mediplas
Respiratory Products Sdn Bhd

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

This is a declaration made in accordance with the requirements of Clause 6.6 of Schedule 3 of the Australian ***Therapeutic Goods (Medical Devices) Regulations 2002*** relating to the stated devices.

Manufacturer's Name: **Mediplas Respiratory Products Sdn Bhd**

Business Address: No. 7 Jalan KIP 3; Taman Perindustrian KIP; 52200 Kuala Lumpur, Malaysia

Medical Device(s): **Circuit Family (sterile and non sterile)**
(Breathing circuits: Anaesthetic and Respiratory Circuits, Mid-O-Gas Circuits, Catheter mounts. Oxygen Tubing, Nasal Cannulas, Tubing Extension Sets, Suction Circuit Tubing, CO_2 sampling lines)

Classification: Class IIa according to Schedule 2, Part 2.2c

GMDN Code and Term:

37021- Breathing circuit, anaesthesia, reusable
37705 - Breathing circuit, ventilator, reusable
35201 - Cannula, nasal, oxygen
12170 - Tubing extension set, intravenous administration
37704 - Breathing circuit, anaesthesia, single use
37706 - Breathing circuit, ventilator, single use
12875 - Tubing, oxygen delivery
16779 - Suction system tubing

Scope of Application: This certificate covers all circuit family devices as specified on this certificate. For each kind of medical device to which the Declaration of Conformity (not requiring assessment by Secretary) procedures have been applied, the production quality assurance procedures have also been applied. Each kind of medical device complies with the applicable provisions of the essential principles, the classification rules before being supplied.

Production Quality Management System Certificate:

Notified Body: SGS United Kingdom Ltd
Weston-super-mare, BS22 6WA, United Kingdom

Identification number CE 0120

(EC) Certificate: No. MY12/00920
Product categories – Breathing Circuits (Including sterile: tubing extension sets, suction circuit tubing, oxygen tubing), Fittings and Adaptors and Sterile Laryngoscopes.

Issue Date: 30-06-2012

Expiry Date: 30-06-2015

Standards Applied:

MDD 93/42/EEC: 1993	European Council Directive/MDD 93/42/EEC concerning medical devices
ISO 13485:2003	Medical devices – Quality management systems – Requirements for regulatory purpose
ISO 5356-1:2004	Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets
ISO 5367:2000	Breathing tubes intended for use with anaesthetic apparatus and ventilators
ISO 5362:2006	Anaesthetic reservoir bags
AS/NZS 2496:1995	Breathing attachments for anaesthetic purposes for human use

Signature: *Wendy Bird (Director)*

29.8.12
Date