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:	***LARYNGOSCOPES - STERILE*** *SEE ATTACHED LIST*
CLASSIFICATION - *ANNEX IX*:	*CLASS IS: RULE 12 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) — 31.5.12 DATE

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Products	UMDN	GMDN
Duoscope	12293 - Laryngoscope	12293 - Laryngoscope <specify>
Onescope		

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 7376	2009	ISO 7376 - Anaesthetic and respiratory equipment – Laryngoscopes for tracheal intubation

BATTERY

3.0V Lithium-Manganese Button Cell, model CR2032

SGS Test Report No EC409995100 concludes that the submitted battery sample does not exceed the limit mentioned in the articles 4(1) and 21(3) of Directive 2006/66/EC.