

Declaration of Conformity

Manufacturer:

Dolphin Medical Inc
12525 Chadron Ave.
Hawthorne CA 90250
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European Representative:

Viamed Limited
15 Station Road
Cross Hills, Keighley
West Yorkshire BD20 7DT
United Kingdom
Tel: 44 1535 634 542
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Product:

Dolphin ONE Pulse Oximeters with accessories.

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:**Performance Standards:**

EN 475 1995 Medical Devices. Electronically Generated Alarm Signals
EN865: 1997 Pulse Oximeter – Particular requirements
EN980: 1997 Graphical symbols for use in the labeling of medical devices
EN1041: 1998 Information supplied by the manufacturer with medical devices
EN60601-1 2001 Medical Electrical Equipment-General Requirements for Safety
EN60601-1-2 1993 Electromagnetic Compatibility
IEC 601-1-4 1996 Programable Medical systems
ISO 9919 1992 Pulse Oximeters for medical use – Particular Requirements
CSA 22.2 #601 Medical Electrical Equipment-General Requirements for Safety
UL 2601-1 Medical Electrical Equipment-General Requirements for Safety
UL 2601 1997 Medical Electrical Equipment
IEC60417: 1973 Graphical symbols for use on equipment
IEC60878: 1988 Graphical symbols for electrical equipment in medical practice
IEC60068-2-6 1995 Sinusoidal Vibration
IEC60068-2-27 Environmental Shock
IEC60068-2-64 Broadband Vibration
ASTM E1112-00 Standard Specification for Electrical Thermometer for Intermittent Use
EN 10993-1 (1995) Biological evaluation of medical devices-part 1 Selection of test
EN 10993-5 (1995) Biological evaluation of medical devices-part 5 Test for cytotoxicity
EN 10993-10 (1995) Biological evaluation of medical devices-part 10 Tests used for irritation and sensitization

Quality System Standards

ISO 9001: 1994 Quality Systems

EN 46001:1996 Application of 9001 to the Manufacture of Medical Devices

MDD: 93/42/EEC Medical Device Directive

ISO 13485 1996 Particular requirements for the application of EN ISO 9001

Notified Body: G-MED
33, avenue du Général Leclerc
92260 Fontenay-aux-Roses
France

EC Certificates: No 1058/B2P3/1 by G-Med

Start of CE Marking: Model 2150 Date 3/17/03
Model 2100 Date 12/01/02
Model 3000 Date 12/01/02

Place of Issue: Dolphin Medical, Hawthorne, CA

Accessories covered	Model 130	Nurse Call Cable
	Model 131	Nurse Call Cable
	Model 210	Adult Reusable Sensor
	Model 220	Adult Reusable Sensor
	Model 510	Adult/Pediatric Disposable Sensor
	Model 520	Adult/Pediatric Disposable Sensor
	Model 550	Infant/Neonatal Disposable Sensor
	Model 560	Infant/Neonatal Disposable Sensor
	Model 320	Adult/Pediatric Y Sensor with Earclip
	Model 360	Neonatal Y Sensor
	Model 120	3' Extension Cable
	Model 110	5' Extension Cable
	Model 911	Replacement Bandages Adult/Ped
	Model 912	Replacement Bandages, Neo/Infant
	Model 913	Replacement Bandages, Y Sensor
	Model 921	Earclip

Signature/Date

Bill Cuman 2/12/04

Bill Cuman / Regulatory Specialist

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