

EC Certificate - Full Quality Assurance System

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

No.

CE 02000

Issued To:

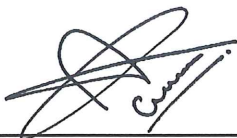
**Teledyne Analytical Instruments
A business unit of Teledyne
Instruments, Inc
16830 Chestnut Street
City of Industry
California
91748
USA**

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 2797):



Albert Roossien, Regulatory Lead

First Issued: **1998-07-09**

Date: **2019-03-25**

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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Certificate History

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Certificate History

| Date | Reference Number | Action |
|---------------|------------------|---|
| 09 July 1998 | | First Issue. |
| 03 March 2000 | | Addition of Ensamblés 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 Ensamblés de Precision, S.A de C.V as a significant subcontractor. |

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| Date | Reference Number | Action |
|-------------|------------------|-----------------------|
| 11 May 2018 | 8896461 | Certificate renewal. |
| Current | 7781684 | Traceable to NB 0086. |

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