Declaration of Conformity

Declaration Number:	FORM 0115 REV.: E
Product:	**ALL ARISTO™ Comp$_2$/Sat Series 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
EN10993-5 (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 29001and EN 46001 and of EN 29002 and EN 46002 for non-active medical device
EN 50103 (1996) Guidance on the application of EN 29001and 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

RECEIVED
30 MAR 2001

Signature: _____

K. T. Siow, Quality Assurance Manager