

Declaration of Conformity – 2011/65/EU
RAC Humidification systems

Doc. No: REG-512

Revision: 0

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 Acute Care Humidification
Medical Device Family:	950, MR850/HC550 and MR810 Respiratory Humidifier and Accessories
Validity of this declaration:	This Declaration of Conformity (DoC), 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 are in compliance with the substance restrictions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2), as per the requirements specified in Article 4.

More specifically, the materials used for the manufacture of this product range do not contain restricted hazardous materials in a quantity greater than the maximum concentration values tolerated by weight in homogeneous materials outlined in Annex II.

All supporting documentation is retained by the manufacturer.

This declaration hereby authorizes the CE Mark to be affixed to the above mentioned product(s).

Notified Body:	TÜV SÜD Product Service GmbH Ridlerstr 65,D-80339 München, Germany
Identification number:	CE 0123

Declaration of Conformity – 2011/65/EU
RAC Humidification systems

Doc. No: REG-512

Revision: 0

REF	Product Description	Start Date
MR810AEA	MR810 Respiratory humidifier	1 ST JUNE 2014
MR810AEK	MR810 Respiratory humidifier	1 ST JUNE 2014
MR810ARU	MR810 Respiratory humidifier	1 ST JUNE 2014
MR810AEU	MR810 Respiratory humidifier	1 ST JUNE 2014
MR810ABU	MR810 Respiratory humidifier	1 ST JUNE 2014
MR810ADU	MR810 Respiratory humidifier	1 ST JUNE 2014
MR810AFU	MR810 Respiratory humidifier	1 ST JUNE 2014
MR810AGU	MR810 Respiratory humidifier	1 ST JUNE 2014
MR810ALU	MR810 Respiratory humidifier	1 ST JUNE 2014
MR810ANU	MR810 Respiratory humidifier	1 ST JUNE 2014
MR810APU	MR810 Respiratory humidifier	1 ST JUNE 2014
MR810GJU	MR810 Respiratory humidifier	1 ST JUNE 2014
MR810JBU	MR810 Respiratory humidifier	1 ST JUNE 2014
MR810JHU	MR810 Respiratory humidifier	1 ST JUNE 2014
MR810JSU	MR810 Respiratory humidifier	1 ST JUNE 2014
MR810ASU	MR810 Respiratory humidifier	18 DEC 2014

REF	Product Description	Start Date
MR850AEA	MR850 Respiratory humidifier	1 ST JUNE 2014
MR850AEK	MR850 Respiratory humidifier	1 ST JUNE 2014
MR850ARU	MR850 Respiratory humidifier	1 ST JUNE 2014
MR850AEU	MR850 Respiratory humidifier	1 ST JUNE 2014
MR850ABU	MR850 Respiratory humidifier	1 ST JUNE 2014
MR850ADU	MR850 Respiratory humidifier	1 ST JUNE 2014
MR850AFU	MR850 Respiratory humidifier	1 ST JUNE 2014
MR850AGU	MR850 Respiratory humidifier	1 ST JUNE 2014
MR850ALU	MR850 Respiratory humidifier	1 ST JUNE 2014

Declaration of Conformity – 2011/65/EU
RAC Humidification systems

Doc. No: REG-512

Revision: 0

REF	Product Description	Start Date
MR850ANU	MR850 Respiratory humidifier	1 ST JUNE 2014
MR850APU	MR850 Respiratory humidifier	1 ST JUNE 2014
MR850GJU	MR850 Respiratory humidifier	1 ST JUNE 2014
MR850JBU	MR850 Respiratory humidifier	1 ST JUNE 2014
MR850JHU	MR850 Respiratory humidifier	1 ST JUNE 2014
MR850JSU	MR850 Respiratory humidifier	1 ST JUNE 2014
MR850AGC	MR850 Respiratory humidifier	1 ST JUNE 2014
MR850JFC	MR850 Respiratory humidifier	1 ST JUNE 2014

REF	Product Description	Start Date
HC550AFU	HC550 Respiratory humidifier	1 ST JUNE 2014
HC550AGU	HC550 Respiratory humidifier	1 ST JUNE 2014
HC550JHU	HC550 Respiratory humidifier	29 OCT 2014
HC550AEK	HC550 Respiratory humidifier	29 OCT 2014

REF	Product Description	Start Date
900MR860	TEMPERATURE FLOW PROBES	9 TH JUNE 2014
900MR861	TEMPERATURE FLOW PROBES	9 TH JUNE 2014
900MR863	TEMPERATURE FLOW PROBES	9 TH JUNE 2014
900MR868	TEMPERATURE FLOW PROBES	9 TH JUNE 2014
900MR869	TEMPERATURE FLOW PROBES	9 TH JUNE 2014
900MR560	TEMPERATURE PROBES	9 TH JUNE 2014
900MR561	TEMPERATURE PROBES	9 TH JUNE 2014
900MR563	TEMPERATURE PROBES	9 TH JUNE 2014
900MR565	TEMPERATURE PROBES	9 TH JUNE 2014
900MR568	TEMPERATURE PROBES	9 TH JUNE 2014
900MR569	TEMPERATURE PROBES	9 TH JUNE 2014
900MR571	TEMPERATURE PROBES	9 TH JUNE 2014

REF	Product Description	Start Date
-----	---------------------	------------

Declaration of Conformity – 2011/65/EU
RAC Humidification systems

Doc. No: REG-512

Revision: 0

900MR805	HEATER WIRE ADAPTORS	9 TH JUNE 2014
900MR806	HEATER WIRE ADAPTORS	9 TH JUNE 2014
900MR858	HEATER WIRE ADAPTORS	9 TH JUNE 2014
900MR441	HEATER WIRE ADAPTORS	9 TH JUNE 2014
900MR901	HEATER WIRE ADAPTORS	5 TH AUG 2014
900MR511S	HEATER WIRE 1.05M 12.4 OHM 35W	18 DEC 2014

REF	Product Description	Start Date
900MR870	MR850 CALIBRATION PROBE	9 TH JUNE 2014
900MR806	MR850 SERIAL CABLE	9 TH JUNE 2014
043042566	CHECK PROBE	9 TH JUNE 2014
900MR146C	Temperature probe housing	5 TH AUG 2014
900MR156	Adaptor	5 TH AUG 2014
900MR755	Heater Wire	5 TH AUG 2014
900MR524	Heater Wire	5 TH AUG 2014
900MR754	Heater Wire	5 TH AUG 2014
900MR558	Heater Wire	5 TH AUG 2014
900MR751	Heater Wire	5 TH AUG 2014
900MR559	Heater Wire	5 TH AUG 2014
900MR533C	ADAPTER	5 TH AUG 2014
900MR830	ADAPTER	5 TH AUG 2014
900MR532	ADAPTER	5 TH AUG 2014
900MR130C	ELBOW	5 TH AUG 2014
900MR070	WIRE	5 TH AUG 2014
MR340E	CHAMBER	5 TH AUG 2014
MR370	CHAMBER	5 TH AUG 2014
MR290	CHAMBER	5 TH AUG 2014
900MR088	BRACKET	5 TH AUG 2014

REF	Product Description	Start Date
900MR033	Airway thermometer	22 ND JULY 2014
900MR042	Hose Clip 22mm	22 ND JULY 2014
900MR047	Hose Clip 15mm	22 ND JULY 2014
900MR125	Adult Y Piece W/P&T	22 ND JULY 2014

Declaration of Conformity – 2011/65/EU
RAC Humidification systems

Doc. No: REG-512

Revision: 0

900MR126	Adult Y-Piece	22 ND JULY 2014
900MR128	Y-Piece Adult Pressure Port	22 ND JULY 2014
900MR130	Adult Elbow	22 ND JULY 2014
900MR136	Y-Piece Pediatric 15mm w/o Ports	22 ND JULY 2014
900MR138	Y-Piece Pediatric / Pressure Port	22 ND JULY 2014
900MR139	Water Trap	22 ND JULY 2014
900MR145	Neonatal Y-Piece	22 ND JULY 2014
900MR146	Temperature Probe Housing	22 ND JULY 2014
900MR164	Plug-dual Y Piece	22 ND JULY 2014
900MR530	Adaptor, 22mm	22 ND JULY 2014
900MR531	Probe Housing-Infant	22 ND JULY 2014
900MR533	Hose Adaptor	22 ND JULY 2014
900MR534	Hose Adaptor	22 ND JULY 2014
900MR761	Reusable Breathing Circuit Kit	22 ND JULY 2014

REF	Product Description	Start Date
RT024	DRY LINE EXTN KIT 20/BOX	1 ST JUNE 2014
RT026	ADLT LIMB EXP HTD S/USE 20/BOX	1 ST JUNE 2014
RT100	CIRCUIT ADULT DUAL-HTD 10BX	1 ST JUNE 2014
RT101	CIRCUIT ADULT CPAP 10BX	1 ST JUNE 2014
RT102	CIRCUIT ADULT CPAP-LINE 10BX	1 ST JUNE 2014
RT103	CIRCUIT ADULT 02THPY 10BX	1 ST JUNE 2014
RT104	CIRCUIT ADULT DUAL-HTD 10BX	1 ST JUNE 2014
RT105	CIRCUIT ADULT INSP-HTD 10BX	1 ST JUNE 2014
RT106	CIRCUIT ADULT INSP-HTD 10BX	1 ST JUNE 2014
RT109	CIRCUIT ANAES ADULT 10BX	1 ST JUNE 2014
RT110	CIRCUIT ADULT DUAL-HTD 10BX	1 ST JUNE 2014
RT111	CIRCUIT ADULT DUAL-HTD 10BX	1 ST JUNE 2014
RT112	CIRCUIT ADULT INSP-HTD 10BX	1 ST JUNE 2014
RT114	CIRCUIT ADULT CPAP LINE 10BX	1 ST JUNE 2014
REF	Product Description	Start Date
RT115	CIRCUIT ADULT INS-HTD 10BX	1 ST JUNE 2014
RT116	CIRCUIT ANAES ADULT 10BX	1 ST JUNE 2014
RT124	CIRCUIT NEO CONT-FLOW 10BX	1 ST JUNE 2014

Declaration of Conformity – 2011/65/EU
RAC Humidification systems

Doc. No: REG-512

Revision: 0

RT125	CIRCUIT NEO BIAS-FLOW 10BX	1 ST JUNE 2014
RT126	CIRCUIT NEO LOW-FLOW 10BX	1 ST JUNE 2014
RT127	CIRCUIT NEO SLE 10BX	1 ST JUNE 2014
RT130	CIRCUIT NEO LOW-FLOW ALLEG x10	1 ST JUNE 2014
RT131	CIRCUIT NEO BIAS-FLO ALLEG x10	1 ST JUNE 2014
RT132	CIRCUIT NEO CONT-FLOW 10BX	1 ST JUNE 2014
RT134	CIRCUIT ADULT NON-HTD 10BX	1 ST JUNE 2014
RT137	CIRCUIT ADUL ALLEG INSP HTD	1 ST JUNE 2014
RT139	CIRCUIT ADULT Bi/CPAP 10BX USA	1 ST JUNE 2014
RT200	CIRCUIT KIT ADULT DUAL-HT 10BX	1 ST JUNE 2014
RT201	CIRCUIT KIT ADULT CPAP 10BX	1 ST JUNE 2014
RT202	CIRCUIT KIT ADULT CPAP-LINEx10	1 ST JUNE 2014
RT203	CIRCUIT KIT ADULT 02THPY 10BX	1 ST JUNE 2014
RT204	CIRCUIT KIT ADULT DUAL-HT 10BX	1 ST JUNE 2014
RT205	CIRCUIT KIT ADULT INS-HTD 10BX	1 ST JUNE 2014
RT206	CIRCUIT KIT ADULT INS-HTD 10BX	1 ST JUNE 2014
RT210	CIRCT ADULT DUAL-HTD 10BX USA	1 ST JUNE 2014
RT211	CIRCT ADULT DUAL-HTD 10BX USA	1 ST JUNE 2014
RT212	CIRCUIT KIT ADULT INS-HTD 10BX	1 ST JUNE 2014
RT215	CIRCT ADULT SING-HTD 10BX USA	1 ST JUNE 2014
RT219	CIRCUIT KIT ADULT Bi/CPAP 10BX	1 ST JUNE 2014
RT224	CIRCUIT KIT NEO CONT-FLOW 10BX	1 ST JUNE 2014
RT225	CIRCUIT KIT NEO BIAS-FLOW 10BX	1 ST JUNE 2014
RT226	CIRCUIT KIT NEO LOW-FLOW 10BX	1 ST JUNE 2014
RT227	CIRCUIT KIT NEO SLE 10BX	1 ST JUNE 2014
RT228	CIRCUIT KIT NEO SLE5000 10BX	1 ST JUNE 2014
RT235	CCT KIT DUAL HTD NEO BIAS 10BX	1 ST JUNE 2014
RT236	CIRCUIT KIT NEO LOW-FLOW 10BX	1 ST JUNE 2014
RT240	HUMID DELIVERY SYSTEM & CHMB	1 ST JUNE 2014
RT241	HUMID DELIVERY SYSTEM & CHMB	1 ST JUNE 2014
REF	Product Description	Start Date
RT245	CCT Adult + MR290	1 ST JUNE 2014
RT265	CCT KIT DUAL HTD 10BX	1 ST JUNE 2014
RT266	CCT KIT DUAL HTD LOW FLOW 10BX	1 ST JUNE 2014

Declaration of Conformity – 2011/65/EU
RAC Humidification systems

Doc. No: REG-512

Revision: 0

RT267	CCT KIT DUAL HTD SLE2000 10BX	1 ST JUNE 2014
RT268	CCT KIT DUAL HTD SLE5000 10BX	1 ST JUNE 2014
RT280	CCT ADULT INSP2 + EVQ2 10BX	1 ST JUNE 2014
RT301	CCT ADULT HTD PEEP/CPAP	1 ST JUNE 2014
RT307	ADULT OXGNTHRPY KIT NHTD 10/BX	1 ST JUNE 2014
RT308	ADULT OXGNTHRPY KIT HTD 10/BX	1 ST JUNE 2014
RT319	CIRCUIT KIT ADULT Bi/CPAP 10BX	1 ST JUNE 2014
RT324	NEO CONT-FLOW WITH CBR & EXT	1 ST JUNE 2014
RT329	CCT NEO CONST FLOW PRES RELIEF	1 ST JUNE 2014
RT330	INFANT NASAL HIGH FLOW SYSTEM	1 ST JUNE 2014
RT340	CCT Adult + MR290 + RT019	1 ST JUNE 2014
RT345	CCT Adult + MR290 + RT019	1 ST JUNE 2014
RT380	CCT ADULT INSP2 + EVQ2 10/BOX	1 ST JUNE 2014
RT385	CCT ADULT INSP2 + EVQ2 10/BOX	1 ST JUNE 2014
RT408	CCT ADULT CPAP KIT HTD (L)	1 ST JUNE 2014
RT443	CIRCUIT ADULT HOMECARE	1 ST JUNE 2014
RT480	Care Continuum™ Kit	12 TH DEC 2016
RT481	Post-Extubation & Care Continuum Kit	24 TH JULY 2017
900MR810	CIRC SING HTD WALL MR810 BX 10	1 ST JUNE 2014
900MR810E	CIRC SING HTD WALL MR810 BX 10	1 ST JUNE 2014
043046437	CIRCUIT 900MR810E SINGLE	1 ST JUNE 2014
043043947	CIRCUIT SNGL 1.5M HTD WALL INS	1 ST JUNE 2014
900MR816	MR850 START UP KIT	1 ST JUNE 2014
900MR817	MR850 START UP KIT	1 ST JUNE 2014
900MR818	MR850 START UP KIT	1 ST JUNE 2014
900MR914	MR850 START UP KIT	1 ST JUNE 2014
900MR923	MR850 START UP KIT	1 ST JUNE 2014
900RD110	RESUS HUMID S/USE W/O MSK (10)	29 TH OCT 2014
BC151	INFANT DELIVERY SYSTEM SLCP	29 TH OCT 2014
BC153	INFANT DELIVERY SYSTEM SLNP	29 TH OCT 2014
BC161	INFANT DELIVERY SYSTEM SMCP	29 TH OCT 2014
BC163	INFANT DELIVERY SYSTEM SMN	29 TH OCT 2014
REF	Product Description	Start Date
BC171	INFANT DELIVERY SYS-SMCF	29 TH OCT 2014

Declaration of Conformity – 2011/65/EU
RAC Humidification systems

Doc. No: REG-512

Revision: 0

BC173	INFANT DELIVERY SYS-SMNF	29 TH OCT 2014
OPT144	OPTIFLOW ANESTHESIA KIT 10\BX	13 TH JAN 2015
AA400	OPTIFLOW THRIVE ANAESTHESIA OXYGEN KIT	28 TH JULY 2015
AA400SU	OPTIFLOW ANAESTHESIA SU	13 TH JAN 2016
AA410	OPTIFLOW THRIVE AIRVO 2 CHAMBER/TUBE KIT	13 TH JAN 2016
AA450	OPTIFLOW THRIVE ANAESTHESIA OXYGEN KIT	17 Nov 2017

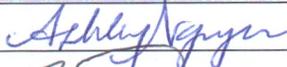
REF	Product Description	Start Date
950ANZ	950 Heater Base	18 OCT 2017
950AGB	950 Heater Base	18 OCT 2017

REF	Product Description	Start Date
950A80	Adult Ventilator Dual Heated Circuit Kit	18 OCT 2017
950A81	Adult Ventilator Dual Heated Circuit Kit (with Filter)	18 OCT 2017
950A82	Adult Ventilator Dual Heated Circuit Kit (with Pressure line)	18 OCT 2017
950A60	Adult Bi-level / CPAP Heater Circuit Kit	18 OCT 2017
950A61	Adult Bi-level / CPAP Heater Circuit Kit (with Filter)	18 OCT 2017
950A40	Adult Optiflow Heater Circuit Kit	18 OCT 2017
950X00	950 Expiratory Heater Wire Adapter	18 OCT 2017
950S01	950 Universal Sensor Cartridge	18 OCT 2017

DHF INDEX CROSS REFERENCES:

DHF-1, DHF-13

APPROVALS

	Name	Position	Signature	Date
Author	Ashley Nguyen	Regulatory Affairs Specialist		17 NOV 2017
Review	Martijn Halbesma	Quality System Engineer		17 NOV 2017
Approval	Primo Flores	QSE Manager - Design		17 NOV 2017

REVISION HISTORY

Rev.	Date	Author	Description
A	20 June 2014	Jon Church	First Issue
B	29 Sept 2014	Jon Church	Added additional accessories and circuits

Declaration of Conformity – 2011/65/EU
RAC Humidification systems

Doc. No: REG-512

Revision: 0

C	16 Oct 2014	Alecia White	Added RT100 and RT101
D	29 Oct 2014	Alecia White	Added HC550AEK and HC550JHU
E	31 Oct 2014	Alecia White	Added 900RD110, BC151, BC153, BC161, BC163, BC171, BC173
F	18 Dec 2014	Alecia White	Added MR810ASU and 900MR511S
G	15 Jan 2014	Primo Flores	Added OPT144 based on DR-2747
H	21 July 2015	Jon Church	Added 900MR033, 900MR042, 900MR047, 900MR125, 900MR126, 900MR128, 900MR130, 900MR136, 900MR138, 900MR139, 900MR145, 900MR146, 900MR164, 900MR530, ,900MR531, 900MR533, 900MR534
I	28 July 2015	Milanjot Assi	Added AA400 based on TR-25471
J	13 Jan 2016	Nicole Senasac	Corrected typo OPT144 Start Date from 13Jan2014 to 13Jan2015. Added AA400SU based on TR-25471 Added AA410 based on DR-3245
K	26 May 2016	D MacCallum	Added 900MR761 based on update to TR25471.
L	12 DEC 2016	A. Rivera	Added RT480, refer to DR-3819
M	24 July 2017	M. Halbesma	Added RT481, refer to DR-4259
N	18 Oct 2017	J. Kerkhofs	Added 950A80, 95081, 950A82, 950A40, 950A60, 950A61, 950ANZ, 950AGB, 950X00, 950S01, refer to TR-27248, TR-27964 and TR-28649
O	17 Nov 2017	A. Nguyen	Added AA450 based on DR-4571