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:	***ARM BOARDS*** SEE ATTACHED LIST
CLASSIFICATION - *ANNEX IX*:	*CLASS I. RULE 1 ACCORDING TO ANNEX IX OF THE MDD*
CONFORMITY ASSESSMENT ROUTE:	*ANNEX APPLIED – ANNEX VII*

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.
ISO 13485 CERTIFICATE:	*NO. MY12/00919*
CE	***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 ***SGS UNITED KINGDOM LTD*** CHESHIRE, CH65 3EN, UNITED KINGDOM ***DATE OF ISSUE:*** *02-05-2012*
PLACE OF DECLARATION:	MALAYSIA
SIGNATURE:	WENDY BIRD (DIRECTOR) — DATE: 31.5.12

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Products	UMDN	GMDN
Arm Boards	-	10184 – Board, arm

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