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 – non sterile** (Duoscope, Onescope)
Classification:	Class I according to Schedule 2, Part 4.1
GMDN Code and Term:	12293 – Laryngoscope <specify>
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	CE
(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
ISO 7376:2009	Anaesthetic and respiratory equipment – Laryngoscopes for tracheal intubation

Signature: _____ *Wendy Bird (Director)*

24.8.12
Date