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
P.O. BOX 60178 - 57001 THERMI
THESSALONIKI GREECE
TEL: [illegible]3388 - FAX: +302310464570
VAT NUMBER: EL094373861

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
PANORAMA-H
PANORAMA-L
PANDORA / 16
PANDORA-EX-R
ELISA / 16
KASSANDRA
ALEXANDRA
ALEXANDRA-R
ALEXANDRA-R-EX
KALLIPOLIS
KALLIPOLIS-L
THEODORO-R
ATHOS (Version I)
ATHOS (Version II)
ATHOS (Version IIIa)
ATHOS (Version IIIb)
ATHOS 16
AEGEAN
PG-EM
PG-EX
OPT CONTROL PANEL
NEFELI
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.
MEDICAL GAS SYSTEMS
P.O. BOX 60178 - 57001 THERMI
THESSALONIKI GREECE
TEL. +302310463388 - FAX +302310463527
VAT NUMBER: EL 09 1577061

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: **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.
MEDICAL GAS SYSTEMS
P.O. BOX 60178 - 57001 THERMI
THESSALONIKI GREECE
TEL.: +302310463388 - FAX: +302310464570
VAT NUMBER: EL 094733861

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.
MEDICAL GAS SYSTEMS
P.O. BOX 60178 - 57001 THERMI
THESSALONIKI GREECE
TEL: +302310463388 - FAX: +302310464570
VAT NUMBER: EL 094773861

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: **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.
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: **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
P.O. BOX 60178 - 57001 THERMI
THESSALONIKI GREECE
TEL.: +30 2310 463388 - FAX: +30 2310 464570
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
P.O. BOX 60178 - 57001 THERMI
THESSALONIKI GREECE
TEL. +30 2310 463388 - FAX +302310464570
VAT NUMBER: EL 094337061

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: **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 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 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

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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

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 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 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. ... FAX: 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

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CE 0653