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

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VAT NUMBER: EL094376161

Menelaos Samaras
Legal Representative

CE 0653

Digitally signed by Cârstocea Ioan-Răzvan
Date: 2023.02.20 10:52:26 EET
Reason: MoldSign Signature
Location: Moldova

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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

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

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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