By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 97289**

Issued To: **Viamed Ltd**
15/17 Station Road
Cross Hills
Keighley
BD20 7DT
United Kingdom

In respect of:

Design and manufacture of Electrochemical 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 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **18 July 2005** Date: **13 May 2015** Expiry Date: **17 July 2020**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 97289**

Date: **13 May 2015**

Issued To: **Viamed Ltd**
15/17 Station Road
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Date	Reference Number	Action
18 July 2005	4705809	First Issue
15 July 2010	7521711	Certificate renewal and change of certificate format to Own Brand Labelling template
13 May 2015	7650664	Certificate renewal

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 97289

Issued To:

Viamed Ltd
15/17 Station Road
Cross Hills
Keighley
BD20 7DT
United Kingdom

This certificate is issued under the OWN BRAND LABELLING process

OEM Information

Name	EnviteC - Wismar GmbH Umweltschutz & Medizintechnik
Address	Alter Holzhafen 18 23966 Wismar GERMANY
Notified Body	TÜV SÜD
Certificate No.	G110 07 21697 013
Scope	Oxygen Saturation Sensors and Monitors, Sensors and Control Units for Monitoring of Respiratory Parameters and Gas Exchange, Non-invasive Blood Pressure Euipment, Temperature Sensors, Fetal Monitor Transducers
Issue / Expiry Date	2 Sept 2010 / 1 Sept 2015
Route to Conformity	OBL Annex II, Section 3.2

The validity of this OBL certificate is conditional on the continuing validity of the Original Equipment Manufacturer's certification under the Medical Device Directive and the maintenance of the relevant controls exercised by the Own Brand Labeller.

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