

**Declaration of Conformity – European Union  
RT series single use breathing tubes**

**Manufacturer:** Fisher & Paykel Healthcare Ltd  
15 Maurice Paykel Place, East Tamaki,  
Auckland 2013, New Zealand

**Authorised Representative:** Fisher & Paykel Healthcare Ltd  
Unit 16, Cordwallis Park, Clivemont Road,  
Maidenhead SL6 7BU, United Kingdom

**Product Category:** Respiratory gas delivery systems

**Medical Device Family:** RT series single use breathing tubes

**Conformity Assessment Route:** Annex II (for class IIa and above)  
Annex VII (for class I)

We, the manufacturer, 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.

All supporting documentation is retained by the manufacturer.


**Quality System Standards:** ISO 13485:2003

**Product Standards Applied:** Refer to Regulatory Requirements (RR-6, RR-13) for the list of standards applied

**Notified Body:** TÜV SÜD Product Service GmbH  
Ridlerstr 65, D-80339 München, Germany

**Identification number:** 0123

**Approval**

Name	Title	Signature	Date
Stéphanie Elvin Author	Regulatory Affairs Engineer		17/Jun/2011

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Doc. No: REG-80

Revision: K

REF	Product Description	Class	GMDN Code	Start Date
RT100	CIRCUIT ADULT DUAL-HTD 10BX	Ila	37498	24/Nov/2005
RT101	CIRCUIT ADULT CPAP 10BX	Ila	37498	24/Nov/2005
RT102	CIRCUIT ADULT CPAP-LINE 10BX	Ila	37498	24/Nov/2005
RT103	CIRCUIT ADULT 02THPY 10BX	Ila	37498	24/Nov/2005
RT104	CIRCUIT ADULT DUAL-HTD 10BX	Ila	37498	24/Nov/2005
RT105	CIRCUIT ADULT INSP-HTD 10BX	Ila	37498	24/Nov/2005
RT106	CIRCUIT ADULT INSP-HTD 10BX	Ila	37498	24/Nov/2005
RT109	CIRCUIT ANAES ADULT 10BX	Ila	37498	04/May/2000
RT112	CIRCUIT ADULT INSP-HTD 10BX	Ila	37498	22/Dec/1999
RT116	CIRCUIT ANAES ADULT 10BX	Ila	37498	18/Jan/2001
RT117	CIRCUIT ANAES ADULT 10BX	Ila	37498	19/Oct/2001
RT124	CIRCUIT NEO CONT-FLOW 10BX	Ila	37498	11/Apr/2002
RT125	CIRCUIT NEO BIAS-FLOW 10BX	Ila	37498	10/Oct/2001
RT125S	CIRCUIT NEO BIAS-FLOWX10 STERI	Ilb	37498	11/Dec/2003
RT126	CIRCUIT NEO LOW-FLOW 10BX	Ila	37498	10/Oct/2001
RT127	CIRCUIT NEO SLE 10BX	Ila	37498	11/Apr/2002
RT132	CIRCUIT NEO CONT-FLOW 10BX	Ila	37498	23/Aug/2002
RT134	CIRCUIT ADULT NON-HTD 10BX	Ila	37498	11/Sep/2002
RT139	CIRCUIT ADULT Bi/CPAP 10BX USA	Ila	37498	13/Jun/2005
RT200	CIRCUIT KIT ADULT DUAL-HT 10BX	Ila	37498	13/Jun/2008
RT201	CIRCUIT KIT ADULT CPAP 10BX	Ila	37498	22/Dec/1999
RT202	CIRCUIT KIT ADULT CPAP-LINEx10	Ila	37498	11/Apr/2000
RT203	CIRCUIT KIT ADULT 02THPY 10BX	Ila	37498	11/Apr/2000
RT204	CIRCUIT KIT ADULT DUAL-HT 10BX	Ila	37498	13/Jun/2008
RT205	CIRCUIT KIT ADULT INS-HTD 10BX	Ila	37498	22/Dec/1999
RT206	CIRCUIT KIT ADULT INS-HTD 10BX	Ila	37498	22/Dec/1999
RT212	CIRCUIT KIT ADULT INS-HTD 10BX	Ila	37498	22/Dec/1999
RT223	CIRCUIT KIT NEO COAX SLE 10BX	Ila	37498	12/Jun/2000
RT224	CIRCUIT KIT NEO CONT-FLOW 10BX	Ila	37498	11/Apr/2002
RT225	CIRCUIT KIT NEO BIAS-FLOW 10BX	Ila	37498	19/Jun/2001
RT226	CIRCUIT KIT NEO LOW-FLOW 10BX	Ila	37498	10/Oct/2001
RT227	CIRCUIT KIT NEO SLE 10BX	Ila	37498	11/Apr/2002
RT228	CIRCUIT KIT NEO SLE 10BX	Ila	37498	24/Feb/2010
RT229	CIRCUIT KIT NEO CONT-FLOW 10BX	Ila	37498	16/Aug/2002
RT235	CCT KIT DUAL HTD NEO BIAS 10BX	Ila	37498	08/Nov/2004
RT236	CIRCUIT KIT NEO LOW-FLOW 10BX	Ila	37498	08/Nov/2004
RT240	CCT ADULT HTD W/ DRYER + CHMBR	Ila	37498	21/Mar/2005
RT241	HUMID DELIVERY SYSTEM & CHMB	Ila	37498	05/Aug/2004
RT265	CCT KIT DUAL HTD 10BX	Ila	37498	30/Mar/2011
RT266	CCT KIT DUAL HTD LOW FLOW 10BX	Ila	37498	30/Mar/2011
RT267	CCT KIT DUAL HTD SLE 2000 10 BX	Ila	37498	30/Mar/2011
RT268	CCT KIT DUAL HTD SLE 5000 10 BX	Ila	37498	30/Mar/2011
RT307	ADULT OXGNTHRPY KIT NHTD 10/BX	Ila	37498	24/Nov/2005
RT308	ADULT OXGNTHRPY KIT HTD 10/BX	Ila	37498	24/Nov/2005
RT319	CIRCUIT KIT ADULT Bi/CPAP 10BX	Ila	37498	18/Jun/2003
RT324	NEO CONT-FLOW WITH CBR & EXT	Ila	37498	06/Sep/2005
RT329	CCT NEO CONST FLOW PRES RELIEF	Ila	37498	21/Mar/2005
RT340	CCT ADULT + MR290 + RT019	Ila	37498	08/Oct/2004

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RT345	CCT Adult + MR290+ RT019	Ila	37498	21/Oct/2010
RT380	CCT ADULT INSP2 + EVQ2 10/BOX	Ila	37498	17/Jun/2011
RT385	CCT ADULT INSP2 + EVQ2 10/BOX	Ila	37498	17/Jun/2011
RT407	ADULT OXGNTHRPY KIT NHTD + EXT	Ila	37498	24/Nov/2004
RT408	ADULT OXGNTHRPY KIT HTD + EXT	Ila	37498	24/Nov/2004
RT443	CIRCUIT ADULT HOMECARE	Ila	37498	07/Dec/2004
RT401S	CCT ADULT CPAP KIT HTD (S)	Ila	37498	22/Mar/2011
RT401M	CCT ADULT CPAP KIT HTD (M)	Ila	37498	22/Mar/2011
RT401L	CCT ADULT CPAP KIT HTD (L)	Ila	37498	22/Mar/2011
RT411S	CCT ADULT CPAP KIT NHTD (S)	Ila	37498	22/Mar/2011
RT411M	CCT ADULT CPAP KIT NHTD (M)	Ila	37498	22/Mar/2011
RT411L	CCT ADULT CPAP KIT NHTD (L)	Ila	37498	22/Mar/2011
RT900	ADLT VENT CCT DUAL+CBR KIT BX	Ila	37498	08/Jul/2003

GMDN Code	Term
37498	Oxygen therapy system

