

## 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):** **Suction Filter Family**  
(Suction Filter, Disposable Twin-o-vac jar)

**Classification:** Class I according to Schedule 2, Part 2.1

**GMDN Code and Term:** 11710 – Filter, <specify>  
34858 – Suction system canister, single-use

**Scope of Application:** All batches, lots or serial numbers to which the Declaration of Conformity (not requiring assessment by Secretary) procedures has been applied. The above mentioned products comply with the applicable provisions of the essential principles and the classification rules before being supplied.

**Quality Management System Certificate:**

Notified Body: SGS United Kingdom Ltd  
Cheshire, CH65 3EN, United Kingdom

Identification number



(EC) Certificate: No. MY12/00919  
Scope – Production & distribution of anaesthetic and respiratory circuits (including sterile: tubing extension sets, suction circuit tubing, oxygen tubing), non-sterile conical connectors, laryngoscopes (sterile and non-sterile), non-sterile suction filters and armboards.

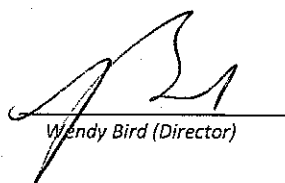
Issue Date: 30-06-2012

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

Signature:

  
Wendy Bird (Director)

29.8.12  
Date