

**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 (Non STERILE)**  
SEE ATTACHED LIST

**CLASSIFICATION - ANNEX IX:**

CLASS I: RULE 12 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



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)

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	15 Dec 2003	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.