

**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993
CONCERNING MEDICAL DEVICES**

MANUFACTURER:



MEDIPLAS PTY LTD
12 REDLAND DRIVE
MITCHAM, VIC 3132, AUSTRALIA
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EUROPEAN REPRESENTATIVE:



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EUROPEAN HEADQUARTER OPERATIONS
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POSTAL ADDRESS: 11, RUE EMILE ZOLA - BP 2332,
38033 GRENOBLE CEDEX 2 -FRANCE

PRODUCT:

ANAESTHETIC ADAPTORS
SEE ATTACHED LIST

CLASSIFICATION:

CLASS 11A, RULE ACCORDING TO ANNEX IX OF THE MDD

CONFORMITY ASSESSMENT ROUTE:

ANNEX APPLIED – ANNEX VII AND V

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES - AS AMENDED BY Directive 98/79/EC ON IN VITRO DIAGNOSTIC MEDICAL DEVICES. 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:

TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTRASSE 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER

CE 0123

(EC) CERTIFICATE(S):

No. G2 07 06 62879 002
PRODUCT CATEGORIES – BREATHING CIRCUITS, FITTINGS
AND ADAPTORS

START OF CE-MARKING:

12-6-2007

PLACE, DATE OF ISSUE:

MÜNCHEN, GERMANY, 12-6-2007

SIGNATURE:


WENDY BIRD (DIRECTOR)

5-9-07
DATE

DECLARATION OF CONFORMITY

Products	
Y Pieces	Elbow connectors
Straight adaptors / connectors	Hose adaptors
Swivel connectors	Tube connectors
Pressure port adaptors	O2 fittings
Plastic mouth pieces	Mid-O-Gas hand pieces
Mask Elbows	

List of Standards for documented evidence.

NUMBER	TITLE
MDD 93/42/EEC	European Council Directive/MDD 93/42/EEC concerning medical devices
ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purpose
ISO 5356-1	Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets
AS/NZS 2496	Breathing attachments for anaesthetic purposes for human use