By Royal Charter

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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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
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Subcontractor:	**Service(s) supplied**
Instrumentation Industries, Inc. 2990 Industrial Boulevard Bethel Park Pennsylvania 15102 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01389**

Date:

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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.