

Declaration of Conformity – European Union
OSA Masks

Doc. No: REG-42


Revision: AQ

Manufacturer:	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand
Authorised Representative:	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon- sur-Yvette, 91946 Courtaboeuf Cedex, France
Product Category:	Nasal and/or Oral Interfaces for Delivery of Respiratory Gases
Medical Device Family:	OSA Masks
Conformity Assessment Route:	Annex II (for class IIa and above)
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
Sylvia Wonner Author	Regulatory Affairs Associate		25 MAR 19 Auckland, NZ

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REF	Product Description	Class	GMDN Code	MDD rule number	Start Date
BRE1 SU	F&P Brevida Nasal Pillows Mask XS-S U Model	Ila	57815	Rule 2 scl 1	11/Aug/16
BRE1MU	F&P Brevida Nasal PillowsMask M-L U Model	Ila	57815	Rule 2 scl 1	11/Aug/16
BRE1SMU	F&P Brevida Nasal Pillows Mask XS-S/M-L U Model	Ila	57815	Rule 2 scl 1	11/Aug/16
BRE1SMSL	F&P Brevida Nasal Pillows Mask XS/M-L SL	Ila	57815	Rule 2 scl 1	11/Aug/16
BRE1SA	F&P Brevida Nasal Pillows Mask XS-S A Model	Ila	57815	Rule 2 scl 1	28/Jul/16
BRE1MA	F&P Brevida Nasal PillowsMask M-L A Model	Ila	57815	Rule 2 scl 1	28/Jul/16
BRE1SMA	F&P Brevida Nasal Pillows Mask XS-S/M-L A Model	Ila	57815	Rule 2 scl 1	28/Jul/16
ESN2SA	F&P Eson™ 2 Nasal Mask – Small A	Ila	57815	Rule 2 scl 1	25/Nov/15
ESN2MA	F&P Eson™ 2 Nasal Mask – Medium A	Ila	57815	Rule 2 scl 1	25/Nov/15
ESN2LA	F&P Eson™ 2 Nasal Mask – Large A	Ila	57815	Rule 2 scl 1	25/Nov/15
ESN2SU	F&P Eson™ 2 Nasal Mask – Small U	Ila	57815	Rule 2 scl 1	25/Nov/15
ESN2MU	F&P Eson™ 2 Nasal Mask – Medium U	Ila	57815	Rule 2 scl 1	25/Nov/15
ESN2LU	F&P Eson™ 2 Nasal Mask – Large U	Ila	57815	Rule 2 scl 1	25/Nov/15
ESN2SS	F&P Eson™ 2 Nasal Mask – Small/Small	Ila	57815	Rule 2 scl 1	25/Nov/15
ESN2MM	F&P Eson™ 2 Nasal Mask – Medium/Medium	Ila	57815	Rule 2 scl 1	25/Nov/15
ESN2LL	F&P Eson™ 2 Nasal Mask – Large/Large	Ila	57815	Rule 2 scl 1	25/Nov/15
ESN2ML	F&P Eson™ 2 Nasal Mask – Medium/Large	Ila	57815	Rule 2 scl 1	25/Nov/15
ESN2SSL	F&P Eson™ 2 Nasal Mask – Small SL	Ila	57815	Rule 2 scl 1	25/Nov/15
ESN2MSL	F&P Eson™ 2 Nasal Mask – Medium SL	Ila	57815	Rule 2 scl 1	25/Nov/15
ESN2LSL	F&P Eson™ 2 Nasal Mask – Large SL	Ila	57815	Rule 2 scl 1	25/Nov/15
ESN2MLSL	F&P Eson™ 2 Nasal Mask – Medium/Large SL	Ila	57815	Rule 2 scl 1	25/Nov/15
HC401U	Aclaim™ 2 Nasal Mask (Single & 10 Pack)	Ila	57815	Rule 2 scl 1	24/Apr/03
HC405U	Flexifit™ HC405 Nasal Mask (Single & 10 Pack)	Ila	57815	Rule 2 scl 1	22/Sep/03
HC405US	Flexifit™ HC405 Nasal Mask - Small (Single & 20 Pack)	Ila	57815	Rule 2 scl 1	16/Nov/11
HC405UL	Flexifit™ HC405 Nasal Mask - Large (Single & 20 Pack)	Ila	57815	Rule 2 scl 1	16/Nov/11
HC406U	Flexifit™ 406 Nasal Mask (Single & 10 Pack)	Ila	57815	Rule 2 scl 1	13/Sep/05
HC407U	Flexifit™ HC407 Nasal Mask (Single & 10 Pack)	Ila	57815	Rule 2 scl 1	07/Apr/04
HC482U	Opus Nasal Pillows Mask (Single & 10 Pack)	Ila	57815	Rule 2 scl 1	06/Mar/07
400421	F&P Pilairo Q Nasal Pillows Mask (Single & 10 Pack)	Ila	57815	Rule 2 scl 1	4/Oct/13
400421SL	F&P Pilairo Q Nasal Pillows Mask – SL (Single & 10 Pack)	Ila	57815	Rule 2 scl 1	9/Oct/13
400439U	Zest™ Petite Nasal Mask (Single & 10 Pack)	Ila	57815	Rule 2 scl 1	16/Feb/09

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400440U	Zest™ Nasal Mask (Single & 10 Pack)	Ila	57815	Rule 2 scl 1	27/Nov/08
400441U	Zest™ Plus Nasal Mask (Single & 10 Pack)	Ila	57815	Rule 2 scl 1	26/May/09
400444U	Zest™ Q Petite Nasal Mask (Single & 10 Pack)	Ila	57815	Rule 2 scl 1	26/Mar/12
400445U	Zest™ Q Standard Nasal Mask (Single & 10 Pack)	Ila	57815	Rule 2 scl 1	20/Oct/11
400446U	Zest™ Q Plus Nasal Mask (Single & 10 Pack)	Ila	57815	Rule 2 scl 1	02/Apr/12
400447	Lady Zest Q Petite Nasal Mask (Single & 10 Pack)	Ila	57815	Rule 2 scl 1	16/Apr/12
400448	Lady Zest Q Standard Nasal Mask (Single & 10 Pack)	Ila	57815	Rule 2 scl 1	16/Apr/12
400449	F&P EsonNasal Mask – Small	Ila	57815	Rule 2 scl 1	19/July/12
400449SL	F&P Eson Nasal Mask SL – Small	Ila	57815	Rule 2 scl 1	18/Mar/14
400450	F&P EsonNasal Mask – Medium	Ila	57815	Rule 2 scl 1	19/July/12
400450SL	F&P EsonNasal Mask SL – Large	Ila	57815	Rule 2 scl 1	31/Jan/14
400451	F&P Eson Nasal Mask – Large	Ila	57815	Rule 2 scl 1	19/July/12
400451SL	F&P Eson Nasal Mask SL – Large	Ila	57815	Rule 2 scl 1	18/Mar/14
400452	Eson™ Medium/Large Nasal Mask	Ila	57815	Rule 2 scl 1	19/July/12
400453	F&P Eson™ Nasal Mask – Small / Small	Ila	57815	Rule 2 scl 1	7/Dec/12
400454	F&P Eson™ Nasal Mask – Medium / Medium	Ila	57815	Rule 2 scl 1	7/Dec/12
400455	F&P Eson™ Nasal Mask – Large / Large	Ila	57815	Rule 2 scl 1	7/Dec/12
HC431U	Flexifit™ HC431 Full Face Mask (Single & 5 Pack)	Ila	57814	Rule 2 scl 1	06/Apr/04
HC432U	Flexifit™ HC432 Full Face Mask – COMBO (Single & 5 Pack)	Ila	57814	Rule 2 scl 1	26/Sep/06
HC432UL	Flexifit™ HC432 Full Face Mask - Large (Single & 5 Pack)	Ila	57814	Rule 2 scl 1	30/Aug/06
HC432UM	Flexifit™ HC432 Full Face Mask - Medium (Single & 5 Pack)	Ila	57814	Rule 2 scl 1	12/Sep/06
HC432US	Flexifit™ HC432 Full Face Mask - Small (Single & 5 Pack)	Ila	57814	Rule 2 scl 1	30/Aug/06
HC432UXL	Flexifit™ HC432 Full Face Mask - X-Large (Single & 5 Pack)	Ila	57814	Rule 2 scl 1	13/Dec/07
400470A	Forma™ Full Face Mask - Small (Single & 5 Pack)	Ila	57814	Rule 2 scl 1	07/Oct/08
400471A	Forma™ Full Face Mask - Medium (Single & 5 Pack)	Ila	57814	Rule 2 scl 1	07/Oct/08
400472A	Forma™ Full Face Mask - Large (Single & 5 Pack)	Ila	57814	Rule 2 scl 1	08/Oct/08
400473A	Forma™ Full Face Mask - X-Large (Single & 5 Pack)	Ila	57814	Rule 2 scl 1	15/Oct/08
400470U	Forma™ Full Face Mask - Small (Single & 5 Pack)	Ila	57814	Rule 2 scl 1	27/Nov/08
400471U	Forma™ Full Face Mask - Medium & Large (Single & 5 Pack)	Ila	57814	Rule 2 scl 1	27/Nov/08

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REF	Product Description	Class	GMDN Code	MDD rule number	Start Date
400472U	Forma™ Full Face Mask - Large (Single & 5 Pack)	Ila	57814	Rule 2 scl 1	4/Jun/09
400473U	Forma™ Full Face Mask - X-Large (Single & 5 Pack)	Ila	57814	Rule 2 scl 1	27/Nov/08
400474U	Forma™ Full Face Mask - Medium (Single & 5 Pack)	Ila	57814	Rule 2 scl 1	4/Jun/09
400475	Simplus Full Face Mask - Small	Ila	57814	Rule 2 scl 1	12/Mar/13
400475SL	Simplus Full Face Mask SL - Small	Ila	57814	Rule 2 scl 1	28/Mar/13
400476	Simplus Full Face Mask – Medium	Ila	57814	Rule 2 scl 1	12/Mar/13
400476SL	Simplus Full Face Mask SL – Medium	Ila	57814	Rule 2 scl 1	28/Mar/13
400477	Simplus Full Face Mask - Large	Ila	57814	Rule 2 scl 1	12/Mar/13
400477SL	Simplus Full Face Mask SL – Large	Ila	57814	Rule 2 scl 1	28/Mar/13
400478	Simplus Full Face Mask – Med/Large	Ila	57814	Rule 2 scl 1	12/Mar/13
400479	Simplus Full Face Mask – Small/Small	Ila	57814	Rule 2 scl 1	12/Mar/13
400480	Simplus Full Face Mask – Med/Med	Ila	57814	Rule 2 scl 1	12/Mar/13
400481	Simplus Full Face Mask – Large/Large	Ila	57814	Rule 2 scl 1	12/Mar/13
HC452U	Oracle™ Oral Mask (Single & 10 Pack)	Ila	57816	Rule 2 scl 1	20/Sep/04
HC407NIV	Flexifit™ 407NIV Nasal Mask (Single & 10 Pack)	Ila	57815	Rule 2 scl 1	16/Feb/05
HC431NIV	Flexifit™ 431NIV Full Face Mask (Single & 5 Pack)	Ila	57814	Rule 2 scl 1	23/Feb/05
HC452NIV	Oracle™ 452NIV Oral Mask (Single & 10 Pack)	Ila	57816	Rule 2 scl 1	16/Feb/05
900HC452	OxygenPressurePort Connector	Ila	42601	Rule 2 scl 1	22/Feb/02
VIT1SU	F&P Vitera Full Face Mask – Small U	Ila	57814	Rule 2 scl 1	22/Mar/19
VIT1MU	F&P Vitera Full Face Mask – Medium U	Ila	57814	Rule 2 scl 1	22/Mar/19
VIT1LU	F&P Vitera Full Face Mask – Large U	Ila	57814	Rule 2 scl 1	22/Mar/19
VIT1SSU	F&P Vitera Full Face Mask – Small/Small U	Ila	57814	Rule 2 scl 1	22/Mar/19
VIT1MMU	F&P Vitera Full Face Mask – Medium/Medium U	Ila	57814	Rule 2 scl 1	22/Mar/19
VIT1LLU	F&P Vitera Full Face Mask – Large/Large U	Ila	57814	Rule 2 scl 1	22/Mar/19
VIT1MLU	F&P Vitera Full Face Mask – Medium/Large U	Ila	57814	Rule 2 scl 1	22/Mar/19
VIT1SSL	F&P Vitera Full Face Mask – Small SL	Ila	57814	Rule 2 scl 1	22/Mar/19
VIT1MSL	F&P Vitera Full Face Mask – Medium SL	Ila	57814	Rule 2 scl 1	22/Mar/19
VIT1LSL	F&P Vitera Full Face Mask – Large SL	Ila	57814	Rule 2 scl 1	22/Mar/19
VIT1MLSL	F&P Vitera Full Face Mask – Medium/Large SL	Ila	57814	Rule 2 scl 1	22/Mar/19
VIT1SZ	F&P Vitera Full Face Mask – Small Z	Ila	57814	Rule 2 scl 1	22/Mar/19
VIT1MZ	F&P Vitera Full Face Mask – Medium Z	Ila	57814	Rule 2 scl 1	22/Mar/19
VIT1LZ	F&P Vitera Full Face Mask – Large Z	Ila	57814	Rule 2 scl 1	22/Mar/19
VIT1SSZ	F&P Vitera Full Face Mask – Small/Small Z	Ila	57814	Rule 2 scl 1	22/Mar/19
VIT1MMZ	F&P Vitera Full Face Mask – Medium/Medium Z	Ila	57814	Rule 2 scl 1	22/Mar/19
VIT1LLZ	F&P Vitera Full Face Mask – Large/Large Z	Ila	57814	Rule 2 scl 1	22/Mar/19
VIT1MLZ	F&P Vitera Full Face Mask – Medium/Large Z	Ila	57814	Rule 2 scl 1	22/Mar/19

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GMDN Code	Term
42601	Tube/mask breathing circuit connector, non-sterile, reusable
57814	CPAP/BPAP face mask, reusable
57815	CPAP/BPAP nasal mask, reusable
57816	CPAP/BPAP oral mask