

Declaration of Conformity – European Union
Humidification chambers

Doc. No: REG-69

Revision: K

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:	Heated humidifiers
Medical Device Family:	Humidification chambers
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	Senior Regulatory Affairs Specialist		Auckland, NZ 17 Jan 2017

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REF	Product Description	Class	GMD N Code	MDD rule number	Start Date
900MR190	WATER FEED SET - 1USE 30/CTN	Ila	60699	Rule 2 scl 1	31/Jul/98
900MR191X	WATER FEED SET EXTENSION 10CTN	Ila	60699	Rule 2 scl 1	21/Aug/00
900PT290E	AUTOFEED CHAMBER PT100 HME SGL	Ila	60699	Rule 2 scl 1	25/Jun/12
MR210	CHAMBER - ADULT - 40/CTN	Ila	60699	Rule 2 scl 1	18/Dec/98
MR210X	CHAMBER - ADULT - 10/CTN	Ila	60699	Rule 2 scl 1	20/Jan/99
MR225	CHAMBER - INFANT - 50/CTN	Ila	60699	Rule 2 scl 1	17/Mar/00
MR225X	CHAMBER - INFANT - 10/CTN	Ila	60699	Rule 2 scl 1	17/Mar/00
MR250	HUMIDIFICATION CHAMBER -40/CTN	Ila	60699	Rule 2 scl 1	15/Dec/98
MR250X	HUMIDIFICATION CHAMBER -10/CTN	Ila	60699	Rule 2 scl 1	02/Feb/99
MR290HFV	CHAMBER-AUTOFEED VENTED HFV40PK	Ila	60699	Rule 2 scl 1	20/Sep/04
MR290UX	CHAMBER-AUTOFEED-UNVENT-10/CTN	Ila	60699	Rule 2 scl 1	02/Feb/99
MR290V	CHAMBER-AUTOFEED-VENTED-40/CTN	Ila	60699	Rule 2 scl 1	20/Jan/99
MR290VX	CHAMBER-AUTOFEED-VENTED-10/CTN	Ila	60699	Rule 2 scl 1	20/Jan/99
MR340E	CHAMBER INFANT ENG/FRE/GER	Ila	60662	Rule 2 scl 1	19/Aug/98
MR340F	CHAMBER INFANT FRE/GER/DUT	Ila	60662	Rule 2 scl 1	23/Jul/98
MR340S	CHAMBER INFANT ITA/SPA/POR	Ila	60662	Rule 2 scl 1	30/Jul/98
MR370	CHAMBER - ADULT REUSABLE	Ila	60662	Rule 2 scl 1	15/Aug/00

GMDN Code	Term
60699	Inspiratory line humidification chamber, single-use
60662	Inspiratory line humidification chamber, reusable