DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVES 93/42/EEC OF 14 JUNE 1993 AND 2007/47/EEC AT 21 MARCH 2010 CONCERNING MEDICAL DEVICES

MANUFACTURER:	***MEDIPLAS RESPIRATORY PRODUCTS SDN BHD*** *No 7 Jalan KIP 3* *Taman Perindustrian KIP* *52200 Kuala Lumpur, Malaysia* *Phone: +60362727625*
MEDICAL DEVICE:	***ADAPTORS*** *SEE ATTACHED LIST*
CLASSIFICATION - *ANNEX IX:*	*CLASS IIA, RULE 2 ACCORDING TO ANNEX IX OF THE MDD*
CONFORMITY ASSESSMENT ROUTE:	*ANNEX APPLIED – ANNEX V*

WE, THE MANUFACTURER UNDER OUR SOLE RESPONSIBILITY, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:	*SEE ATTACHED LIST OF STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.*
NOTIFIED BODY:	SGS UNITED KINGDOM LTD WESTON-SUPER-MARE, BS22 6WA, UNITED KINGDOM
IDENTIFICATION NUMBER	CE 0120
(EC) CERTIFICATE(S):	*NO. MY12/00920* *PRODUCT CATEGORIES – BREATHING CIRCUITS (INCLUDING STERILE: TUBING EXTENSION SETS, SUCTION CIRCUIT TUBING, OXYGEN TUBING), FITTINGS AND ADAPTORS AND STERILE LARYNGOSCOPES*
EUROPEAN REPRESENTATIVE: EC REP	***MEDIMARK® EUROPE SARL*** *EUROPEAN HEADQUARTER OPERATIONS* *PHONE: +33 (0)4 76 86 43 22* *POSTAL ADDRESS: 11, RUE EMILE ZOLA - BP 2332, 38033 GRENOBLE CEDEX 2 –FRANCE*
START OF CE-MARKING:	*02-05-2012*
PLACE, DATE OF DECLARATION:	UNITED KINGDOM, 02-05-2012
SIGNATURE:	WENDY BIRD (DIRECTOR) — DATE: 31.5.12

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Products	
Connectors: Straight, swivel, tube, elbow, CPAP, straight scavenge	
Adaptors: Hose, pressure port, straight, luer	
Pieces: Y, T, mouth, Mid-O-Gas hand	
Valves: one way, expiratory, bleed, MCHP	
Mask Elbows	
O2 fittings	
UMDN	11726 Fittings / Adaptors 11729 Fittings / Adaptors, Luer
GMDN	34838 Connector, Breathing circuit

List of Standards for documented evidence.

NUMBER	ISSUE	TITLE
MDD 93/42/EEC	14 Jun 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	15 May 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
AS/NZS 2496	1995	Breathing attachments for anaesthetic purposes for human use