

**Declaration of Conformity – European Union  
Respiratory humidifiers**

Doc. No: REG-76

Revision: I

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

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

**Product Category:** Heated humidifiers

**Medical Device Family:** Respiratory humidifiers

**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-23 and RR-45) 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
Adele Bindon Author	Regulatory Affairs Manager		6/APR/2011

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REF	Product Description	Class	GMDN Code	Start Date
HC550AFU	HUMIDIFIER HC550 230V F/D/G EU	IIb	12050	23/Nov/2004
HC550AGU	HUMIDIFIER HC550 230V G/F/I EU	IIb	12050	07/Oct/2004
MR410ASU	HUMIDIFIER MR410 230V SPA/ENG	IIb	12050	04/Mar/1998
MR810ABU	HUMIDIFIER MR810 230V E/S/P BR	IIa	12050	18/Nov/2010
MR810ADU	HUMIDIFIER MR810 230V DANISH	IIa	12050	14/Apr/2004
MR810AEK	HUMIDIFIER MR810 230V UK/MALAY	IIa	12050	04/Feb/2004
MR810AEU	HUMIDIFIER MR810 230V EN/FR/SP	IIa	12050	04/Feb/2004
MR810AFU	HUMIDIFIER MR810 230V FR/DU/GE	IIa	12050	04/Feb/2004
MR810AGU	HUMIDIFIER MR810 230V GE/FR/IT	IIa	12050	04/Feb/2004
MR810ALU	HUMIDIFIER MR810 230V IT/PT/SP	IIa	12050	04/Feb/2004
MR810ANU	HUMIDIFIER MR810 230V SW/FI/NO	IIa	12050	26/May/2004
MR810APU	HUMIDIFIER MR810 230V EN/PT	IIa	12050	26/Aug/2010
MR810ARU	HUMIDIFIER MR810 230V RUS/POL	IIa	12050	02/Sep/2004
MR850ABU	HUMIDIFIER MR850 230V E/S/P BR	IIb	12050	17/Nov/2010
MR850ADU	HUMIDIFIER MR850 230V DAN DK	IIb	12050	15/May/2000
MR850AEK	HUMIDIFIER MR850 230V ENG UK	IIb	12050	01/Sep/1998
MR850AEU	HUMIDIFIER MR850 230V EN/SP/FR	IIb	12050	20/Dec/1999
MR850AFU	HUMIDIFIER MR850 230V F/D/G EU	IIb	12050	19/Oct/1998
MR850AGC	HUMIDIFIER MR850 230V GE/FR CH	IIb	12050	09/Nov/2004
MR850AGU	HUMIDIFIER MR850 230V GE/FR EU	IIb	12050	09/Mar/1999
MR850ALU	HUMIDIFIER MR850 230V I/S/P EU	IIb	12050	18/Dec/1999
MR850ANU	HUMIDIFIER MR850 230V NO/SW/FI	IIb	12050	20/Dec/1999
MR850APU	HUMIDIFIER MR850 230V E/S/F TH	IIb	12050	19/Nov/2010
MR850ARU	HUMIDIFIER MR850 230V RU/PO/EN	IIb	12050	27/Jun/2002
MR880AEK	HUMIDIFIER MR880 230V UK	IIb	12050	15/Feb/2005
MR880ADU	HUMIDIFIER MR880 230V DAN DK	IIb	12050	19/Feb/2010
MR880AEU	HUMIDIFIER MR880 230V EN/SP/FR	IIb	12050	19/Feb/1200
MR880AFU	HUMIDIFIER MR880 230V F/D/G EU	IIb	12050	29/Sep/2006
MR880AGU	HUMIDIFIER MR880 230V GE/FR EU	IIb	12050	19/Feb/2010
MR880ALU	HUMIDIFIER MR880 230V I/S/P EU	IIb	12050	19/Feb/2010
MR880ANU	HUMIDIFIER MR880 230V NO/SW/FI	IIb	12050	19/Feb/2010
MR880ARU	HUMIDIFIER MR880 230V RU/PO/HU	IIb	12050	19/Feb/2010

GMDN Code	Term
12050	Humidifier, heated