

EC Declaration of Conformity

Analytical Industries Inc. described hereafter:

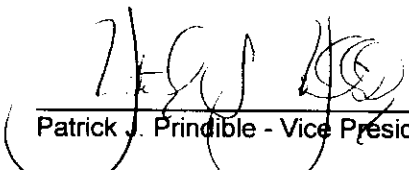
Oxygen Sensors / Analyzers

Have been classified as IIb and are in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC for Medical Devices, subject to the procedures set out in Annex II of the Council Directive and compliance assessment by the Notified Body **AMTEC Certification Services Ltd, Davy Avenue, Knowhill Milton Keynes, MK5 8NL, United Kingdom**

And is CE marked as: CE 0473

Manufacturer:

European Representative


Patrick J. Prindible - Vice President

Analytical Industries Inc
Metropolitan Place
Pomona, CA 91767


Date


John S Lamb - CEO

VIAMED
15 Station Road – Cross, West
Yorkshire – BD 20 7DT
Leighley / UK

Analytical Industries Inc.

2.1 Declaration of Conformity

Manufacturer: Analytical Industries Inc.
2855 Metropolitan Place
Pomona, California 91767 USA
Tel: 909-392-6900, Fax: 909-392-3665
e-mail: info@ali1.com

Authorized Representative: Insanex, S.L.
Josefa Valcarcel, 8.3
28027 Madrid
Spain

Product: AII 2000 Series Oxygen Analyzer & Monitor

Classification: IIb

Directives: Medical Device Directive
Council Directive 93/42/EEC of 14 June 1993
concerning medical devices (MDD 93/42/EEC)
Annex IX, section III Classification,
Clause 3.1 Rule 9, paragraph #2

Standards & Certificates: Annex II of MDD 93/42/EEC – Certificate 485CE
ISO 7767: 1997 / EN 12598:1999, based on
IEC 601-1:1977 Oxygen monitors for monitoring
patient breathing mixtures – Safety requirements
EN 55011 Class B - Radiation
IEC 60601-1-2: 2001 per IEC 61000-4-2, 3, 4, 5,
6, 8, 11 – Immunity Testing
ISO 9001:2000 – Certificate 485
ISO 13485:1996 – Certificate 485A

Notified Body: AMTAC Certification Services Limited
Dary Avenue, Knowhill
Milton Keynes MK5 8NL
United Kingdom

Date CE mark affixed:

Name: Patrick J. Prindible, Manager Quality Systems

We hereby declare the above product meets the provisions of the directives and standards specified. All supporting documents are retained on the premises of the manufacturer and the notified body.