

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 02000**

Issued To:

Teledyne Analytical Instruments
A business unit of Teledyne
Instruments, Inc
16830 Chestnut Street
City of Industry
California
91748
USA

In respect of:

The design and manufacture of oxygen monitors and sensors

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **1998-07-09**Date: **2018-05-11**Expiry Date: **2023-07-08**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.



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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	Service(s) supplied
Viamed Ltd 15 Station Road Cross Hills Keighley West Yorkshire BD20 7DT United Kingdom	EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

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Certificate History

Date	Reference Number	Action
09 July 1998		First Issue
03 March 2000		Addition of Ensembles de Precision, S.A de C.V as manufacturing subcontractor of oxygen sensors and printed wiring assemblies
11 June 2002		Change of company name
29 April 2004		Certificate renewal. New certificate format
07 July 2008	7230667	Certificate renewal
26 April 2012	7817544	Name change from Teledyne Electronic Technologies to Teledyne Analytical Instruments, A business unit of Teledyne Instruments, Inc.
18 June 2013	7945519	Certificate renewal. Addition of Viamed Ltd as EU representative and removal of Ensembles de Precision, S.A de C.V as a significant subcontractor
Current	8896461	Certificate renewal.

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