

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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **23 August 1996**

Date: **06 September 2016**

Expiry Date: **22 August 2021**

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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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Cross Hills
Keighley
West Yorkshire
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Subcontractor:

Service(s) supplied

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

Manufacture

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Certificate History

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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.

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