

## DECLARATION OF CONFORMITY

### Medical Device(s)

Manufacturer:

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

Device(s): 0012400

Class: IIb

Part number: 0012400

Description: Multi parameter monitor for SpO2, non-invasive hemoglobin and methmoglobin

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/Eec (Medical Devices Directive) of the 14<sup>th</sup> June 1993 and considering the amendments by directive 2007/47/EC - as transposed into National Law in the countries where the product is intended to be marketed.

This declaration is supported by:

Technical documentation required by MDD ( Annex II )

EC Quality Assurance Certificate No. CE 540537, first issued by the British Standards Institute (CE0086) on the 20th Aug 2008.

Certificate of Registration No. MD 78787 to ISO 13485:2003 of original registration date 27th January 2004, issued by the British Standards Institute (CE0086)

Certificate of Registration No. FS 28344 to ISO 9001:2008 of original registration date 15th June 1994, issued by the British Standards Institute (CE0086)

For and on behalf of Viamed Ltd. \_\_\_\_\_

Signature:

Name: **Derek Lamb - Managing Director**

Date: **Unsigned**