC will be held in order to verify that the manufacturer maintains and applies the quality system.
6. Όταν τηρούνται τα ανωτέρω, ο κατασκευαστής μπορεί να συντάσσει δήλωση συμμόρφωσης ΕΚ και να επιθέτει τη σήμανση CE 0653 στα καλυπτόμενα προϊόντα.
   When meeting with the terms and conditions above, the manufacturer may draw up an EC declaration of conformity and legally affix the CE 0653 mark.

ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
PIKROU - MORAITAKI ELEFTHERIA, President & Managing Director

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G. SAMARAS S.A. MEDICAL GAS SYSTEMS

EC DECLARATION OF CONFORMITY

according to ANNEX II of European Directive (MDD) 93/42/EEC

Certificate N°:	304021047RE and ANNEX No. 304021047RE CERTIFICATE
Manufacturer:	G. SAMARAS S.A. MEDICAL GAS SYSTEMS
Address:	Industrial area of Thermi, 57001, P.O. Box 60 178, Thermi – Thessaloniki – Greece, Tel.: +30 2310 46 33 88, - Fax:+30 2314 410113
Product:	**TERMINAL UNITS FOR COMPRESSED MEDICAL GASES-VACUUM-ANAESTHETIC GAS SCAVENGING DISPOSAL SYSTEMS**
Type:	ENV 737-6 DIN 13260-2 AFNOR NF90-116 SS 875 24 30 EN ISO 7396-2 BS 5682:1998 UNI 9507 NIST EN 15908 DISS SANS JIS AS
Classification:	Class IIb , (according to Rule 9 & 11)

We declare the compliance of the above medical devices with the relevant provisions of the Council Directive 93/42/EEC of June 14th 1993.

The conformity in accordance to Council Directive 93/42/EEC is certified by Notified Body, National Evaluation Center of Quality & Technology In Health SA, EKAPTY, with identification number 0653.

The conformity is certified with CE Certification N° 304021047RE validity until 24/05/2024.

This product conforms to the following European Standards:

EN ISO 11197:2016	*Medical supply units*
EN ISO 5359:2014	*Low pressure hose assemblies for use with medical gases*
EN ISO 7396-1:2016	*Medical gas pipeline systems – Part1: Pipelines for compressed medical gases and vacuum*
EN ISO 7396-2:2007	*Medical gas pipeline systems – Part2: Anaesthetic gas scavenging disposal systems*
EN ISO 9170-1:2017	*Terminal units for medical gas pipeline systems -- Part 1: Terminal units for use with compressed medical gases and vacuum*
EN ISO 9170-2:2008	*Terminal units for medical gas pipeline systems -- Part 2: Terminal units for anaesthetic gas scavenging systems*
EN ISO 14971:2019	*Risk management for medical devices includes risk analysis, evaluation, control and post production information*
EN ISO 15001:2010	*Anaesthetic and respiratory equipment - Compatibility with oxygen (ISO 15001:2010*
EN 60601-1:2015	*Medical electrical equipment. General requirements for basic safety and essential performance*
CGA V-5 -2008	*Diameter Index Safety System*
SANS 1409:2014	*South African National Standard*
JIS	*JIS T 7101*
AS 2473.3-2007	*Outlet Connections For Medical Gases*

Thessaloniki, 04/01/2021

G. SAMARAS S.A.
MEDICAL GAS SYSTEMS
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TEL: [illegible]3388 - FAX: +302310464570
VAT NUMBER: EL 094373861

Menelaos Samaras
Legal Representative

CE 0653

G. SAMARAS S.A. MEDICAL GAS SYSTEMS

EC DECLARATION OF CONFORMITY

according to ANNEX II of European Directive (MDD) 93/42/EEC

Certificate N°: 304021047RE and ANNEX No. 304021047RE CERTIFICATE

Manufacturer: *G. SAMARAS S.A. MEDICAL GAS SYSTEMS*

Address: *Industrial area of Thermi, 57001*
P.O. Box 60 178, Thermi – Thessaloniki - Greece
Tel.: +30 2310 46 33 88, - Fax:+30 2314 410113

Product: ***BED HEAD UNITS (BHU)***

Type:

PANORAMA	THEODORO-R
PANORAMA-H	ATHOS (Version I)
PANORAMA-L	ATHOS (Version II)
PANDORA / 16	ATHOS (Version IIIa)
PANDORA-EX-R	ATHOS (Version IIIb)
ELISA / 16	ATHOS 16
KASSANDRA	AEGEAN
ALEXANDRA	PG-EM
ALEXANDRA-R	PG-EX
ALEXANDRA-R-EX	OPT CONTROL PANEL
KALLIPOLIS	NEFELI
KALLIPOLIS-L	KALIPOLIS EX

Classification: *Class IIb , (according to Rule 9 & 11)*

We declare the compliance of the above medical devices with the relevant provisions of the Council Directive 93/42/EEC of June 14,1993 and RoHS2 Directive 2011/65/EU.

The conformity in accordance to Council Directive 93/42/EEC is certified by Notified Body, National Evaluation Center of Quality & Technology In Health SA, EKAPTY, with identification number 0653.

The conformity is certified with CE Certification N° 304021047RE, validity until 24/05/2024.

This product conforms to the following European Standards:

EN ISO 11197:2016	*Medical supply units*
EN ISO 7396-1:2016	*Medical gas pipeline systems – Part1: Pipelines for compressed medical gases and vacuum*
EN ISO 7396-2:2007	*Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems*
EN ISO 9170-1:2017	*Terminal units for medical gas pipeline systems -- Part 1: Terminal units for use with compressed medical gases and vacuum*
EN ISO 9170-2:2008	*Terminal units for medical gas pipeline systems - Part 2: Terminal units for anaesthetic gas scavenging systems*
EN 13348:2016	*Copper and copper alloys. Seamless, round copper tubes for medical gases or vacuum.*
EN ISO 5359:2014	*Low pressure hose assemblies for use with medical gases*
ISO/DIS 3744:2010	*Acoustics -- Determination of sound power levels and sound energy levels of noise sources using sound pressure -- Engineering methods for an essentially free field over a reflecting plane*
EN ISO 14971:2019	*Medical devices – Application of risk management to medical devices*
EN 60598-1:2015	*Luminaires – Part 1: General requirements and tests (IEC 598-1:1992)*
EN 60601-1-11:2015	*Medical electrical equipment. General requirements for basic safety and essential performance*
EN 60601-1-2:2015	*Medical electrical equipment – Part 1: General requirements for safety – Electromagnetic compatibility - Requirements and tests*
EN 60669-1:2018	*Switches for household and similar fixed electrical installations – Part 1: General requirements (IEC 669-1: 1993, modified)*
IEC 884-1:2002	*Plugs and socket-outlets for household and similar purposes - General requirements*

EN 55015:2005, EN 61000-3-2:2004 + A2:2005(U)
EN 61000-3-3:1997 + A1:2005 + A2:2006(U)
EN 61547:2002, included in EN 60601-1-2:2002(U)
ISO 15001:2010 Anesthetic and respiratory equipment – Compatibility with oxygen

Thessaloniki, 04/01/2021

G. SAMARAS S.A.
MEDICAL GAS SYSTEMS
P.O. BOX 60178 - 57001 THERMI
THESSALONIKI GREECE

Menelaos Samaras
Legal Representative

CE 0653

G. SAMARAS S.A. MEDICAL GAS SYSTEMS

EC DECLARATION OF CONFORMITY

according to ANNEX II of European Directive (MDD) 93/42/EEC

Certificate N°: 304021047RE and ANNEX No. 304021047RE CERTIFICATE

Manufacturer: G. SAMARAS S.A. MEDICAL GAS SYSTEMS

Address: Industrial area of Thermi, 57001
P.O. Box 60 178, Thermi – Thessaloniki - Greece
Tel.: +30 2310 46 33 88, - Fax:+30 2314 410113

Product: **PENDANT ARMS (CP)**

Type:
PELLA
OLYMPIA 04
OLYMPIA 06
THESSALONIKI
VERGINA
THERMI
MAKEDONIA-ICU
PELLA E13

Classification: *Class IIb , (according to Rule 9 & 11)*

We declare the compliance of the above medical devices with the relevant provisions of the Council Directive 93/42/EEC of June 14,1993 and RoHS2 Directive 2011/65/EU.

The conformity in accordance to Council Directive 93/42/EEC is certified by Notified Body, National Evaluation Center of Quality & Technology In Health SA, EKAPTY, with identification number 0653.

The conformity is certified with CE Certification N° 304021047RE, validity until 24/05/2024.

This product conforms to the following European Standards:

EN ISO 11197:2016	*Medical supply units*
EN ISO 7396-1:2016	*Medical gas pipeline systems – Part1: Pipelines for compressed medical gases and vacuum*
EN ISO 7396-2:2007	*Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems*
EN ISO 9170-1:2017	*Terminal units for medical gas pipeline systems – Part 1: Terminal units for use with compressed medical gases and vacuum*
EN ISO 9170-2:2008	*Terminal units for medical gas pipeline systems - Part 2: Terminal units for anaesthetic gas scavenging systems*
EN 13348:2016	*Copper and copper alloys. Seamless, round copper tubes for medical gases or vacuum.*
EN ISO 5359:2014	*Low pressure hose assemblies for use with medical gases*
ISO/DIS 3744:2010	*Acoustics – Determination of sound power levels and sound energy levels of noise sources using sound pressure – Engineering methods for an essentially free field over a reflecting plane*
EN ISO 14971:2019	*Medical devices – Application of risk management to medical devices*
ISO 7396-2:2007	*Non-flammable medical gas pipeline systems*
EN 60601-1:2015	*Medical electrical equipment. General requirements for basic safety and essential performance*
EN 60601-1-2:2015	*Medical electrical equipment – Part 1: General requirements for safety – Electromagnetic compatibility – Requirements and tests*
EN 60669-1:2018	*Switches for household and similar fixed electrical installations – Part 1: General requirements (IEC 669-1: 1993, modified)*
IEC 884-1:2002	*Plugs and socket-outlets for household and similar purposes - General requirements*
ISO 15001:2010	Anaesthetic and respiratory equipment – Compatibility with oxygen

Thessaloniki, 04/01/2021

G. SAMARAS S.A.
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Menelaos Samaras
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G. SAMARAS S.A. MEDICAL GAS SYSTEMS

EC DECLARATION OF CONFORMITY

according to ANNEX II of European Directive (MDD) 93/42/EEC

Certificate N°: 304021047RE and ANNEX No. 304021047RE CERTIFICATE

Manufacturer: G. SAMARAS S.A. MEDICAL GAS SYSTEMS

Address: Industrial area of Thermi, 57001
P.O. Box 60 178, Thermi – Thessaloniki - Greece
Tel.: +30 2310 46 33 88, - Fax:+30 2314 410113

Product: **ANAESTHETIC GAS SCAVENGING DISPOSAL SYSTEMS, AGSS GS series**

Type:

1. 2x 30 m^3/h
2. 2x 40 m^3/h
3. 2x 75 m^3/h
4. 2x 80 m^3/h
5. 2x 135 m^3/h
6. 2x 145 m^3/h
7. 2x 200 m^3/h
8. 2x 205 m^3/h
9. 2x 230 m^3/h
10. 2x 306 m^3/h
11. 2x 330 m^3/h

Classification: Class IIb , (according to Rule 9 & 11)

We declare the compliance of the above medical devices with the relevant provisions of the Council Directive 93/42/EEC of June 14,1993 and RoHS2 Directive 2011/65/EU.

The conformity in accordance to Council Directive 93/42/EEC is certified by Notified Body, National Evaluation Center of Quality & Technology In Health SA, EKAPTY, with identification number 0653.

The conformity is certified with CE Certification N° 304021047RE, validity until 24/05/2024.

This product conforms to the following European Standards:

EN ISO 7396-1:2016	*Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum (replace EN 737-3)*
EN ISO 7396-2:2007	*Medical gas pipeline systems – Part 2: Anaesthetic gas scavenging disposal systems*
EN ISO 9170-2:2008	*Terminal units for medical gas pipeline systems - Part 2: Terminal units for anaesthetic gas scavenging systems*
EN 143: 1990	*Respiratory protective devices – Particle filters – Requirements, testing, marking*
EN ISO 5359:2014	*Low-pressure hose assemblies for use with medical gases*
EN 14971:2019	*Medical devices – Risk analysis*
EN 475:1995	*Medical devices – Electrically – generated alarm signals*
EN 286-1:1998	*Regulations for vessel in pressure*
HD 384	*Electrical installations of buildings*

Thessaloniki, 04/01/2021

G. SAMARAS S.A.
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Menelaos Samaras
Legal Representative

CE 0653

G. SAMARAS S.A. MEDICAL GAS SYSTEMS

EC DECLARATION OF CONFORMITY

according to ANNEX II of European Directive (MDD) 93/42/EEC

Certificate N°: 304021047RE and ANNEX No. 304021047RE CERTIFICATE

Manufacturer: G. SAMARAS S.A. MEDICAL GAS SYSTEMS

Address: Industrial area of Thermi, 57001
P.O. Box 60 178, Thermi – Thessaloniki - Greece
Tel.: +30 2310 46 33 88, - Fax:+30 2314 410113

Product: **MEDICAL VACUUM CENTRAL STATION, *MVCS* series**

Type:

1. *MVCS 3x 10 m³/h , 250 lts*
2. *MVCS 3x 12 m³/h , 250 lts*
3. *MVCS 3x 17 m³/h , 250 lts*
4. *MVCS 3x 28 m³/h , 500 lts*
5. *MVCS 3x 40 m³/h , 500 lts*
6. *MVCS 3x 60 m³/h , 1000 lts*
7. *MVCS 3x 100 m³/h , 2000 lts*
8. *MVCS 3x 150 m³/h , 2000 lts*
9. *MVCS 3x 200 m³/h , 4000 lts*
10. *MVCS 3x 220 m³/h , 4000 lts*
11. *MVCS 3x 300 m³/h , 4000 lts*
12. *MVCS 3x 350 m³/h , 6000 lts*
13. *MVCS 3x 500 m³/h , 9000 lts*
14. *MVCS 3x 600 m³/h , 10000 lts*

Classification: Class IIb , (according to Rule 11)

We declare the compliance of the above medical devices with the relevant provisions of the Council Directive 93/42/EEC of June 14,1993 and RoHS2 Directive 2011/65/EU.

The conformity in accordance to Council Directive 93/42/EEC is certified by Notified Body, National Evaluation Center of Quality & Technology In Health SA, EKAPTY, with identification number 0653.

The conformity is certified with CE Certification N° 304021047RE, validity until 24/05/2024.

This product conforms to the following European Standards:

EN ISO 7396-1	Medical gas pipeline systems – Part1: Pipelines for compressed medical gases and vacuum (replaces EN 737-3)
EN 143: 1990	Respiratory protective devices – Particle filters – Requirements, testing, marking
EN 475	Medical devices – Electrically – generated alarm signals
EN ISO 9170	Medical gas pipeline systems – Part1: Terminal units for compressed medical gases and vacuum
EN ISO 5359	Low pressure hose assemblies for use with medical gases
EN 14971	Medical devices – Risk analysis
HD 384	Electrical installations of buildings
EN 286-1	Regulations for vessel in pressure

Thessaloniki, 04/01/2021

G. SAMARAS S.A.
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VAT NUMBER: EL 094[illegible]3861

Menelaos Samaras
Legal Representative

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G. SAMARAS S.A. MEDICAL GAS SYSTEMS

EC DECLARATION OF CONFORMITY

according to ANNEX II of European Directive (MDD) 93/42/EEC

Certificate Nº: 304021047RE and ANNEX No. 304021047RE CERTIFICATE

Manufacturer: G. SAMARAS S.A. MEDICAL GAS SYSTEMS

Address: Industrial area of Thermi, 57001
P.O. Box 60 178, Thermi – Thessaloniki - Greece
Tel.: +30 2310 46 33 88, - Fax:+30 2314 410113

Product: **CYLINDER STATION FOR MEDICAL GASES**
O_2, N_2O, N_2, CO_2, C.AIR
(2xm+1xn , m=R/L lots of cylinders n= lots of reserve sources/vessels)

Type:

MGCYLS	**200/8bar, 180m³/h @ 8 bar, *2xm+1xn***
MGCYLS	**200/8bar, 160m³/h @ 8 bar, *2xm+1xn***
MGCYLS	**200/8bar, 75m³/h @ 8 bar, *2xm+1xn***
MGCYLS	**200/8bar, 180m³/h @ 4/5 bar, *2xm+1xn***
MGCYLS	**200/8bar, 160m³/h @ 4/5 bar, *2xm+1xn***
MGCYLS	**200/8bar, 75m³/h @ 4/5 bar, *2xm+1xn***

Classification: Class IIb , (according to Rule 9 & 11)

We declare the compliance of the above medical devices with the relevant provisions of the Council Directive 93/42/EEC of June 14,1993 and RoHS2 Directive 2011/65/EU.

The conformity in accordance to Council Directive 93/42/EEC is certified by Notified Body, National Evaluation Center of Quality & Technology In Health SA, EKAPTY, with identification number 0653.

The conformity is certified with CE Certification Nº 304021047RE, validity until 24/05/2024.

This product conforms to the following European Standards:

EN ISO 11197-2016	*Medical supply units*
EN ISO 7396-1:2016	*Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1)*
EN ISO 10524-2:2018	*Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators*
EN ISO 10524-4 :2008	*Pressure regulators for use with medical gases - Part 4: Low-pressure regulators*
EN ISO 21969:2009	*High-pressure flexible connections for use with medical gas systems*
EN 13221:2000	*Flexible high pressure connections for use with medical gases*
EN 13348:2016	*Copper and copper alloys. Seamless, round copper tubes for medical gases or vacuum.*
EN ISO 5359:2014	*Low-pressure hose assemblies for use with medical gases*
EN ISO 9170-1:2017	*Terminal units for medical gas pipeline systems - Part 1: Terminal units for use with compressed medical gases and vacuum*
EN 837-1:1998	*Pressure gauges. Bourdon tube pressure gauges. Dimensions, metrology, requirements and testing*
EN ISO 14971:2019	*Risk management for medical devices includes risk analysis, evaluation, control and post production information*
ISO/DIS 3744:2010	*Acoustics -- Determination of sound power levels and sound energy levels of noise sources using sound pressure -- Engineering methods for an essentially free field over a reflecting plane*
EN 60601-1:2020	*Medical electrical equipment. General requirements for basic safety and essential performance*
HD 384:2003	*Requirements for electrical installations*
EN ISO 15001:2004	*Compatibility with oxygen*

Thessaloniki, 04/01/2021

G. SAMARAS S.A.
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Menelaos Samaras
Legal Representative

CE 0653

G. SAMARAS S.A. MEDICAL GAS SYSTEMS

EC DECLARATION OF CONFORMITY

according to ANNEX II of European Directive (MDD) 93/42/EEC

Certificate N°: 304021047RE and ANNEX No. 304021047RE CERTIFICATE

Manufacturer: G. SAMARAS S.A. MEDICAL GAS SYSTEMS

Address: Industrial area of Thermi, 57001
P.O. Box 60 178, Thermi – Thessaloniki - Greece
Tel.: +30 2310 46 33 88, - Fax:+30 2314 410113

Product: **AIR COMPRESSORS SYSTEM FOR BREATHING AIR, MACS series**

Type:

1.	MACS	3x17	m^3/h	-	500	lts
2.	MACS	3x24	m^3/h	-	500	lts
3.	MACS	3x35	m^3/h	-	500	lts
4.	MACS	3x42	m^3/h	-	1000	lts
5.	MACS	3x56	m^3/h	-	1000	lts
6.	MACS	3x87	m^3/h	-	2000	lts
7.	MACS	3x90	m^3/h	-	2000	lts
8.	MACS	3x120	m^3/h	-	2000	lts
9.	MACS	3x150	m^3/h	-	3000	lts
10.	MACS	3x177	m^3/h	-	3000	lts
11.	MACS	3x246	m^3/h	-	4000	lts
12.	MACS	3x306	m^3/h	-	5000	lts
13.	MACS	3x366	m^3/h	-	6000	lts
14.	MACS	3x498	m^3/h	-	9000	lts
15.	MACS	3x630	m^3/h	-	10000	lts
16.	MACS	3x774	m^3/h	-	13000	lts

Classification: Class IIb , (according to Rule 11)

We declare the compliance of the above medical devices with the relevant provisions of the Council Directive 93/42/EEC of June 14,1993 and RoHS2 Directive 2011/65/EU.

The conformity in accordance to Council Directive 93/42/EEC is certified by Notified Body, National Evaluation Center of Quality & Technology In Health SA, EKAPTY, with identification number 0653.

The conformity is certified with CE Certification N° 304021047RE, validity until 24/05/2024.

This product conforms to the following European Standards:

EN ISO 7396-1:2016	*Medical gas pipeline systems – Part3: Pipelines for compressed medical gases and vacuum – Basic requirements (replaces EN 737-3)*
EN 143: 1990	*Respiratory protective devices – Particle filters – Requirements, testing, marking*
EN 475: 1995	*Medical devices – Electrically – generated alarm signals*
EN ISO 9170-1:2008	*Medical gas pipeline systems – Part1: Terminal units for compressed medical gases and vacuum (replaces EN 737-1)*
EN ISO 5359:2014	*Low pressure hose assemblies for use with medical gases (replaces EN 739)*
EN 14971 : 2019	*Medical devices – Risk analysis*
EN 286-1:1998	*Regulations for vessel in pressure*
HD 384	*Electrical installations of buildings*
EN 60529:1992	*Specification for degrees of protection provided by enclosures*

Thessaloniki, 04/01/2021

G. SAMARAS S.A.
MEDICAL GAS SYSTEMS
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TEL.: [illegible] - FAX: [illegible]164570
VAT NUMBER: EL 0[illegible]

Menelaos Samaras
Legal Representative

CE 0653

G. SAMARAS S.A. MEDICAL GAS SYSTEMS

EC DECLARATION OF CONFORMITY

according to ANNEX II of European Directive (MDD) 93/42/EEC

Certificate N°:	304021047RE and ANNEX No. 304021047RE CERTIFICATE
Manufacturer:	G. SAMARAS S.A. MEDICAL GAS SYSTEMS
Address:	Industrial area of Thermi, 57001 P.O. Box 60 178, Thermi – Thessaloniki - Greece Tel.: +30 2310 46 33 88, - Fax:+30 2314 410113
Product:	**MGSAP L/C/CL/C1T1, MONITORING AND ALARM SYSTEMS**
Type:	LOCAL ALARM PANEL, L/L6 CENTRAL ALARM PANEL FOR MEDICAL GASES , C/CG CENTRALIZED PANEL OF LOCAL ALARM PANELS, CL CENTRALIZED PANEL OF LOCAL ALARM PANELS, C1T1
Classification:	Class IIb , (according to Rule 9)

We declare the compliance of the above medical devices with the relevant provisions of the Council Directive 93/42/EEC of June 14,1993 and RoHS2 Directive 2011/65/EU.

The conformity in accordance to Council Directive 93/42/EEC is certified by Notified Body, National Evaluation Center of Quality & Technology In Health SA, EKAPTY, with identification number 0653.

The conformity is certified with CE Certification N° 304021047RE, validity until 24/05/2024.

This product conforms to the following European Standards:

EN ISO 7396-1:2016	*Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum*
EN ISO 14971:2019	*Medical devices – Risk analysis*
EN ISO 11197:2016	*Medical electrical equipment – Particular requirements for safety of medical supply units*
EN 60601-1:2005	*Medical electrical equipment. General requirements for basic safety and essential performance*
EN 60601-1-2:2014	*Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests*
EN 55011:2016	*Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement*
EN 60101-1-8: 2006	*Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
EN 60669-1:2018	*Switches for household and similar fixed electrical installations – Part 1: General requirements (IEC 669-1: 1993, modified)*
EN 475	*Medical device – electrically-generated alarm signals*

Thessaloniki, 04/01/2021

G. SAMARAS S.A.
MEDICAL GAS SYSTEMS
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VAT NUMBER: EL [illegible]

Menelaos Samaras
Legal Representative

CE 0653

G. SAMARAS S.A. MEDICAL GAS SYSTEMS

EC DECLARATION OF CONFORMITY

according to ANNEX II of European Directive (MDD) 93/42/EEC

Certificate Nº: 304021047RE and ANNEX No. 304021047RE CERTIFICATE

Manufacturer: G. SAMARAS S.A. MEDICAL GAS SYSTEMS

Address: Industrial area of Thermi, 57001
P.O. Box 60 178, Thermi – Thessaloniki - Greece
Tel.: +30 2310 46 33 88, - Fax:+30 2314 410113

Product: **MEDICAL GASES LINE REDUCER (LPR GS)**

Type:
LPR GS1
LPR GS1D
LPR GS2
LPR GS2D
LPR GS5-DV

Classification: *Class IIb , (according to Rule 11)*

We declare the compliance of the above medical devices with the relevant provisions of the Council Directive 93/42/EEC of June 14,1993.

The conformity in accordance to Council Directive 93/42/EEC is certified by Notified Body, National Evaluation Center of Quality & Technology In Health SA, EKAPTY, with identification number 0653.

The conformity is certified with CE Certification Nº 304021047RE, validity until 24/05/2024.

This product conforms to the following European Standards:

EN ISO 7396-1:2016	*Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum*
EN ISO 10524-2:2018	*Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators*
EN ISO 9170-1:2017	*Terminal units for medical gas pipeline systems - Part 1: Terminal units for use with compressed medical gases and vacuum*
EN ISO 5359:2014	*Low-pressure hose assemblies for use with medical gases*
EN 13348:2007	*Copper and copper alloys. Seamless, round copper tubes for medical gases or vacuum.*
EN 837-1:1998	*Pressure gauges. Bourdon tube pressure gauges. Dimensions, metrology, requirements and testing*
EN ISO 15001:2004	*Anaesthetic and respiratory equipment - Compatibility with oxygen*
EN ISO 14971:2019	*Risk management for medical devices includes risk analysis, evaluation, control and post production information*
ISO/DIS 3744:2010	*Acoustics -- Determination of sound power levels and sound energy levels of noise sources using sound pressure -- Engineering methods for an essentially free field over a reflecting plane*

Thessaloniki, 04/01/2021

Menelaos Samaras
Legal Representative

CE 0653

EC DECLARATION OF CONFORMITY

according to ANNEX II of European Directive (MDD) 93/42/EEC

Certificate N°:	304021047RE and ANNEX No. 304021047RE CERTIFICATE
Manufacturer:	G. SAMARAS S.A. MEDICAL GAS SYSTEMS
Address:	Industrial area of Thermi, 57001 P.O. Box 60 178, Thermi – Thessaloniki - Greece Tel.: +30 2310 46 33 88, - Fax:+30 2314 410113
Product:	**CONTROL AND REDUCER PANELS**
Type:	AREA VALVE SERVICE UNITS – AVSU (KIB GS N) 2nd STAGE REDUCER PANELS (Y/S GS N S/D)
Classification:	Class IIb , (according to Rule 9 & 11)

We declare the compliance of the above medical devices with the relevant provisions of the Council Directive 93/42/EEC of June 14,1993.

The conformity in accordance to Council Directive 93/42/EEC is certified by Notified Body, National Evaluation Center of Quality & Technology In Health SA, EKAPTY, with identification number 0653.

The conformity is certified with CE Certification N° 304021047RE, validity until 24/05/2024.

This product conforms to the following European Standards:

EN ISO 11197:2016	*Medical supply units*
EN ISO 7396-1:2016	*Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1)*
EN ISO 10524-2:2018	*Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators (ISO 10524-2:2005)*
EN ISO 9170-1:2008	*Terminal units for medical gas pipeline systems - Part 1: Terminal units for use with compressed medical gases and vacuum*
EN ISO 5359:2014	*Low-pressure hose assemblies for use with medical gases*
EN 13348:2007	*Copper and copper alloys. Seamless, round copper tubes for medical gases or vacuum.*
EN 837-1:1998	*Pressure gauges. Bourdon tube pressure gauges. Dimensions, metrology, requirements and testing*
EN ISO 14971:2019	*Risk management for medical devices includes risk analysis, evaluation, control and post production information*
ISO/DIS 3744:2010	*Acoustics -- Determination of sound power levels and sound energy levels of noise sources using sound pressure -- Engineering methods for an essentially free field over a reflecting plane*
EN 60601-1:2020	*Medical electrical equipment. General requirements for basic safety and essential performance*

Thessaloniki, 04/01/2021

G. SAMARAS
MEDICAL GAS SYSTEMS
P.O. BOX 60178 - 57001 THERMI
GREECE

CE 0653

Menelaos Samaras
Legal Representative

G. SAMARAS S.A. MEDICAL GAS SYSTEMS

EC DECLARATION OF CONFORMITY

according to ANNEX II of European Directive (MDD) 93/42/EEC

Certificate Nº: 304021047RE and ANNEX No. 304021047RE CERTIFICATE

Manufacturer: G. SAMARAS S.A. MEDICAL GAS SYSTEMS

Address: Industrial area of Thermi, 57001
P.O. Box 60 178, Thermi – Thessaloniki - Greece
Tel.: +30 2310 46 33 88, - Fax:+30 2314 410113

Product: **MEDICAL OXYGEN CONCENTRATOR SUPPLY SYSTEM FOR USE WITH MEDICAL PIPELINE SYSTEMS, *MO2CSS series***

Type:

1.	MO2CSS	N x	0,68	/	0,5	Nm³/h @ 93% / 95%
2.	MO2CSS	N x	1,1	/	1,1	Nm³/h @ 93% / 95%
3.	MO2CSS	N x	2,2	/	2	Nm³/h @ 93% / 95%
4.	MO2CSS	N x	3,1	/	2,8	Nm³/h @ 93% / 95%
5.	MO2CSS	N x	4,3	/	3,9	Nm³/h @ 93% / 95%
6.	MO2CSS	N x	6,3	/	5,7	Nm³/h @ 93% / 95%
7.	MO2CSS	N x	6,4	/	6,0	Nm³/h @ 93% / 95%
8.	MO2CSS	N x	7,5	/	6,7	Nm³/h @ 93% / 95%
9.	MO2CSS	N x	8,6	/	8,0	Nm³/h @ 93% / 95%
10.	MO2CSS	N x	10,4	/	9,3	Nm³/h @ 93% / 95%
11.	MO2CSS	N x	11,5	/	10,7	Nm³/h @ 93% / 95%
12	MO2CSS	N x	14,3	/	12,9	Nm³/h @ 93% / 95%
13.	MO2CSS	N x	17,2	/	15,4	Nm³/h @ 93% / 95%
14.	MO2CSS	N x	20	/	18	Nm³/h @ 93% / 95%
15.	MO2CSS	N x	21,5	/	20,0	Nm³/h @ 93% / 95%
16.	MO2CSS	N x	29	/	26	Nm³/h @ 93% / 95%
17.	MO2CSS	N x	36	/	33	Nm³/h @ 93% / 95%
18.	MO2CSS	N x	38	/	36	Nm³/h @ 93% / 95%
19.	MO2CSS	N x	43	/	38	Nm³/h @ 93% / 95%
20.	MO2CSS	N x	50	/	45	Nm³/h @ 93% / 95%
21.	MO2CSS	N x	74,2	/	66,4	Nm³/h @ 93% / 95%
22.	MO2CSS	N x	80	/	72	Nm³/h @ 93% / 95%
23.	MO2CSS	N x	86	/	77	Nm³/h @ 93% / 95%
24.	MO2CSS	N x	103	/	92	Nm³/h @ 93% / 95%
25.	MO2CSS	N x	125,4	/	112,3	Nm³/h @ 93% / 95%
26.	MO2CSS	N x	148,3	/	133	Nm³/h @ 93% / 95%
27.	MO2CSS	N x	188,2	/	168,4	Nm³/h @ 93% / 95%
28.	MO2CSS	N x	221	/	204	Nm³/h @ 93% / 95%

Classification: Class IIb , (according to Rule 11)

We declare the compliance of the above medical devices with the relevant provisions of the Council Directive 93/42/EEC of June 14,1993 and RoHS2 Directive 2011/65/EU .

The conformity in accordance to Council Directive 93/42/EEC is certified by Notified Body, National Evaluation Center of Quality & Technology In Health SA, EKAPTY, with identification number 0653.

The conformity is certified with CE Certification Number 304021047RE, validity until 24/05/2024.

This product conforms to the following European Standards:

EN ISO 7396-1	*Medical gas pipeline systems -Part 1: Pipeline systems for compressed medical gases and vacuum*
ISO 10083	*Oxygen concentrator supply systems for use with medical gas pipeline systems*
EN ISO 15001	*Anaesthetic and respiratory equipment. Compatibility with oxygen*
EN ISO 14971	*Medical devices Application of risk management to medical devices*
EN 286-1	*Regulations for vessel in pressure*
EN ISO 10524-2	*Pressure regulators for use with medical gases. Manifold and line pressure regulators*
EN ISO 10524-4	*Pressure regulators for use with medical gases - Part 4: Low-pressure regulators*
EN 60601-1	*Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance*

Thessaloniki, 04/01/2021

G. SAMARAS S.A.
MEDICAL GAS SYSTEMS
P.O. BOX 60178 - 57001 THERMI
THESSALONIKI GREECE
TEL. 2310464570

Menelaos Samaras
Legal Representative

CE 0653

G. SAMARAS S.A. MEDICAL GAS SYSTEMS

EC DECLARATION OF CONFORMITY

according to ANNEX II of European Directive (MDD) 93/42/EEC

Certificate N°:	304021047RE and ANNEX No. 304021047RE CERTIFICATE
Manufacturer:	G. SAMARAS S.A. MEDICAL GAS SYSTEMS
Address:	Industrial area of Thermi, 57001 P.O. Box 60 178, Thermi – Thessaloniki - Greece Tel.: +30 2310 46 33 88, - Fax:+30 2314 410113
Product:	**PCMGS: NETWOK, PIPELINES AND COMPONENTS FOR DISTRIBUTION SYSTEMS OF MEDICAL GASES /VACUUM /AGSS** ***(list of consisting parts/components in Annex I)***
Classification:	*Class IIa , (according to Rule 2)*

We declare the compliance of the above medical devices with the relevant provisions of the Council Directive 93/42/EEC of June 14,1993.

The conformity in accordance to Council Directive 93/42/EEC is certified by Notified Body, National Evaluation Center of Quality & Technology In Health SA, EKAPTY, with identification number 0653.

The conformity is certified with CE Certification N° 304021047RE, validity until 24/05/2024.

This product conforms to the following European Standards:

EN ISO 7396-1	*Medical gas pipeline systems – Part3: Pipelines for compressed medical gases and vacuum – Basic requirements (replaces EN 737-3)*
EN ISO 7396-2	*Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems (replaces EN 737-2)*
EN 13348	*Copper and copper alloys - Seamless, round copper tubes for medical gases or vacuum*
EN ISO 15001	*Anaesthetic and respiratory equipment - Compatibility with oxygen*
EN ISO 5359	*Low pressure hose assemblies for use with medical gases (replaces EN 739)*
EN ISO 14971	*Medical devices - Application of risk management to medical devices*
EN 1041	*Information supplied by the manufacturer of medical devices*

Thessaloniki, 04/01/2021

Menelaos Samaras
Legal Representative

CE 0653

ANNEX I / ΠΑΡΑΡΤΗΜΑ Ι

ITEM	DESCRIPTION
1.	COPPER PIPE
2.	COPPER ELBOWS
3.	COPPER TEES
4.	COPPER COUPLING
5.	COPPER COUPLING REDUCING
6.	BRASS ADAPTER MALE
7.	BRASS UNION (MALE / FEMALE)
8.	BRASS TEE FEMALE
9.	BRASS NIPPLE MALE
10.	BRASS NIPPLE REDUCING
11.	BRASS REDUCING HEX BUSHING
12.	BRASS REDUCING ADAPTER
13.	BRASS ELBOW
14.	BRASS TEE
15.	BRASS FITTING COUPLING
16.	BRASS CAP (MALE / FEMALE)
17.	BRASS UNION STRAIGHT
18.	BALL VALVE
19.	NON RETURN VALVE
20.	LOW PRESSURE FLEXIBLE HOSE FOR MEDICAL GASES
21.	PRESSURE GAUGE
22.	MOUNTING COMPONENTS FOR PIPES
23.	TAPE FOR MEDICAL GASES

Thessaloniki, 04/01/2021

Menelaos Samaras
Legal Representative

CE 0653

3.2.7 Oxygen - Nitrogen Generators (MO2CSS series)

HTM02-01

CE0653
EN ISO 7396-1
ISO 10083
93/42 MED
NFPA 99

Pressure Swing Adsorption (PSA) is a low power consuming solution, efficient and reliable for onsite production of high purity oxygen. It uses the basic principle of passing air over adsorbent material which bound with nitrogen to leave rich stream of oxygen.

G. Samaras S.A can offer different solutions for Oxygen generator in different sizes and different flows. A typical Oxygen generator system comprise from:

Compressed Air Systems:

- Air Compressor
- Air Treatment unit by refrigerating dryer and filters
- Air Receiver in proper size

Oxygen Generator:

- PSA Plant
- PLC
- Oxygen Analyser
- Oxygen Receiver & high efficiency O_2 filter

High Pressure Filling System

Booster to fill the cylinders bank (150 bar at 5 bar inlet pressure / 200 bar at 8 bar inlet Pressure).

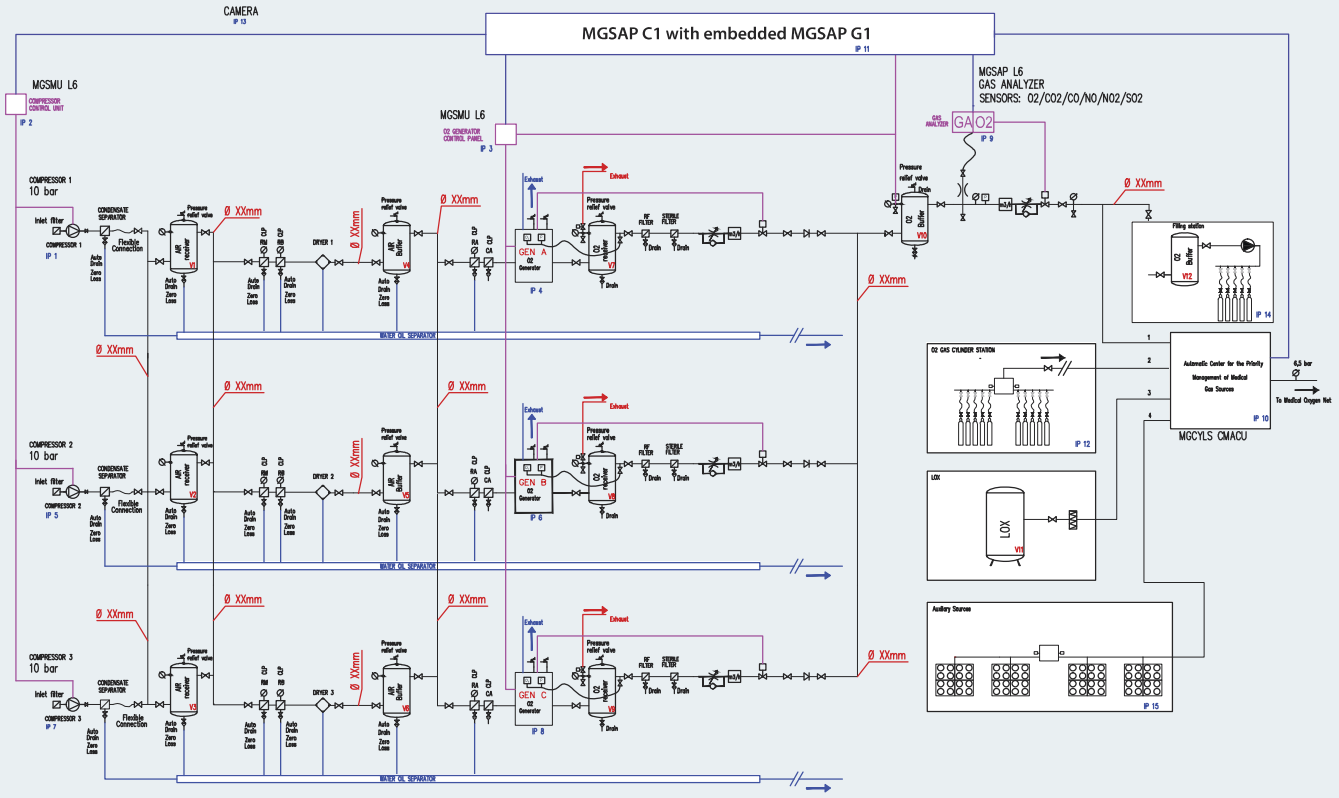
Available types of O_2 generators – MO_2CSS SERIES

Type Generator	Volume of side bed (lt)	O_2 capacity (m^3/h) 93±3%	Size of pipe or vessel (in)	Max. height (m)	m^3/h air	Min. air vessels (lt)	Min. vessel O_2	Recom. min. size of dryer	Dryer	Input connection	IN				OUT		INPUT CODE		OUTPUT CODE	
											WS	XA	XA/CA	CA	XA	Sterile	Pipe input	GS code input filters	Pipe output	GS code output filters
$MO_2CSS20C1$	20	1,0	6″	1,5	13	50	50	26	intergrated	1/2″	1	1	1		1	1	1/2″	GS119	1/2″	GS 119
$MO_2CSS20C2$	40	2,0	8″	1,8	26	90	90	52	intergrated	1/2″	1	1	1		1	1	1/2″	GS119	1/2″	GS 119
$MO_2CSS20C3$	60	3,0	10″	1,9	39	150	150	78	intergrated	1/2″	1	1	1		1	1	1/2″	GS119	1/2″	GS 119
$MO_2CSS20C4$	80	4,0	10″	2,1	52	200	200	104	intergrated	1/2″	1	1	1		1	1	1/2″	GS119	1/2″	GS 119
$MO_2CSS20C5$	100	5,0	12″	2	65	270	270	130	intergrated	1/2″	1	1	1		1	1	1/2″	GS119	1/2″	GS 119
$MO_2CSS20C6$	120	6,0	12″	2,4	78	300	300	156	SDE-160	3/4″	1		1		1	1	1/2″	GS119	1/2″	GS 119
$MO_2CSS20C7$	140	7,0	2×10″	2	91	400	400	182	SDE-190	3/4″	1		1		1	1	3/4″	GS144	1/2″	GS 119
$MO_2CSS20C8$	160	8,0	2×10″	2,4	104	500	500	208	SDE-190	3/4″	1		1		1	1	3/4″	GS144	1/2″	GS 119
$MO_2CSS20C10$	200	10,0	2×12″	2	130	500	500	260	SDE-310	1 ½″	1		1		1	1	3/4″	GS144	1/2″	GS 119
$MO_2CSS20S27$	270	11,0	270lt	2,2	138	500	500	248	SDE-310	1½″	1		1		1	1	1″	GS297	1/2″	GS 119
$MO_2CSS20C6-2$	240	12,0	2×12″	2,4	150	500	500	270	SDE-310	1½″	1		1		1	1	1″	GS297	1/2″	GS 119
$MO_2CSS20S30$	300	13,5	300lt	2,2	169	900	900	304	SDE-310	1½″	1		1		1	1	1″	GS297	1/2″	GS 119
$MO_2CSS20C6-3$	340	17,0	3×12″	2,4	213	900	900	383	SDE-500 (495)	2″	1		1		1	1	1″	GS297	1/2″	GS 119
$MO_2CSS20D41$	400	18,0	2×200lt	2,2	225	900	1000	405	SDE-500 (495)	2″	1		1		1	1	1″	GS297	1/2″	GS 119
$MO_2CSS20S50$	500	21,0	500lt	2,25	263	1000	1000	473	SDE-500 (495)	2″	1		1		1	1	1″	GS297	1/2″	GS 119
$MO_2CSS20D54$	540	22,0	2×270lt	2,2	275	1500	1500	495	SDE-600 (588)	2″	1	1		1	1	1	1½″	GS680	1/2″	GS 119
$MO_2CSS20C6-4$	460	23,0	4×12″	2,4	288	1500	1500	518	SDE-600 (588)	2″	1	1		1	1	1	1½″	GS680	1/2″	GS 119
$MO_2CSS20D60$	600	26,0	2×300lt	2,2	325	1500	1500	585	SDE-600 (588)	2″	1	1		1	1	1	1½″	GS680	1/2″	GS 119
$MO_2CSS20C6-5$	620	31,0	5×12″	2,4	388	2000	2000	698	SDE-830 (825)	2″	1	1		1	1	1	1½″	GS680	1/2″	GS 119
$MO_2CSS20T81$	810	33,0	3×270lt	2,2	413	2000	2000	743	SDE-830 (825)	2″	1	1		1	1	1	1½″	GS680	1/2″	GS 119
$MO_2CSS20C6-6$	760	38,0	6×12″	2,4	475	2000	2000	855	SDE-1100	2″	1	1		1	1	1	1½″	GS680	1/2″	GS 119
$MO_2CSS20T90$	900	40,0	3×300lt	2,2	500	2000	2000	900	SDE-1100	2″	1	1		1	1	1	1½″	GS680	1/2″	GS 119
$MO_2CSS20Q100$	1000	42,0	2×500lt	2,25	525	2000	2000	945	SDE-1100	2″	1	1		1	1	1	1½″	GS680	1/2″	GS 119
$MO_2CSS20C6-7$	900	45,0	7×12″	2,4	563	2×2000	2×2000	1013	SDE-1100	2″	1	1		1	1	1	1½″	GS680	1/2″	GS 119
$MO_2CSS20C6-8$	1000	50,0	8×12″	2,4	625	2×2000	2×2000	1125	SDE-1300 (1331)	3″	1	1		1	1	1	2″	GS765	1/2″	GS 119
$MO_2CSS20C6-9$	1100	55,0	9×12″	2,4	688	2×2000	2×2000	1238	SDE-1300 (1331)	3″	1	1		1	1	1	2″	GS765	1/2″	GS 119
$MO_2CSS20C6-10$	1240	62,0	10×12″	2,4	775	2×2000	2×2000	1395	SDE-2200	3″	1	1		1	1	1	2″	GS765	1/2″	GS 119

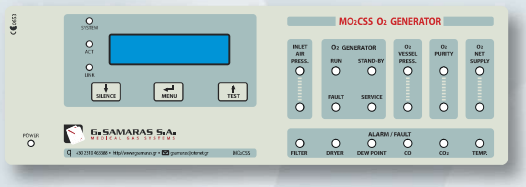
- Purity according to ISO 10083, Oxygen 93 European Pharmacopoeia 7.1, USP Oxygen 93
- Feed Air inlet pressure: 7–10 bar(g)
- Feed Air minimum quality class 1.4.1 acc to ISO 8573.1
- Oxygen pressure: 6 bar(g) ±10%
- Flow rate reference conditions acc to DIN 1343, (0°C, 1013mbar)
- Air compressors and dryers could be oversized in order to compensate tolerances and ambient conditions impact
- Due to a continuous policy of research and development, the manufacturer reserves the right to update and/or modify technical specifications without prior notice.
- All types max inlet pressure 10 bar
- Types with higher capacity upon request

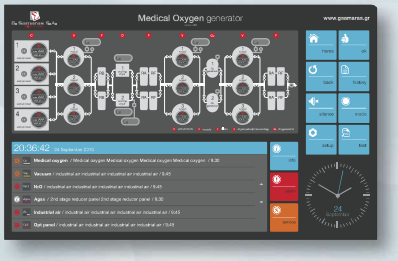
AIR COMPRESSOR
DRYER
LP AND MP ISOLATION BALL VALVE
NON–RETURN VALVE
FILTER
LOW PRESS REGULATOR
FLOW RESTRICTOR
PRESSURE TRANSDUSE
MANOMETER
OXYGEN ANALYZER

Schematic lay-out of Oxygen Central Station with 3×PSA + 1×LOX + 2×Cylinder Pack + 2 Cylinder Station + Filling Station

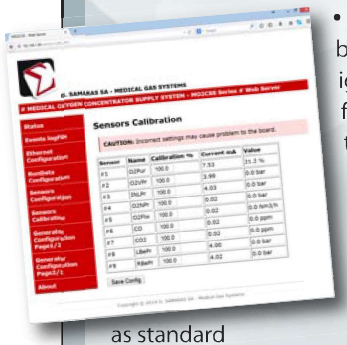


OXYGEN / NITROGEN GENERATOR CONTROL PANEL





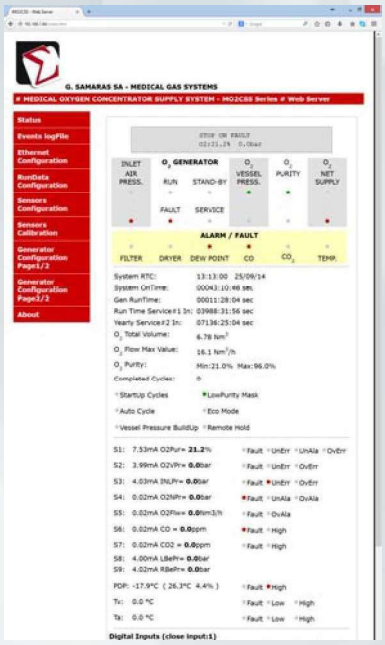
Product highlights:



- LCD screen, 3 buttons for navigation, 18 leds for visual indication, audible signaling
- O_2 analyzer, with long life zirconia sensor, supplied as standard
- Automatic restart (on electrical power failure)
- Automatic purity recover procedure, if purity falls below a limit(user programmable, code protected)
- Automatic shutdown
- Automatic recover on any fault condition (if the fault condition doesn't exist yet)
- Three operation modes: FIX, AUTO, AUTO ECO (ECO mode is an automatic mode with lower air consumption, providing standard O_2 purity 93%±3)
- Automatic O_2 generator start up / purity built up (no user action required, the only action needed is to START the O_2 generator, all automatically implemented). Useful function at first installation and during services
- Smart algorithm included for O_2 purity protection function (on inlet air pressure over/under range)
- O_2 purity measurement with instant value and min / max value records (available as standard)
- O_2 Flow measurements with instant value (Nm^3/h), min, max and total volume counter
- O_2 Dew point measurement
- Inlet, O_2 product and outlet pressure measurement
- Two temperature sensors
- Run and service timers
- Internal storage up to 200 records for any alarm/event with time/date stamp, unlimited if our report software used (a pc needed)
- User friendly WEB interface, using RJ45 port (Ethernet) and any internet browser for on line monitoring and code protected configuration. Multiple users supported.
- Inlet filters monitoring
- Alarm signal (dry contacts C/NC/NO) available for any BMS system connection
- Master / Slave supported
- Remote control (start/stop) digital inputs
- MODBUS TCP/IP communication protocol
- CO/CO_2 sensors (available as an option)
- Report and monitoring SCADA based software (available as an option)
- Remote monitoring panel, remote device with repeater function (available as an option)
- Controller redundancy (available as option)
- **ability to connect to MEDIMOTE portal, providing SMS / E-mail: alert (www.medimote.gr)**

Future options:

- GSM/GPRS module for SMS alerts
- 4.3" TFT Touch Screen
- O_2 generator, MO_2CSS+ Series with multiple beds /columns (improved O_2 to air production ratio)



STANDARDS / REGULATIONS OF CONFORMITY

- **ISO 10083:26** Oxygen concentrator supply systems for use with medical gas pipeline systems
- **EN ISO 7396-1:2007** Medical gas pipeline systems Part 1: Pipeline systems for compressed medical gases and vacuum
- **European Pharmacopoeia 7.1 monograph 4/2011:2455, OXYGEN (93%)**
- **HTM 02-01**
- **Directive 93/42/EEC, class IIb**
- **National Pharmaceuticals Organization (in Greek: ΕΟΦ) 22288/28.3.2011**

Filling station 200 bar – Booster 10 bar

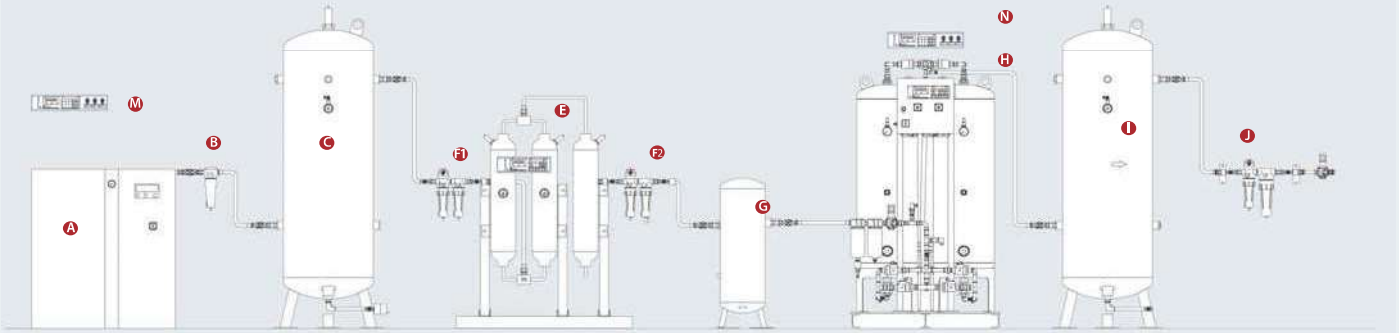
DLE2 (-GG)	Inlet/Outlet: ½ BSP
Maximum operating temperature	60°C
Net weight	20 kg
Oxygen service	DLE 2-GG-S

Filling station, electrically or pneumatic

O_2/N_2 COMPRESSOR (BOOSTER) FOR FILLING STATIONS			
Code	Model	Nm^3/h	Bar
10604010019	OXICOMP 2	2	150
10604010018	OXICOMP 3	3.3	170
10604010020	OXICOMP 4	4.6	200
10604010021	OXICOMP 10	11.2	200
10604010022	OXICOMP 12	16.9	200
10604010011	D-230	0.45	150
10604010005	2PS2B-.85-H50	3.2	150
10604010012	2V3B	16	200
10604010013	4V4B	32.5	200

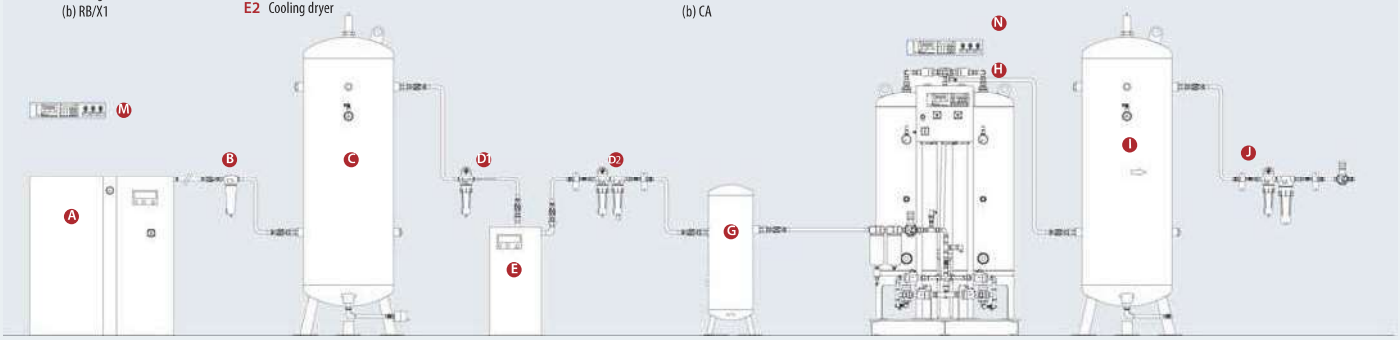
P in 5 bar

O_2 Generator

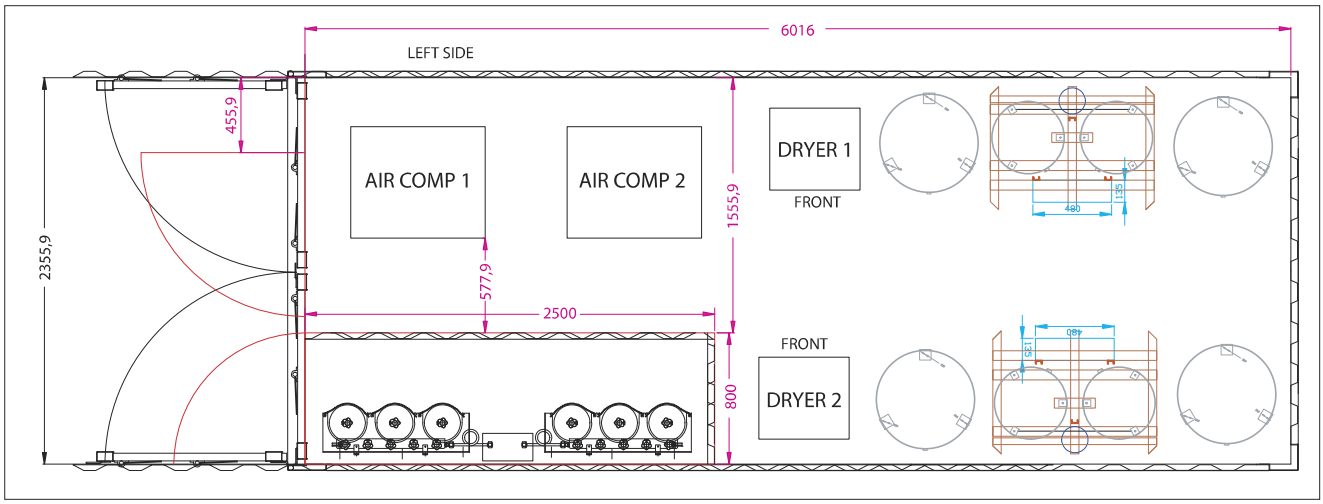


A Air compressor
B Condensate separator
C Compressed air vessel
D1 Pre filters (RB + RA type)
(a) integrated
(b) RB/X1
D2 Pre filters (RB type)
(a) RA/XA+CA/AC+STR/SR
(b) XAC(XA+CA)+STR/SR
(c) CA/AC+STR/SRE1
E1 Adsorption dryer
E2 Cooling dryer
F1 Pre filters (RB/X1+ RA/XA)
F2 After filters
(a) X5
(b) RF
G Carbon active tower
H Oxygen generator
I Oxygen vessel (Buffer)
J Compressed air filter
(a) XA
(b) CA

ALARM PANELS
M Alarm panel for compressors
N Alarm panel for O_2 generator



General Hospital "Papageorgiou", Thessaloniki



O_2 Generator Container Systems

The oxygen generator can be installed inside a container together with a compressor or cylinder filling station. The oxygen generator container system is a turnkey solution that can be customized as needed, available in various capacities and oxygen concentrations. The container can easily be transported by road or sea and can easily be placed on site. The O_2 generator system can be equipped with greater levels of sound attenuation, different fuel tanks or any other value added features you might need.

3.2.8 PSA Nitrogen Generators

Capacity: 0.2 Nm³/h – 2500 Nm³/h. Purity: 95 % – 99.999%

Pressure Swing Adsorption (PSA) type nitrogen generation systems are used to separate and enrich Nitrogen (N_2) from Oxygen (O_2) by using Carbon Molecular Sieve (CMS) as adsorbent. Carbon Molecular Sieve (CMS) adsorbs oxygen and water vapor molecules under certain pressure, while allowing nitrogen to pass through the bed. The Nitrogen Generator is a two-bed adsorption system. The Nitrogen Generator consists of two adsorber vessels filled with CMS, a valve assembly, air filters, main pressure regulator, and a product receiver tank. Clean and dry air is directed to one of the adsorber beds where oxygen is adsorbed faster than nitrogen in the pore structure of the CMS, thus increasing the nitrogen purity of the product gas stream to the desired level (95–99.999% as required by the process). This product flows out of the top of the adsorber bed, through the discharge valve, and into the product receiver at a pressure slightly below the feed air pressure.

Available types of Nitrogen Generators:

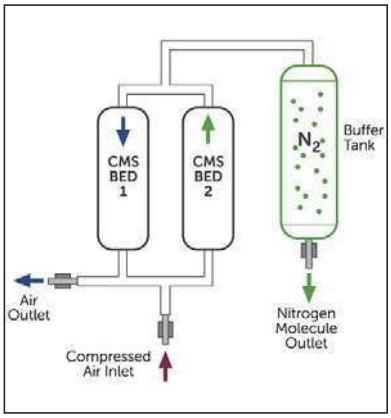
	Free Nitrogen Delivery@following purity level (m³/h)									Buffer	Connections		Dimensions		
Model	95%	97%	98%	99%	99,50%	99,90%	99,95%	99,99%	99,999%	Tank	Inlet	Outlet	Length	Width	Height
MGDNG-10	2,7	2,2	1,9	1,5	1,0	0,8	0,7	0,5	0,2	26 L	1/2″	1/2″	1120	610	1090
MGDNG-20	4,4	3,5	3,1	2,4	2,0	1,3	1,1	0,8	0,4	35 L	1/2″	1/2″	1081	560	1284
MGDNG-35	8,1	6,5	5,6	4,4	3,5	2,3	2,0	1,4	0,7	52 L	1/2″	1/2″	1179	736	1787
MGDNG-60	13,5	10,8	9,4	7,3	6,0	3,8	3,4	2,4	1,2	70 L	1/2″	1/2″	1115,5	932,5	1485
MGDNG-95	23,3	18,6	16,2	12,6	10,4	6,6	5,9	4,1	2,0	97 L	1″	1″	1659	760	1485
MGDNG-120	31,0	24,8	21,6	16,8	13,9	8,8	7,8	5,5	2,7	126 L	1″	1″	1634	890	1442
MGDNG-150	38,0	30,4	26,4	20,6	17,0	10,8	9,6	6,7	3,3	151 L	1″	1″	1634	890	1639
MGDNG-250	60,5	48,3	42,1	32,7	27,1	17,2	15,2	10,6	5,3	280 L	1″	1″	1760	892	1975
MGDNG-330	80,0	63,9	55,7	43,3	35,8	22,8	20,1	14,1	7,0	408 L	1″	1″	1910	950	2025
MGDNG-450	108,2	86,4	75,2	58,5	48,4	30,8	27,2	19,0	9,5	464 L	1″	1″	2218	1010	2134
MGDNG-510	123,9	99,0	86,2	67,1	55,5	35,3	31,2	21,8	10,9	515 L	1 1/2″	1 1/2″	2208	1010	2028
MGDNG-570	137,6	109,9	95,7	74,5	61,6	39,2	34,6	24,2	12,1	573 L	1 1/2″	1 1/2″	2208	1010	2226
MGDNG-730	180,1	143,9	125,3	97,5	80,6	51,3	45,3	31,6	15,8	712 L	1 1/2″	1 1/2″	2685	1110	2084
MGDNG-910	220,3	176,0	153,2	119,2	98,6	62,7	55,5	38,7	19,3	1,042 m³	1 1/2″	1 1/2″	2727	1220	2485
MGDNG-1110	267,8	214,0	186,3	145,0	119,9	76,2	67,4	47,0	23,5	1,290 m³	1 1/2″	1 1/2″	2896	1322	2521
MGDNG-1230	295,4	236,0	205,5	159,9	132,3	84,1	74,4	51,9	25,9	1,402 m³	2″	2″	2898	1322	2724
MGDNG-1370	327,4	261,5	227,7	177,2	146,6	93,2	82,4	57,5	28,7	1,498 m³	2″	2″	2895	1355	2941
MGDNG-1820	442,6	353,6	307,9	239,6	198,2	126,0	111,4	77,8	38,8	2,019 m³	2″	2″	3599	1793	2634
MGDNG-2050	516,2	412,4	359,0	279,4	231,1	146,9	130,0	90,7	45,3	2,336 m³	DN80	DN80	3390	1964	3124
MGDNG-2550	618,8	494,4	430,4	334,9	277,1	176,1	155,8	108,7	54,3	2,336 m³	DN80	DN80	3666	2139	3194
MGDNG-2950	763,2	609,8	530,9	413,1	341,8	217,2	192,1	134,1	67,0	2,336 m³	DN80	DN80	4074	2245	2787
MGDNG-3540	894,5	714,6	622,1	484,1	400,5	254,6	225,1	157,1	78,5	2,336 m³	DN80	DN80	4024	2375	3054
MGDNG-4160	1031,4	824,1	717,4	558,3	461,9	293,6	259,6	181,2	90,5	2,336 m³	DN80	DN80	4020	2376	3361
MGDNG-5560	1241,7	992,0	863,6	672,1	556,0	353,4	312,5	218,1	109,0	2,336 m³	DN100	DN100	4125	2425	3890
MGDNG-9170	2048,0	1636,1	1424,3	1108,4	917,0	582,9	515,5	359,7	179,7	2,336 m³	DN150	DN150	4502	2986	4364
MGDNG-11200	2501,2	1998,3	1740,0	1353,8	1120,0	712,0	629,6	439,4	219,4	2,336 m³3	DN150	DN150	3081	4672	4728

Note: G. SAMARAS S.A. supplies buffer tank volumes for 99,5% and higher Nitrogen purities. For purities lower than 99,5%, it may be necessary to use an additional tank.

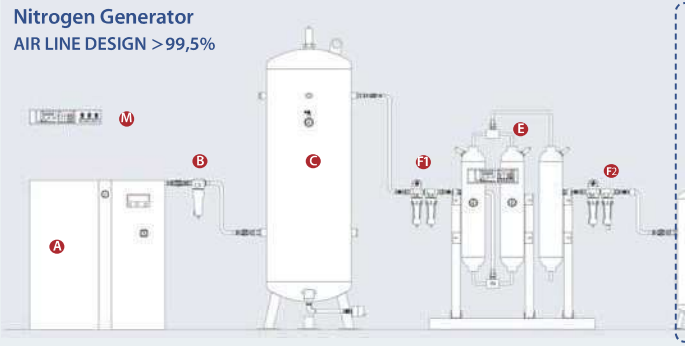
CORRECTION FACTORS	
Purity (%)	Air/N_2 Ratio
95	2.3
97	2.56
98	2.68
99	3.01
99.5	3.34
99.9	4.46
99.95	4.56
99.99	5.75
99.999	9.38

CORRECTION FACTORS			
Pressure (bar)	F1	Inlet Temp. (°C)	F2
6	0,82	5	0,85
6,5	0,88	10	1
7	0,94	15	1
7,5	1	20	1
8	1,05	25	1
8,5	1,1	30	0,91
9	1,14	35	0,82
9,5	1,2	40	0,74
10	1,21	45	0,6

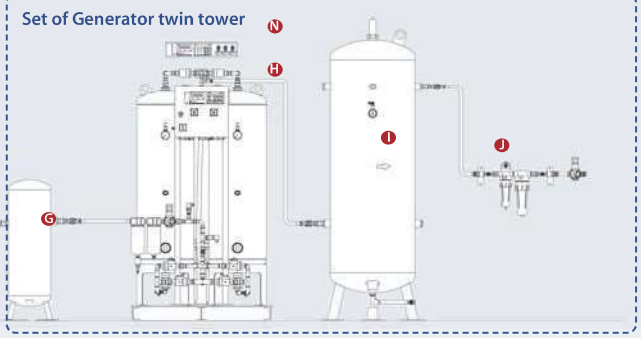
To determine the nitrogen generator model in the reference conditions divide the nitrogen ow rate to the factors mentioned above.



Nitrogen Generator
AIR LINE DESIGN >99,5%



Set of Generator twin tower

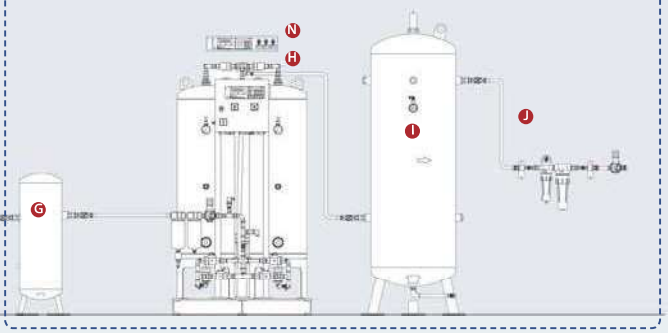


- A Air compressor
- B Condensate separator
- C Compressed air vessel
- D1 Pre filters (RB + RA type)
  (a) integrated
  (b) RB/X1
- D2 Pre filters (RB type)
  (a) RA/XA+CA/AC+STR/SR
  (b) XAC(XA+CA)+STR/SR
  (c) CA/AC+STR/SRE1
- E1 Adsorption dryer
- E2 Cooling dryer
- F1 Pre filters (RB/X1+ RA/XA)
- F2 After filters
  (a) (RF/X1+CA/AC+STR/SR)
  (b) (RF/X1+XAC(XA+CA) +STR/SR)
  (c) XAC (XA+CA)+STR/SR)
- G Carbon active tower
- H Nitrogen generator
- I Nitrogen vessel (Buffer)
- J Compressed air filter

ALARM PANELS
- M Alarm panel for compressors
- N Alarm panel for N_2 generator

AIR LINE DESIGN ≤99,5%

Set of Generator twin tower*



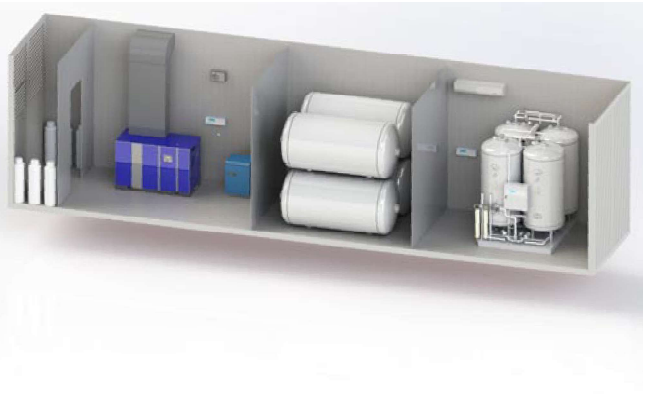
*Modular Generator does not include the set

N_2 Nitrogen Generators / Technical Specifications:

	Model	Air Demand @ Following Purity Level (m³/h)								
		95%	97%	98%	99%	99.50%	99.90%	99.95%	99.99%	99.999%
Modular*	MNG-10	6,3	5,6	5,1	4,5	4,1	3,5	3,1	2,8	2,2
	MNG-20	10,1	9,0	8,2	7,2	7,0	5,6	5,1	4,4	3,6
	MNG-35	18,6	16,6	15,1	13,2	12,1	10,3	9,3	8,2	6,7
	MNG-60	31,0	27,6	25,1	22,0	20,2	17,1	15,5	13,6	11,1
Twin tower	MNG-95	53,4	47,6	43,3	37,9	34,7	29,5	26,7	23,5	19,1
	MNG-120	71,3	63,6	57,8	50,6	46,4	39,4	35,6	31,4	25,5
	MNG-150	87,2	77,8	70,7	62,0	56,8	48,2	43,6	38,4	31,3
	MNG-250	138,8	123,8	112,5	98,6	90,3	76,7	69,4	61,1	49,7
	MNG-330	183,7	163,8	148,9	130,5	119,5	101,5	91,8	80,8	65,8
	MNG-450	248,2	221,4	201,2	176,3	161,5	137,2	124,1	109,2	89,0
	MNG-510	284,3	253,6	230,5	202,0	185,0	157,1	142,1	125,1	101,9
	MNG-570	315,8	281,6	256,0	224,3	205,5	174,5	157,8	139,0	113,2
	MNG-730	413,3	368,6	335,1	293,6	268,9	228,4	206,6	181,9	148,2
	MNG-910	505,6	450,9	409,9	359,1	329,0	279,4	252,7	222,5	181,2
	MNG-1110	614,6	548,2	498,3	436,6	399,9	339,7	307,2	270,5	220,3
	MNG-1230	678,0	604,7	549,7	481,6	441,2	374,7	338,9	298,4	243,1
	MNG-1370	751,3	670,1	609,1	533,7	488,9	415,2	375,5	330,6	269,3
	MNG-1820	1015,8	906,0	823,5	721,6	661,0	561,3	507,8	447,0	364,2
	MNG-2050	1185,0	1056,5	960,3	841,5	770,8	654,6	592,1	521,3	424,7
	MNG-2550	1420,1	1266,6	1151,3	1008,8	924,1	784,8	709,8	625,0	509,1
	MNG-2950	1751,6	1562,3	1420,0	1244,3	1139,8	968,0	875,6	770,9	627,9
	MNG-3540	2052,8	1830,9	1664,2	1458,2	1335,8	1134,4	1026,1	903,4	735,9
	MNG-4160	2367,2	2111,2	1919,0	1681,5	1540,3	1308,1	1183,2	1041,7	848,6
	MNG-5560	2849,7	2541,5	2310,1	2024,4	1854,0	1610,0	1424,2	1253,9	1022,2
	MNG-9170	4700,2	4191,7	3810,0	3338,5	3057,0	2655,5	2349,4	2068,1	1685,2
	MNG-11200	5740,3	5119,6	4654,5	4077,6	3734,0	3243,6	2869,4	2526,3	2057,5

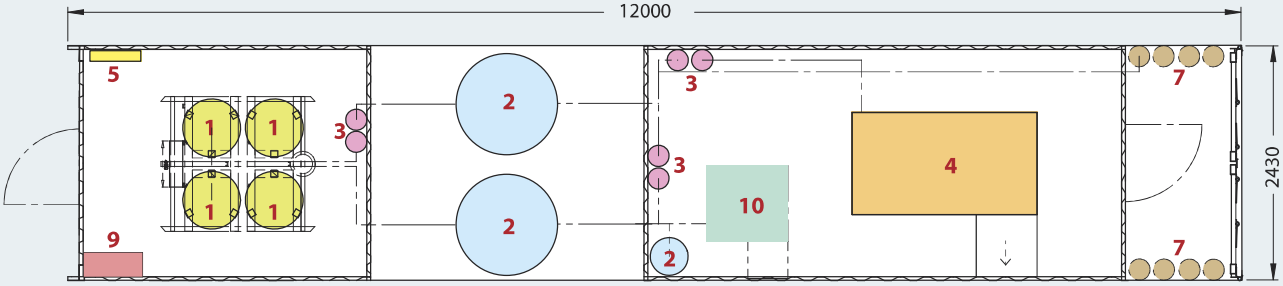
3.2.9 Medical Gases Central Stations Container Cabinets

All medical central stations can be accommodated in special-made containerized cabinet for outdoor installations according to EN ISO 7396-1, HTM 02-01 and NFPA 99 standards. Every part of the station is fitted inside the container including the medical gases and electrical connections.

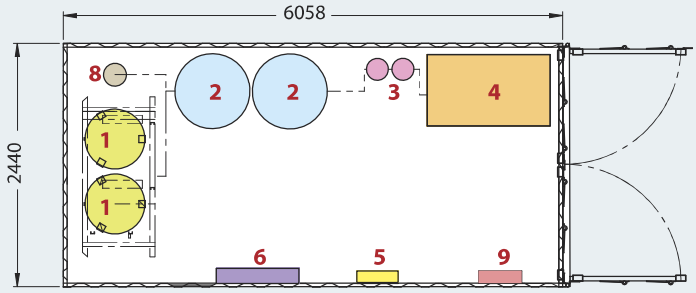


Metal frame	Galvanized elements C type, 3mm thickness, 180×6. Anti-corrosion protection
Columns	Galvanized beams 60×60 4mm thickness
Paint	Primer-painted metal and polyurethane 2 components suspension points 4 suspension points on the roof of the cabin. Interior surfaces white RAL 9010. Exterior surfaces silver metallic RAL 9006
Subfloor - Floor	Galvanized corrugated sheets 4/10mm, on which there is waterproof plywood. The floors have a gentle slope leading to surface waters in floor-standing stainless steel channel located along the long side.
Walls - Partitions - Roof	4-5cm Polyurethane panels. Type B2 (autoextinquishing) Rainwater removed with the help of surrounding horizontal galvanized gutters, then driven through vertical gutter on the ground.
Doors	Aluminum frames with projected outward functioning. Perimeter sealing the window frame profiles with rubber gasket. The doors are aluminum.
Electrical	External grounding point
Heating / Cooling	Included wall mounted air-conditioning units ecologically Class A.

40ft Container

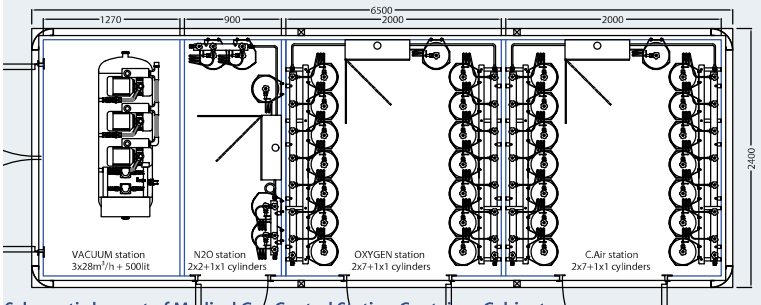


20ft Container



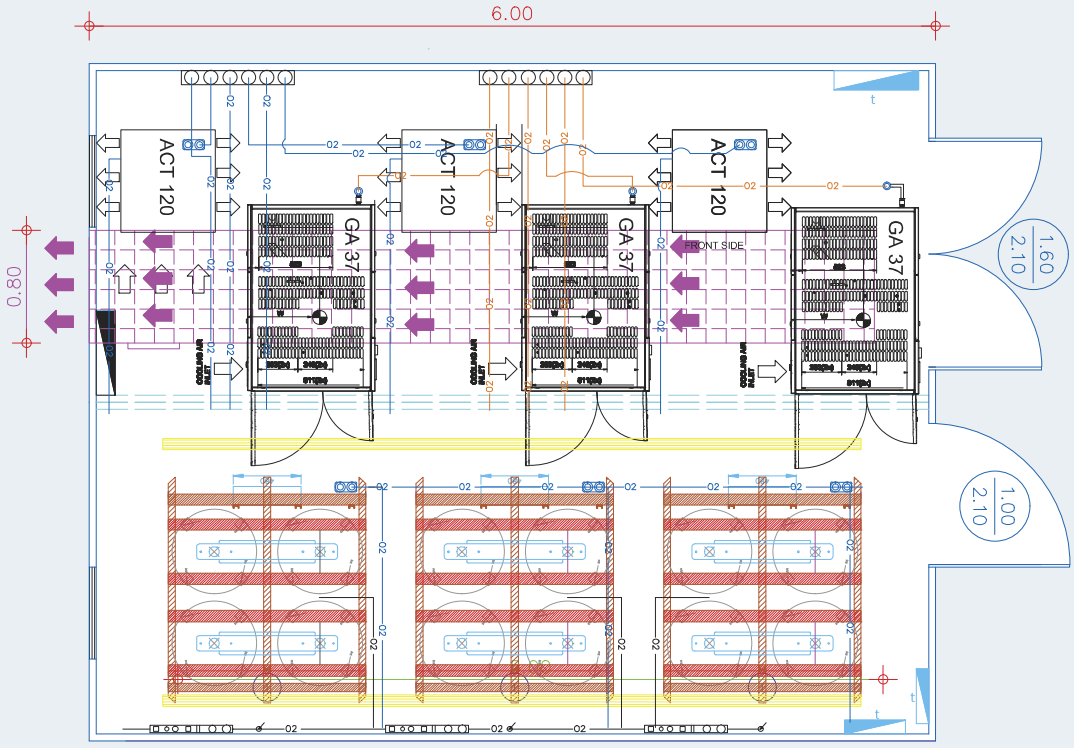
1 Generator
2 Vessels
3 Filters (Prefilter)
4 Compressor (with integrated dryer)
5 L6 Panel (electric control panel)
6 Air condition system
7 Cylinders (for filling or stand by)
8 Water oil seperator
9 Electrical panel
10 Filling station

Container Cabinet



Schematic lay-out of Medical Gas Central Station Container Cabinet

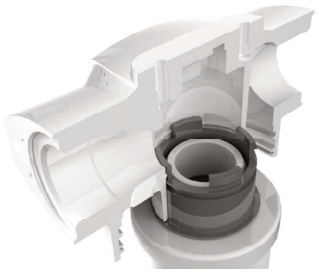
Typical system 3x50m³/h

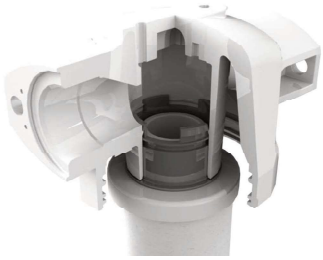


F2. GS W Type Filters

F.2.1 Compressed Air Coalescing Filters

The GS W type filter has been tested to provide a saturated differential pressure of <125 mbar across X1 and XA grades –proving to be our most advanced filter to date. With class leading performance and exceptional results in oil aerosol and particle retention, delivers significantly reduced pressure loss and optimum filtration efficiencies– to ensure continually low operational costs.



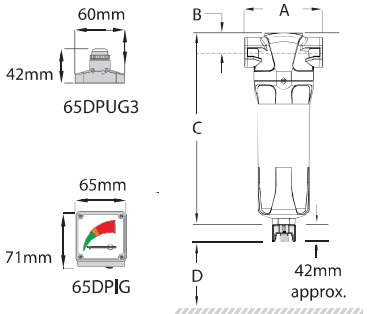


Filter model	Pipe size inches	Inlet flow rate Nm³/hr	Inlet flow rate SCFM	Dimensions mm A	B	C	D	Weight Kg
GS AF119	½	119	70	127	32	285	80	1.7
GS AF144	¾	144	85	127	32	285	80	1.7
GS AF212	¾	212	125	127	32	371	80	2
GS AF297	1	297	175	127	32	371	80	2
GS AF680	1½	680	400	170	53	508	100	4.9
GS AF1189	2	1189	700	170	53	708	100	5.5
GS AF1529	3	1529	900	220	70	736	100	10.5

Pressure correction factors	For maximum flow rate, multiply model flow rate by the correction factor corresponding to the minimum operating pressure									
Operating pressure barg (psig)	4 (58)	5 (72)	6 (87)	7 (100)	8 (115)	10 (145)	12 (174)	14 (203)	16 (232)	20 (290)
7 barg – correction factor	0.76	0.84	0.92	1.00	1.07	1.19	1.31	1.41	1.51	1.6

	PREFILTER						AFTER FILTER							
Test method	ISO 12500-1, 8573-2, ISO 12500-3, EN1822-5													
Grade	X25		X1		XA		X5		AC		SR		DXA		DAC	
Particle removal	25 micron		1 micron		0.01 micron		5 micron		0.01 micron		0.01 micron		0.01 micron		0.01 micron	
Maximum particle size class	–		3		1		4		1		N/A		1		1	
Maximum oil content	–		3		1		4		1		N/A		1		1	
Maximum oil carryover at 20°C (68°F)	10 mg/m³		0.3 mg/m³		0.01 mg/m³		5 mg/m³		0.003 mg/m³		–		0.01 mg/m³		0.003 mg/m³	
Pressure loss - clean & dry	30 mbar	0.4 psi	55 mbar	0.8 psi	85 mbar	1.2 psi	40 mbar	0.6 psi	115 mbar	1.7 psi	100 mbar	1.5 psi	85 mbar	1.2 psi	75 mbar	1.1 psi
Pressure loss - saturated	50 mbar	0.7 psi	125 mbar	1.8 psi	125 mbar	1.8 psi	75 mbar	1.1 psi	N/A	N/A	N/A	N/A	125 mbar	1.8 psi	N/A	N/A
Pressure loss - element change	12 months	8000 hrs	12 months	8000 hrs	12 months	8000 hrs	12 months	8000 hrs	at least every 6 months		N/A	N/A	12 months	8000 hrs	at least every 6 months	
Maximum temperature - automatic drain	80°C	176°F	80°C	176°F	80°C	176°F	80°C	176°F	50°C	122°F	120°C	248°F	50°C	122°F	50°C	122°F
Maximum working pressure - automatic drain	16 barg	232 psig	16 barg	232 psig	16 barg	232 psig	16 barg	232 psig	16 barg	232 psig	N/A	N/A	16 barg	232 psig	16 barg	232 psig
Maximum temperature - manual drain	120°C	248°F	120°C	248°F	120°C	248°F	120°C	248°F	50°C	122°F	134°C	273°F	N/A	N/A	N/A	N/A
Maximum working pressure - manual drain	20.7 barg	300 psig	20.7 barg	300 psig	20.7 barg	300 psig	20.7 barg	300 psig	20.7 barg	300 psig	20.7 barg	300 psig	N/A	N/A	N/A	N/A
Element end cap colour	Black		Red		Blue		Green		Black		Stainless steel		Black		Black	

Evaluation of Filtration Efficiency for Compliance with AS 2896-2011 (Medical Gas Systems) ISO 8573-1:2010 Class 1 (Particles), ISO 7396-1:2016 (Medical Gas Pipeline Systems) ISO 29463-1:2011 Filter Classification & NFPA 99 Edition 2018 (Health Care Facilities Code) IEST RP CC001.6 (2016) HEPA and ULPA Filters.

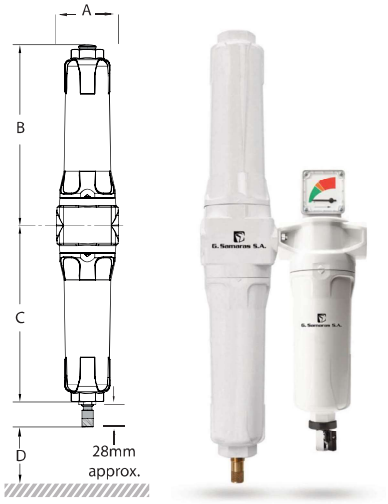


F.2.2 Compressed Air Duplex Filters

With exceptionally improved performance, the intelligent design combines a two-stage filtration system in a single unit, ensuring twice the filtration capability. The Duplex Filters space saving modular design utilizes deep pleated media technology to deliver market leading performance. The 0.01 micron (DXA grade) element delivers exceptional results in oil aerosol removal and particle retention - with a significantly reduced differential pressure of <125 mbar. The Activated Carbon element utilises a finely divided activated carbon media to remove odours and tastes.

Filter model	Pipe size inches	Inlet flow rate Nm³/hr	Inlet flow rate SCFM	Dimensions mm A	B	C	D	Weight Kg	No. of Elements
GS AF D119	½	119	70	100	236	240	80	2.3	1/1
GS AF D144	¾	144	85	100	236	240	80	2.3	1/1
GS AF D212	¾	212	125	100	356	360	80	3.1	1/1
GS AF D297	1	297	175	100	356	360	80	3.2	1/1

Pressure correction factors	For maximum flow rate, multiply model flow rate by the correction factor corresponding to the minimum operating pressure								
Operating pressure barg (psig)	4 (58)	5 (72)	6 (87)	7 (100)	8 (115)	10 (145)	12 (174)	14 (203)	16 (232)
7 barg – correction factor	0.76	0.84	0.92	1.00	1.07	1.19	1.31	1.41	1.51

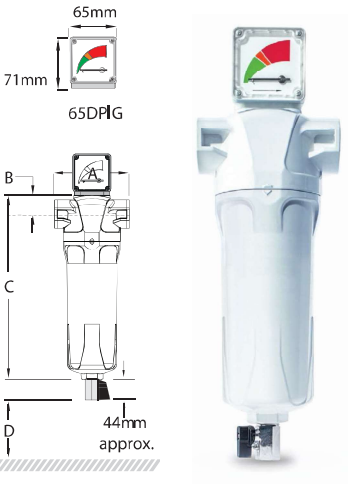


F.2.3 Medical Sterile Filters

Sterile Filters guarantees reliable and outstanding air purity that meets internationally certified medical performance levels. 100% integrity tested, Medical Sterile elements are guaranteed for a minimum of 100 sterilisations at 120°C (248°F), ensuring your compressed air is free from live bacteria and other submicron particles.

Filter model	Pipe size inches	Inlet flow rate Nm³/hr	Inlet flow rate SCFM	Dimensions mm A	B	C	D	Weight Kg
GS SF119	½	119	70	127	32	285	80	2.1
GS SF144	¾	144	85	127	32	285	80	2.1
GS SF297	1	297	175	127	32	371	80	2.4
GS SF680	1½	680	400	170	53	508	100	5.6
GS SF1189	2	1189	700	170	53	708	100	6.2
GS SF1529	3	1529	900	220	70	736	100	11.6

Pressure correction factors	For maximum flow rate, multiply model flow rate by the correction factor corresponding to the minimum operating pressure									
Operating pressure barg (psig)	4 (58)	5 (72)	6 (87)	7 (100)	8 (115)	10 (145)	12 (174)	14 (203)	16 (232)	20 (290)
7 barg – correction factor	0.76	0.84	0.92	1.00	1.07	1.19	1.31	1.41	1.51	1.6



F.2.4 Hopcalite Filter

Filter model	Pipe size inches	Inlet flow ratet Nm³/hr	Inlet flow ratet SCFM
GS HP25	½	26	6.7
GS HP65	¾	65	18.1
GS HP120	1	120	33.3
GS HP158	1½	158	43.9

*apply at 7 Barg

Pressure correction factors	For maximum flow rate, multiply model flow rate by the correction factor corresponding to the minimum operating pressure									
Operating pressure barg (psig)	4 (58)	5 (72)	6 (87)	7 (100)	8 (115)	10 (145)	12 (174)	14 (203)	16 (232)	20 (290)
7 barg – correction factor	0.76	0.84	0.92	1.00	1.07	1.19	1.31	1.41	1.51	1.6

B. Condensate Separators

The condensate separators are being used to remove liquids and particles from medical compressed air systems. At the internal of the separator there is controlled rotation of the air flow. In this case the liquids and particles stay at the housing wall and slow down to the bottom of the separator. The turbulent section in the lower part of the cyclone housing prevents condensate from being picked up and "carried over" into the airstream. To remove the condensate from the separator it is important to install an electronic or automatic drain. The condensate drains are available also in stainless steel version.

Water Separators

Filter model	Pipe size inches	Inlet flow rate Nm³/hr	Inlet flow rate SCFM	Dimensions mm A	B	C	D	Weight Kg
GS WS119	½	119	70	127	32	285	80	1.7
GS WS212	¾	212	125	127	32	285	80	1.7
GS WS297	1	297	175	127	32	285	80	1.7
GS WS680	1½	680	400	170	53	508	100	4.9
GS WS1189	2	1189	700	170	53	508	100	4.9
GS WS1444	2½	1444	850	220	70	420	100	8
GS WS2550	3	2550	1500	220	70	420	100	8

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TRAINING CERTIFICATE

Certificate number: 01.22

Mr. Ciobanu Sergiu has successfully completed a training course in medical gas systems on 01st of February 2022.

The training was held in various hospitals of Thessaloniki.

The training included the following features:

- **GENERAL FEATURES OF G. SAMARAS S.A.**
- **PRODUCT RANGE ON MEDICAL GAS SYSTEM**
- **NEW PRODUCTS OF G. SAMARAS S.A.**

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Responsible for training
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General Manager

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To: Whom it may concern

Date, 30/06/2022

Clarification letter

We G. Samaras S.A. who are official manufacturers of medical gas systems, having our premises at the Industrial Area of Thermi, Thessaloniki, Greece, do hereby clarify that we provide ten years of useful time for: Medical Oxygen Generators MO2CSS Series, GSAF and GSSF filters. The aforementioned period is valid only when full and proper maintenance schedule is followed along with compliance with the maintenance instructions and manuals of the equipment.
In case of use without following the manufacturer's recommendations, all these declared are considered null.

For G. Samaras S.A.

Menelaos Samaras
General Manager