

Declaration of Conformity

Declaration Number: FORM 0114 REV.: E

Product: ALL DOLPHIN 2000™ Oximetry Sensors
Classification: Class IIb, under Rule 10 of Annex IX
Conformity Assessment Route: Annex II

Manufacturer: Opto Sensors (M) Sdn. Bhd.
No. 6, Jalan Angkasa Mas 1,
Tebrau Industrial Estate II
81100 Johore Bahru, Malaysia

European Representative: Rapiscan Security Products Ltd
Unit B1, The Fleming Centre
Fleming Way
Crawley, West Sussex
England RH10 2NN

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:

EN 980 Graphical symbols for use in the labeling of medical devices
EN 10993-1 (1995) Biological evaluation of medical devices - part 1: Selection of Tests
EN 10993-5 (1995) Biological evaluation of medical devices - part 5: Test for cytotoxicity: in vitro method
EN 10993-10 (1995) Biological evaluation of medical devices - part 10: Tests used for irritation and sensitization
EN 29001 (1994) Quality systems - Model for quality assurance in design, development production, installation and servicing
EN 46001 (1996) Application of EN 29001 to the manufacture of medical devices
EN 60601-1 (1990) Medical electrical equipment - part 1: General requirements for safety
EN 60601-1-1 (1993) Medical electrical equipment - part 1: General requirements for safety - 1. Collateral standard: Safety requirements for medical electrical systems
EN 60601-1-2 (1993) Medical electrical equipment - part 1: General requirements for safety - 2. Collateral standard: Electromagnetic compatibility - requirements and tests
IEC 513 Electromedical equipment basic safety philosophy
EN 1041 Information to be supplied by the manufacturer
EN 1441 (1997) Medical devices - Risk analysis
EN 45014 (1998) General criteria for supplier's declaration of conformity
EN 865 (1997) Pulse Oximeters - Particular Requirements
EN 724 (1995) application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical device
EN 50103 (1996) Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the active (including active implantable) medical device medical device industry
ISO 13485 (1996) Quality Systems - Medical Devices - Particular Requirements for the application of ISO 9001

Notified Body: TUV Product Service GmbH
Reidler 65,
80335, Munich,
Germany.
Notified Body #0123

EC Certificate Number: G1 99 12 37176 003
Start of CE Marking: 16 December 1999
Place, Date of Issue: Johore Bahru, Malaysia 16 December 1999

Signature: 
K. T. Siow, Quality Assurance Manager