



Declaration of Conformity Class IIb Medical Devices

Manufacturer's name: Viamed Limited

Manufacturer's address: 15 Station Road, Cross Hills
Keighley, West Yorkshire BD20 7DT
United Kingdom

Devices:

SpO₂ probes - pulse oximetry sensors:

For use with pulse oximeters in order to determine saturation of haemoglobin non-invasively from light signals of two wavelengths transmitted through tissue or reflected from tissues.

SpO₂ is the percent haemoglobin saturation with oxygen, either fractional or functional, as measured by a pulse oximeter and displayed as a percentage.

SpO₂ probe extension cables:

For connecting SpO₂ probes to pulse oximeters or for extending the cable of the SpO₂ probe.

It is hereby declared that the medical devices specified above conform with the essential requirements listed in Annex I of the EC Council Directive 93/42/EEC of 14 June 1993.

This declaration is supported by:

Technical documentation required by the MDD (Annex VII) retained by: Viamed Limited

EC Quality Assurance Certificate No. CE 01389
(Annex V)

Issued by: British Standards Institute

Date: 8 February 1999

Notified body number CE 0086

Signed:

Date: 23 April 1999

Position: Managing Director