

# 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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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:

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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.

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

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