VIAMED

Declaration of Conformity
Class IIa Medical Devices

Manufacturer's name: Viamed Limited

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

Devices:

SpO_2 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.

SpO_2 is the percent haemoglobin saturation with oxygen, either fractional or functional, as measured by a pulse oximeter and displayed as a percentage.

SpO_2 probe extension cables:
For connecting SpO_2 probes to pulse oximeters or for extending the cable of the SpO_2 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: 2 June 1998

Notified body number CE 0086

Signed: Date: 2 June 1998 Position: Managing Director

Document number: CE-DC-007

BS 28345 BS 28344

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