

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

Doc. No: REG-80

Revision: U

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 and kits*

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

Validity of this declaration: This Declaration of Conformity, for each model listed, is valid from the start date recorded against the model and for as long as the model is listed on the DoC. When a model is no longer covered by the DoC, it is transferred to a Discontinued Medical Devices list and an end date recorded against it.

We, the manufacturer, declare under our sole responsibility that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC concerning medical devices.
All supporting documentation is retained by the manufacturer.

Notified Body (for class IIa and above): TÜV SÜD Product Service GmbH
Ridlerstr 65, D-80339 München, Germany

Identification number: CE 0123

Approval

Name	Title	Signature	Date and Location
Reena Daken Author	Senior Regulatory Affairs Specialist		Auckland 27 July 2017

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REF	Product Description	Class	GMDN Code	MDD rule number	Start Date
RT100	CIRCUIT ADULT DUAL-HTD 10BX	IIa	37706	Rule 2 scl 1	24/Nov/2005
RT101	CIRCUIT ADULT CPAP 10BX	IIa	37706	Rule 2 scl 1	24/Nov/2005
RT102	CIRCUIT ADULT CPAP-LINE 10BX	IIa	37706	Rule 2 scl 1	24/Nov/2005
RT103	CIRCUIT ADULT O2THPY 10BX	IIa	37706	Rule 2 scl 1	24/Nov/2005
RT104	CIRCUIT ADULT DUAL-HTD 10BX	IIa	37706	Rule 2 scl 1	24/Nov/2005
RT105	CIRCUIT ADULT INSP-HTD 10BX	IIa	37706	Rule 2 scl 1	24/Nov/2005
RT106	CIRCUIT ADULT INSP-HTD 10BX	IIa	37706	Rule 2 scl 1	24/Nov/2005
RT109	CIRCUIT ANAES ADULT 10BX	IIa	37704	Rule 2 scl 1	04/May/2000
RT112	CIRCUIT ADULT INSP-HTD 10BX	IIa	37706	Rule 2 scl 1	22/Dec/1999
RT116	CIRCUIT ANAES ADULT 10BX	IIa	37704	Rule 2 scl 1	18/Jan/2001
RT124	CIRCUIT NEO CONT-FLOW 10BX	IIa	37706	Rule 2 scl 1	11/Apr/2002
RT125	CIRCUIT NEO BIAS-FLOW 10BX	IIa	37706	Rule 2 scl 1	10/Oct/2001
RT126	CIRCUIT NEO LOW-FLOW 10BX	IIa	37706	Rule 2 scl 1	10/Oct/2001
RT127	CIRCUIT NEO SLE 10BX	IIa	37706	Rule 2 scl 1	11/Apr/2002
RT132	CIRCUIT NEO CONT-FLOW 10BX	IIa	37706	Rule 2 scl 1	23/Aug/2002
RT134	CIRCUIT ADULT NON-HTD 10BX	IIa	37706	Rule 2 scl 1	11/Sep/2002
RT139	CIRCUIT ADULT Bi/CPAP 10BX USA	IIa	37706	Rule 2 scl 1	13/Jun/2005
RT200	CIRCUIT KIT ADULT DUAL-HT 10BX	IIa	37706	Rule 2 scl 1	13/Jun/2008
RT201	CIRCUIT KIT ADULT CPAP 10BX	IIa	37706	Rule 2 scl 1	22/Dec/1999
RT202	CIRCUIT KIT ADULT CPAP-LINEx10	IIa	37706	Rule 2 scl 1	11/Apr/2000
RT203	CIRCUIT KIT ADULT O2THPY 10BX	IIa	37706	Rule 2 scl 1	11/Apr/2000
RT204	CIRCUIT KIT ADULT DUAL-HT 10BX	IIa	37706	Rule 2 scl 1	13/Jun/2008
RT205	CIRCUIT KIT ADULT INS-HTD 10BX	IIa	37706	Rule 2 scl 1	22/Dec/1999
RT206	CIRCUIT KIT ADULT INS-HTD 10BX	IIa	37706	Rule 2 scl 1	22/Dec/1999
RT212	CIRCUIT KIT ADULT INS-HTD 10BX	IIa	37706	Rule 2 scl 1	22/Dec/1999
RT219	CIRCUIT KIT ADULT Bi/CPAP 10BX	IIa	37706	Rule 2 scl 1	10/Dec/2010
RT224	CIRCUIT KIT NEO CONT-FLOW 10BX	IIa	37706	Rule 2 scl 1	11/Apr/2002
RT225	CIRCUIT KIT NEO BIAS-FLOW 10BX	IIa	37706	Rule 2 scl 1	19/Jun/2001
RT226	CIRCUIT KIT NEO LOW-FLOW 10BX	IIa	37706	Rule 2 scl 1	10/Oct/2001
RT227	CIRCUIT KIT NEO SLE 10BX	IIa	37706	Rule 2 scl 1	11/Apr/2002
RT228	CIRCUIT KIT NEO SLE 10BX	IIa	37706	Rule 2 scl 1	24/Feb/2010
RT235	CCT KIT DUAL HTD NEO BIAS 10BX	IIa	37706	Rule 2 scl 1	08/Nov/2004
RT236	CIRCUIT KIT NEO LOW-FLOW 10BX	IIa	37706	Rule 2 scl 1	08/Nov/2004
RT240	CCT ADULT HTD W/ DRYER + CHMBR	IIa	37706	Rule 2 scl 1	21/Mar/2005
RT241	HUMID DELIVERY SYSTEM & CHMB	IIa	37706	Rule 2 scl 1	05/Aug/2004
RT265	CCT KIT DUAL HTD 10BX	IIa	37706	Rule 2 scl 1	30/Mar/2011
RT266	CCT KIT DUAL HTD LOW FLOW 10BX	IIa	37706	Rule 2 scl 1	30/Mar/2011
RT267	CCT KIT DUAL HTD SLE 2000 10 BX	IIa	37706	Rule 2 scl 1	30/Mar/2011
RT268	CCT KIT DUAL HTD SLE 5000 10 BX	IIa	37706	Rule 2 scl 1	30/Mar/2011
RT301	CCT ADULT HTD PEEP/CPAP	IIa	37706	Rule 2 scl 1	12/Dec/2012
RT307	ADULT OXGNTHRPY KIT NHTD 10/BX	IIa	37706	Rule 2 scl 1	24/Nov/2005
RT308	ADULT OXGNTHRPY KIT HTD 10/BX	IIa	37706	Rule 2 scl 1	24/Nov/2005
RT319	CIRCUIT KIT ADULT Bi/CPAP 10BX	IIa	37706	Rule 2 scl 1	18/Jun/2003
RT324	NEO CONT-FLOW WITH CBR & EXT	IIa	37706	Rule 2 scl 1	06/Sep/2005
RT329	CCT NEO CONST FLOW PRES RELIEF	IIa	37706	Rule 2 scl 1	21/Mar/2005
RT330	OPTIFLOW TUBING KIT	IIa	37706	Rule 2 scl 1	17/Jan/2012
RT340	CCT ADULT + MR290 + RT019	IIa	37706	Rule 2 scl 1	08/Oct/2004
RT345	CCT Adult + MR290+ RT019	IIa	37706	Rule 2 scl 1	21/Oct/2010
RT380	CCT ADULT INSP2 + EVQ2 10/BOX	IIa	37706	Rule 2 scl 1	17/Jun/2011

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RT385	CCT ADULT INSP2 + EVQ2 10/BOX	lia	37706	Rule 2 scl 1	17/Jun/2011
RT408	ADULT OXGNTHRPY KIT HTD + EXT	lia	37706	Rule 2 scl 1	24/Nov/2004
RT443	CIRCUIT ADULT HOMECARE	lia	37706	Rule 2 scl 1	07/Dec/2004
RT480	CARE CONTINUUM™ KIT	lia	37498	Rule 2 scl 1	16/Dec/2016
RT481	ADULT EVAQUA 2 DUAL HEATED VENTILATOR CIRCUIT AND OPTIFLOW NASAL CANNULA	IIa	37498	Rule 2 scl 1	25/Jul/2017

GMDN Code	Term
37704	Anaesthesia breathing circuit, single-use
37706	Ventilator breathing circuit, single-use
37498	Respiratory oxygen therapy system