

Teledyne Instruments, Inc. 16830 Chestnut Street City of Industry, California 91748-1020 Phone: 626.934.1500 Fax: 626.961.2538 www.teledyne-ai.com

EU Declaration of Conformity

Pi	roduct Identification	
Product Name	Model Number	
Oxygen Monitors	MX 300 and MX 300-I	

Manufacturer 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 Operations [Manufacturing, SCM, QA, RA]		

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 RoHS Directive 2011/65/EU, along with Annex IV, item 1(b) exception	EN 60601-1, 3 rd Edition EN 60601-1-2 EN 60601-1-6 EN 14971:2012 EN ISO 80601-2-55:2011	

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 and the Council Directive on RoHS, 2011/65/EU. All supporting documents are retained at the premises of the manufacturer.

Signature:

Vasu Narasimhan

Signature:

Name:

Stephen Broy

Name: Title:

Director of Operations

Title:

Director of Engineering

Date:

May 2, 2014

Date:

May 2, 2014