

EC Certificate - Full Quality Assurance System

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

No.**CE 01389****Issued To:**

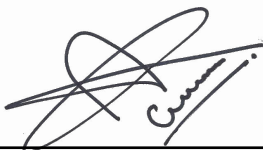
**Viamed Limited
15 Station Road
Cross Hills
Keighley
West Yorkshire
BD20 7DT
United Kingdom**

In respect of:

The design and manufacture of microstim nerve stimulators, oxygen hoods, gas respiratory adapters, gas respiratory valves and phototherapy light shields

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: **1996-08-23**

Date: **2019-03-07**

Expiry Date: **2021-08-22**

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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:

Certificate No: **CE 01389**
 Date:
 Issued To: **Viamed Limited
 15 Station Road
 Cross Hills
 Keighley
 West Yorkshire
 BD20 7DT
 United Kingdom**

Subcontractor:

Service(s) supplied

Instrumentation Industries, Inc.
 2990 Industrial Boulevard
 Bethel Park
 Pennsylvania
 15102
 USA

Manufacture

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Certificate History

Certificate No: **CE 01389**
 Date:
 Issued To: **Viamed Limited
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Date	Reference Number	Action
27 July 1998		Addition of additional oxygen monitors Addition of Pulse Oximeter Probes and associated Leads.
26 July 1999		Addition of design and development to scope.
10 September 1999		Addition of Temperature Probes.
09 April 2004		Addition of Breathing Monitors, Headboxes and UV Light Shields. Removal of associated Leads. Certificate Renewal.
22 March 2005		Addition of Oxygen tents within the scope.
18 July 2005		Addition of 'Gas Respiratory Adapters' and 'Gas Respiratory Valves' within the scope.
19 June 2006		5 year certificate renewal.
16 August 2011	7521662	Certificate renewal. Scope rationalisation.
06 September 2016	8486089	Certificate renewal. Deleted "pulse oximeter probes," from scope at manufacturer's request.
Current	8922802	Traceable to NB 0086.

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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

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