



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: CYLINDER STATION FOR MEDICAL GASES
O₂, N₂O, N₂, CO₂, 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)

"In relation of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD), EC Certificate 304021047RE and the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

We, as the manufacturer declare under our sole responsibility:

for the above listed Directive Certificate the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and the listed device(s) and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service."

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, 04/01/2024

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VAT NUMBER: EL 694373861

Menelaos Samaras
Legal Representative

CE 0653



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Industrial area of Themi, 57001

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Product:

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

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%

Type:

Classification: Class IIb , (according to Rule 11)

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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, 04/01/2024

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