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):	**Laryngoscope Family - sterile** (Duoscope, Onescope)
Classification:	Class Is according to Schedule 2, Part 4.1
GMDN Code and Term:	15076 – Laryngoscope, intubation

Scope of Application: This certificate covers all sterile Laryngoscope 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 7376:2009	Anaesthetic and respiratory equipment – Laryngoscopes for tracheal intubation

Signature: _____ *Wendy Bird (Director)*

29.8.12
Date