VIAMED

Declaration of Conformity.

Class IIb Medical Device(s).

Manufacturer:	Viamed Limited. 15 Station Road, Cross Hills, Keighley, West Yorkshire, BD20 7DT. United Kingdom.
Device(s):	0014770 Soft Sensor – Paediatric Nonin compatible
Description of Device(s):	For use with pulse oximeters in oerder to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues

It is hereby declared that the medical device(s) specified above is (are) in compliance with EC Council Directive 93/42/EEC (Medical Device Directive) of 14th June 1993 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 the MDD (Annex II) retained by: Viamed Limited.
- EC Quality Assurance Certificate No. CE 01389, first issued by the British Standards Institute (CE0086) on the 23rd August 1996.
- Certificate of Registration No. FS28344 to BS EN ISO 9001:2000 of original registration date 15th June 1994, issued by the British Standards Institute (CE0086).
- Certificate of Registration No. MD78787 to ISO 13485:2003 of original registration date 27th January 2004, issued by the British Standards Institute (CE0086).

Signed: ……..…… **Date**: …14/July/2009

Position: Managing Director.