

Fisher & Paykel HEALTHCARE MDR Declaration of Conformity – European Union F&P OSA Masks	Page 1 of 117
	Doc. No: REG – 1317
	Revision: L

English

Device Group as per EC Certificate	R030101 – Ventilation Masks
Intended Purpose as per EC Certificate	Class IIa
Medical Device Family	F&P OSA Masks
Manufacturer	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand SRN NZ-MF-000002556
Authorised Representative	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, France SRN FR-AR-000000294
Notified Body	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Germany NB number 0123
Conformity Assessment	Class IIa, IIb, III: Annex IX – QMS and Annex IX Chap II
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, a discontinued date is added.
EC certificate (MDR)	EC Certificate No. G10 010815 0039
This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer. We, the manufacturer, declare that the stated medical devices: • Are in conformity with Regulation 2017/745 on medical devices (MDR). • Are in conformity with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity, noted below:	
Other Legislation	
1) Directive 2011/65/EU amended by 2015/863 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS). It has been demonstrated that the requirements specified in Article 4 have been met.	
2) Directive 2014/53/EU Radio Equipment (RED). We, the manufacturer, declare under our sole responsibility that the stated medical devices meet the provisions of the Council Directive 2014/53/EU.	

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Approval

Signed for and on behalf of Fisher & Paykel Healthcare Ltd.

Name	Title	Signature	Place and date of issue
Jayanti Karandikar	Senior Regulatory Affairs Specialist		Auckland, NZ 29/Nov/2024

Intended Purpose

The OSA Mask is intended to be used as a patient interface in a non-invasive positive airway pressure (PAP) therapy system to deliver pressurized air from the breathing tube to the patient's upper airway. The patients are intended to be adults weighing ≥ 66 lb (30 kg). The mask is intended to be used for single patient re-use in the home for the treatment of a respiratory condition and multi-patient re-use in a hospital or other clinical setting to investigate the optimal pressure required for the treatment of a respiratory condition.

The specific technical details, contra-indications and warnings are contained in the instructions for use of each device listed on this Declaration

Medical Devices

REF	Trade Name	Basic UDI-DI	EMDN	Common Specifications	Class	Rule	Other Legislation
VIT1SU	F&P Vitera Full Face PAP Therapy Mask - Small U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MU	F&P Vitera Full Face PAP Therapy Mask - Medium U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LU	F&P Vitera Full Face PAP Therapy Mask - Large U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSU	F&P Vitera Full Face PAP Therapy Mask - Small/Small U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MMU	F&P Vitera Full Face PAP Therapy Mask - Medium/Medium U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-

VIT1LLU	F&P Vitera Full Face PAP Therapy Mask - Large/Large U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLU	F&P Vitera Full Face PAP Therapy Mask - Medium/Large U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SZ	F&P Vitera Full Face PAP Therapy Mask - Small Z	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MZ	F&P Vitera Full Face PAP Therapy Mask - Medium Z	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LZ	F&P Vitera Full Face PAP Therapy Mask - Large Z	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSZ	F&P Vitera Full Face PAP Therapy Mask - Small/Small Z	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MMZ	F&P Vitera Full Face PAP Therapy Mask - Medium/Medium Z	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LLZ	F&P Vitera Full Face PAP Therapy Mask - Large/Large Z	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSL	F&P Vitera Full Face PAP Therapy Mask - Small SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-

VIT1MSL	F&P Vitera Full Face PAP Therapy Mask - Medium SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LSL	F&P Vitera Full Face PAP Therapy Mask - Large SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLSL	F&P Vitera Full Face PAP Therapy Mask - Medium/Large SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SU	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Small U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Medium U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LU	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Large U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Wide U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLU	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – SML U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Small Small U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-

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SLN1MMU	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Medium Medium U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Large Large U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SU	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – Small U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MU	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – Medium U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LU	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – Large U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLU	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – SMLU	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSU	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – Small Small U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MMU	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – Medium Medium U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-

SLP1LLU	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – Large Large U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSL	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Small SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MSL	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Medium SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LSL	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Large SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WSL	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Wide SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLSL	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – SML SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSL	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – Small SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MSL	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – Medium SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LSL	F&P Solo™ Pillows (Nasal Pillows PAP	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-

	Therapy Mask) – Large SL						
SLP1SMLSL	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – SML SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SZ	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Small Z	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MZ	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Medium Z	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LZ	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Large Z	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WZ	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Wide Z	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLZ	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – SMLZ	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SZ	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – Small Z	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MZ	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – Medium Z	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-

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SLP1LZ	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – Large Z	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLZ	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) –SMLZ	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SU	F&P Nova Micro™ (Nasal Pillows PAP Therapy Mask) – Small U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MU	F&P Nova Micro™ (Nasal Pillows PAP Therapy Mask) – Medium U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LU	F&P Nova Micro™ (Nasal Pillows PAP Therapy Mask) – Large U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLU	F&P Nova Micro™ (Nasal Pillows PAP Therapy Mask) – Fit Pack S/M/L U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSU	F&P Nova Micro™ (Nasal Pillows PAP Therapy Mask) – Small/Small U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MMU	F&P Nova Micro™ (Nasal Pillows PAP	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

	Therapy Mask) – Medium/Medium U						
NVP1LLU	F&P Nova Micro™ (Nasal Pillows PAP Therapy Mask) – Large/Large U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSL	F&P Nova Micro™ (Nasal Pillows PAP Therapy Mask) – Small SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MSL	F&P Nova Micro™ (Nasal Pillows PAP Therapy Mask) – Medium SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LSL	F&P Nova Micro™ (Nasal Pillows PAP Therapy Mask) – Large SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLSL	F&P Nova Micro™ (Nasal Pillows PAP Therapy Mask) – Fit Pack S/M/L SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SZ	F&P Nova Micro™ (Nasal Pillows PAP Therapy Mask) – Small Z	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MZ	F&P Nova Micro™ (Nasal Pillows PAP Therapy Mask) – Medium Z	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

NVP1LZ	F&P Nova Micro™ (Nasal Pillows PAP Therapy Mask) – Large Z	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLZ	F&P Nova Micro™ (Nasal Pillows PAP Therapy Mask) – Fit Pack S/M/L Z	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1SU	F&P Nova™ Nasal (Nasal PAP Therapy Mask) – Small U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1MU	F&P Nova™ Nasal (Nasal PAP Therapy Mask) – Medium U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1LU	F&P Nova™ Nasal (Nasal PAP Therapy Mask) – Large U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1SMLU	F&P Nova™ Nasal (Nasal PAP Therapy Mask) – Fit Pack S/M/L U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1SSU	F&P Nova™ Nasal (Nasal PAP Therapy Mask) – Small/Small U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1MMU	F&P Nova™ Nasal (Nasal PAP Therapy Mask) – Medium/Medium U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

NVN1LLU	F&P Nova™ Nasal (Nasal PAP Therapy Mask) – Large/Large U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1SSL	F&P Nova™ Nasal (Nasal PAP Therapy Mask) – Small SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1MSL	F&P Nova™ Nasal (Nasal PAP Therapy Mask) – Medium SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1LSL	F&P Nova™ Nasal (Nasal PAP Therapy Mask) – Large SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1SMLSL	F&P Nova™ Nasal (Nasal PAP Therapy Mask) – Fit Pack S/M/L SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1SZ	F&P Nova™ Nasal (Nasal PAP Therapy Mask) – Small Z	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1MZ	F&P Nova™ Nasal (Nasal PAP Therapy Mask) – Medium Z	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1LZ	F&P Nova™ Nasal (Nasal PAP Therapy Mask) – Large Z	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1SMLZ	F&P Nova™ Nasal (Nasal PAP Therapy Mask) – Fit Pack S/M/L Z	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

EMDN Code	Description
R0301010201	CPAP Masks

Standards Compliance MDR

Standard Reference	Standard Title
ISO 5356-1:2015/ EN ISO 5356-1:2015	Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and Sockets
ISO 10993-1:2018* / EN ISO 10993-1:2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ISO 18562-1:2017*/ EN ISO 18562-1:2020	Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process
EN ISO 17510:2020	Sleep apnoea breathing therapy. Sleep apnoea breathing therapy equipment
ISO 17664-1:2017*/ EN ISO 17664-1:2021	Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices
EN ISO 15223-1:2016*	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied
EN ISO 20417: 2021	Medical devices- Information to be supplied by the manufacturer.

* Standard applied by Vitera.

Materials Compliance – Applicable to all products

Reference	Description
REACH 1907:2006	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency
POP 2019/1021	Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (recast)

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Bulgarian български

Група на изделието според ЕО сертификата	R030101 – вентилационни маски;
Предназначение според ЕО сертификата	Клас IIa
Семейство на медицинско изделие	F&P OSA Masks
Производител	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Нова Зеландия SRN NZ-MF-000002556
Упълномощен представител	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Vilbobon-sur-Yvette, 91946 Courtaboeuf Cedex, Франция SRN FR-AR-000000294
Нотифициран орган	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Германия NB номер 0123
Оценка на съответствието	Клас IIa, IIb, III: Приложение IX – СУК и Приложение IX, Глава II
Валидност на настоящата декларация	Настоящата Декларация за съответствие за всеки изброен модел е валидна от началната дата, записана до модела, и докато моделът е посочен в ДС. Когато даден модел вече не е обхванат от ДС, се добавя дата на прекратяване.
ЕО сертификат (MDR)	ЕО сертификат № G10 010815 0039

Настоящата Декларация за съответствие на ЕС се издава под изключителната отговорност на производителя.

Ние, производителят, декларираме, че посочените медицински изделия:

- Са в съответствие с Регламент 2017/745 за медицинските изделия (MDR).
- Са в съответствие с всяко друго приложимо законодателство на Съюза, което предвижда издаването на декларация за съответствие на ЕС, отбелязано по-долу:

Друго законода-телство

1) Директива 2011/65/ЕС с изменение от 2015/863 относно ограничението за употребата на определени опасни вещества в електрическото и електронното оборудване (RoHS).
Доказано е, че изискванията, посочени в член 4, са изпълнени.

2) Директива 2014/53/ЕС относно радиосъоръженията (RED).
Ние, в качеството си на производител, декларираме на наша изключителна отговорност, че посочените медицински изделия отговарят на разпоредбите на Директива 2014/53/ЕС на Съвета.

Медицински изделия

РЕФ.	Търговско наименование	Базов UDI-DI	EMDN	Общи спецификации	Клас	Правило	Друго законодателство
VIT1SU	Терапевтична PAP маска за цяло лице F&P Vitera™ – малка U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MU	Терапевтична PAP маска за цяло лице F&P Vitera™ – средна U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LU	Терапевтична PAP маска за цяло лице F&P Vitera™ – голяма U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSU	Терапевтична PAP маска за цяло лице F&P Vitera™ – малка/малка U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MMU	Терапевтична PAP маска за цяло лице F&P Vitera™ – средна/средна U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LLU	Терапевтична PAP маска за цяло лице F&P Vitera™ – голяма/голяма U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLU	Терапевтична PAP маска за цяло лице F&P Vitera™ – средна/голяма U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-

Fisher & Paykel HEALTHCARE MDR izjava o sukladnosti – Europska unija F&P OSA Masks	Stranica 17 od 117
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Croatian Hrvatski

Grupa proizvoda prema potvrdi EZ-a	R030101 – maske za ventilaciju;
Namjena prema potvrdi EZ-a	Klasa IIa
Asortiman medicinskih proizvoda	F&P OSA Masks
Proizvođač	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Novi Zeland SRN NZ-MF-000002556
Ovlašteni zastupnik	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Francuska SRN FR-AR-000000294
Ovlašteno tijelo	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Njemačka NB broj 0123
Procjena sukladnosti	Klasa IIa, IIb, III: Prilog IX – QMS i Prilog IX Poglavlje II
Valjanost ove izjave	Ova Izjava o sukladnosti, za svaki navedeni model, vrijedi od datuma početka zabilježenog na modelu i sve dok je model naveden na Izjavi o sukladnosti. Kada model više nije obuhvaćen Izjavom o sukladnosti, dodaje se datum obustave.
„EZ” potvrda (MDR)	„EZ” potvrda br. G10 010815 0039

Ova EU izjava o sukladnosti izdaje se isključivo na odgovornost proizvođača.

Mi, proizvođač izjavljujemo da su navedeni medicinski proizvodi:

- sukladni s Uredbom 2017/745 o medicinskim proizvodima,
- sukladni s drugim relevantnim zakonima Unije kojim se predviđa izdavanje EU izjave o sukladnosti, kako je navedeno u nastavku:

Ostali zakoni

1)	Direktiva 2011/65/EU, izmijenjena i dopunjena direktivom 2015/863, o ograničenju uporabe određenih opasnih tvari u električnoj i elektroničkoj opremi (RoHS). Pokazano je da su ispunjeni zahtjevi navedeni u članku 4.
2)	Direktiva 2014/53/EU o radijskoj opremi (RED). Mi, proizvođač, izjavljujemo pod vlastitom odgovornošću da navedeni medicinski proizvodi ispunjavaju odredbe Direktive Vijeća 2014/53/EU (RED).

Medicinski proizvodi

REF. BR.	Trgovački naziv	Osnovni UDI-DI	EMDN	Zajedničke specifikacije	Klasa	Pravilo	Ostali zakoni
VIT1SU	Maska za cijelo lice F&P Vitera™ za liječenje pozitivnim tlakom zraka u dišnim putevima (PAP) – mala U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MU	Maska za cijelo lice F&P Vitera™ za liječenje pozitivnim tlakom zraka u dišnim putevima (PAP) – srednja U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LU	Maska za cijelo lice F&P Vitera™ za liječenje pozitivnim tlakom zraka u dišnim putevima (PAP) – velika U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSU	Maska za cijelo lice F&P Vitera™ za liječenje pozitivnim tlakom zraka u dišnim putevima (PAP) – mala/mala U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MMU	Maska za cijelo lice F&P Vitera™ za liječenje pozitivnim tlakom zraka u dišnim putevima (PAP) – srednja/srednja U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LLU	Maska za cijelo lice F&P Vitera™ za liječenje	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-

REF. BR.	Trgovački naziv	Osnovni UDI-DI	EMDN	Zajedničke specifikacije	Klasa	Pravilo	Ostali zakoni
	pozitivnim tlakom zraka u dišnim putevima (PAP) – velika/velika U						
VIT1MLU	Maska za cijelo lice F&P Vitera™ za liječenje pozitivnim tlakom zraka u dišnim putevima (PAP) – srednja/velika U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-

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Czech Česky

Skupina zařízení podle osvědčení ES	R030101 – Dýchací masky
Zamýšlený účel podle osvědčení ES	Třída II
Skupina zdravotnických prostředků	F&P OSA Masks
Výrobce	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Nový Zéland SRN NZ-MF-000002556
Zplnomocněný zástupce	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Francie SRN FR-AR-000000294
Oznámený subjekt	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Německo Číslo subjektu 0123
Posuzování shody	Třída IIa, IIb, III: Příloha IX – SZJ a Příloha IX kapitola II
Platnost tohoto prohlášení	Toto prohlášení o shodě platí pro každý uvedený model od data zahájení stanoveného podle modelu a po dobu, po kterou je model uveden v prohlášení o shodě. Pokud se prohlášení o shodě na model již nevztahuje, přidá se datum ukončení.
Certifikát ES (MDR)	Certifikát ES č. G10 010815 0039

Toto EU prohlášení o shodě se vydává na výhradní odpovědnost výrobce.

My, výrobce, prohlašujeme, že uvedené zdravotnické prostředky:

- Jsou v souladu s nařízením 2017/745 o zdravotnických prostředcích (MDR).
- Jsou v souladu s dalšími, příslušnými právními předpisy Unie, které upravují vydávání EU prohlášení o shodě, a které jsou uvedeny níže:

Ostatní právní předpisy

- 1) Směrnice 2011/65/EU ve znění 2015/863 o omezení používání některých nebezpečných látek v elektrických a elektronických zařízeních (RoHS).
Bylo prokázáno, že byly splněny požadavky uvedené v článku 4.
- 2) Směrnice 2014/53/EU o rádiových zařízeních (RED).
My, výrobce, na vlastní odpovědnost prohlašujeme, že uvedené zdravotnické prostředky splňují ustanovení směrnice Rady 2014/53/EU.

Zdravotnické prostředky

REF	Obchodní název	Základní UDI-DI	EMDN	Společné specifikace	Třída	Pravidlo	Ostatní právní předpisy
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N/A

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Danish Dansk

Enhedsgruppe i henhold til EF-certifikat	R030101 – Respirationsmasker
Formål ifølge EF-certifikat	Klasse IIa
Gruppe af medicinsk udstyr	F&P OSA Masks
Producent	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand SRN NZ-MF-000002556
Autoriseret repræsentant	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Frankrig SRN FR-AR-000000294
Underrettede organ	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Tyskland NB-nummer 0123
Overensstemmelses-vurdering	Klasse IIa, IIb, III: Bilag IX – QMS og bilag IX, kapitel II
Denne erklærings gyldighed	Denne overensstemmelseserklæring, for hver af de anførte modeller, er gyldig fra den startdato, der er registreret i forhold til modellen, og så længe modellen er anført på overensstemmelseserklæringen. Når en model ikke længere er dækket af overensstemmelseserklæringen, tilføjes en udgået-dato.
EF-certifikat (MDR)	EF-certifikat nr. G10 010815 0039

Denne EU-overensstemmelseserklæring er udstedt udelukkende under producentens ansvar.

Vi, producenten, erklærer hermed, at det angivne medicinske udstyr:

- Er i overensstemmelse med forordning 2017/745 om medicinsk udstyr (MDR).
- Er i overensstemmelse med enhver anden form for relevant EU-lovgivning, der indeholder bestemmelser om udstedelse af en EU-overensstemmelseserklæring, som anført nedenfor:

Anden lovgivning

- 1) Direktiv 2011/65/EU ændret ved 2015/863 om begrænsning af anvendelsen af visse farlige stoffer i elektrisk og elektronisk udstyr (RoHS).
Det er påvist, at de præciserede krav i artikel 4 er opfyldt.
- 2) Direktiv 2014/53/EU Radioudstyr (RED).
Vi, producenten, erklærer på eget ansvar, at det angivne medicinske udstyr opfylder bestemmelserne i Rådets direktiv 2014/53/EU.

Medicinsk udstyr

REF	Handelsnavn	Grundlæggende UDI-DI	EMDN	Almindelige specifikationer	Klasse	Regel	Anden lovgivning
VIT1SU	F&P Vitera™ Full Face PAP-terapi maske – Lille U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MU	F&P Vitera™ Full Face PAP-terapi maske – Medium U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LU	F&P Vitera™ Full Face PAP-terapi maske – Stor U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSU	F&P Vitera™ Full Face PAP-terapi maske – Lille/Lille U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MMU	F&P Vitera™ Full Face PAP-terapi maske – Medium/Medium U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LLU	F&P Vitera™ Full Face PAP-terapi maske – Stor/Stor U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLU	F&P Vitera™ Full Face PAP-terapi maske – Medium/Stor U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSL	F&P Vitera™ Full Face PAP-terapi maske – Lille SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MSL	F&P Vitera™ Full Face PAP-terapi maske – Medium SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LSL	F&P Vitera™ Full Face PAP-terapi maske – Stor SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLSL	F&P Vitera™ Full Face PAP-terapi maske – Medium/Stor SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-

SLN1SU	F&P Solo™ Nasal (næsemaske til PAP- behandling) – Small U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (næsemaske til PAP- behandling) – Medium U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LU	F&P Solo™ Nasal (næsemaske til PAP- behandling) – Large U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (næsemaske til PAP- behandling) – Wide U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLU	F&P Solo™ Nasal (næsemaske til PAP- behandling) – SML U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (næsemaske til PAP- behandling) – Small Small U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MMU	F&P Solo™ Nasal (næsemaske til PAP- behandling) – Medium Medium U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (næsemaske til PAP- behandling) – Large Large U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SU	F&P Solo™ Pillows (maske med næsepuder til PAP- behandling) – Small U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MU	F&P Solo™ Pillows (maske med næsepuder til PAP- behandling) – Medium U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-

SLP1LU	F&P Solo™ Pillows (maske med næsepuder til PAP-behandling) – Large U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLU	F&P Solo™ Pillows (maske med næsepuder til PAP-behandling) – SML U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSU	F&P Solo™ Pillows (maske med næsepuder til PAP-behandling) – Small Small U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MMU	F&P Solo™ Pillows (maske med næsepuder til PAP-behandling) – Medium Medium U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LLU	F&P Solo™ Pillows (maske med næsepuder til PAP-behandling) – Large Large U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSL	F&P Solo™ Nasal (næsemaske til PAP-behandling) – Small SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MSL	F&P Solo™ Nasal (næsemaske til PAP-behandling) – Medium SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LSL	F&P Solo™ Nasal (næsemaske til PAP-behandling) – Large SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WSL	F&P Solo™ Nasal (næsemaske til PAP-behandling) – Wide SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLSL	F&P Solo™ Nasal (næsemaske til PAP-behandling) – SML SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-

SLP1SSL	F&P Solo™ Pillows (maske med næsepuder til PAP-behandling) – Small SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MSL	F&P Solo™ Pillows (maske med næsepuder til PAP-behandling) – Medium SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LSL	F&P Solo™ Pillows (maske med næsepuder til PAP-behandling) – Large SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLSL	F&P Solo™ Pillows (maske med næsepuder til PAP-behandling) – SML SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SU	F&P Nova™ Micro (næsepuder til maske til PAP-behandling) – Lille U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MU	F&P Nova™ Micro (næsepuder til maske til PAP-behandling) – Medium U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LU	F&P Nova™ Micro (næsepuder til maske til PAP-behandling) – Stor U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLU	F&P Nova™ Micro (næsepuder til maske til PAP-behandling) – Tilpasningspakke S/M/L U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSU	F&P Nova™ Micro (næsepuder til maske til PAP-behandling) – Lille/lille U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MMU	F&P Nova™ Micro (næsepuder til maske til	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

	PAP-behandling) – Medium/medium U						
NVP1LLU	F&P Nova™ Micro (næsepuder til maske til PAP-behandling) – Stor/stor U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSL	F&P Nova™ Micro (næsepuder til maske til PAP-behandling) – Lille SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MSL	F&P Nova™ Micro (næsepuder til maske til PAP-behandling) – Medium SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LSL	F&P Nova™ Micro (næsepuder til maske til PAP-behandling) – Stor SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLSL	F&P Nova™ Micro (næsepuder til maske til PAP-behandling) – Tilpasningspakke S/M/L SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

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Dutch Nederlands

Apparaatgroep volgens EG-certificaat	R030101 - Beademingsmaskers
Beoogd doel volgens EG-certificaat	Klasse IIa
Familie van medische hulpmiddelen	F&P OSA Masks
Fabrikant	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Nieuw-Zeeland SRN NZ-MF-000002556
Gemachtigde vertegenwoordiger	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Frankrijk SRN FR-AR-000000294
Aangemelde instantie	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Duitsland NB-nummer 0123
Beoordeling conformiteit	Klasse IIa, IIb, III: Bijlage IX - QMS en bijlage IX, hoofdstuk II
Geldigheid van deze verklaring	Deze Conformiteitsverklaring is voor elk model in de lijst geldig vanaf de datum waarop het model in gebruik is genomen en zolang het model in de DoC is opgenomen. Wanneer een model niet langer onder de DoC valt, wordt een datum van stopzetting toegevoegd.
EG-certificaat (MDR)	EG-certificaat nr. G10 010815 0039

Deze EU-conformiteitsverklaring wordt afgegeven onder de uitsluitende verantwoordelijkheid van de fabrikant.

Wij, de fabrikant, verklaren dat de vermelde medische hulpmiddelen:

- In overeenstemming zijn met Verordening 2017/745 betreffende medische hulpmiddelen (MDR).
- In overeenstemming zijn met alle andere relevante wetgeving van de Unie die voorziet in de afgifte van een EU-conformiteitsverklaring, zoals hieronder vermeld:

Andere wetgeving

- 1) Richtlijn 2011/65/EU, gewijzigd door 2015/863 betreffende beperking van het gebruik van bepaalde gevaarlijke stoffen in elektrische en elektronische apparatuur (RoHS). Er werd aangetoond dat aan de eisen van artikel 4 is voldaan.
- 2) Richtlijn 2014/53/EU betreffende radioapparatuur (RED).
Wij, de fabrikant, verklaren onder onze uitsluitende verantwoordelijkheid dat de vermelde medische hulpmiddelen voldoen aan de bepalingen van Richtlijn 2014/53/EU van de Raad.

Medische hulpmiddelen

REF	Handelsnaam	Basis UDI-DI	EMDN	Gemeenschap pelijke specificaties	Klasse	Regel	Andere wetgeving
VIT1SU	F&P Vitera™ Full Face-masker voor PAP-therapie, Small U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MU	F&P Vitera™ Full Face-masker voor PAP-therapie, Medium U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LU	F&P Vitera™ Full Face-masker voor PAP-therapie, Large U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSU	F&P Vitera™ Full Face-masker voor PAP-therapie, Small/Small U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MMU	F&P Vitera™ Full Face-masker voor PAP-therapie, Medium/Medium U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LLU	F&P Vitera™ Full Face-masker voor PAP-therapie, Large/Large U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLU	F&P Vitera™ Full Face-masker voor PAP-therapie, Medium/Large U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSL	F&P Vitera™ Full Face-masker voor PAP-therapie, Small SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MSL	F&P Vitera™ Full Face-masker voor PAP-therapie, Medium SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-

VIT1LSL	F&P Vitera™ Full Face-masker voor PAP-therapie, Large SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLSL	F&P Vitera™ Full Face-masker voor PAP-therapie, Medium/Large SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SU	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Small U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Medium U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LU	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Large U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Wide U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLU	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – SML U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Small Small U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MMU	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Medium Medium U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Large Large U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSL	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Small SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-

SLN1MSL	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Medium SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LSL	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Large SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WSL	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Wide SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLSL	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – SML SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SU	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – Small U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MU	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – Medium U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LU	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – Large U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLU	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – SML U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSU	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – Small Small U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MMU	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – Medium Medium U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-

SLP1LLU	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – Large Large U	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSL	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – Small SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MSL	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – Medium SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LSL	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – Large SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLSL	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – SML SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SU	F&P Nova™ Micro (intranasaal PAP-therapiemasker) – Small U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MU	F&P Nova™ Micro (intranasaal PAP-therapiemasker) – Medium U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LU	F&P Nova™ Micro (intranasaal PAP-therapiemasker) – Large U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLU	F&P Nova™ Micro (intranasaal PAP-therapiemasker) - Fit Pack S/M/L U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSU	F&P Nova™ Micro (intranasaal PAP-	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

	therapiemasker) – Small/Small U						
NVP1MMU	F&P Nova™ Micro (intranasaal PAP- therapiemasker) – Medium/Medium U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LLU	F&P Nova™ Micro (intranasaal PAP- therapiemasker) – Large/Large U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSL	F&P Nova™ Micro (intranasaal PAP- therapiemasker) – Small SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MSL	F&P Nova™ Micro (intranasaal PAP- therapiemasker) – Medium SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LSL	F&P Nova™ Micro (intranasaal PAP- therapiemasker) – Large SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLSL	F&P Nova™ Micro (intranasaal PAP- therapiemasker) - Fit Pack S/M/L SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

Fisher & Paykel HEALTHCARE MDR-i vastavusdeklaratsioon – Euroopa Liit F&P OSA Masks	Lehekülg 34 / 117
	Dokumendi nr: REG – 1317
	Versioon: L

Estonian Eesti

Seadmerühm vastavalt EÜ sertifikaadile	R030101 – ventilatsioonimaskid;
Sihtotstarve vastavalt EÜ sertifikaadile	Ila klass
Meditsiiniseadmete perekond	F&P OSA Masks
Tootja	Fisher & Paykel Healthcare Ltd. 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Uus-Meremaa SRN NZ-MF-000002556
Volitatud esindaja	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Prantsusmaa SRN FR-AR-000000294
Teavitatud asutus	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Saksamaa NB nr 0123
Vastavushindamine	Ila, IIb, III klass: IX lisa – QMS ja IX lisa II peatükk
Käesoleva deklaratsiooni kehtivus	Käesolev vastavusdeklaratsioon kehtib iga loetletud mudeli puhul alates mudeli kohta registreeritud alguskuupäevast ja seni, kuni mudel on vastavusdeklaratsioonis loetletud. Kui vastavusdeklaratsioon ei hõlma enam mudelit, siis lisatakse katkestamise kuupäev.
EÜ sertifikaat (MDR)	EÜ sertifikaat nr G10 010815 0039

Käesolev ELi vastavusdeklaratsioon antakse välja tootja ainuvastutusel.

Meie, tootja, kinnitame, et nimetatud meditsiiniseadmed:

- vastavad meditsiiniseadmeid käsitlevale määrusele 2017/745.
- on kooskõlas muude asjakohaste liidu õigusaktidega, millega nähakse ette ELi vastavusdeklaratsiooni väljaandmine, nagu on märgitud allpool:

Muud õigusaktid

1)	Direktiivi 2011/65/EL on muudetud direktiiviga 2015/863 teatavate ohtlike ainete kasutamise piiramise kohta elektri- ja elektroonikaseadmetes. On tõendatud, et artiklis 4 sätestatud nõuded on täidetud.
2)	Direktiiv 2014/53/EL Raadioseadmed. Meie, tootja, kinnitame oma ainuvastutusel, et nimetatud meditsiiniseadmed vastavad nõukogu direktiivi 2014/53/EL.

Meditsiiniseadmed

REF	Kaubanimi	Põhiline UDI-DI	EMDN	Ühised spetsifikatsioonid	Klass	Reegel	Muud õigusaktid
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N/A

Fisher & Paykel HEALTHCARE MDR-vaatimustenmukaisuusvakuutus – Euroopan unioni F&P OSA Masks	Sivu 36/117
	Asiakirjan nro: REG – 1317
	Versio: L

Finnish Suomi

Laiteryhmä EY-todistuksen mukaan	R030101 – ventilaatiomaskit
Käyttötarkoitus EY-todistuksen mukaan	Luokka IIa
Lääkinnällisten laitteiden valikoima	F&P OSA Masks
Valmistaja	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand SRN NZ-MF-000002556
Valtuutettu edustaja	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, France SRN FR-AR-000000294
Ilmoitettu laitos	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Saksa Ilmoitetun laitoksen nro 0123
Vaatimustenmukaisuuden arviointi	Luokka IIa, IIb, III: Liite IX – QMS ja liitteen IX luku II
Tämän vakuutuksen voimassaolo	Tämä vaatimustenmukaisuusvakuutus on voimassa kunkin luetellun mallin osalta malliin kirjatusta aloituspäivästä alkane ja niin kauan kuin malli on ilmoitettu vaatimustenmukaisuusvakuutuksessa. Kun asiakirja ei enää koske mallia, lisätään lopetuspäivämäärä.
EY-todistus (MDR)	EY-todistuksen nro G10 010815 0039

Tämä EU-vaatimustenmukaisuusvakuutus annetaan yksinomaan valmistajan vastuulla.

Me, valmistaja, vakuutamme, että ilmoitetut lääkkinnälliset laitteet:

- ovat lääkkinnällisistä laitteista annetun asetuksen 2017/745 mukaisia
- noudattavat unionin muita asianmukaisia lakeja, joissa säädetään EUvaatimustenmukaisuuslausekkeen julkaisemisesta, katso alla:

Muu lainsäädäntö

1)	Direktiivi 2011/65/EU, muokattu 2015/863, joka koskee tiettyjen vaarallisten aineiden käyttöä sähköisissä ja elektronisissa laitteissa (RoHS). On osoitettu, että artikkelissa 4 täsmennetyt vaatimukset täyttyvät.
2)	Radiolaitedirektiivi 2014/53/EU (RED). Me, valmistaja, vakuutamme omalla vastuullamme, että ilmoitetut lääkkinnälliset laitteet täyttävät neuvoston direktiivin 2014/53/EU vaatimukset.

Lääkinnälliset laitteet

VIITE	Kauppanimi	Perus-UDI-DI	EMDN	Yleiset tekniset tiedot	Luokka	Sääntö	Muu lainsäädäntö
VIT1SU	F&P Vitera™ - kokokasvomaski ylipainehoitoon – pieni U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MU	F&P Vitera™ - kokokasvomaski ylipainehoitoon – keskikokoinen U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LU	F&P Vitera™ - kokokasvomaski ylipainehoitoon – suuri U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSU	F&P Vitera™ - kokokasvomaski ylipainehoitoon – pieni / pieni U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MMU	F&P Vitera™ - kokokasvomaski ylipainehoitoon – keskikokoinen / keskikokoinen U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LLU	F&P Vitera™ - kokokasvomaski ylipainehoitoon – suuri / suuri U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLU	F&P Vitera™ - kokokasvomaski ylipainehoitoon – keskikokoinen / suuri U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-

SLN1SU	(fi) F&P Solo™ Nasal (nenämaski ylipainehoitoon) – pieni U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MU	(fi) F&P Solo™ Nasal (nenämaski ylipainehoitoon) – keskikokoinen U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LU	(fi) F&P Solo™ Nasal (nenämaski ylipainehoitoon) – suuri U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WU	(fi) F&P Solo™ Nasal (nenämaski ylipainehoitoon) – leveä U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLU	(fi) F&P Solo™ Nasal (nenämaski ylipainehoitoon) – SML U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSU	(fi) F&P Solo™ Nasal (nenämaski ylipainehoitoon) – pieni, pieni U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MMU	(fi) F&P Solo™ Nasal (nenämaski ylipainehoitoon) – keskikokoinen, keskikokoinen U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LLU	(fi) F&P Solo™ Nasal (nenämaski ylipainehoitoon) – suuri, suuri U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-

SLP1SU	(fi) F&P Solo™ Pillows (nenätyyny ylipainehoitomaskiin) – pieni U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MU	(fi) F&P Solo™ Pillows (nenätyyny ylipainehoitomaskiin) – keskikokoinen U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LU	(fi) F&P Solo™ Pillows (nenätyyny ylipainehoitomaskiin) – suuri U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLU	(fi) F&P Solo™ Pillows (nenätyyny ylipainehoitomaskiin) – SML U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSU	(fi) F&P Solo™ Pillows (nenätyyny ylipainehoitomaskiin) – pieni, pieni U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MMU	(fi) F&P Solo™ Pillows (nenätyyny ylipainehoitomaskiin) – keskikokoinen, keskikokoinen U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LLU	(fi) F&P Solo™ Pillows (nenätyyny ylipainehoitomaskiin) – suuri, suuri U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSL	(fi) F&P Solo™ Nasal (nenämaski ylipainehoitoon) – pieni SL	94200124SOLONMSL017D	R0301010201	-	Ila	Rule 2 Scl 1	-

SLN1MSL	(fi) F&P Solo™ Nasal (nenämaski ylipainehoitoon) – keskikokoinen SL	94200124SOLOONMSL017D	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LSL	(fi) F&P Solo™ Nasal (nenämaski ylipainehoitoon) – suuri SL	94200124SOLOONMSL017D	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WSL	(fi) F&P Solo™ Nasal (nenämaski ylipainehoitoon) – leveä SL	94200124SOLOONMSL017D	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLSL	(fi) F&P Solo™ Nasal (nenämaski ylipainehoitoon) – SML SL	94200124SOLOONMSL017D	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSL	(fi) F&P Solo™ Pillows (nenätyyny ylipainehoitomaskiin) – pieni SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MSL	(fi) F&P Solo™ Pillows (nenätyyny ylipainehoitomaskiin) – keskikokoinen SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LSL	(fi) F&P Solo™ Pillows (nenätyyny ylipainehoitomaskiin) – suuri SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLSL	(fi) F&P Solo™ Pillows (nenätyyny ylipainehoitomaskiin) – SML SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-

NVP1SU	F&P Nova™ Micro (nenämaski CPAP- hoitoon) – pieni U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MU	F&P Nova™ Micro (nenämaski CPAP- hoitoon) – keskikokoinen U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LU	F&P Nova™ Micro (nenämaski CPAP- hoitoon) – suuri U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLU	F&P Nova™ Micro (nenämaski CPAP- hoitoon) – monipakkaus S/M/L U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSU	F&P Nova™ Micro (nenämaski CPAP- hoitoon) – pieni / pieni U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MMU	F&P Nova™ Micro (nenämaski CPAP- hoitoon) – keskikokoinen / keskikokoinen U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LLU	F&P Nova™ Micro (nenämaski CPAP- hoitoon) – suuri / suuri U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSL	F&P Nova™ Micro (nenämaski CPAP- hoitoon) – pieni SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MSL	F&P Nova™ Micro (nenämaski CPAP- hoitoon) – keskikokoinen SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

NVP1LSL	F&P Nova™ Micro (nenämaski CPAP- hoitoon) – suuri SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLSL	F&P Nova™ Micro (nenämaski CPAP- hoitoon) – monipakkaus S/M/L SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

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French Français

Groupe de dispositifs selon le certificat CE	R030101 – Masques de ventilation
Objectif prévu selon le certificat CE	Classe IIa
Gamme de dispositifs médicaux	F&P OSA Masks
Fabricant	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Nouvelle-Zélande SRN NZ-MF-000002556
Représentant autorisé	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, France SRN FR-AR-000000294
Organisme notifié	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Allemagne Numéro NB 0123
Évaluation de la conformité	Classe IIa, IIb, III : Annexe IX - QMS et Annexe IX Chap. II
Validité de cette déclaration	Cette déclaration de conformité, pour chaque modèle répertorié, est valable à partir de la date de début enregistrée par rapport au modèle et aussi longtemps que le modèle est répertorié sur la DC. Lorsqu'un modèle n'est plus couvert par la DC, une date d'arrêt est ajoutée.
Certificat CE (MDR)	Certificat CE n° G10 010815 0039

Cette déclaration de conformité UE est émise sous la seule responsabilité du fabricant.

Nous, le fabricant, déclarons que les dispositifs médicaux mentionnés:

- Sont conformes au règlement 2017/745 sur les dispositifs médicaux (RDM).
- Sont conformes à toute autre législation pertinente de l'UE prévoyant la délivrance d'une déclaration de conformité UE, indiquée ci-dessous:

Autre législation

1)	Directive 2011/65/UE modifiée par 2015/863 sur la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques (RoHS). Il a été démontré que les exigences spécifiées à l'article 4 ont été satisfaites.
2)	Directive relative aux équipements radioélectriques (RED) 2014/53/UE. Nous, le fabricant, déclarons sous notre seule responsabilité que les dispositifs médicaux mentionnés satisfont aux dispositions de la directive du Conseil 2014/53/UE.

Dispositifs médicaux

RÉF.	Marque de commerce	UDI-DI de base	EMDN	Spécifications communes	Classe	Réglementation	Autre législation
VIT1SU	Masque facial pour traitement par PPC F&P Vitera™ – Petit U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MU	Masque facial pour traitement par PPC F&P Vitera™ – Moyen U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LU	Masque facial pour traitement par PPC F&P Vitera™ – Grand U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSU	Masque facial pour traitement par PPC F&P Vitera™ – Petit/Petit U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MMU	Masque facial pour traitement par PPC F&P Vitera™ – Moyen/Moyen U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LLU	Masque facial pour traitement par PPC F&P Vitera™ – Grand/Grand U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLU	Masque facial pour traitement par PPC F&P Vitera™ – Moyen/Grand U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSL	Masque facial pour traitement par PPC F&P Vitera™ – Petit SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-

VIT1MSL	Masque facial pour traitement par PPC F&P Vitera™ – Moyen SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LSL	Masque facial pour traitement par PPC F&P Vitera™ – Grand SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLSL	Masque facial pour traitement par PPC F&P Vitera™ – Moyen/Grand SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SU	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Petit U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Moyen U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LU	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Grand U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Large U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLU	F&P Solo™ Nasal (masque nasal de traitement par PPC) – SML U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Petit Petit U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-

SLN1MMU	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Moyen Moyen U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Grand Grand U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SU	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – Petit U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MU	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – Moyen U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LU	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – Grand U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLU	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – SML U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSU	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – Petit Petit U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MMU	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – Moyen Moyen U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LLU	F&P Solo™ Pillows (masque narinaire de	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-

	traitement par PPC) – Grand Grand U						
SLN1SSL	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Petit SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MSL	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Moyen SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LSL	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Grand SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WSL	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Large SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLSL	F&P Solo™ Nasal (masque nasal de traitement par PPC) – SML SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSL	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – Petit SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MSL	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – Moyen SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LSL	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – Grand SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-

SLP1SMLSL	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – SML SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SU	F&P Nova™ Micro (masque nasal de traitement par PPC avec coussins) – Petit U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MU	F&P Nova™ Micro (masque nasal de traitement par PPC avec coussins) – Moyen U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LU	F&P Nova™ Micro (masque nasal de traitement par PPC avec coussins) – Grand U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLU	F&P Nova™ Micro (masque nasal de traitement par PPC avec coussins) – Paquet 3 tailles S/M/L U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSU	F&P Nova™ Micro (masque nasal de traitement par PPC avec coussins) – Petit/Petit U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MMU	F&P Nova™ Micro (masque nasal de traitement par PPC avec coussins) – Moyen/Moyen U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LLU	F&P Nova™ Micro (masque nasal de traitement par PPC avec	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

	coussins) – Grand/Grand U						
NVP1SSL	F&P Nova™ Micro (masque nasal de traitement par PPC avec coussins) – Petit SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MSL	F&P Nova™ Micro (masque nasal de traitement par PPC avec coussins) – Moyen SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LSL	F&P Nova™ Micro (masque nasal de traitement par PPC avec coussins) – Grand SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLSL	F&P Nova™ Micro (masque nasal de traitement par PPC avec coussins) – Paquet 3 tailles S/M/L SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1SU	F&P Nova™ Nasal (masque nasal de traitement par PPC) – Petit U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1MU	F&P Nova™ Nasal (masque nasal de traitement par PPC) – Moyen U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1LU	F&P Nova™ Nasal (masque nasal de traitement par PPC) – Grand U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1SMLU	F&P Nova™ Nasal (masque nasal de	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

	traitement par PPC) – Paquet 3 tailles S/M/L U						
NVN1SSU	F&P Nova™ Nasal (masque nasal de traitement par PPC) – Petit/Petit U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1MMU	F&P Nova™ Nasal (masque nasal de traitement par PPC) – Moyen/Moyen U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1LLU	F&P Nova™ Nasal (masque nasal de traitement par PPC) – Grand/Grand U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1SSL	F&P Nova™ Nasal (masque nasal de traitement par PPC) – Petit SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1MSL	F&P Nova™ Nasal (masque nasal de traitement par PPC) – Moyen SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1LSL	F&P Nova™ Nasal (masque nasal de traitement par PPC) – Grand SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1SMLSL	F&P Nova™ Nasal (masque nasal de traitement par PPC) – Paquet 3 tailles S/M/L SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

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German Deutsch

Gerätegruppe gemäß EC-Zertifikat	R030101 – Beatmungsmasken
Verwendungszweck gemäß EC-Zertifikat	Klasse IIa
Medizinproduktgruppe	F&P OSA Masks
Hersteller	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Neuseeland SRN NZ-MF-000002556
Bevollmächtigter Vertreter	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Frankreich SRN FR-AR-000000294
Benannte Stelle	TÜV SÜD Produkt Service GmbH Ridlerstr 65, D-80339 München, Deutschland NB-Nummer 0123
Konformitätsbewertung	Klasse IIa, IIb, III: Anhang IX – QMS und Anhang IX Kap. II
Gültigkeit dieser Erklärung	Diese Konformitätserklärung ist für jedes aufgelistete Modell ab dem für das Modell eingetragenen Startdatum und so lange gültig, wie das Modell in der DoC aufgeführt ist. Wenn ein Modell nicht mehr durch die DoC abgedeckt ist, wird ein Auslaufdatum hinzugefügt.
EG-Zertifikat (MDR)	EG-Zertifikat Nr G10 010815 0039

Diese EU-Konformitätserklärung wird in alleiniger Verantwortung des Herstellers ausgestellt.

Wir, der Hersteller, erklären, dass die genannten Medizinprodukte:

- mit der Verordnung 2017/745 über Medizinprodukte (MDR) konform sind.
- mit allen anderen einschlägigen Rechtsvorschriften der Union konform sind, die die Ausstellung einer EU-Konformitätserklärung vorsehen (siehe unten):

Andere Gesetzgebung

- 1) Richtlinie 2011/65/EU, geändert durch 2015/863, zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten (RoHS).
Es wurde nachgewiesen, dass die in Artikel 4 genannten Anforderungen erfüllt sind.
- 2) Richtlinie 2014/53/EU Funkanlagen (RED).
Wir, der Hersteller, erklären in alleiniger Verantwortung, dass die genannten Medizinprodukte den Bestimmungen der Richtlinie 2014/53/EU das Rates entsprechen.

Medizinprodukte

REF	Handelsname	Basic UDI-DI	EMDN	Allgemeine Spezifikationen	Klasse	Regel	Andere Gesetzgebung
VIT1SU	F&P Vitera™ Vollgesichtsmaske für die PAP-Therapie – Klein U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MU	F&P Vitera™ Vollgesichtsmaske für die PAP-Therapie – Mittel U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LU	F&P Vitera™ Vollgesichtsmaske für die PAP-Therapie – Groß U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSU	F&P Vitera™ Vollgesichtsmaske für die PAP-Therapie – Klein/Klein U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MMU	F&P Vitera™ Vollgesichtsmaske für die PAP-Therapie – Mittel/Mittel U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LLU	F&P Vitera™ Vollgesichtsmaske für die PAP-Therapie – Groß/Groß U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLU	F&P Vitera™ Vollgesichtsmaske für die PAP-Therapie – Mittel/Groß U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSL	F&P Vitera™ Vollgesichtsmaske für die PAP-Therapie – Klein SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MSL	F&P Vitera™ Vollgesichtsmaske für die PAP-Therapie – Mittel SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LSL	F&P Vitera™ Vollgesichtsmaske für die PAP-Therapie – Groß SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLSL	F&P Vitera™ Vollgesichtsmaske für die PAP-Therapie – Mittel/Groß SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SU	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Klein U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Mittel U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-

SLN1LU	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Groß U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Weite U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLU	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – SML U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Klein Klein U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MMU	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Mittel Mittel U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Groß Groß U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SU	F&P Solo™ Pillows (Nasenkissen für PAP-Therapiemaske) – Klein U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MU	F&P Solo™ Pillows (Nasenkissen für PAP-Therapiemaske) – Mittel U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LU	F&P Solo™ Pillows (Nasenkissen für PAP-Therapiemaske) – Groß U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLU	F&P Solo™ Pillows (Nasenkissen für PAP-Therapiemaske) – SML U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSU	F&P Solo™ Pillows (Nasenkissen für PAP-Therapiemaske) – Klein Klein U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MMU	F&P Solo™ Pillows (Nasenkissen für PAP-Therapiemaske) – Mittel Mittel U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LLU	F&P Solo™ Pillows (Nasenkissen für PAP-Therapiemaske) – Groß Groß U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSL	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Klein SL	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-

SLN1MSL	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Mittel SL	94200124SOLOONMSL017D	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LSL	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Groß SL	94200124SOLOONMSL017D	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WSL	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Weite SL	94200124SOLOONMSL017D	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLSL	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – SML SL	94200124SOLOONMSL017D	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSL	F&P Solo™ Pillows (Nasenkissen für PAP-Therapiemaske) – Klein SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MSL	F&P Solo™ Pillows (Nasenkissen für PAP-Therapiemaske) – Mittel SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LSL	F&P Solo™ Pillows (Nasenkissen für PAP-Therapiemaske) – Groß SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLSL	F&P Solo™ Pillows (Nasenkissen PAP-Therapiemaske) – SML SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SU	F&P Nova™ Micro (Nasenkissen für PAP-Therapiemaske) – Klein U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MU	F&P Nova™ Micro (Nasenkissen für PAP-Therapiemaske) – Mittel U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LU	F&P Nova™ Micro (Nasenkissen für PAP-Therapiemaske) – Groß U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLU	F&P Nova™ Micro (Nasenkissen für PAP-Therapiemaske) – Fit Pack S/M/L U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSU	F&P Nova™ Micro (Nasenkissen für PAP-Therapiemaske) – Klein Klein U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MMU	F&P Nova™ Micro (Nasenkissen für PAP-Therapiemaske) – Mittel Mittel U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

NVP1LLU	F&P Nova™ Micro (Nasenkissen für PAP-Therapiemaske) – Groß Groß U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSL	F&P Nova™ Micro (Nasenkissen für PAP-Therapiemaske) – Klein SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MSL	F&P Nova™ Micro (Nasenkissen für PAP-Therapiemaske) – Mittel SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LSL	F&P Nova™ Micro (Nasenkissen für PAP-Therapiemaske) – Groß SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLSL	F&P Nova™ Micro (Nasenkissen für PAP-Therapiemaske) – Fit Pack S/M/L SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

Fisher & Paykel HEALTHCARE Δήλωση συμμόρφωσης MDR – Ευρωπαϊκή Ένωση F&P OSA Masks	Σελίδα 56 από 117
	Αρ. εγγρ.: REG – 1317
	Αναθεώρηση: L

Greek Ελληνικά

Ομάδα τεχνολογικών προϊόντων σύμφωνα με το πιστοποιητικό ΕΚ	R030101 – Μάσκες αερισμού
Προβλεπόμενη χρήση σύμφωνα με το πιστοποιητικό ΕΚ	Κατηγορία IIa
Οικογένεια ιατροτεχνολογικών προϊόντων	F&P OSA Masks
Κατασκευαστής	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Νέα Ζηλανδία SRN NZ-MF-000002556
Εξουσιοδοτημένος Αντιπρόσωπος	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Γαλλία SRN FR-AR-000000294
Κοινοποιημένος οργανισμός	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Γερμανία Αριθμός NB 0123
Αξιολόγηση συμμόρφωσης	Κατηγορία IIa, IIb, III: Παράρτημα IX – QMS και Παράρτημα IX Κεφ. II
Εγκυρότητα της παρούσας δήλωσης	Η παρούσα Δήλωση Συμμόρφωσης, για κάθε μοντέλο που παρατίθεται, ισχύει από την ημερομηνία έναρξης που καταγράφεται για το μοντέλο και για όσο διάστημα το μοντέλο περιλαμβάνεται στην DoC. Όταν ένα μοντέλο δεν καλύπτεται πλέον από την DoC, προστίθεται μια ημερομηνία διακοπής.
Πιστοποιητικό ΕΚ (MDR)	Πιστοποιητικό ΕΚ αριθ. G10 010815 0039

Η παρούσα Δήλωση Συμμόρφωσης ΕΕ εκδίδεται με την αποκλειστική ευθύνη του κατασκευαστή.

Εμείς, ο κατασκευαστής, δηλώνουμε ότι τα αναφερόμενα ιατροτεχνολογικά προϊόντα:

- Συμμορφώνονται με τον Κανονισμό 2017/745 για τα ιατροτεχνολογικά προϊόντα (MDR).
- Συμμορφώνονται με οποιαδήποτε άλλη σχετική νομοθεσία της Ένωσης που προβλέπει την έκδοση δήλωσης συμμόρφωσης ΕΕ, όπως σημειώνεται παρακάτω:

Άλλη νομοθεσία

- 1) Οδηγία 2011/65/ΕΕ όπως τροποποιήθηκε από την οδηγία 2015/863 για τον περιορισμό της χρήσης ορισμένων επικίνδυνων ουσιών σε ηλεκτρικό και ηλεκτρονικό εξοπλισμό(RoHS). Έχει καταδειχθεί ότι πληρούνται οι απαιτήσεις του άρθρου 4.
- 2) Οδηγία 2014/53/ΕΕ για τον ραδιοεξοπλισμό (RED).
Εμείς, ο κατασκευαστής, δηλώνουμε με αποκλειστική μας ευθύνη ότι τα αναφερόμενα ιατροτεχνολογικά προϊόντα πληρούν τις διατάξεις της Οδηγίας 2014/53/ΕΕ του Συμβουλίου.

Ιατροτεχνολογικά προϊόντα

REF	Εμπορική ονομασία	Βασικό UDI-DI	EMDN	Κοινές προδιαγραφές	Κατηγορία	Κανόνας	Άλλη νομοθεσία
VIT1SU	Μάσκα πλήρους προσώπου F&P Vitera™ για θεραπεία PAP – Μικρή U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MU	Μάσκα πλήρους προσώπου F&P Vitera™ για θεραπεία PAP – Μεσαία U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LU	Μάσκα πλήρους προσώπου F&P Vitera™ για θεραπεία PAP – Μεγάλη U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSU	Μάσκα πλήρους προσώπου F&P Vitera™ για θεραπεία PAP – Μικρή/Μικρή U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MMU	Μάσκα πλήρους προσώπου F&P Vitera™ για θεραπεία PAP – Μεσαία/Μεσαία U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LLU	Μάσκα πλήρους προσώπου F&P Vitera™ για θεραπεία PAP – Μεγάλη/Μεγάλη U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLU	Μάσκα πλήρους προσώπου F&P Vitera™	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-

	για θεραπεία PAP – Μεσαία/Μεγάλη U						
SLN1SU	F&P Solo™ Nasal (Πινική Μάσκα Θεραπείας PAP) – Μικρή U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (Πινική Μάσκα Θεραπείας PAP) – Μεσαία U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LU	F&P Solo™ Nasal (Πινική Μάσκα Θεραπείας PAP) – Μεγάλη U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (Πινική Μάσκα Θεραπείας PAP) – Φαρδιά U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLU	F&P Solo™ Nasal (Πινική Μάσκα Θεραπείας PAP) – SML U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (Πινική Μάσκα Θεραπείας PAP) – Μικρή Μικρή U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MMU	F&P Solo™ Nasal (Πινική Μάσκα Θεραπείας PAP) – Μεσαία Μεσαία U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (Πινική Μάσκα Θεραπείας PAP) – Μεγάλη Μεγάλη U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-

SLP1SU	F&P Solo™ Pillows (Πινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – Μικρή U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MU	F&P Solo™ Pillows (Πινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – Μεσαία U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LU	F&P Solo™ Pillows (Πινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – Μεγάλη U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLU	F&P Solo™ Pillows (Πινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – SML U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSU	F&P Solo™ Pillows (Πινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – Μικρή Μικρή U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MMU	F&P Solo™ Pillows (Πινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – Μεσαία Μεσαία U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LLU	F&P Solo™ Pillows (Πινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – Μεγάλη Μεγάλη U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SU	F&P Nova™ Micro (Πινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – Μικρή U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

NVP1MU	F&P Nova™ Micro (Πινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – Μεσαία U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LU	F&P Nova™ Micro (Πινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – Μεγάλη U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLU	F&P Nova™ Micro (Πινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – Σετ Εφαρμογής S/M/L U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSU	F&P Nova™ Micro (Πινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – Μικρή/Μικρή U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MMU	F&P Nova™ Micro (Πινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – Μεσαία/Μεσαία U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LLU	F&P Nova™ Micro (Πινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – Μεγάλη/Μεγάλη U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1SU	F&P Nova™ Nasal (Πινική Μάσκα Θεραπείας PAP) – Μικρή U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1MU	F&P Nova™ Nasal (Πινική Μάσκα Θεραπείας PAP) – Μεσαία U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1LU	F&P Nova™ Nasal (Πινική Μάσκα Θεραπείας PAP) – Μεγάλη U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

NVN1SMLU	F&P Nova™ Nasal (Ρινική Μάσκα Θεραπείας PAP) – Σετ Εφαρμογής S/M/L U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1SSU	F&P Nova™ Nasal (Ρινική Μάσκα Θεραπείας PAP) – Μικρή/Μικρή U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1MMU	F&P Nova™ Nasal (Ρινική Μάσκα Θεραπείας PAP) – Μεσαία/Μεσαία U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1LLU	F&P Nova™ Nasal (Ρινική Μάσκα Θεραπείας PAP) – Μεγάλη/Μεγάλη U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

Fisher & Paykel HEALTHCARE MDR-megfelelőségi nyilatkozat – Európai Unió F&P OSA Masks	Oldal: 62/117
	Dok. száma: REG – 1317
	Változat: L

Hungarian Magyar

EK-tanúsítvány szerinti eszközcsoport	R030101 – Lélegeztetőmaszkok
EK-tanúsítvány szerinti rendeltetés	Ila. osztály
Orvostechnikai eszközcsalád	F&P OSA Masks
Gyártó	Fisher & Paykel Healthcare Ltd Maurice Paykel Place 15, Kelet-Tamaki, Auckland 2013, Új-Zéland SRN NZ-MF-000002556
Meghatalmazott képviselő	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Franciaország SRN FR-AR-000000294
Bejelentett szervezet	TÜV SÜD Product Services GmbH Ridlerstr 65, D-80339 München, Németország NB-szám: 0123
Megfelelőségi értékelés	Ila., Ilb., III. osztály: IX. melléklet – MIR és IX. melléklet II. fejezet Műszaki dokumentáció
A nyilatkozat érvényessége	Ez a megfelelőségi nyilatkozat – minden felsorolt modell esetén – a modellhez tartozó kezdő dátumtól kezdve mindaddig érvényes, amíg a modell szerepel a megfelelőségi nyilatkozatban. Ha egy modellre már nem terjed ki a DoC hatálya, akkor egy megszűnési dátumot kell hozzáadni.
EK-tanúsítvány (MDR)	G10 010815 0039 számú EK-tanúsítvány

Ezt az EU-megfelelőségi nyilatkozatot a gyártó kizárólagos felelőssége mellett állítják ki.

Mi, a gyártó kijelentjük, hogy a megjelölt orvostechnikai eszközök:

- Megfelelnek az orvostechnikai eszközökről szóló 2017/745/EK (MDR) rendeletnek.
- Megfelelnek az alábbiakban felsorolt, az EU-megfelelőségi nyilatkozat kiadását előíró egyéb vonatkozó uniós jogszabályoknak:

Egyéb jogszabályok

1)	Az egyes veszélyes anyagok elektromos és elektronikus berendezésekben való alkalmazásának korlátozásáról szóló, a 2015/863/EU irányelvvel módosított 2011/65/EU irányelv. Bebizonyosodott, hogy a 4. cikkben meghatározott követelmények teljesülnek.
2)	A 2014/53/EU irányelv rádióberendezésekről (Radio Equipment Directive – RED). Mi, a gyártó, saját kizárólagos felelősségünkre kijelentjük, hogy a megadott orvostechnikai eszközök megfelelnek a 2014/53/EU tanácsi irányelv rendelkezéseinek.

Fisher & Paykel HEALTHCARE MDR-megfelelőségi nyilatkozat – Európai Unió F&P OSA Masks	Oldal: 63/117
	Dok. száma: REG – 1317
	Változat: L

Orvostechnikai eszközök

HIV.	Kereskedelmi név	Egyszerű UDI-DI	EMDN	Közös specifikációk	Osztály	Szabály	Egyéb jogszabályok
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N/A

Fisher & Paykel HEALTHCARE Dichiarazione di conformità MDR – Unione Europea F&P OSA Masks	Pagina 64 di 117
	Doc. No: REG – 1317
	Revisione: L

Italian Italiano

Gruppo di dispositivi come da certificato CE	R030101 - Maschere per ventilazione
Scopo previsto come da certificato CE	Classe IIa
Famiglia di dispositivi medici	F&P OSA Masks
Produttore	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Nuova Zelanda SRN NZ-MF-000002556
Rappresentate autorizzato	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Francia SRN FR-AR-000000294
Organismo notificato	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 Monaco, Germania Numero ON 0123
Valutazione della conformità	Classe IIa, IIb, III: Allegato IX – QMS e Allegato IX Capitolo II
Validità di questa Dichiarazione	La presente Dichiarazione di conformità, per ogni modello elencato, è valida dalla data di inizio registrata rispetto al modello e per tutto il tempo in cui il modello è elencato nella DoC. Quando un modello non è più coperto dalla DoC, viene aggiunta una data di cessazione.
Certificato CE (MDR)	Certificato CE n. G10 010815 0039

La presente dichiarazione di conformità UE viene rilasciata sotto l'esclusiva responsabilità del produttore.

Noi, il produttore, dichiariamo che i dispositivi medici indicati:

- Sono conformi al Regolamento 2017/745 sui dispositivi medici (MDR).
- Sono conformi a qualsiasi altra normativa dell'Unione Europea pertinente, che prevede il rilascio di una dichiarazione di conformità UE, di seguito indicata:

Altra legislazione

- 1) Direttiva 2011/65/UE, modificata dalla 2015/863, relativa alla limitazione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche (RoHS).
È stato dimostrato che i requisiti di cui all'articolo 4 sono stati soddisfatti.
- 2) Direttiva 2014/53/UE sulle apparecchiature radio (RED).
Noi, il produttore, dichiariamo sotto la nostra esclusiva responsabilità che i dispositivi medici indicati soddisfano le disposizioni della Direttiva del Consiglio 2014/53/UE.

Dispositivi medici

RIF	Nome depositato	UDI-DI base	EMDN	Specifiche comuni	Classe	Regola	Altra legislazione
VIT1SU	Maschera oro-nasale F&P Vitera™ per terapia PAP - Small U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MU	Maschera oro-nasale F&P Vitera™ per terapia PAP - Medium U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LU	Maschera oro-nasale F&P Vitera™ per terapia PAP - Large U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSU	Maschera oro-nasale F&P Vitera™ per terapia PAP - Small/Small U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MMU	Maschera oro-nasale F&P Vitera™ per terapia PAP - Medium/Medium U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LLU	Maschera oro-nasale F&P Vitera™ per terapia PAP - Large/Large U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLU	Maschera oro-nasale F&P Vitera™ per terapia PAP - Medium/Large U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSL	Maschera oro-nasale F&P Vitera™ per terapia PAP - Small SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MSL	Maschera oro-nasale F&P Vitera™ per terapia PAP - Medium SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LSL	Maschera oro-nasale F&P Vitera™ per terapia PAP - Large SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLSL	Maschera oro-nasale F&P Vitera™ per terapia PAP - Medium/Large SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SU	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Small U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-

SLN1MU	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Medium U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LU	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Large U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Wide U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLU	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – SML U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Small Small U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MMU	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Medium Medium U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Large Large U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SU	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – Small U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MU	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – Medium U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LU	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – Large U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLU	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – SML U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-

SLP1SSU	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – Small Small U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MMU	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – Medium Medium U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LLU	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – Large Large U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSL	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Small SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MSL	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Large SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LSL	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Medium SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WSL	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Wide SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLSL	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – SML SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSL	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – Small SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MSL	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – Medium SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LSL	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – Large SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-

SLP1SMLSL	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – SML SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SU	F&P Nova™ Micro (Maschera a cuscinetti nasali per terapia PAP) – Small U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MU	F&P Nova™ Micro (Maschera a cuscinetti nasali per terapia PAP) – Medium U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LU	F&P Nova™ Micro (Maschera a cuscinetti nasali per terapia PAP) – Large U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLU	F&P Nova™ Micro (Maschera a cuscinetti nasali per terapia PAP) – Multitaglia S/M/L U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSU	F&P Nova™ Micro (Maschera a cuscinetti nasali per terapia PAP) – Small/Small U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MMU	F&P Nova™ Micro (Maschera a cuscinetti nasali per terapia PAP) – Medium/Medium U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LLU	F&P Nova™ Micro (Maschera a cuscinetti nasali per terapia PAP) – Large/Large U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSL	F&P Nova™ Micro (Maschera a cuscinetti nasali per terapia PAP) – Small SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MSL	F&P Nova™ Micro (Maschera a cuscinetti nasali per terapia PAP) – Medium SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LSL	F&P Nova™ Micro (Maschera a cuscinetti nasali per terapia PAP) – Large SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

NVP1SMLSL	F&P Nova™ Micro (Maschera a cuscinetti nasali per terapia PAP) – Multitaglia S/M/L SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
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Fisher & Paykel HEALTHCARE ESMDR atbilstības deklarācija — Eiropas Savienība F&P OSA Masks	70. lpp. no 117
	Dok. Nr.: REG – 1317
	Pārskatīšana: L

Latvian Latviešu

Ierīču grupa atbilstoši EK sertifikātam	R030101 – ventilācijas maskas
Paredzētais nolūks atbilstoši EK sertifikātam	Ila klase
Medicīnas ierīču saime	F&P OSA Masks
Ražotājs	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Jaunzēlande SRN NZ-MF-000002556
Pilnvarotais pārstāvis	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Francija SRN FR-AR-000000294
Paziņotā struktūra	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Vācija PS identifikācijas numurs 0123
Atbilstības novērtējums	Klase Ila, Iib, III: IX. pielikums — KVS un IX. pielikuma II. nodaļa,
Šīs deklarācijas derīgums	Šī atbilstības deklarācija katram norādītajam modelim ir derīga no sākuma datuma, kas norādīts pretī modelim, un tik ilgi, kamēr modelis ir norādīts atbilstības deklarācijā. Ja atbilstības deklarācija uz modeli vairs neattiecas, tiek pievienots pārtraukšanas datums.
EK sertifikāts (MDR)	EK sertifikāts Nr. G10 010815 0039

Šī ES atbilstības deklarācija ir izdota vienīgi ar ražotāja atbildību.

Mēs, ražotājs, paziņojam, ka norādītās medicīnas ierīces:

- atbilst Regulai (ES) 2017/745, kas attiecas uz medicīnas ierīcēm (MDR):
- atbilst visiem citiem tālāk norādītajiem attiecīgajiem Savienības tiesību aktiem, kas paredz izdot ES atbilstības deklarāciju:

Citi tiesību akti

1)	Direktīvai 2011/65/ES, kas grozīta ar 2015/863 par noteiktu bīstamu vielu izmantošanas ierobežošanu elektriskās un elektroniskās iekārtās (RoHS). Ir norādīts, ka 4. pantā noteiktās prasības ir izpildītas.
2)	Direktīvai 2014/53/ES par radioiekārtām (RED). Mēs, ražotājs, vienīgi ar savu atbildību apstiprinām, ka norādītās medicīnas ierīces atbilst Padomes Direktīvas 2014/53/ES noteikumiem.

Fisher & Paykel HEALTHCARE ESMDR atbilstības deklarācija — Eiropas Savienība F&P OSA Masks	71. lpp. no 117
	Dok. Nr.: REG – 1317
	Pārskatīšana: L

Medicīnas ierīces

ATS.	Tirdzniecības nosaukums	Pamata UDI-DI	EMDN	Vispārīgās specifikācijas	Klase	Notei kums	Citi tiesību akti
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N/A

Fisher & Paykel HEALTHCARE MDR atitikties deklaracija – Europos Sąjunga F&P OSA Masks	72 iš. 117 psl.
	Dok. Nr.: REG – 1317
	Redakcija: L

Lithuanian Lietuvių

Prietaisų grupė pagal EB sertifikatą	R030101 – ventiliacijos kaukės
Numatytoji paskirtis pagal EB sertifikatą	Ila klasė
Medicinos prietaisų šeima	F&P OSA Masks
Gamintojas	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Naujoji Zelandija SRN NZ-MF-000002556
Įgaliotasis atstovas	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Prancūzija SRN FR-AR-000000294
Notifikuotoji įstaiga	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Vokietija NB numeris 0123
Atitikties įvertinimas	Ila, Ilb, III klasės: IX priedas – KVS ir IX priedo II skyrius
Šios deklaracijos galiojimas	Ši kiekvieno nurodyto modelio atitikties deklaracija galioja nuo modelio užregistruotos pradžios datos tol, kol modelis yra nurodytas atitikties deklaracijoje. Kai modeliui atitikties deklaracija nebetaikoma, pridedama „Nebenaudoti po“ data.
EB sertifikatas (MDR)	EB sertifikatas Nr. G10 010815 0039

Ši ES atitikties deklaracija išduota tik gamintojo atsakomybe.

Mes, gamintojas, pareiškiame, kad nurodyti medicinos prietaisai:

- Atitinka Reglamentą 2017/745 dėl medicinos prietaisų (MDR).
- Atitinka visus kitus susijusius Sąjungos teisės aktus, kuriuose nurodoma išduoti toliau nurodytą ES atitikties deklaraciją:

Kiti teisės aktai

1)	Direktyva 2011/65/ES, iš dalies pakeista 2015/863 dėl tam tikrų pavojingų medžiagų naudojimo elektros ir elektroninėje įrangoje apribojimo (RoHS). Įrodyta, kad laikomasi 4 straipsnyje nurodytų reikalavimų.
2)	Direktyva 2014/53/ES dėl radijo įrenginių (RED). Mes, gamintojas, prisiimdami visą atsakomybę pareiškiame, kad nurodyti medicinos prietaisai atitinka Tarybos direktyvos 2014/53/ES nuostatas.

Medicinos prietaisai

NUOR.	Prekės pavadinimas	Pagrindinis UDI-DI	EMDN	Bendrosios specifikacijos	Klasė	Taisyklė	Kiti teisės aktai
VIT1SU	F&P Vitera™ viso veido PAP terapijos kaukė – maža U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MU	F&P Vitera™ viso veido PAP terapijos kaukė – vidutinė U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LU	F&P Vitera™ viso veido PAP terapijos kaukė – didelė U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSU	F&P Vitera™ viso veido PAP terapijos kaukė – maža / maža U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MMU	F&P Vitera™ viso veido PAP terapijos kaukė – vidutinė / vidutinė U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LLU	F&P Vitera™ viso veido PAP terapijos kaukė – didelė / didelė U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLU	F&P Vitera™ viso veido PAP terapijos kaukė – vidutinė / didelė U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-

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Norwegian Norsk

Enhetsgruppe i henhold til EF-sertifikat	R030101 – Ventilasjonsmaske
Tiltenkt formål i henhold til EF-sertifikat	Klasse IIa
Medisinsk utstyrstype	F&P OSA Masks
Produsent	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand SRN NZ-MF-000002556
Autorisert representant	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Frankrike SRN FR-AR-000000294
Teknisk kontrollorgan	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Tyskland NB-nummer 0123
Samsvarsvurdering	Klasse IIa, IIb, III: Vedlegg IX – QMS og vedlegg IX kap. II
Gyldigheten av denne erklæringen	Denne samsvarserklæringen, for hver modell som er oppført, er gyldig fra startdatoen som er registrert for modellen, og så lenge modellen er oppført i samsvarserklæringen. Når en modell ikke lenger dekkes av samsvarserklæringen, legges det til en "utgått dato".
EF-sertifikat (MDR)	EF-sertifikatnr G10 010815 0039

Denne EU-samsvarserklæringen utstedes på produsentens fulle ansvar.

Vi, produsenten, erklærer at det oppgitte medisinske utstyret:

- er i samsvar med forskrift 2017/745 om medisinsk utstyr (MDR)
- er i samsvar med annen relevant EU-lovgivning som regulerer utstedelse av en EUsamsvarserklæring, bemerket nedenfor:

Annen lovgivning

- 1) Direktiv 2011/65/EU endret av 2015/863 om begrensning av bruken av visse farlige stoffer i elektrisk og elektronisk utstyr (RoHS).
Det er vist at kravene spesifisert i artikkel 4 er oppfylt.
- 2) Direktiv 2014/53/EU Radioutstyr (RED).
Vi, produsenten, erklærer på vårt eget fulle ansvar at det oppgitte medisinske utstyret oppfyller bestemmelsene i rådsdirektivet 2014/53/EU.

Medisinsk utstyr

REF	Handelsnavn	Grunnleggende UDI-DI	EMDN	Vanlige spesifikasjoner	Klasse	Regel	Annen lovgivning
VIT1SU	F&P Vitera™ hel ansiktsmaske til PAP-behandling – liten U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MU	F&P Vitera™ hel ansiktsmaske til PAP-behandling – medium U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LU	F&P Vitera™ hel ansiktsmaske til PAP-behandling – stor U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSU	F&P Vitera™ hel ansiktsmaske til PAP-behandling – liten/liten U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MMU	F&P Vitera™ hel ansiktsmaske til PAP-behandling – medium/medium U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LLU	F&P Vitera™ hel ansiktsmaske til PAP-behandling – stor/stor U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLU	F&P Vitera™ hel ansiktsmaske til PAP-behandling – medium/stor U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSL	F&P Vitera™ hel ansiktsmaske til PAP-behandling – liten SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MSL	F&P Vitera™ hel ansiktsmaske til PAP-behandling – medium SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-

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VIT1LSL	F&P Vitera™ hel ansiktsmaske til PAP-behandling – stor SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLSL	F&P Vitera™ hel ansiktsmaske til PAP-behandling – medium/stor SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SU	F&P Solo™ Nasal (nasal PAP-behandlingsmaske) – liten U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (nasal PAP-behandlingsmaske) – medium U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LU	F&P Solo™ Nasal (nasal PAP-behandlingsmaske) – stor U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (nasal PAP-behandlingsmaske) – bred U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SML U	F&P Solo™ Nasal (nasal PAP-behandlingsmaske) – SML U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (nasal PAP-behandlingsmaske) – liten liten U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MMU	F&P Solo™ Nasal (nasal PAP-behandlingsmaske) – medium medium U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (nasal PAP-behandlingsmaske) – stor stor U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SU	F&P Solo™ Pillows (neseputer til PAP-	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-

	behandlingsmaske) – liten U						
SLP1MU	F&P Solo™ Pillows (neseputer til PAP-behandlingsmaske) – medium U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LU	F&P Solo™ Pillows (neseputer til PAP-behandlingsmaske) – stor U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SML U	F&P Solo™ Pillows (neseputer til PAP-behandlingsmaske) – SML U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSU	F&P Solo™ Pillows (neseputer til PAP-behandlingsmaske) – liten liten U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MMU	F&P Solo™ Pillows (neseputer til PAP-behandlingsmaske) – medium medium U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LLU	F&P Solo™ Pillows (neseputer til PAP-behandlingsmaske) – stor stor U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSL	F&P Solo™ Nasal (nasal PAP-behandlingsmaske) – liten SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MSL	F&P Solo™ Nasal (nasal PAP-behandlingsmaske) – medium SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-

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SLN1LSL	F&P Solo™ Nasal (nasal PAP-behandlingsmaske) – stor SL	94200124SOLOONMSL017D	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WSL	F&P Solo™ Nasal (nasal PAP-behandlingsmaske) – bred SL	94200124SOLOONMSL017D	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SML SL	F&P Solo™ Nasal (nasal PAP-behandlingsmaske) – SML SL	94200124SOLOONMSL017D	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSL	F&P Solo™ Pillows (neseputer til PAP-behandlingsmaske) – liten SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MSL	F&P Solo™ Pillows (neseputer til PAP-behandlingsmaske) – medium SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LSL	F&P Solo™ Pillows (neseputer til PAP-behandlingsmaske) – stor SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SML SL	F&P Solo™ Pillows (neseputer til PAP-behandlingsmaske) – SML SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SU	F&P Nova™ Micro (neseputer til PAP-behandlingsmaske) – liten U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MU	F&P Nova™ Micro (neseputer til PAP-behandlingsmaske) – medium U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

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NVP1LU	F&P Nova™ Micro (neseputer til PAP- behandlingsmaske) – stor U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SML U	F&P Nova™ Micro (neseputer til PAP- behandlingsmaske) – Fit Pack S/M/L U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSU	F&P Nova™ Micro (neseputer til PAP- behandlingsmaske) – liten /liten U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MMU	F&P Nova™ Micro (neseputer til PAP- behandlingsmaske) – medium / medium U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LLU	F&P Nova™ Micro (neseputer til PAP- behandlingsmaske) – stor / stor U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSL	F&P Nova™ Micro (neseputer til PAP- behandlingsmaske) – liten SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MSL	F&P Nova™ Micro (neseputer til PAP- behandlingsmaske) – medium SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LSL	F&P Nova™ Micro (neseputer til PAP- behandlingsmaske) – stor SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SML SL	F&P Nova™ Micro (neseputer til PAP-	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

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	behandlingsmaske) – Fit Pack S/M/L SL						
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Fisher & Paykel HEALTHCARE Deklaracja zgodności MDR - Unia Europejska F&P OSA Masks	Strona 81 z 117
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Polish Polski

Grupa urządzeń zgodnie z certyfikatem WE	R030101 – Maski do wentylacji
Przeznaczenie zgodnie z certyfikatem WE	Klasa IIa
Rodzina wyrobów medycznych	F&P OSA Masks
Producent	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Nowa Zelandia SRN NZ-MF-000002556
Autoryzowany przedstawiciel	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Francja SRN FR-AR-000000294
Jednostka notyfikowana	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 Monachium, Niemcy Numer NB 0123
Ocena zgodności	Klasa IIa, IIb, III: Załącznik IX - system zarządzania jakością i załącznik IX, rozdział II
Ważność niniejszej deklaracji	Niniejsza deklaracja zgodności dla każdego wymienionego modelu jest ważna od daty rozpoczęcia podanej dla modelu i tak długo, jak model jest wymieniony w deklaracji zgodności. Gdy model nie jest już objęty deklaracją zgodności, dodaje się datę wycofania.
Certyfikat WE (MDR)	Certyfikat WE nr G10 010815 0039

Niniejsza deklaracja zgodności UE została wydana na wyłączną odpowiedzialność producenta.

Jako producent oświadczamy, że wymienione wyroby medyczne:

- Są zgodne z rozporządzeniem 2017/745 w sprawie wyrobów medycznych (MDR).
- Są zgodne z wszelkimi innymi odpowiednimi przepisami unijnymi, które przewidują wystawianie deklaracji zgodności UE, wymienionymi poniżej:

Inne przepisy

1) Dyrektywa 2011/65/UE zmieniona 2015/863 w sprawie ograniczenia stosowania niektórych niebezpiecznych substancji w sprzęcie elektrycznym i elektronicznym (RoHS). Wykazano, że wymagania określone w art. 4 zostały spełnione.
2) Dyrektywa 2014/53/UE w sprawie urządzeń radiowych (RED). Jako producent oświadczamy na swoją wyłączną odpowiedzialność, że wykazano zgodność wymienionych wyrobów medycznych z postanowieniami Dyrektywy Rady 2014/53/UE.

Wyroby medyczne

REF.	Nazwa handlowa	Kod Basic UDI-DI	EMDN	Wspólne specyfikacje	Klasa	Reguła	Inne przepisy
VIT1SU	Maska pełnotwarzowa F&P Vitera™ do terapii PAP – mała U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MU	Maska pełnotwarzowa F&P Vitera™ do terapii PAP – średnia U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LU	Maska pełnotwarzowa F&P Vitera™ do terapii PAP – duża U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSU	Maska pełnotwarzowa F&P Vitera™ do terapii PAP – mała/mała U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MMU	Maska pełnotwarzowa F&P Vitera™ do terapii PAP – średnia/średnia U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LLU	Maska pełnotwarzowa F&P Vitera™ do terapii PAP – duża/duża U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLU	Maska pełnotwarzowa F&P Vitera™ do terapii PAP – średnia/duża U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SU	F&P Solo™ Nasal (maska nosowa do terapii PAP) – mała U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (maska nosowa do terapii PAP) – średnia U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-

SLN1LU	F&P Solo™ Nasal (maska nosowa do terapii PAP) – duża U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (maska nosowa do terapii PAP) – szeroka U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLU	F&P Solo™ Nasal (maska nosowa do terapii PAP) – SML U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (maska nosowa do terapii PAP) – mała mała U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MMU	F&P Solo™ Nasal (maska nosowa do terapii PAP) – średnia średnia U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (maska nosowa do terapii PAP) – duża duża U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SU	F&P Solo™ Pillows (maska nosowa do terapii PAP z poduszkami) – mała U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MU	F&P Solo™ Pillows (maska nosowa do terapii PAP z poduszkami) – średnia U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LU	F&P Solo™ Pillows (maska nosowa do terapii PAP z poduszkami) – duża U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLU	F&P Solo™ Pillows (maska nosowa do terapii PAP z poduszkami) – SML U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSU	F&P Solo™ Pillows (maska nosowa do terapii PAP z poduszkami) – mała mała U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-

SLP1MMU	F&P Solo™ Pillows (maska nosowa do terapii PAP z poduszkami) – średnia średnia U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LLU	F&P Solo™ Pillows (maska nosowa do terapii PAP z poduszkami) – duża duża U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SU	F&P Nova™ Micro (maska nosowa do terapii PAP z poduszkami) – mała U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MU	F&P Nova™ Micro (maska nosowa do terapii PAP z poduszkami) – średnia U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LU	F&P Nova™ Micro (maska nosowa do terapii PAP z poduszkami) – duża U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLU	F&P Nova™ Micro (maska nosowa do terapii PAP z poduszkami) – zestaw do doboru rozmiaru S/M/L U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSU	F&P Nova™ Micro (maska nosowa do terapii PAP z poduszkami) — mała/mała U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MMU	F&P Nova™ Micro (maska nosowa do terapii PAP z poduszkami) — średnia/średnia U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LLU	F&P Nova™ Micro (maska nosowa do terapii PAP z poduszkami) — duża/duża U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1SU	F&P Nova™ Nasal (maska nosowa do terapii PAP) – mała U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

NVN1MU	F&P Nova™ Nasal (maska nosowa do terapii PAP) – średnia U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1LU	F&P Nova™ Nasal (maska nosowa do terapii PAP) – duża U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1SMLU	F&P Nova™ Nasal (maska nosowa do terapii PAP) – zestaw do doboru rozmiaru S/M/L U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1SSU	F&P Nova™ Nasal (maska nosowa do terapii PAP) – mała/mała U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1MMU	F&P Nova™ Nasal (maska nosowa do terapii PAP) – średnia/średnia U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVN1LLU	F&P Nova™ Nasal (maska nosowa do terapii PAP) – duża/duża U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

Fisher & Paykel HEALTHCARE Declaração de conformidade com o RDM – União Europeia F&P OSA Masks	Página 86 de 117
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Portuguese Português (Portugal)

Grupo de dispositivos de acordo com o Certificado da CE	R030101 – Máscaras de ventilação
Finalidade prevista de acordo com o Certificado da CE	Classe IIa
Família de dispositivos médicos	F&P OSA Masks
Fabricante	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Nova Zelândia SRN NZ-MF-000002556
Representante autorizado	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, França SRN FR-AR-000000294
Organismo notificado	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Alemanha Número NB 0123
Avaliação da conformidade	Classe IIa, IIb, III: Anexo IX – QMS e Anexo IX, Capítulo II
Validade da presente declaração	Esta Declaração de conformidade, para cada modelo listado, é válida a partir da data de início registada no modelo e enquanto o modelo estiver listado na DC. Quando um modelo já não for abrangido pela DC, é acrescentada uma data de descontinuação.
Certificado da CE (RDM)	Certificado da CE n.º G10 010815 0039
A presente Declaração de conformidade da UE é emitida sob a exclusiva responsabilidade do fabricante. Nós, o fabricante, declaramos que os dispositivos médicos indicados: • Estão em conformidade com o Regulamento 2017/745 relativo a dispositivos médicos (RDM). • Estão em conformidade com qualquer outra legislação pertinente da União Europeia que preveja a emissão de uma declaração de conformidade da UE, a seguir indicada:	
Outra legislação	
1) Diretiva 2011/65/UE alterada por 2015/863 relativa à restrição do uso de determinadas substâncias perigosas em equipamentos elétricos e eletrónicos (RoHS). Foi demonstrado que os requisitos especificados no artigo 4.º foram cumpridos.	
2) Diretiva 2014/53/UE Equipamento de rádio (RED). Nós, o fabricante, declaramos sob a nossa exclusiva responsabilidade que os dispositivos médicos indicados cumprem as disposições da Diretiva do Conselho 2014/53/UE.	

Dispositivos médicos

REF	Nome comercial	UDI-DI básico	EMDN	Especificações comuns	Classe	Regra	Outra legislação
VIT1SU	Máscara facial completa de terapia PAP F&P Vitera™ – Pequena U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MU	Máscara facial completa de terapia PAP F&P Vitera™ – Média U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LU	Máscara facial completa de terapia PAP F&P Vitera™ – Grande U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSU	Máscara facial completa de terapia PAP F&P Vitera™ – Pequena/Pequena U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MMU	Máscara facial completa de terapia PAP F&P Vitera™ – Média/Média U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LLU	Máscara facial completa de terapia PAP F&P Vitera™ – Grande/Grande U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLU	Máscara facial completa de terapia PAP F&P Vitera™ – Média/Grande U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SU	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Pequeno U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Médio U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LU	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Grande U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Largo U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLU	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - SML U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Pequeno Pequeno U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-

SLN1MMU	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Médio Médio U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Grande Grande U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SU	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - Pequeno U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MU	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - Médio U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LU	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - Grande U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLU	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - SML U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSU	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - Pequeno Pequeno U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MMU	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - Médio Médio U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LLU	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - Grande Grande U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSL	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Pequeno SL	94200124SOLONM001SL	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MSL	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Médio SL	94200124SOLONM001SL	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LSL	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Grande SL	94200124SOLONM001SL	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WSL	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Largo SL	94200124SOLONM001SL	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLSL	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - SML SL	94200124SOLONM001SL	R0301010201	-	Ila	Rule 2 Scl 1	-

SLP1SSL	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - Pequeno SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MSL	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - Médio SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LSL	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - Grande SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLSL	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - SML SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SU	F&P Nova™ Micro (Máscara de terapia PAP com almofadas nasais) – Pequena U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MU	F&P Nova™ Micro (Máscara de terapia PAP com almofadas nasais) – Média U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LU	F&P Nova™ Micro (Máscara de terapia PAP com almofadas nasais) – Grande U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLU	F&P Nova™ Micro (Máscara de terapia PAP com almofadas nasais) – Pequena/Pequena U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSU	F&P Nova™ Micro (Máscara de terapia PAP com almofadas nasais) – Média/Média U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MMU	F&P Nova™ Micro (Máscara de terapia PAP com almofadas nasais) – Grande/Grande U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LLU	F&P Nova™ Micro (Máscara de terapia PAP com almofadas nasais) – Grande/Grande U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSL	F&P Nova™ Micro (Máscara de terapia PAP com almofadas nasais) – Pequena SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

NVP1MSL	F&P Nova™ Micro (Máscara de terapia PAP com almofadas nasais) – Média SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LSL	F&P Nova™ Micro (Máscara de terapia PAP com almofadas nasais) – Grande SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLSL	F&P Nova™ Micro (Máscara de terapia PAP com almofadas nasais) – Fit Pack de ajuste S/M/L SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

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Romanian Română

Grup de dispozitive conform certificatului CE	R030101 - Măști de ventilație
Scopul preconizat conform certificatului CE	Clasa IIa
Seria de dispozitive medicale	F&P OSA Masks
Producător	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Noua Zeelandă SRN NZ-MF-000002556
Reprezentant autorizat	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Franța SRN FR-AR-000000294
Organismul notificat	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Germania NB numărul 0123
Evaluarea conformității	Clasa IIa, IIb, III: Anexa IX - QMS și Anexa IX Cap II
Termenul de valabilitate al acestei declarații	Această declarație de conformitate, pentru fiecare model enumerat, este valabilă de la data de începere înregistrată pentru model pe perioada în care modelul este enumerate pe DoC. Când un model nu mai este acoperit de DoC, se adaugă data întreruperii.
Certificat CE (MDR)	Certificat CE nr. G10 010815 0039
Această declarație de conformitate UE este emisă pe răspunderea exclusivă a producătorului. Prin prezenta, producătorul declară că dispozitivele medicale menționate: • Sunt conforme cu Regulamentul 2017/745 privind dispozitivele medicale (MDR). • Sunt conforme cu orice altă legislație relevantă a Uniunii care prevede emiterea unei declarații de conformitate UE, menționată mai jos:	
Alte norme legislative	
1) Directiva 2011/65/UE modificată de 2015/863 privind restricționarea utilizării anumitor substanțe periculoase în echipamentele electrice și electronice (RoHS). S-a demonstrat că au fost îndeplinite cerințele specificate la articolul 4.	
2) Directiva 2014/53/UE privind echipamentele radio (RED). Prin prezentul document, producătorul declară pe propria răspundere că dispozitivele medicale enumerate respectă prevederile Directivei Consiliului 2014/53/UE.	

Dispozitive medicale RE F	Denumire comercială	UDI-DI de bază	EMDN	Specificații comune	Clasă	Regulă	Alte norme legislative
VIT1SU	Mască de față integrală F&P Vitera™ pentru terapie PAP – mică U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MU	Mască de față integrală F&P Vitera™ pentru terapie PAP – medie U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LU	Mască de față integrală F&P Vitera™ pentru terapie PAP – mare U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSU	Mască de față integrală F&P Vitera™ pentru terapie PAP – mică/mică U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MMU	Mască de față integrală F&P Vitera™ pentru terapie PAP – medie/medie U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LLU	Mască de față integrală F&P Vitera™ pentru terapie PAP – mare/mare U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLU	Mască de față integrală F&P Vitera™ pentru terapie PAP – medie/mare U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SU	F&P Solo™ Nasal (Mască nazală pentru terapie PAP) - mică U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (Mască nazală pentru terapie PAP) - medie U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LU	F&P Solo™ Nasal (Mască nazală pentru terapie PAP) - mare U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (Mască nazală pentru terapie PAP) - foarte mare U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLU	F&P Solo™ Nasal (Mască nazală pentru terapie PAP) - SML U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (Mască nazală pentru terapie PAP) - mică, mică U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-

SLN1MMU	F&P Solo™ Nasal (Mască nazală pentru terapie PAP) - medie, medie U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (Mască nazală pentru terapie PAP) - mare, mare U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SU	F&P Solo™ Pillows (Mască nazală cu pernițe pentru terapie PAP) - mică U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MU	F&P Solo™ Pillows (Mască nazală cu pernițe pentru terapie PAP) - medie U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LU	F&P Solo™ Pillows (Mască nazală cu pernițe pentru terapie PAP) - mare U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLU	F&P Solo™ Pillows (Mască nazală cu pernițe pentru terapie PAP) - SML U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSU	F&P Solo™ Pillows (Mască nazală cu pernițe pentru terapie PAP) - mică, mică U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MMU	F&P Solo™ Pillows (Mască nazală cu pernițe pentru terapie PAP) - medie, medie U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LLU	F&P Solo™ Pillows (Mască nazală cu pernițe pentru terapie PAP) - mare, mare U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SU	F&P Nova™ Micro (Mască nazală cu pernițe pentru terapie PAP) - mică U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MU	F&P Nova™ Micro (Mască nazală cu pernițe pentru terapie PAP) - medie U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LU	F&P Nova™ Micro (Mască nazală cu pernițe pentru terapie PAP) - mare U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLU	F&P Nova™ Micro (Mască nazală cu pernițe pentru terapie PAP) - Fit Pack S/M/L U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

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F&P OSA Masks

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NVP1SSU	F&P Nova™ Micro (Mască nazală cu pernițe pentru terapie PAP) - mică/mică U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MMU	F&P Nova™ Micro (Mască nazală cu pernițe pentru terapie PAP) - medie/medie U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LLU	F&P Nova™ Micro (Mască nazală cu pernițe pentru terapie PAP) - mare/mare U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

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Slovak Slovenčina

Skupina pomôcok podľa certifikátu ES	R030101 – Ventilačné masky
Zamýšľaný účel podľa certifikátu ES	Trieda IIa
Skupina zdravotníckych pomôcok	F&P OSA Masks
Výrobca	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Nový Zéland SRN NZ-MF-000002556
Oprávnený zástupca	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Francúzsko SRN FR-AR-000000294
Notifikovaný orgán	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Nemecko Číslo NB 0123
Posudzovanie zhody	Trieda IIa, IIb, III: Príloha IX – QMS a Príloha IX kapitola II
Platnosť tohto vyhlásenia	Toto vyhlásenie o zhode platí pre každý uvedený model od dátumu začiatku zaznamenaného v porovnaní s modelom a dovtedy, kým je model uvedený v DoC. Ak sa na model už nevzťahuje DoC, pridáva sa datum platnosti.
ES certifikát (MDR)	Certifikát ES č. G10 010815 0039
Toto vyhlásenie o zhode EÚ sa vydáva na výhradnú zodpovednosť výrobcu. My, výrobca, vyhlasujeme, že uvedené zdravotnícke pomôcky: • Sú v súlade s nariadením 2017/745 o zdravotníckych pomôckach. • Sú v súlade s akýmikoľvek inými príslušnými právnymi predpismi Únie, ktorými sa ustanovuje vydávanie EÚ vyhlásenia o zhode, uvedenými nižšie:	
Iné právne predpisy	
1) Smernica 2011/65/EÚ zmenená 2015/863 o obmedzení používania určitých nebezpečných látok v elektrických a elektronických zariadeniach (RoHS). Bolo preukázané, že požiadavky uvedené v článku 4 boli splnené.	
2) Smernica 2014/53/EÚ o rádiovom zariadení (RED). My, výrobca, vyhlasujeme na vlastnú zodpovednosť, že uvedené zdravotnícke pomôcky spĺňajú ustanovenia smernice Rady 2014/53/EÚ.	

Zdravotnícke pomôcky

REF	Obchodný názov	Základné UDI-DI	EMDN	Spoločné špecifikácie	Trieda	Pravidlo	Iné právne predpisy
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N/A

Fisher & Paykel HEALTHCARE Izjava o skladnosti po uredbi o medicinskih pripomočkih – Evropska unija F&P OSA Masks	Stran 97 od 117
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Slovenian Slovenščina

Skupina pripomočka v skladu s certifikatom ES	R030101 – Maske za ventilacijo
Predvidena uporaba v skladu s certifikatom ES	Razred IIa
Družina medicinskih pripomočkov	F&P OSA Masks
Proizvajalec	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Nova Zelandija SRN NZ-MF-000002556
Pooblaščen zastopnik	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Francija SRN FR-AR-000000294
Priglašeni organ	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Nemčija Številka priglasenega organa 0123
Ocena skladnosti	Razred IIa, IIb, III: Priloga IX – sistem kakovosti in Priloga IX, Poglavje II
Veljavnost te izjave	Ta izjava o skladnosti za vsak navedeni model velja od datuma začetka, zabeleženega ob modelu, in dokler je model naveden na DoC. Kadar model ni več zajet v DoC, se doda datum prenehanja.
Certifikat ES (uredba o medicinskih pripomočkih)	Št. certifikata ES G10 0108150039
Ta izjava EU o skladnosti se izda na izključno odgovornost proizvajalca. Proizvajalec izjavlja, da so navedeni medicinski pripomočki: • skladni z Uredbo 2017/745 o medicinskih pripomočkih (MDR): • skladni s katero koli drugo ustrezno zakonodajo Unije, ki določa izdajo izjave EU o skladnosti, navedeno spodaj:	
Druška zakonodaja	
1) Direktiva 2011/65/EU, kakor je bila spremenjena z Uredbo 2015/863 o omejevanju uporabe določenih nevarnih snovi v električni in elektronski opremi (RoHS). Dokazano je bilo, da so zahteve iz 4. člena izpolnjene.	
2) Direktiva 2014/53/EU o radijski opremi (RED). Proizvajalec izključno na svojo odgovornost izjavlja, da navedeni medicinski pripomočki izpolnjujejo določila Direktive Sveta 2014/53/EU.	

Medicinski pripomočki

REF.	Trgovsko ime	Osnovni UDI-DI	EMDN	Skupne specifikacije	Razred	Pravilo	Druga zakonodaja
VIT1SU	F&P Vitera™ – celoobrazna maska za terapijo PAP – majhna U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MU	F&P Vitera™ – celoobrazna maska za terapijo PAP – srednja U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LU	F&P Vitera™ – celoobrazna maska za terapijo PAP – velika U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSU	F&P Vitera™ – celoobrazna maska za terapijo PAP – majhna/majhna U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MMU	F&P Vitera™ – celoobrazna maska za terapijo PAP – srednja/srednja U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LLU	F&P Vitera™ – celoobrazna maska za terapijo PAP – velika/velika U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MLU	F&P Vitera™ – celoobrazna maska za terapijo PAP – srednja/velika U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-

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Spanish Español

Grupo de dispositivos según certificado CE	R030101: máscaras de ventilación
Indicación prevista según certificado CE	Clase IIa
Familia de productos sanitarios	F&P OSA Masks
Fabricante	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Nueva Zelanda SRN NZ-MF-000002556
Representante autorizado	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Francia SRN FR-AR-000000294
Organismo notificado	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 Múnich, Alemania NB número 0123
Evaluación de conformidad	Clase IIa, IIb, III: Anexo IX - QMS y Anexo IX Capítulo II
Validez de esta declaración	Esta declaración de conformidad, para cada modelo indicado, es válida desde la fecha de inicio registrada en el modelo y durante todo el tiempo que el modelo figure en la DdC. Cuando un modelo ya no está cubierto por la DdC, se agrega una fecha de interrupción.
Certificado CE (MDR)	Certificado CE N.º G10 0108150039

Esta declaración de conformidad de la UE se emite bajo la responsabilidad exclusiva del fabricante.

Nosotros, el fabricante, declaramos que los productos sanitarios indicados:

- Cumplen con el Reglamento 2017/745 sobre los productos sanitarios (MDR).
- Son conformes con cualquier otra legislación pertinente de la Unión que prevea la emisión de una declaración de conformidad de la UE, que se indica a continuación:

Otra legislación

1)	Directiva 2011/65/UE modificada por 2015/863 sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos (RoHS). Se ha demostrado que se cumplen los requisitos especificados en el artículo 4.
2)	Directiva 2014/53/UE sobre equipos de radio (RED). Nosotros, el fabricante, declaramos bajo nuestra única responsabilidad que los productos sanitarios indicados cumplen las disposiciones de la Directiva del Consejo 2014/53/UE.

Productos sanitarios

REF.	Nombre comercial	UDI-DI básico	EMDN	Especificaciones comunes	Clase	Regla	Otra legislación
VIT1SU	Máscara facial completa para terapia PAP F&P Vitera™ – Pequeña U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MU	Máscara facial completa para terapia PAP F&P Vitera™ – Mediana U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LU	Máscara facial completa para terapia PAP F&P Vitera™ – Grande U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSU	Máscara facial completa para terapia PAP F&P Vitera™ – Pequeña/Pequeña U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MMU	Máscara facial completa para terapia PAP F&P Vitera™ – Mediana/Mediana U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LLU	Máscara facial completa para terapia PAP F&P Vitera™ – Grande/Grande U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLU	Máscara facial completa para terapia PAP F&P Vitera™ – Mediana/Grande U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SZ	Máscara facial completa para terapia PAP F&P Vitera™ – Pequeña Z	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-

VIT1MZ	Máscara facial completa para terapia PAP F&P Vitera™ – Mediana Z	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LZ	Máscara facial completa para terapia PAP F&P Vitera™ – Grande Z	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSZ	Máscara facial completa para terapia PAP F&P Vitera™ – Pequeña/Pequeña Z	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MMZ	Máscara facial completa para terapia PAP F&P Vitera™ – Mediana/Mediana Z	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LLZ	Máscara facial completa para terapia PAP F&P Vitera™ – Grande/Grande Z	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSL	Máscara facial completa para terapia PAP F&P Vitera™ – Pequeña SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MSL	Máscara facial completa para terapia PAP F&P Vitera™ – Mediana SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LSL	Máscara facial completa para terapia PAP F&P Vitera™ – Grande SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLSL	Máscara facial completa para terapia PAP F&P Vitera™ – Mediana/Grande SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	2

SLN1SU	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - Pequeña U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - Mediana U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LU	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - Grande U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - Ancha U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLU	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - SML U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - Pequeña Pequeña U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MMU	F&P Solo™ Nasal (mascarilla de terapia de PAP nasal) - Mediana Mediana U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - Grande Grande U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SU	F&P Solo™ Pillows (mascarilla de terapia PAP con almohadillas nasales) - Pequeña U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MU	F&P Solo™ Pillows (mascarilla de terapia PAP	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-

	con almohadillas nasales) - Mediana U						
SLP1LU	F&P Solo™ Pillows (mascarilla de terapia PAP con almohadillas nasales) - Grande U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLU	F&P Solo™ Pillows (mascarilla de terapia PAP con almohadillas nasales) - SML U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSU	F&P Solo™ Pillows (mascarilla de terapia PAP con almohadillas nasales) - Pequeña Pequeña U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MMU	F&P Solo™ Pillows (mascarilla de terapia PAP con almohadillas nasales) - Mediana Mediana U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LLU	F&P Solo™ Pillows (mascarilla de terapia PAP con almohadillas nasales) - Grande Grande U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSL	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - Pequeña SL	94200124SOLONMSL017D	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MSL	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - Mediana SL	94200124SOLONMSL017D	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LSL	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - Grande SL	94200124SOLONMSL017D	R0301010201	-	Ila	Rule 2 Scl 1	-

SLN1WSL	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - Ancha SL	94200124SOLOONMSL017D	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLSL	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - SML SL	94200124SOLOONMSL017D	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSL	F&P Solo™ Pillows (mascarilla de terapia PAP con almohadillas nasales) - Pequeña SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MSL	F&P Solo™ Pillows (mascarilla de terapia PAP con almohadillas nasales) - Mediana SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LSL	F&P Solo™ Pillows (mascarilla de terapia PAP con almohadillas nasales) - Grande SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLSL	F&P Solo™ Pillows (mascarilla de terapia PAP con almohadillas nasales) - SML SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SU	F&P Nova™ Micro (mascarilla de terapia PAP con almohadillas nasales) – Pequeña U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MU	F&P Nova™ Micro (mascarilla de terapia PAP con almohadillas nasales) – Mediana U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LU	F&P Nova™ Micro (mascarilla de terapia PAP	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

	con almohadillas nasales) – Grande U						
NVP1SMLU	F&P Nova™ Micro (mascarilla de terapia PAP con almohadillas nasales) – Set de adaptación S/M/L U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSU	F&P Nova™ Micro (mascarilla de terapia PAP con almohadillas nasales) – Pequeña/Pequeña U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MMU	F&P Nova™ Micro (mascarilla de terapia PAP con almohadillas nasales) – Mediana/Mediana U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LLU	F&P Nova™ Micro (mascarilla de terapia PAP con almohadillas nasales) – Grande/Grande U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSL	F&P Nova™ Micro (mascarilla de terapia PAP con almohadillas nasales) – Pequeña SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MSL	F&P Nova™ Micro (mascarilla de terapia PAP con almohadillas nasales) – Mediana SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LSL	F&P Nova™ Micro (mascarilla de terapia PAP	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

	con almohadillas nasales) – Grande SL						
NVP1SMLSL	F&P Nova™ Micro (mascarilla de terapia PAP con almohadillas nasales) – Set de adaptación S/M/L SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

Fisher & Paykel HEALTHCARE MDR-försäkran om överensstämmelse – Europeiska unionen F&P OSA Masks	Sida 107 av 117
	Dok. Nr: REG – 1317
	Version: L

Swedish Svenska

Enhetsgrupp enligt EG-certifikat	R030101 – ventilationsmasker
Avsett ändamål enligt EG-certifikat	Klass IIa
Medicinteknisk produktfamilj	F&P OSA Masks
Tillverkare	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Nya Zeeland SRN NZ-MF-000002556
Auktoriserad representant	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Frankrike SRN FR-AR-000000294
Anmält organ	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Tyskland NB-nummer 0123
Bedömning av överensstämmelse	Klass IIa, IIb, III: Bilaga IX – QMS och bilaga IX kap II
Denna försäkran s giltighet	Denna försäkran om överensstämmelse gäller, för varje modell som listas, från det startdatum som registrerats för modellen och så länge som modellen anges i aktuell försäkran om överensstämmelse. När en modell inte längre omfattas av en försäkran om överensstämmelse läggs ett upphörandedatum till.
EG-certifikat (MDR)	EG-certifikat nr G10 0108150039

Denna EU-försäkran om överensstämmelse utfärdas på tillverkarens eget ansvar.

Vi, tillverkaren, intygar att de angivna medicintekniska produkterna:

- Överensstämmer med förordning 2017/745 om medicintekniska produkter (MDR).
- Överensstämmer med annan relevant unionslagstiftning som föreskriver utfärdande av en EU-försäkran om överensstämmelse och som anges nedan:

Annan lagstiftning

- 1) Direktiv 2011/65/EU ändrad genom 2015/863 om begränsning av användningen av vissa farliga ämnen i elektrisk och elektronisk utrustning (RoHS).
Det har visats att kraven i artikel 4 har uppfyllts.
- 2) Direktiv 2014/53/EU radioutrustning (RED).
Vi, tillverkaren, intygar på eget ansvar att den angivna medicintekniska produkten uppfyller bestämmelserna i rådets direktiv 2014/53/EU.

Medicintekniska produkter

Referens	Handelsnamn	Grundläggande UDI-DI	EMDN	Allmänna specifikationer	Klass	Regel	Annan lagstiftning
VIT1SU	F&P Vitera™ Full hel ansiktsmask PAP-behandlingsmask – Small U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MU	F&P Vitera™ Full hel ansiktsmask PAP-behandlingsmask – Medium U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LU	F&P Vitera™ Full hel ansiktsmask PAP-behandlingsmask – Large U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSU	F&P Vitera™ Full hel ansiktsmask PAP-behandlingsmask – Small/Small U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MMU	F&P Vitera™ Full hel ansiktsmask PAP-behandlingsmask – Medium/Medium U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LLU	F&P Vitera™ Full hel ansiktsmask PAP-behandlingsmask – Large/Large U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLU	F&P Vitera™ Full hel ansiktsmask PAP-behandlingsmask – Medium/Large U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSL	F&P Vitera™ Full hel ansiktsmask PAP-	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-

	behandlingsmask – Small SL						
VIT1MSL	F&P Vitera™ Full hel ansiktsmask PAP- behandlingsmask – Medium SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LSL	F&P Vitera™ Full hel ansiktsmask PAP- behandlingsmask – Large SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLSL	F&P Vitera™ Full hel ansiktsmask PAP- behandlingsmask – Medium/Large SL	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SU	F&P Solo™ Nasal (näsmask för PAP- behandling) – small U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (näsmask för PAP- behandling) – medium U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LU	F&P Solo™ Nasal (näsmask för PAP- behandling) – large U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (näsmask för PAP- behandling) – bred U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLU	F&P Solo™ Nasal (näsmask för PAP- behandling) – small small U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (näsmask för PAP-	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-

	behandling) – large large U						
SLN1MMU	F&P Solo™ Nasal (näsmask för PAP- behandling) – medium medium U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (näsmask för PAP- behandling) – SML U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SU	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – small U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MU	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – medium U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LU	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – large U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLU	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – SML U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSU	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – small small U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MMU	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – medium medium U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-

SLP1LLU	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – large large U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSL	F&P Solo™ Nasal (näsmask för PAP- behandling) – small SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MSL	F&P Solo™ Nasal (näsmask för PAP- behandling) – medium SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LSL	F&P Solo™ Nasal (näsmask för PAP- behandling) – large SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WSL	F&P Solo™ Nasal (näsmask för PAP- behandling) – bred SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLSL	F&P Solo™ Nasal (näsmask för PAP- behandling) – SML SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSL	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – small SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MSL	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – medium SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LSL	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – large SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-

NVP1SU	F&P Nova™ Micro (näskuddemask för PAP-behandling) – liten U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MU	F&P Nova™ Micro (näskuddemask för PAP-behandling) – medium U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LU	F&P Nova™ Micro (näskuddemask för PAP-behandling) – stor U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLU	F&P Nova™ Micro (näskuddemask för PAP-behandling) – inpassningssats S/M/L U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSU	F&P Nova™ Micro (näskuddemask för PAP-behandling) – liten/liten U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MMU	F&P Nova™ Micro (näskuddemask för PAP-behandling) – medium/medium U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LLU	F&P Nova™ Micro (näskuddemask för PAP-behandling) – stor/stor U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSL	F&P Nova™ Micro (näskuddemask för PAP-behandling) – liten SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

NVP1MSL	F&P Nova™ Micro (näskuddemask för PAP-behandling) – medium SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LSL	F&P Nova™ Micro (näskuddemask för PAP-behandling) – stor SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLSL	F&P Nova™ Micro (näskuddemask för PAP-behandling) – inpassningssats S/M/L SL	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-

Fisher & Paykel HEALTHCARE MDR Uygunluk Beyanı – Avrupa Birliği F&P OSA Masks	Sayfa 114 / 117
	Belge. No: REG – 1317
	Revizyon: L

Turkish Türkçe

EC Sertifikasına Göre Cihaz Grubu	R030101 – Ventilasyon Maskeleri
EC Sertifikasına Göre Kullanım Amacı	Sınıf IIa
Tıbbi Cihaz Ailesi	F&P OSA Masks
Üretici	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Yeni Zelanda SRN NZ-MF-000002556
Yetkili Temsilci	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Fransa SRN FR-AR-000000294
Onaylı Kuruluş	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 Münih, Almanya NB Numarası 0123
Uygunluk Değerlendirmesi	Sınıf IIa, IIb, III: Ek IX – KYS ve Ek IX Bölüm II
Bu Beyannamenin Geçerliliği	Listelenen her model için bu Uygunluk Beyanı, model için başlangıç tarihinden itibaren ve model DoC'de listelendiği sürece geçerlidir. Bir model artık DoC kapsamında yer almadığında sona erdiği tarih eklenir.
EC Sertifikası (MDR)	EC Sertifika No. G10 010815 0039

Bu AB Uygunluk Beyanı, yalnızca üreticinin sorumluluğu kapsamında yayınlanmıştır.

Üretici olarak, belirtilen tıbbi cihazlar için şu hususları beyan ediyoruz:

- Tıbbi cihazlara (MDR) ilişkin 2017/745 Yönetmeliğine uygundur.
- Aşağıdaki bir AB uygunluk beyanının yayınlanmasını öngören diğer ilgili Birlik mevzuatına uygundur:

Diğer Mevzuat

- 1) Elektrikli ve elektronik ekipmanlarda (RoHS) belirli tehlikeli maddelerin kullanımının kısıtlanmasına ilişkin 2015/863 ile değiştirilen 2011/65/AB Direktifi.
4. Maddede belirtilen gereksinimlerin karşılandığı kanıtlanmıştır.
- 2) 2014/53/AB Radyo Ekipmanları Direktifi (RED).
Üretici olarak, belirtilen tıbbi cihazların Konsey Direktifi 2014/53/AB hükümlerini karşıladığını yalnızca kendi sorumluluğumuz kapsamında beyan ediyoruz.

Tıbbi cihazlar

REF	Ticari Ad	Temel UDI-DI	EMDN	Ortak Spesifikasyonlar	Sınıf	Kural	Diğer Mevzuat
VIT1SU	F&P Vitera™ Tam Yüz PAP Terapi Maskesi – Küçük U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MU	F&P Vitera™ Tam Yüz PAP Terapi Maskesi – Orta U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LU	F&P Vitera™ Tam Yüz PAP Terapi Maskesi – Büyük U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1SSU	F&P Vitera™ Tam Yüz PAP Terapi Maskesi – Küçük/Küçük U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MMU	F&P Vitera™ Tam Yüz PAP Terapi Maskesi – Orta/Orta U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1LLU	F&P Vitera™ Tam Yüz PAP Terapi Maskesi – Büyük/Büyük U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
VIT1MLU	F&P Vitera™ Tam Yüz PAP Terapi Maskesi – Orta/Büyük U	94200124VITERAFFM01PH	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SU	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Küçük U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Orta U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LU	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Büyük U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Geniş U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLU	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – SML U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Küçük Küçük U	94200124SOLONM001BF	R0301010201	-	Ila	Rule 2 Scl 1	-

REF	Ticari Ad	Temel UDI-DI	EMDN	Ortak Spesifikasyonlar	Sınıf	Kural	Diğer Mevzuat
SLN1MMU	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Orta Orta U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Büyük Büyük U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SU	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – Küçük U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MU	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – Orta U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LU	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – Büyük U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLU	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – SML U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SSU	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – Küçük Küçük U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MMU	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – Orta Orta U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LLU	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – Büyük Büyük U	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SSL	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Küçük SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1MSL	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Orta SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1LSL	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Büyük SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1WSL	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Geniş SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-
SLN1SMLSL	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – SML SL	94200124SOLOPM001C5	R0301010201	-	Ila	Rule 2 Scl 1	-

REF	Ticari Ad	Temel UDI-DI	EMDN	Ortak Spesifikasyonlar	Sınıf	Kural	Diğer Mevzuat
SLP1SSL	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – Küçük SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1MSL	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – Orta SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1LSL	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – Büyük SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
SLP1SMLSL	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – SML SL	94200124SOLOPMSL0187	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SU	F&P Nova™ Micro (Nazal Yastıklı PAP Terapi Maskesi) – Küçük U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MU	F&P Nova™ Micro (Nazal Yastıklı PAP Terapi Maskesi) – Orta U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LU	F&P Nova™ Micro (Nazal Yastıklı PAP Terapi Maskesi) – Büyük U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SMLU	F&P Nova™ Micro (Nazal Yastıklı PAP Terapi Maskesi) – Uyum Paketi S/M/L U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1SSU	F&P Nova™ Micro (Nazal Yastıklı PAP Terapi Maskesi) – Küçük/Küçük U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1MMU	F&P Nova™ Micro (Nazal Yastıklı PAP Terapi Maskesi) – Orta/Orta U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-
NVP1LLU	F&P Nova™ Micro (Nazal Yastıklı PAP Terapi Maskesi) – Büyük/Büyük U	94200124NP01GE	R0301010201	-	Ila	Rule 2 Scl 1	-