

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

MANUFACTURER:



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12 REDLAND DRIVE  
MITCHAM, VIC 3132, AUSTRALIA  
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EUROPEAN REPRESENTATIVE:



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

PRODUCT:

ANAESTHETIC CIRCUITS  
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
Catheter mounts
Anaesthetic and respiratory circuits
Mid-O-Gas Circuits

### 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