

# EC Certificate - Full Quality Assurance System

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

**No. CE 540537**

Issued To:

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

In respect of:

**The Own Brand Labelling of pulse oximeter monitors and sensors, flow sensors, breathing gas exchange monitors and sensors, and temperature probes**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding (4). The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II (4) certificate is required.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):



Gary Fenton, Global Assurance Director

First Issued: **20/08/2008**

Date:

Expiry Date: **19/08/2013**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A member of BSI Group of Companies.

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## Supplementary Information to CE 540537

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

The design and manufacture of pulse oximeter monitors and sensors, certified by MEDCERT Certificate Number 4026GB410080312 (Directive 93/42 EEC Annex II Section 3)

The above certificate is issued to:

**Bluepoint Medical GmbH & Co. KG**  
**An der Trave 15**  
**23923 Selmsdorf**  
**Germany**



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Date:

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## Certificate History

Certificate No: **CE 540537**  
Date: **03 Jul 2013**  
Issued To: **Viamed Ltd**  
**15/17 Station Road**  
**Cross Hills**  
**Keighley**  
**BD20 7DT**  
**United Kingdom**

Date	Reference Number	Action
20 August 2008	7243354	First Issue

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