MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURE

This is a declaration made in accordance with the requirements of Clause 1.8 of Schedule 3 of the Australian

Therapeutic Goods (Medical Devices) Regulations 2002 relating to the stated devices

Reference: *Not Applicable*

Manufacturer's Name: *Flotec, Inc.*
Business Address: *7625 West New York Street, Indianapolis, IN 46214, USA*

Medical Device(s): *Regulator, Pressure, Gas Cylinder(CAN); Conserver, Oxygen(NFB); Flowmeter, Calibration, Gas(BXY)*

Classification: *Regulator, Pressure, Gas Cylinder(IIb); Conserver, Oxygen(IIb); Flowmeter, Calibration, Gas(IIb)*

GMDN Code and Term: *35300, Regulator, Gas, High-Pressure*

Scope of Application: *Flotec units with serial number 514,000 and later, Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.*

Full Quality Management System Certificate:

ISO 9001:2000; EN ISO 9001:2000; BS EN ISO 9001:2000; ANSI/ASQ Q9001:2000 Certificate number A12714, Issue date December 16, 2003, Revision date: June 9, 2004, Renewal date: December 16, 2006, Issued by Underwriters Laboratories, Inc. to Flotec, Inc.

ISO 13485:1996; CAN/CSA-ISO – 13485-98; CEN EN ISO – 13485:2000; BS EN ISO 13485:2001 Certificate number A12714, Issue date December 16, 2003, Revision date: June 9, 2004, Renewal date: December 15, 2006, Issued by Underwriters Laboratories, Inc. to Flotec, Inc.

ISO 13485:1996; CAN/CSA-ISO – 13485-98; CEN EN ISO – 13485:2000; BS EN ISO 13485:2001 Certificate number A12714, Issue date December 16 , 2003, Revision date: June 9, 2004, Renewal date: December 15, 2006, Issued by Underwriters Laboratories, Inc. to Flotec, Inc. assessed in accordance with Canadian Medical Device Conformity Assessment System (CMDCAS) Q90R0:2000-04-19 requirements.

EC Certificate – Full Quality Assurance System Approval Certificate (Annex II, section 3 of the Directive 93/42/EEC on Medical Devices, Original certificate 15 December 2004, Current certificate 15 December 2004, Certificate expiry 15 December 2007, Issued by Underwriters Laboratories, Inc. to Flotec, Inc., EC code number 0843

Design Examination Certificate:

Not applicable (not class III device). Applicable requirements included in scope of above certificates.

Standards Applied:

ISO 13485

Authorised Signatory:

Brian R. Davidson

Brian R. Davidson, President
Flotec, Inc.

May 13, 2005
date