

**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:

CIRCUITS (STERILE AND NON-STERILE)

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)

31.5.12
DATE

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CONCERNING MEDICAL DEVICES

Products	
Breathing Circuits: Anaesthetic and respiratory circuits Mid-O-Gas Circuits Catheter mounts	UMDNS Code and Term: 15562- Breathing circuits GMDN Code and Term: 37021- Breathing circuit, anaesthesia, reusable 37704 - Breathing circuit, anaesthesia, single use 37705 - Breathing circuit, ventilator, reusable 37706 - Breathing circuit, ventilator, single use
Oxygen Tubing	GMDN Code and Term: 12875 – Tubing, oxygen delivery
Nasal Cannulas	GMDN Code and Term: 35201 – Cannula, nasal, oxygen
Tubing Extension Set	GMDN Code and Term: 12170 – Tubing extension set, intravenous administration
Suction Circuit Tubing	GMDN Code and Term: 16779 – Suction system tubing
CO ₂ sampling lines	

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
ISO 5362	2006	Anaesthetic reservoir bags