

# 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 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):



Gary E Slack, Senior Vice President Medical Devices

**First Issued: 1998-07-09****Date: 2021-02-03****Expiry Date: 2023-07-08**

...making excellence a habit.™

Page 1 of 2

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.

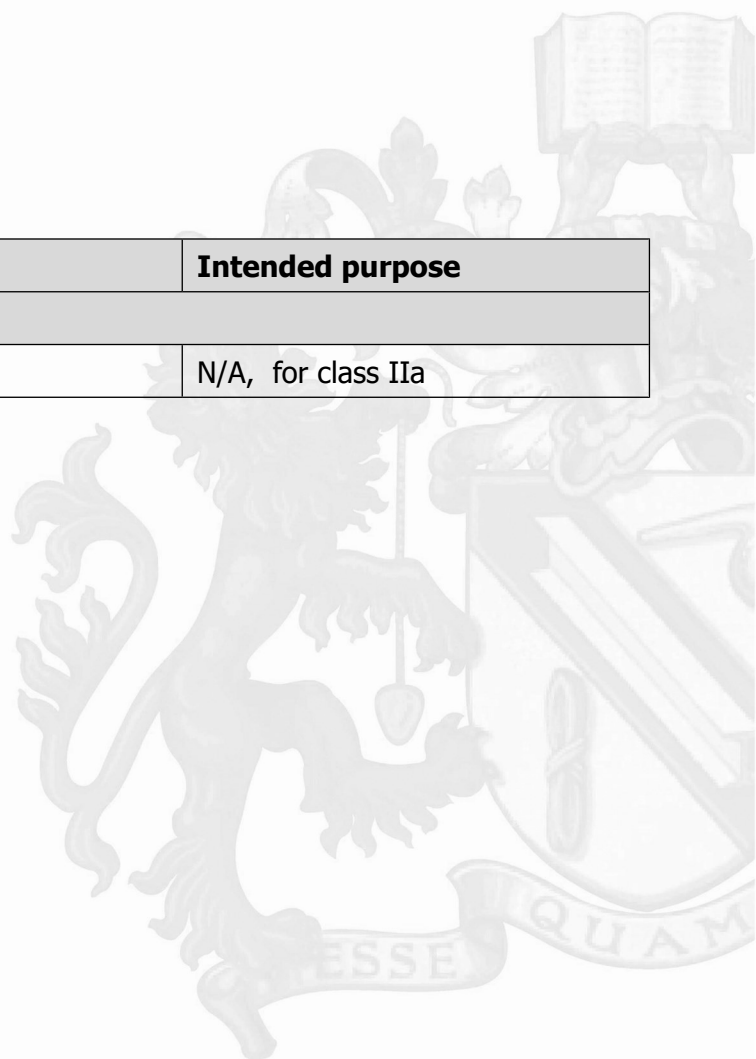
# EC Certificate - Full Quality Assurance System

## Supplementary Information to CE 02000

Issued To:

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

NBOG code(s)	Device description	Intended purpose
<b>Class IIa</b>		
MD 1102	Oxygen Sensors	N/A, for class IIa

First Issued: **1998-07-09**Date: **2021-02-03**Expiry Date: **2023-07-08**

...making excellence a habit.™

Page 2 of 2

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.

# EC Certificate - Full Quality Assurance System

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

## List of Significant Subcontractors

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

Certificate No: **CE 02000**  
 Date: **2021-02-03**  
 Issued To: **Teledyne Analytical Instruments**  
**A business unit of Teledyne**  
**Instruments, Inc**  
**16830 Chestnut Street**  
**City of Industry**  
**California**  
**91748**  
**USA**

### Subcontractor:

### Service(s) supplied

Viamed GmbH-UG  
 An der Trave 15  
 23923 Selmsdorf  
 Germany

**EU Representative**

...making excellence a habit.™

# EC Certificate - Full Quality Assurance System

## Certificate History

Certificate No: **CE 02000**  
 Date: **2021-02-03**  
 Issued To: **Teledyne Analytical Instruments**  
**A business unit of Teledyne**  
**Instruments, Inc**  
**16830 Chestnut Street**  
**City of Industry**  
**California**  
**91748**  
**USA**

## 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.

...making excellence a habit.™

Page 1 of 2

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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Certificate - Full Quality Assurance System

## Certificate History

Certificate No: **CE 02000**  
Date: **2021-02-03**  
Issued To: **Teledyne Analytical Instruments  
A business unit of Teledyne  
Instruments, Inc  
16830 Chestnut Street  
City of Industry  
California  
91748  
USA**

Date	Reference Number	Action
11 May 2018	8896461	Certificate renewal.
25 March 2019	7781684	Traceable to NB 0086.
Current	3372813	Removed Oxygen Monitors/analyzer from the scope. Added device table. EU Representative change from "Viamed Ltd, 15 Station Road, Cross Hills, Keyghley, West Yorkshire BD20 7DT, United Kingdom" to "Viamed GmbH-UG, An der Trave 15, 23923 Selmsdorf, Germany".

...making excellence a habit.™

Page 2 of 2

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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.