



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 14th 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**