

**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:**

**SUCTION FILTERS**

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



**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
Suction Filter	11710 - Filter	11710 – Filter <specify>
Disposable Twin-O-Vac jar	-	34858 – Suction system canister, single-use

**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