

Teledyne Instruments, Inc. 16830 Chestrut Street City of Industry, Colifornia 91748-1020 Phone: 626,934.1500 Fax: 626,961,2538 www.teledyneol.com

EU Declaration of Conformity

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Product Name	Model Number
Oxygen Monitor	MX 300 and MX 300-I

	Manufacturer	
Company Name	Address	Management Representative
Teledyne Analytical Instruments a business unit of Teledyne Instruments, Inc	16830 Chestnut Street City of Industry, CA 91748, USA	Vasu Narasimhan Director of Regulatory Affairs & Quality Assurance

	Authorized Representative	
Company Name	Address	Contact Information
Viamed Limited	15 Station Road, Cross Hills Kieghley, W. Yorkshire BD20 7DT United Kingdom	Phone: +44 (0) 1535 634542 URL: <u>www.viamed.co.uk</u> E-mail: Jean@Viamed.co.uk

	Registration Information	
Notified Body / ID #	CE Certificate Number	Date CE Marking first applied
BSI, UK / 0086	CE 02000	09 July 1998

	Conformity Assessment	
Device Classification	Route of Compliance	Standards Applied
Class IIb (Annex IX, Rule 9)	Annex II, Section 3.2, of MDD 93/42/EEC, as amended by Directive 2007/47/EC	EN 60601-1, 3 rd Edition EN 60601-1-2 EN 60601-1-6 EN 14971:2007 EN ISO 21647

We, Teledyne Analytical Instruments, a business unit of Teledyne Instruments, Inc, declare that the above mentioned products meet the provision of the Council Directive 93/42/EEC, as amended by Council Directive 2007/47/EC, for Medical Devices. All supporting documents are retained at the premises of the manufacturer.

Signature:

Signature:

Name:

Vasu Narasimhan

Name:

Stephen Broy

Title:

Director of RA & QA

Title:

Director of Engineering

Date:

June 1, 2012

Date:

June 1, 2012