

SINGAPORE - DECLARATION OF CONFORMITY

Name and Address of Product Owner:

Mediplus Respiratory Products SDN BHD

NO 7 Jalan KIP 3; Taman Perindustrian KIP; 52200 Kuala Lumpur, Malaysia

We hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the Health Products (Medical Devices) Regulations.

Medical Device(s): CIRCUIT FAMILY

Anaesthetic and respiratory circuits; Mid-O-Gas Circuits; Catheter mounts; Oxygen Tubing; Nasal Cannulas; Tubing Extension Set; Suction Circuit Tubing

Manufacturing Site: Mediplus Respiratory Products SDN BHD

NO 7 Jalan KIP 3; Taman Perindustrian KIP; 52200 Kuala Lumpur, Malaysia

Risk Classification: Class B according to the classification rule 2

Quality Management System Certificate:

Certification Body: SGS United Kingdom Ltd, 202B Worle Parkway, Weston-super-Mare, BS22 6WA, UK

ISO 13485 Certificate: No. MY12/00919; Issue Date 30-06-2012; Expiry Date 30-06-2015

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

EC Certificate: No. MY12/00920; Issue Date 30-06-2012; Expiry Date 30-06-2015

Product Categories – Breathing Circuits (including Sterile: Tubing Extension Sets, Suction Circuit Tubing, Oxygen Tubing), Fittings and Adaptors and Sterile Laryngoscopes

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

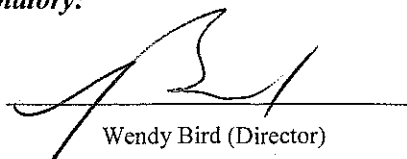
ISO 5356-1: 2004 Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets

ISO 5367:2000 Breathing tubes intended for use with anaesthetic apparatus and ventilators

ISO 5362:2006 Anaesthetic reservoir bags

This declaration of conformity is valid from 1st August 2012

Authorised Signatory:


Wendy Bird (Director)

29. 8. 12
Date