



# **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.*

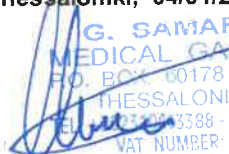
*The conformity in accordance to Council Directive 93/42/EEC is certified by Notified Body, National Evaluation Center of Quality & Technology In Health SA, EKAPTY, with identification number 0653.*

*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: +30 2310 46 33 88 - FAX: +30 2314 410113  
VAT NUMBER: EL 094373861

**Menelaos Samaras**  
Legal Representative

**CE 0653**