

<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> MDR Declaration of Conformity – European Union F&P OSA Masks	Page 1 of 92
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English

<b>Device Group as per EC Certificate</b>	R030101 – Ventilation Masks
<b>Intended Purpose as per EC Certificate</b>	Class IIa
<b>Medical Device Family</b>	F&P OSA Masks
<b>Manufacturer</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand SRN NZ-MF-000002556
<b>Authorised Representative</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, France SRN FR-AR-000000294
<b>Notified Body</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Germany NB number 0123
<b>Conformity Assessment</b>	Class IIa, IIb, III: Annex IX – QMS and Annex IX Chap II
<b>Validity of this Declaration</b>	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.
<b>EC certificate (MDR)</b>	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 24/Jan/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  $\geq 66$  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

#### Vitera models

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	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MU	F&P Vitera Full Face PAP Therapy Mask - Medium U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LU	F&P Vitera Full Face PAP Therapy Mask - Large U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSU	F&P Vitera Full Face PAP Therapy Mask - Small/Small U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MMU	F&P Vitera Full Face PAP Therapy Mask - Medium/Medium U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-

VIT1LLU	F&P Vitera Full Face PAP Therapy Mask - Large/Large U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MLU	F&P Vitera Full Face PAP Therapy Mask - Medium/Large U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SZ	F&P Vitera Full Face PAP Therapy Mask - Small Z	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MZ	F&P Vitera Full Face PAP Therapy Mask - Medium Z	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LZ	F&P Vitera Full Face PAP Therapy Mask - Large Z	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSZ	F&P Vitera Full Face PAP Therapy Mask - Small/Small Z	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MMZ	F&P Vitera Full Face PAP Therapy Mask - Medium/Medium Z	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LLZ	F&P Vitera Full Face PAP Therapy Mask - Large/Large Z	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSL	F&P Vitera Full Face PAP Therapy Mask - Small SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MSL	F&P Vitera Full Face PAP Therapy Mask - Medium SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-

VIT1LSL	F&P Vitera Full Face PAP Therapy Mask - Large SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MSL	F&P Vitera Full Face PAP Therapy Mask - Medium/Large SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SU	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Small U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Medium U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LU	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Large U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Wide U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SML U	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – SML U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Small Small U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MMU	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Medium Medium U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-

SLN1LLU	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Large Large U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SU	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – Small U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1MU	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – Medium U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1LU	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – Large U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SML U	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – SML U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SSU	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – Small Small U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1MMU	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – Medium Medium U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1LLU	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – Large Large U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SSL	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Small SL	94200124SOLONM0017D	R030101	-	Ila	Rule 2 Scl 1	-

SLN1MSL	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Medium SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LSL	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Large SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Scl 1	-
SLN1WSL	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – Wide SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SML SL	F&P Solo™ Nasal (Nasal PAP Therapy Mask) – SML SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SSL	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – Small SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Scl 1	-
SLP1MSL	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – Medium SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Scl 1	-
SLP1LSL	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – Large SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SML SL	F&P Solo™ Pillows (Nasal Pillows PAP Therapy Mask) – SML SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Scl 1	-

EMDN Code	Description
R030101	Ventilation 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)



MDR Declaration of Conformity – European Union  
F&P OSA Masks

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<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> Декларация за съответствие с MDR – Европейски съюз F&P OSA Masks	Страница <b>10</b> от <b>92</b>
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Bulgarian български

<b>Група на изделието според ЕО сертификата</b>	R030101 – вентилационни маски;
<b>Предназначение според ЕО сертификата</b>	Клас IIa
<b>Семейство на медицинско изделие</b>	F&P OSA Masks
<b>Производител</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Нова Зеландия SRN NZ-MF-000002556
<b>Упълномощен представител</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Vilbobon-sur-Yvette, 91946 Courtaboeuf Cedex, Франция SRN FR-AR-000000294
<b>Нотифициран орган</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Германия NB номер 0123
<b>Оценка на съответствието</b>	Клас IIa, IIb, III: Приложение IX – СУК и Приложение IX, Глава II
<b>Валидност на настоящата декларация</b>	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.
<b>ЕО сертификат (MDR)</b>	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	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MU	Терапевтична PAP маска за цяло лице F&P Vitera™ – средна U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LU	Терапевтична PAP маска за цяло лице F&P Vitera™ – голяма U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSU	Терапевтична PAP маска за цяло лице F&P Vitera™ – малка/малка U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MMU	Терапевтична PAP маска за цяло лице F&P Vitera™ – средна/средна U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LLU	Терапевтична PAP маска за цяло лице F&P Vitera™ – голяма/голяма U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MLU	Терапевтична PAP маска за цяло лице F&P Vitera™ – средна/голяма U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-

<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> MDR izjava o sukladnosti – Europska unija F&P OSA Masks	Stranica <b>12</b> od <b>92</b>
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Croatian      Hrvatski

<b>Grupa proizvoda prema potvrdi EZ-a</b>	R030101 – maske za ventilaciju;
<b>Namjena prema potvrdi EZ-a</b>	Klasa IIa
<b>Asortiman medicinskih proizvoda</b>	F&P OSA Masks
<b>Proizvođač</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Novi Zeland SRN NZ-MF-000002556
<b>Ovlašteni zastupnik</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Francuska SRN FR-AR-000000294
<b>Ovlašteno tijelo</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Njemačka NB broj 0123
<b>Procjena sukladnosti</b>	Klasa IIa, IIb, III: Prilog IX – QMS i Prilog IX Poglavlje II
<b>Valjanost ove izjave</b>	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.
<b>„EZ” potvrda (MDR)</b>	„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	R030101	-	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	R030101	-	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	R030101	-	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	R030101	-	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	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LLU	Maska za cijelo lice F&P Vitera™ za liječenje	94200124VITERAFFM01PH	R030101	-	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	R030101	-	Ila	Rule 2 Sc1 1	-

<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> Prohlášení o shodě podle MDR – Evropská unie F&P OSA Masks	Strana <b>15</b> z <b>92</b>
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Czech                      Česky

<b>Skupina zařízení podle osvědčení ES</b>	R030101 – Dýchací masky
<b>Zamýšlený účel podle osvědčení ES</b>	Třída II
<b>Skupina zdravotnických prostředků</b>	F&P OSA Masks
<b>Výrobce</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Nový Zéland SRN NZ-MF-000002556
<b>Zplnomocněný zástupce</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Francie SRN FR-AR-000000294
<b>Oznámený subjekt</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Německo Číslo subjektu 0123
<b>Posuzování shody</b>	Třída IIa, IIb, III: Příloha IX – SZJ a Příloha IX kapitola II
<b>Platnost tohoto prohlášení</b>	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.
<b>Certifikát ES (MDR)</b>	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



<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> MDR-overensstemmelseserklæring – Den Europæiske Union F&P OSA Masks	Side <b>17</b> af <b>92</b>
	Dok. nr.: REG – 1317
	Revision: F

Danish                  Dansk

<b>Enhedsgruppe i henhold til EF-certifikat</b>	R030101 – Respirationsmasker
<b>Formål ifølge EF-certifikat</b>	Klasse IIa
<b>Gruppe af medicinsk udstyr</b>	F&P OSA Masks
<b>Producent</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand SRN NZ-MF-000002556
<b>Autoriseret repræsentant</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Frankrig SRN FR-AR-000000294
<b>Underrettede organ</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Tyskland NB-nummer 0123
<b>Overensstemmelses-vurdering</b>	Klasse IIa, IIb, III: Bilag IX – QMS og bilag IX, kapitel II
<b>Denne erklærings gyldighed</b>	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.
<b>EF-certifikat (MDR)</b>	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	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MU	F&P Vitera™ Full Face PAP-terapi maske – Medium U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LU	F&P Vitera™ Full Face PAP-terapi maske – Stor U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSU	F&P Vitera™ Full Face PAP-terapi maske – Lille/Lille U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MMU	F&P Vitera™ Full Face PAP-terapi maske – Medium/Medium U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LLU	F&P Vitera™ Full Face PAP-terapi maske – Stor/Stor U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MLU	F&P Vitera™ Full Face PAP-terapi maske – Medium/Stor U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSL	F&P Vitera™ Full Face PAP-terapi maske – Lille SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MSL	F&P Vitera™ Full Face PAP-terapi maske – Medium SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LSL	F&P Vitera™ Full Face PAP-terapi maske – Stor SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MLS	F&P Vitera™ Full Face PAP-terapi maske – Medium/Stor SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-

REF	Handelsnavn	Grundlæggende UDI-DI	EMDN	Almindelige specifikationer	Klasse	Regel	Anden lovgivning
SLN1SU	F&P Solo™ Nasal (næsemaske til PAP-behandling) – Small U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (næsemaske til PAP-behandling) – Medium U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LU	F&P Solo™ Nasal (næsemaske til PAP-behandling) – Large U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (næsemaske til PAP-behandling) – Wide U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SML U	F&P Solo™ Nasal (næsemaske til PAP-behandling) – SML U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (næsemaske til PAP-behandling) – Small Small U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MMU	F&P Solo™ Nasal (næsemaske til PAP-behandling) – Medium Medium U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (næsemaske til PAP-behandling) – Large Large U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SU	F&P Solo™ Pillows (maske med næsepuder til PAP-behandling) – Small U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1MU	F&P Solo™ Pillows (maske med næsepuder til PAP-behandling) – Medium U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1LU	F&P Solo™ Pillows (maske med næsepuder til PAP-behandling) – Large U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-

SLP1SML U	F&P Solo™ Pillows (maske med næsepuder til PAP-behandling) – SML U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SSU	F&P Solo™ Pillows (maske med næsepuder til PAP-behandling) – Small Small U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1MMU	F&P Solo™ Pillows (maske med næsepuder til PAP-behandling) – Medium Medium U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1LLU	F&P Solo™ Pillows (maske med næsepuder til PAP-behandling) – Large Large U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SSL	F&P Solo™ Nasal (næsemaske til PAP-behandling) – Small SL	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MSL	F&P Solo™ Nasal (næsemaske til PAP-behandling) – Medium SL	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LSL	F&P Solo™ Nasal (næsemaske til PAP-behandling) – Large SL	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLN1WSL	F&P Solo™ Nasal (næsemaske til PAP-behandling) – Wide SL	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SML SL	F&P Solo™ Nasal (næsemaske til PAP-behandling) – SML SL	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SSL	F&P Solo™ Pillows (maske med næsepuder til PAP-behandling) – Small SL	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1MSL	F&P Solo™ Pillows (maske med næsepuder til PAP-behandling) – Medium SL	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-

SLP1LSL	F&P Solo™ Pillows (maske med næsepuder til PAP-behandling) – Large SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 ScI 1	-
SLP1SML SL	F&P Solo™ Pillows (maske med næsepuder til PAP-behandling) – SML SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 ScI 1	-

<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> MDR-conformiteitsverklaring - Europese Unie F&P OSA Masks	Pagina <b>22</b> van <b>92</b>
	Doc. Nr.: REG – 1317
	Herziening: F

Dutch                      Nederlands

<b>Apparaatgroep volgens EG-certificaat</b>	R030101 - Beademingsmaskers
<b>Beoogd doel volgens EG-certificaat</b>	Klasse IIa
<b>Familie van medische hulpmiddelen</b>	F&P OSA Masks
<b>Fabrikant</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Nieuw-Zeeland SRN NZ-MF-000002556
<b>Gemachtigde vertegenwoordiger</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Frankrijk SRN FR-AR-000000294
<b>Aangemelde instantie</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Duitsland NB-nummer 0123
<b>Beoordeling conformiteit</b>	Klasse IIa, IIb, III: Bijlage IX - QMS en bijlage IX, hoofdstuk II
<b>Geldigheid van deze verklaring</b>	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.
<b>EG-certificaat (MDR)</b>	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:	
<ul style="list-style-type: none"> <li>• In overeenstemming zijn met Verordening 2017/745 betreffende medische hulpmiddelen (MDR).</li> <li>• In overeenstemming zijn met alle andere relevante wetgeving van de Unie die voorziet in de afgifte van een EU-conformiteitsverklaring, zoals hieronder vermeld:</li> </ul>	
<b>Andere wetgeving</b>	
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	Gemeenschappelijke specificaties	Klasse	Regel	Andere wetgeving
VIT1SU	F&P Vitera™ Full Face-masker voor PAP-therapie, Small U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MU	F&P Vitera™ Full Face-masker voor PAP-therapie, Medium U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LU	F&P Vitera™ Full Face-masker voor PAP-therapie, Large U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSU	F&P Vitera™ Full Face-masker voor PAP-therapie, Small/Small U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MMU	F&P Vitera™ Full Face-masker voor PAP-therapie, Medium/Medium U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LLU	F&P Vitera™ Full Face-masker voor PAP-therapie, Large/Large U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MLU	F&P Vitera™ Full Face-masker voor PAP-therapie, Medium/Large U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSL	F&P Vitera™ Full Face-masker voor PAP-therapie, Small SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MSL	F&P Vitera™ Full Face-masker voor PAP-therapie, Medium SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-

VIT1LSL	F&P Vitera™ Full Face-masker voor PAP-therapie, Large SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MLSL	F&P Vitera™ Full Face-masker voor PAP-therapie, Medium/Large SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SU	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Small U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Medium U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LU	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Large U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Wide U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SML U	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – SML U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Small Small U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MMU	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Medium Medium U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Large Large U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SSL	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Small SL	94200124SOLONM0017D	R030101	-	Ila	Rule 2 Scl 1	-



SLN1MSL	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Medium SL	94200124SOLOMMSL017D	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1LSL	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Large SL	94200124SOLOMMSL017D	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1WSL	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – Wide SL	94200124SOLOMMSL017D	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1SMLS	F&P Solo™ Nasal (nasaal PAP-therapiemasker) – SML SL	94200124SOLOMMSL017D	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SU	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – Small U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1MU	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – Medium U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1LU	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – Large U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SMLU	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – SML U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SSU	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – Small Small U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1MMU	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – Medium Medium U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1LLU	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – Large Large U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Sc1 1	-

SLP1SSL	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – Small SL	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1MSL	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – Medium SL	94200124SOLOM017D	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1LSL	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – Large SL	94200124SOLOM017D	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SML SL	F&P Solo™ Pillows (Nasal Pillows PAP-therapiemasker) – SML SL	94200124SOLOM017D	R030101	-	Ila	Rule 2 Sc1 1	-

<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> MDR-i vastavusdeklaratsioon – Euroopa Liit F&P OSA Masks	Lehekülg <b>27 / 92</b>
	Dokumendi nr: REG – 1317
	Versioon: F

Estonian Eesti

<b>Seadmerühm vastavalt EÜ sertifikaadile</b>	R030101 – ventilatsioonimaskid;
<b>Sihtotstarve vastavalt EÜ sertifikaadile</b>	Ila klass
<b>Meditsiiniseadmete perekond</b>	F&P OSA Masks
<b>Tootja</b>	Fisher & Paykel Healthcare Ltd. 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Uus-Meremaa SRN NZ-MF-000002556
<b>Volitatud esindaja</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Prantsusmaa SRN FR-AR-000000294
<b>Teavitatud asutus</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Saksamaa NB nr 0123
<b>Vastavushindamine</b>	Ila, I Ib, III klass: IX lisa – QMS ja IX lisa II peatükk
<b>Käesoleva deklaratsiooni kehtivus</b>	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.
<b>EÜ sertifikaat (MDR)</b>	EÜ sertifikaat nr G10 010815 0039
<p>Käesolev ELi vastavusdeklaratsioon antakse välja tootja ainuvastutusel.</p> <p>Meie, tootja, kinnitame, et nimetatud meditsiiniseadmed:</p> <ul style="list-style-type: none"> <li>vastavad meditsiiniseadmeid käsitlevale määrusele 2017/745.</li> <li>on kooskõlas muude asjakohaste liidu õigusaktidega, millega nähakse ette ELi vastavusdeklaratsiooni väljaandmine, nagu on märgitud allpool:</li> </ul>	
<b>Muud õigusaktid</b>	
<p>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.</p>	
<p>2) Direktiiv 2014/53/EL Raadioseadmed. Meie, tootja, kinnitame oma ainuvastutusel, et nimetatud meditsiiniseadmed vastavad nõukogu direktiivi 2014/53/EL.</p>	

**Meditsiiniseadmed**

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

<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> MDR-vaatimustenmukaisuusvakuutus – Euroopan unioni F&P OSA Masks	Sivu <b>29/92</b>
	Asiakirjan nro: REG – 1317
	Versio: F

Finnish Suomi

<b>Laiteryhmä EY-todistuksen mukaan</b>	R030101 – ventilaatiomaskit
<b>Käyttötarkoitus EY-todistuksen mukaan</b>	Luokka Ila
<b>Lääkinnällisten laitteiden valikoima</b>	F&P OSA Masks
<b>Valmistaja</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand SRN NZ-MF-000002556
<b>Valtuutettu edustaja</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, France SRN FR-AR-000000294
<b>Ilmoitettu laitos</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Saksa Ilmoitetun laitoksen nro 0123
<b>Vaatimustenmukaisuuden arviointi</b>	Luokka Ila, Ilb, III: Liite IX – QMS ja liitteen IX luku II
<b>Tämän vakuutuksen voimassaolo</b>	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.
<b>EY-todistus (MDR)</b>	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 artiklassa 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	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MU	F&P Vitera™ - kokokasvomaski ylipainehoitoon – keskikokoinen U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LU	F&P Vitera™ - kokokasvomaski ylipainehoitoon – suuri U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSU	F&P Vitera™ - kokokasvomaski ylipainehoitoon – pieni / pieni U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MMU	F&P Vitera™ - kokokasvomaski ylipainehoitoon – keskikokoinen / keskikokoinen U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LLU	F&P Vitera™ - kokokasvomaski ylipainehoitoon – suuri / suuri U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MLU	F&P Vitera™ - kokokasvomaski ylipainehoitoon – keskikokoinen / suuri U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-

SLN1SU	(fi) F&P Solo™ Nasal (nenämämaski ylipainehoitoon) – pieni U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MU	(fi) F&P Solo™ Nasal (nenämämaski ylipainehoitoon) – keskikokoinen U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LU	(fi) F&P Solo™ Nasal (nenämämaski ylipainehoitoon) – suuri U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1WU	(fi) F&P Solo™ Nasal (nenämämaski ylipainehoitoon) – leveä U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SML U	(fi) F&P Solo™ Nasal (nenämämaski ylipainehoitoon) – SML U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SSU	(fi) F&P Solo™ Nasal (nenämämaski ylipainehoitoon) – pieni, pieni U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MMU	(fi) F&P Solo™ Nasal (nenämämaski ylipainehoitoon) – keskikokoinen, keskikokoinen U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LLU	(fi) F&P Solo™ Nasal (nenämämaski ylipainehoitoon) – suuri, suuri U	94200124SOLOM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SU	(fi) F&P Solo™ Pillows (nenätyyny ylipainehoitomaskiin) – pieni U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1MU	(fi) F&P Solo™ Pillows (nenätyyny ylipainehoitomaskiin) – keskikokoinen U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-

SLP1LU	(fi) F&P Solo™ Pillows (nenätyyny ylipainehoitomaskiin) – suuri U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SML U	(fi) F&P Solo™ Pillows (nenätyynynt ylipainehoitomaskiin) – SML U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SSU	(fi) F&P Solo™ Pillows (nenätyynynt ylipainehoitomaskiin) – pieni, pieni U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1MMU	(fi) F&P Solo™ Pillows (nenätyynynt ylipainehoitomaskiin) – keskikokoinen, keskikokoinen U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1LLU	(fi) F&P Solo™ Pillows (nenätyynynt ylipainehoitomaskiin) – suuri, suuri U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SSL	(fi) F&P Solo™ Nasal (nenämaski ylipainehoitoon) – pieni SL	94200124SOLONMSL017D	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MSL	(fi) F&P Solo™ Nasal (nenämaski ylipainehoitoon) – keskikokoinen SL	94200124SOLONMSL017D	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LSL	(fi) F&P Solo™ Nasal (nenämaski ylipainehoitoon) – suuri SL	94200124SOLONMSL017D	R030101	-	Ila	Rule 2 Scl 1	-
SLN1WSL	(fi) F&P Solo™ Nasal (nenämaski ylipainehoitoon) – leveä SL	94200124SOLONMSL017D	R030101	-	Ila	Rule 2 Scl 1	-



SLN1SML SL	(fi) F&P Solo™ Nasal (nenämäski ylipainehoitoon) – SML SL	94200124SOLOPMSL017D	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SSL	(fi) F&P Solo™ Pillows (nenätyyny ylipainehoitomaskiin) – pieni SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Scl 1	-
SLP1MSL	(fi) F&P Solo™ Pillows (nenätyyny ylipainehoitomaskiin) – keskikokoinen SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Scl 1	-
SLP1LSL	(fi) F&P Solo™ Pillows (nenätyyny ylipainehoitomaskiin) – suuri SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SML SL	(fi) F&P Solo™ Pillows (nenätyynyt ylipainehoitomaskiin) – SML SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Scl 1	-

<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> Déclaration de conformité RDM - Union européenne F&P OSA Masks	Page 34 de 92
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French                      Français

<b>Groupe de dispositifs selon le certificat CE</b>	R030101 – Masques de ventilation
<b>Objectif prévu selon le certificat CE</b>	Classe IIa
<b>Gamme de dispositifs médicaux</b>	F&P OSA Masks
<b>Fabricant</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Nouvelle-Zélande SRN NZ-MF-000002556
<b>Représentant autorisé</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, France SRN FR-AR-000000294
<b>Organisme notifié</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Allemagne Numéro NB 0123
<b>Évaluation de la conformité</b>	Classe IIa, IIb, III : Annexe IX - QMS et Annexe IX Chap. II
<b>Validité de cette déclaration</b>	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.
<b>Certificat CE (MDR)</b>	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	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MU	Masque facial pour traitement par PPC F&P Vitera™ – Moyen U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LU	Masque facial pour traitement par PPC F&P Vitera™ – Grand U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSU	Masque facial pour traitement par PPC F&P Vitera™ – Petit/Petit U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MMU	Masque facial pour traitement par PPC F&P Vitera™ – Moyen/Moyen U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LLU	Masque facial pour traitement par PPC F&P Vitera™ – Grand/Grand U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MLU	Masque facial pour traitement par PPC F&P Vitera™ – Moyen/Grand U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSL	Masque facial pour traitement par PPC F&P Vitera™ – Petit SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MSL	Masque facial pour traitement par PPC F&P Vitera™ – Moyen SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-

VIT1LSL	Masque facial pour traitement par PPC F&P Vitera™ – Grand SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MLSL	Masque facial pour traitement par PPC F&P Vitera™ – Moyen/Grand SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SU	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Petit U	94200124SOLOLM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Moyen U	94200124SOLOLM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LU	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Grand U	94200124SOLOLM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Large U	94200124SOLOLM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SML U	F&P Solo™ Nasal (masque nasal de traitement par PPC) – SML U	94200124SOLOLM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Petit Petit U	94200124SOLOLM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MMU	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Moyen Moyen U	94200124SOLOLM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Grand Grand U	94200124SOLOLM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SU	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – Petit U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-

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SLP1MU	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – Moyen U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1LU	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – Grand U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SML U	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – SML U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SSU	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – Petit Petit U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1MMU	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – Moyen Moyen U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1LLU	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – Grand Grand U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SSL	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Petit SL	94200124SOLONMSL017D	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MSL	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Moyen SL	94200124SOLONMSL017D	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LSL	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Grand SL	94200124SOLONMSL017D	R030101	-	Ila	Rule 2 Scl 1	-
SLN1WSL	F&P Solo™ Nasal (masque nasal de traitement par PPC) – Large SL	94200124SOLONMSL017D	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SML SL	F&P Solo™ Nasal (masque nasal de traitement par PPC) – SML SL	94200124SOLONMSL017D	R030101	-	Ila	Rule 2 Scl 1	-

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F&P OSA Masks

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SLP1SSL	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – Petit SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1MSL	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – Moyen SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1LSL	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – Grand SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SML SL	F&P Solo™ Pillows (masque narinaire de traitement par PPC) – SML SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Sc1 1	-

<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> MDR-Konformitätserklärung – Europäische Union F&P OSA Masks	Seite <b>39</b> von <b>92</b>
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German      Deutsch

<b>Gerätegruppe gemäß EC-Zertifikat</b>	R030101 – Beatmungsmasken
<b>Verwendungszweck gemäß EC-Zertifikat</b>	Klasse IIa
<b>Medizinproduktgruppe</b>	F&P OSA Masks
<b>Hersteller</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Neuseeland SRN NZ-MF-000002556
<b>Bevollmächtigter Vertreter</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Frankreich SRN FR-AR-000000294
<b>Benannte Stelle</b>	TÜV SÜD Produkt Service GmbH Ridlerstr 65, D-80339 München, Deutschland NB-Nummer 0123
<b>Konformitätsbewertung</b>	Klasse IIa, IIb, III: Anhang IX – QMS und Anhang IX Kap. II
<b>Gültigkeit dieser Erklärung</b>	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.
<b>EG-Zertifikat (MDR)</b>	EG-Zertifikat Nr G10 010815 0039
<p>Diese EU-Konformitätserklärung wird in alleiniger Verantwortung des Herstellers ausgestellt.</p> <p>Wir, der Hersteller, erklären, dass die genannten Medizinprodukte:</p> <ul style="list-style-type: none"> <li>• mit der Verordnung 2017/745 über Medizinprodukte (MDR) konform sind.</li> <li>• mit allen anderen einschlägigen Rechtsvorschriften der Union konform sind, die die Ausstellung einer EU-Konformitätserklärung vorsehen (siehe unten):</li> </ul>	
<b>Andere Gesetzgebung</b>	
<p>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.</p>	
<p>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.</p>	

**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	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MU	F&P Vitera™ Vollgesichtsmaske für die PAP-Therapie – Mittel U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LU	F&P Vitera™ Vollgesichtsmaske für die PAP-Therapie – Groß U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSU	F&P Vitera™ Vollgesichtsmaske für die PAP-Therapie – Klein/Klein U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MMU	F&P Vitera™ Vollgesichtsmaske für die PAP-Therapie – Mittel/Mittel U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LLU	F&P Vitera™ Vollgesichtsmaske für die PAP-Therapie – Groß/Groß U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MLU	F&P Vitera™ Vollgesichtsmaske für die PAP-Therapie – Mittel/Groß U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSL	F&P Vitera™ Vollgesichtsmaske für die PAP-Therapie – Klein SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MSL	F&P Vitera™ Vollgesichtsmaske für die PAP-Therapie – Mittel SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-



VIT1LSL	F&P Vitera™ Vollgesichtsmaske für die PAP- Therapie – Groß SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MLS	F&P Vitera™ Vollgesichtsmaske für die PAP- Therapie – Mittel/Groß SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SU	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Klein U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Mittel U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LU	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Groß U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Weite U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SML U	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – SML U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Klein Klein U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MMU	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Mittel Mittel U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Groß Groß U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SU	F&P Solo™ Pillows (Nasenkissen für PAP- Therapiemaske) – Klein U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLP1MU	F&P Solo™ Pillows (Nasenkissen für PAP- Therapiemaske) – Mittel U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-

SLP1LU	F&P Solo™ Pillows (Nasenkissen für PAP- Therapiemaske) – Groß U	94200124SOLOLM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SML U	F&P Solo™ Pillows (Nasenkissen für PAP- Therapiemaske) – SML U	94200124SOLOLM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SSU	F&P Solo™ Pillows (Nasenkissen für PAP- Therapiemaske) – Klein Klein U	94200124SOLOLM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLP1MMU	F&P Solo™ Pillows (Nasenkissen für PAP- Therapiemaske) – Mittel Mittel U	94200124SOLOLM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLP1LLU	F&P Solo™ Pillows (Nasenkissen für PAP- Therapiemaske) – Groß Groß U	94200124SOLOLM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SSL	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Klein SL	94200124SOLOLM017D	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MSL	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Mittel SL	94200124SOLOLM017D	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LSL	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Groß SL	94200124SOLOLM017D	R030101	-	Ila	Rule 2 Scl 1	-
SLN1WSL	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – Weite SL	94200124SOLOLM017D	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SML SL	F&P Solo™ Nasal (Nasale PAP-Therapiemaske) – SML SL	94200124SOLOLM017D	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SSL	F&P Solo™ Pillows (Nasenkissen für PAP- Therapiemaske) – Klein SL	94200124SOLOPM0187	R030101	-	Ila	Rule 2 Scl 1	-

SLP1MSL	F&P Solo™ Pillows (Nasenkissen für PAP- Therapiemaske) – Mittel SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1LSL	F&P Solo™ Pillows (Nasenkissen für PAP- Therapiemaske) – Groß SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SML SL	F&P Solo™ Pillows (Nasenkissen PAP- Therapiemaske) – SML SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Sc1 1	-

<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> Δήλωση συμμόρφωσης MDR – Ευρωπαϊκή Ένωση F&P OSA Masks	Σελίδα <b>44</b> από <b>92</b>
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Greek Ελληνικά

<b>Ομάδα τεχνολογικών προϊόντων σύμφωνα με το πιστοποιητικό ΕΚ</b>	R030101 – Μάσκες αερισμού·
<b>Προβλεπόμενη χρήση σύμφωνα με το πιστοποιητικό ΕΚ</b>	Κατηγορία IIa
<b>Οικογένεια ιατροτεχνολογικών προϊόντων</b>	F&P OSA Masks
<b>Κατασκευαστής</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Νέα Ζηλανδία SRN NZ-MF-000002556
<b>Εξουσιοδοτημένος Αντιπρόσωπος</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Γαλλία SRN FR-AR-000000294
<b>Κοινοποιημένος οργανισμός</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Γερμανία Αριθμός NB 0123
<b>Αξιολόγηση συμμόρφωσης</b>	Κατηγορία IIa, IIb, III: Παράρτημα IX – QMS και Παράρτημα IX Κεφ. II
<b>Εγκυρότητα της παρούσας δήλωσης</b>	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.
<b>Πιστοποιητικό ΕΚ (MDR)</b>	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	94200124VITERAFFM01P H	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1MU	Μάσκα πλήρους προσώπου F&P Vitera™ για θεραπεία PAP – Μεσαία U	94200124VITERAFFM01P H	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1LU	Μάσκα πλήρους προσώπου F&P Vitera™ για θεραπεία PAP – Μεγάλη U	94200124VITERAFFM01P H	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1SSU	Μάσκα πλήρους προσώπου F&P Vitera™ για θεραπεία PAP – Μικρή/Μικρή U	94200124VITERAFFM01P H	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1MMU	Μάσκα πλήρους προσώπου F&P Vitera™ για θεραπεία PAP – Μεσαία/Μεσαία U	94200124VITERAFFM01P H	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1LLU	Μάσκα πλήρους προσώπου F&P Vitera™ για θεραπεία PAP – Μεγάλη/Μεγάλη U	94200124VITERAFFM01P H	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1MLU	Μάσκα πλήρους προσώπου F&P Vitera™ για θεραπεία PAP – Μεσαία/Μεγάλη U	94200124VITERAFFM01P H	R030101	-	Ila	Rule 2 Sc1 1	-

SLN1SU	F&P Solo™ Nasal (Πινική Μάσκα Θεραπείας PAP) – Μικρή U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (Πινική Μάσκα Θεραπείας PAP) – Μεσαία U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LU	F&P Solo™ Nasal (Πινική Μάσκα Θεραπείας PAP) – Μεγάλη U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (Πινική Μάσκα Θεραπείας PAP) – Φαρδιά U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SML U	F&P Solo™ Nasal (Πινική Μάσκα Θεραπείας PAP) – SML U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (Πινική Μάσκα Θεραπείας PAP) – Μικρή Μικρή U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MMU	F&P Solo™ Nasal (Πινική Μάσκα Θεραπείας PAP) – Μεσαία Μεσαία U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (Πινική Μάσκα Θεραπείας PAP) – Μεγάλη Μεγάλη U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SU	F&P Solo™ Pillows (Πινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – Μικρή U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-

SLP1MU	F&P Solo™ Pillows (Ρινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – Μεσαία U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1LU	F&P Solo™ Pillows (Ρινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – Μεγάλη U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SML U	F&P Solo™ Pillows (Ρινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – SML U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SSU	F&P Solo™ Pillows (Ρινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – Μικρή Μικρή U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1MMU	F&P Solo™ Pillows (Ρινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – Μεσαία Μεσαία U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1LLU	F&P Solo™ Pillows (Ρινική Μάσκα Θεραπείας PAP με Μαξιλαράκια) – Μεγάλη Μεγάλη U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-

<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> MDR-megfelelőségi nyilatkozat – Európai Unió F&P OSA Masks	Oldal: <b>48/92</b>
	Dok. száma: REG – 1317
	Változat: F

Hungarian Magyar

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



**Orvostechnikai eszközök**

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

<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> Dichiarazione di conformità MDR – Unione Europea F&P OSA Masks	Pagina <b>50</b> di <b>92</b>
	Doc. No: REG – 1317
	Revisione: F

Italian                      Italiano

<b>Gruppo di dispositivi come da certificato CE</b>	R030101 - Maschere per ventilazione
<b>Scopo previsto come da certificato CE</b>	Classe IIa
<b>Famiglia di dispositivi medici</b>	F&P OSA Masks
<b>Produttore</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Nuova Zelanda SRN NZ-MF-000002556
<b>Rappresentate autorizzato</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Francia SRN FR-AR-000000294
<b>Organismo notificato</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 Monaco, Germania Numero ON 0123
<b>Valutazione della conformità</b>	Classe IIa, IIb, III: Allegato IX – QMS e Allegato IX Capitolo II
<b>Validità di questa Dichiarazione</b>	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.
<b>Certificato CE (MDR)</b>	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	R030101	-	Ila	Rule 2 ScI 1	-
VIT1MU	Maschera oro-nasale F&P Vitera™ per terapia PAP - Medium U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 ScI 1	-
VIT1LU	Maschera oro-nasale F&P Vitera™ per terapia PAP - Large U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 ScI 1	-
VIT1SSU	Maschera oro-nasale F&P Vitera™ per terapia PAP - Small/Small U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 ScI 1	-
VIT1MMU	Maschera oro-nasale F&P Vitera™ per terapia PAP - Medium/Medium U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 ScI 1	-
VIT1LLU	Maschera oro-nasale F&P Vitera™ per terapia PAP - Large/Large U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 ScI 1	-
VIT1MLU	Maschera oro-nasale F&P Vitera™ per terapia PAP - Medium/Large U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 ScI 1	-
VIT1SSL	Maschera oro-nasale F&P Vitera™ per terapia PAP - Small SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 ScI 1	-
VIT1MSL	Maschera oro-nasale F&P Vitera™ per terapia PAP - Medium SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 ScI 1	-

VIT1LSL	Maschera oro-nasale F&P Vitera™ per terapia PAP - Large SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1MLSL	Maschera oro-nasale F&P Vitera™ per terapia PAP - Medium/Large SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1SU	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Small U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1MU	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Medium U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1LU	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Large U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1WU	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Wide U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1SML U	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – SML U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1SSU	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Small Small U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1MMU	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Medium Medium U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1LLU	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Large Large U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Sc1 1	-

SLP1SU	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – Small U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 ScI 1	-
SLP1MU	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – Medium U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 ScI 1	-
SLP1LU	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – Large U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 ScI 1	-
SLP1SML U	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – SML U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 ScI 1	-
SLP1SSU	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – Small Small U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 ScI 1	-
SLP1MMU	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – Medium Medium U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 ScI 1	-
SLP1LLU	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – Large Large U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 ScI 1	-
SLN1SSL	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Small SL	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 ScI 1	-
SLN1MSL	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Large SL	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 ScI 1	-

SLN1LSL	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Medium SL	94200124SOLOONMSL017D	R030101	-	Ila	Rule 2 ScI 1	-
SLN1WSL	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – Wide SL	94200124SOLOONMSL017D	R030101	-	Ila	Rule 2 ScI 1	-
SLN1SML SL	F&P Solo™ Nasal (Maschera nasale per terapia PAP) – SML SL	94200124SOLOONMSL017D	R030101	-	Ila	Rule 2 ScI 1	-
SLP1SSL	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – Small SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 ScI 1	-
SLP1MSL	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – Medium SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 ScI 1	-
SLP1LSL	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – Large SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 ScI 1	-
SLP1SML SL	F&P Solo™ Pillows (Maschera a cuscinetti nasali per terapia PAP) – SML SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 ScI 1	-

<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> ESMR atbilstības deklarācija — Eiropas Savienība F&P OSA Masks	<b>55. lpp. no 92</b>
	Dok. Nr.: REG – 1317
	Pārskatīšana: F

Latvian                      Latviesū

<b>Ierīču grupa atbilstoši EK sertifikātam</b>	R030101 – ventilācijas maskas
<b>Paredzētais nolūks atbilstoši EK sertifikātam</b>	Ila klase
<b>Medicīnas ierīču saime</b>	F&P OSA Masks
<b>Ražotājs</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Jaunzēlande SRN NZ-MF-000002556
<b>Pilnvarotais pārstāvis</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Francija SRN FR-AR-000000294
<b>Paziņotā struktūra</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Vācija PS identifikācijas numurs 0123
<b>Atbilstības novērtējums</b>	Klase Ila, I Ib, III: IX. pielikums — KVS un IX. pielikuma II. nodaļa,
<b>Šīs deklarācijas derīgums</b>	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.
<b>EK sertifikāts (MDR)</b>	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.

**Medicīnas ierīces**

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



<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> MDR atitikties deklaracija – Europos Sąjunga F&P OSA Masks	<b>57 iš. 92</b> psl.
	Dok. Nr.: REG – 1317
	Redakcija: F

Lithuanian      Lietuvių

<b>Prietaisų grupė pagal EB sertifikata</b>	R030101 – ventilacijos kaukės
<b>Numatytoji paskirtis pagal EB sertifikata</b>	Ila klasė
<b>Medicinos prietaisų šeima</b>	F&P OSA Masks
<b>Gamintojas</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Naujoji Zelandija SRN NZ-MF-000002556
<b>Įgaliotasis atstovas</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Prancūzija SRN FR-AR-000000294
<b>Notifikuotoji įstaiga</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Vokietija NB numeris 0123
<b>Atitikties įvertinimas</b>	Ila, Ilb, III klasės: IX priedas – KVS ir IX priedo II skyrius
<b>Šios deklaracijos galiojimas</b>	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.
<b>EB sertifikatas (MDR)</b>	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	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MU	F&P Vitera™ viso veido PAP terapijos kaukė – vidutinė U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LU	F&P Vitera™ viso veido PAP terapijos kaukė – didelė U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSU	F&P Vitera™ viso veido PAP terapijos kaukė – maža / maža U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MMU	F&P Vitera™ viso veido PAP terapijos kaukė – vidutinė / vidutinė U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LLU	F&P Vitera™ viso veido PAP terapijos kaukė – didelė / didelė U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MLU	F&P Vitera™ viso veido PAP terapijos kaukė – vidutinė / didelė U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-

<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b>  MDR-samsvarserklæring – EU F&P OSA Masks	Side <b>59</b> av <b>92</b>
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Norwegian      Norsk

<b>Enhetsgruppe i henhold til EF-sertifikat</b>	R030101 – Ventilasjonsmaske
<b>Tiltenkt formål i henhold til EF-sertifikat</b>	Klasse IIa
<b>Medisinsk utstyrstype</b>	F&P OSA Masks
<b>Produsent</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, New Zealand SRN NZ-MF-000002556
<b>Autorisert representant</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Frankrike SRN FR-AR-000000294
<b>Teknisk kontrollorgan</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Tyskland NB-nummer 0123
<b>Samsvarsvurdering</b>	Klasse IIa, IIb, III: Vedlegg IX – QMS og vedlegg IX kap. II
<b>Gyldigheten av denne erklæringen</b>	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".
<b>EF-sertifikat (MDR)</b>	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	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MU	F&P Vitera™ hel ansiktsmaske til PAP-behandling – medium U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LU	F&P Vitera™ hel ansiktsmaske til PAP-behandling – stor U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSU	F&P Vitera™ hel ansiktsmaske til PAP-behandling – liten/liten U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MMU	F&P Vitera™ hel ansiktsmaske til PAP-behandling – medium/medium U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LLU	F&P Vitera™ hel ansiktsmaske til PAP-behandling – stor/stor U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MLU	F&P Vitera™ hel ansiktsmaske til PAP-behandling – medium/stor U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSL	F&P Vitera™ hel ansiktsmaske til PAP-behandling – liten SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MSL	F&P Vitera™ hel ansiktsmaske til PAP-behandling – medium SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-

VIT1LSL	F&P Vitera™ hel ansiktsmaske til PAP-behandling – stor SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1MLSL	F&P Vitera™ hel ansiktsmaske til PAP-behandling – medium/stor SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-

<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> Deklaracja zgodności MDR - Unia Europejska F&P OSA Masks	Strona <b>62 z 92</b>
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Polish                      Polski

<b>Grupa urządzeń zgodnie z certyfikatem WE</b>	R030101 – Maski do wentylacji
<b>Przeznaczenie zgodnie z certyfikatem WE</b>	Klasa IIa
<b>Rodzina wyrobów medycznych</b>	F&P OSA Masks
<b>Producent</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Nowa Zelandia SRN NZ-MF-000002556
<b>Autoryzowany przedstawiciel</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Francja SRN FR-AR-000000294
<b>Jednostka notyfikowana</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 Monachium, Niemcy Numer NB 0123
<b>Ocena zgodności</b>	Klasa IIa, IIb, III: Załącznik IX - system zarządzania jakością i załącznik IX, rozdział II
<b>Ważność niniejszej deklaracji</b>	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.
<b>Certyfikat WE (MDR)</b>	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	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1MU	Maska pełnotwarzowa F&P Vitera™ do terapii PAP – średnia U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1LU	Maska pełnotwarzowa F&P Vitera™ do terapii PAP – duża U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1SSU	Maska pełnotwarzowa F&P Vitera™ do terapii PAP – mała/mała U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1MMU	Maska pełnotwarzowa F&P Vitera™ do terapii PAP – średnia/średnia U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1LLU	Maska pełnotwarzowa F&P Vitera™ do terapii PAP – duża/duża U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1MLU	Maska pełnotwarzowa F&P Vitera™ do terapii PAP – średnia/duża U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1SU	F&P Solo™ Nasal (maska nosowa do terapii PAP) – mała U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1MU	F&P Solo™ Nasal (maska nosowa do terapii PAP) – średnia U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-

SLN1LU	F&P Solo™ Nasal (maska nosowa do terapii PAP) – duża U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1WU	F&P Solo™ Nasal (maska nosowa do terapii PAP) – szeroka U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1SML U	F&P Solo™ Nasal (maska nosowa do terapii PAP) – SML U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1SSU	F&P Solo™ Nasal (maska nosowa do terapii PAP) – mała mała U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1MMU	F&P Solo™ Nasal (maska nosowa do terapii PAP) – średnia średnia U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1LLU	F&P Solo™ Nasal (maska nosowa do terapii PAP) – duża duża U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SU	F&P Solo™ Pillows (maska nosowa do terapii PAP z poduszkami) – mała U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1MU	F&P Solo™ Pillows (maska nosowa do terapii PAP z poduszkami) – średnia U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1LU	F&P Solo™ Pillows (maska nosowa do terapii PAP z poduszkami) – duża U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SML U	F&P Solo™ Pillows (maska nosowa do terapii PAP z poduszkami) – SML U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SSU	F&P Solo™ Pillows (maska nosowa do terapii PAP z poduszkami) – mała mała U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-



SLP1MMU	F&P Solo™ Pillows (maska nosowa do terapii PAP z poduszkami) – średnia średnia U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1LLU	F&P Solo™ Pillows (maska nosowa do terapii PAP z poduszkami) – duża duża U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-

<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> Declaração de conformidade com o RDM – União Europeia F&P OSA Masks	Página <b>66</b> de <b>92</b>
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Portuguese      Português (Portugal)

<b>Grupo de dispositivos de acordo com o Certificado da CE</b>	R030101 – Máscaras de ventilação
<b>Finalidade prevista de acordo com o Certificado da CE</b>	Classe IIa
<b>Família de dispositivos médicos</b>	F&P OSA Masks
<b>Fabricante</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Nova Zelândia SRN NZ-MF-000002556
<b>Representante autorizado</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, França SRN FR-AR-000000294
<b>Organismo notificado</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Alemanha Número NB 0123
<b>Avaliação da conformidade</b>	Classe IIa, IIb, III: Anexo IX – QMS e Anexo IX, Capítulo II
<b>Validade da presente declaração</b>	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.
<b>Certificado da CE (RDM)</b>	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	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MU	Máscara facial completa de terapia PAP F&P Vitera™ – Média U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LU	Máscara facial completa de terapia PAP F&P Vitera™ – Grande U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSU	Máscara facial completa de terapia PAP F&P Vitera™ – Pequena/Pequena U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MMU	Máscara facial completa de terapia PAP F&P Vitera™ – Média/Média U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LLU	Máscara facial completa de terapia PAP F&P Vitera™ – Grande/Grande U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MLU	Máscara facial completa de terapia PAP F&P Vitera™ – Média/Grande U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SU	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Pequeno U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Médio U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-

SLN1LU	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Grande U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Largo U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SML U	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - SML U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Pequeno Pequeno U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MMU	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Médio Médio U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Grande Grande U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SU	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - Pequeno U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1MU	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - Médio U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1LU	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - Grande U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SML U	F&P Solo™ Pillows (Máscara de terapia PAP	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Scl 1	-

	com almofadas nasais) - SML U						
SLP1SSU	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - Pequeno Pequeno U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1MMU	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - Médio Médio U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1LLU	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - Grande Grande U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1SSL	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Pequeno SL	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1MSL	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Médio SL	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1LSL	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Grande SL	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1WSL	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - Largo SL	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1SML SL	F&P Solo™ Nasal (Máscara de terapia PAP nasal) - SML SL	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SSL	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - Pequeno SL	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-

Declaração de conformidade com o RDM – União Europeia  
F&P OSA Masks

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SLP1MSL	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - Médio SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 ScI 1	-
SLP1LSL	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - Grande SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 ScI 1	-
SLP1SML SL	F&P Solo™ Pillows (Máscara de terapia PAP com almofadas nasais) - SML SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 ScI 1	-

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	Revizia: F

Romanian      Română

<b>Grup de dispozitive conform certificatului CE</b>	R030101 - Măști de ventilație
<b>Scopul preconizat conform certificatului CE</b>	Clasa IIa
<b>Seria de dispozitive medicale</b>	F&P OSA Masks
<b>Producător</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Noua Zeelandă SRN NZ-MF-000002556
<b>Reprezentant autorizat</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Franța SRN FR-AR-000000294
<b>Organismul notificat</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Germania NB numărul 0123
<b>Evaluarea conformității</b>	Clasa IIa, IIb, III: Anexa IX - QMS și Anexa IX Cap II
<b>Termenul de valabilitate al acestei declarații</b>	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.
<b>Certificat CE (MDR)</b>	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**

REF	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	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MU	Mască de față integrală F&P Vitera™ pentru terapie PAP – medie U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LU	Mască de față integrală F&P Vitera™ pentru terapie PAP – mare U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSU	Mască de față integrală F&P Vitera™ pentru terapie PAP – mică/mică U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MMU	Mască de față integrală F&P Vitera™ pentru terapie PAP – medie/medie U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LLU	Mască de față integrală F&P Vitera™ pentru terapie PAP – mare/mare U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MLU	Mască de față integrală F&P Vitera™ pentru terapie PAP – medie/mare U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-



<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> Vyhlásenie o zhode MDR – Európska únia F&P OSA Masks	Strana <b>73 / 92</b>
	Doc. Č.: REG – 1317
	Revízia: F

Slovak                      Slovenčina

<b>Skupina pomôcok podľa certifikátu ES</b>	R030101 – Ventilačné masky
<b>Zamýšľaný účel podľa certifikátu ES</b>	Trieda IIa
<b>Skupina zdravotníckych pomôcok</b>	F&P OSA Masks
<b>Výrobca</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Nový Zéland SRN NZ-MF-000002556
<b>Oprávnený zástupca</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Francúzsko SRN FR-AR-000000294
<b>Notifikovaný orgán</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Nemecko Číslo NB 0123
<b>Posudzovanie zhody</b>	Trieda IIa, IIb, III: Príloha IX – QMS a Príloha IX kapitola II
<b>Platnosť tohto vyhlásenia</b>	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.
<b>ES certifikát (MDR)</b>	Certifikát ES č. G10 010815 0039
<p>Toto vyhlásenie o zhode EÚ sa vydáva na výhradnú zodpovednosť výrobcu.</p> <p>My, výrobca, vyhlasujeme, že uvedené zdravotnícke pomôcky:</p> <ul style="list-style-type: none"> <li>• Sú v súlade s nariadením 2017/745 o zdravotníckych pomôckach.</li> <li>• Sú v súlade s akýmikoľvek inými príslušnými právnymi predpismi Únie, ktorými sa ustanovuje vydávanie EÚ vyhlásenia o zhode, uvedenými nižšie:</li> </ul>	
<b>Iné právne predpisy</b>	
<p>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.</p>	
<p>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.</p>	

**Zdravotnícke pomôcky**

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

<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> Izjava o skladnosti po uredbi o medicinskih pripomočkih – Evropska unija F&P OSA Masks	Stran <b>75</b> od <b>92</b>
	Dok. št.: REG – 1317
	Različica: F

Slovenian Slovenščina

<b>Skupina pripomočka v skladu s certifikatom ES</b>	R030101 – Maske za ventilacijo
<b>Predvidena uporaba v skladu s certifikatom ES</b>	Razred IIa
<b>Družina medicinskih pripomočkov</b>	F&P OSA Masks
<b>Proizvajalec</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Nova Zelandija SRN NZ-MF-000002556
<b>Pooblaščen zastopnik</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Francija SRN FR-AR-000000294
<b>Priglašeni organ</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Nemčija Številka priglašenega organa 0123
<b>Ocena skladnosti</b>	Razred IIa, IIb, III: Priloga IX – sistem kakovosti in Priloga IX, Poglavje II
<b>Veljavnost te izjave</b>	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.
<b>Certifikat ES (uredba o medicinskih pripomočkih)</b>	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:

#### **Druge zakonodaje**

- 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	-

<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> Declaración de conformidad MDR - Unión Europea F&P OSA Masks	Página <b>77</b> de <b>92</b>
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	Revisión: F

Spanish      Español

<b>Grupo de dispositivos según certificado CE</b>	R030101: máscaras de ventilación
<b>Indicación prevista según certificado CE</b>	Clase IIa
<b>Familia de productos sanitarios</b>	F&P OSA Masks
<b>Fabricante</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Nueva Zelanda SRN NZ-MF-000002556
<b>Representante autorizado</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Francia SRN FR-AR-000000294
<b>Organismo notificado</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 Múnich, Alemania NB número 0123
<b>Evaluación de conformidad</b>	Clase IIa, IIb, III: Anexo IX - QMS y Anexo IX Capítulo II
<b>Validez de esta declaración</b>	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.
<b>Certificado CE (MDR)</b>	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	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MU	Máscara facial completa para terapia PAP F&P Vitera™ – Mediana U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LU	Máscara facial completa para terapia PAP F&P Vitera™ – Grande U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSU	Máscara facial completa para terapia PAP F&P Vitera™ – Pequeña/Pequeña U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MMU	Máscara facial completa para terapia PAP F&P Vitera™ – Mediana/Mediana U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LLU	Máscara facial completa para terapia PAP F&P Vitera™ – Grande/Grande U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MLU	Máscara facial completa para terapia PAP F&P Vitera™ – Mediana/Grande U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SZ	Máscara facial completa para terapia PAP F&P Vitera™ – Pequeña Z	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-

VIT1MZ	Máscara facial completa para terapia PAP F&P Vitera™ – Mediana Z	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1LZ	Máscara facial completa para terapia PAP F&P Vitera™ – Grande Z	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1SSZ	Máscara facial completa para terapia PAP F&P Vitera™ – Pequeña/Pequeña Z	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1MMZ	Máscara facial completa para terapia PAP F&P Vitera™ – Mediana/Mediana Z	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1LLZ	Máscara facial completa para terapia PAP F&P Vitera™ – Grande/Grande Z	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1SSL	Máscara facial completa para terapia PAP F&P Vitera™ – Pequeña SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1MSL	Máscara facial completa para terapia PAP F&P Vitera™ – Mediana SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1LSL	Máscara facial completa para terapia PAP F&P Vitera™ – Grande SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1MLSL	Máscara facial completa para terapia PAP F&P Vitera™ – Mediana/Grande SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	2

SLN1SU	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - Pequeña U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - Mediana U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LU	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - Grande U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
SLN1WU	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - Ancha U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SML U	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - SML U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SSU	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - Pequeña Pequeña U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MMU	F&P Solo™ Nasal (mascarilla de terapia de PAP nasal) - Mediana Mediana U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LLU	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - Grande Grande U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
SLP1SU	F&P Solo™ Pillows (mascarilla de terapia PAP con almohadillas nasales) - Pequeña U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
SLP1MU	F&P Solo™ Pillows (mascarilla de terapia PAP	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-



	con almohadillas nasales) - Mediana U						
SLP1LU	F&P Solo™ Pillows (mascarilla de terapia PAP con almohadillas nasales) - Grande U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SML U	F&P Solo™ Pillows (mascarilla de terapia PAP con almohadillas nasales) - SML U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SSU	F&P Solo™ Pillows (mascarilla de terapia PAP con almohadillas nasales) - Pequeña Pequeña U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1MMU	F&P Solo™ Pillows (mascarilla de terapia PAP con almohadillas nasales) - Mediana Mediana U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1LLU	F&P Solo™ Pillows (mascarilla de terapia PAP con almohadillas nasales) - Grande Grande U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1SSL	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - Pequeña SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1MSL	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - Mediana SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1LSL	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - Grande SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-

SLN1WSL	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - Ancha SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1SML SL	F&P Solo™ Nasal (mascarilla de terapia PAP nasal) - SML SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SSL	F&P Solo™ Pillows (mascarilla de terapia PAP con almohadillas nasales) - Pequeña SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1MSL	F&P Solo™ Pillows (mascarilla de terapia PAP con almohadillas nasales) - Mediana SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1LSL	F&P Solo™ Pillows (mascarilla de terapia PAP con almohadillas nasales) - Grande SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SML SL	F&P Solo™ Pillows (mascarilla de terapia PAP con almohadillas nasales) - SML SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-

<b>Fisher &amp; Paykel</b> <b>HEALTHCARE</b> MDR-försäkran om överensstämmelse – Europeiska unionen F&P OSA Masks	Sida <b>83</b> av <b>92</b>
	Dok. Nr: REG – 1317
	Version: F

Swedish      Svenska

<b>Enhetsgrupp enligt EG-certifikat</b>	R030101 – ventilationsmasker
<b>Avsett ändamål enligt EG-certifikat</b>	Klass IIa
<b>Medicinteknisk produktfamilj</b>	F&P OSA Masks
<b>Tillverkare</b>	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki, Auckland 2013, Nya Zeeland SRN NZ-MF-000002556
<b>Auktoriserad representant</b>	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, Frankrike SRN FR-AR-000000294
<b>Anmält organ</b>	TÜV SÜD Product Service GmbH Ridlerstr 65, D-80339 München, Tyskland NB-nummer 0123
<b>Bedömning av överensstämmelse</b>	Klass IIa, IIb, III: Bilaga IX – QMS och bilaga IX kap II
<b>Denna försäkran s giltighet</b>	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.
<b>EG-certifikat (MDR)</b>	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	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MU	F&P Vitera™ Full hel ansiktsmask PAP-behandlingsmask – Medium U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LU	F&P Vitera™ Full hel ansiktsmask PAP-behandlingsmask – Large U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSU	F&P Vitera™ Full hel ansiktsmask PAP-behandlingsmask – Small/Small U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MMU	F&P Vitera™ Full hel ansiktsmask PAP-behandlingsmask – Medium/Medium U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LLU	F&P Vitera™ Full hel ansiktsmask PAP-behandlingsmask – Large/Large U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MLU	F&P Vitera™ Full hel ansiktsmask PAP-behandlingsmask – Medium/Large U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSL	F&P Vitera™ Full hel ansiktsmask PAP-behandlingsmask – Small SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-

VIT1MSL	F&P Vitera™ Full hel ansiktsmask PAP-behandlingsmask – Medium SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1LSL	F&P Vitera™ Full hel ansiktsmask PAP-behandlingsmask – Large SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
VIT1MLSL	F&P Vitera™ Full hel ansiktsmask PAP-behandlingsmask – Medium/Large SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1SU	F&P Solo™ Nasal (näsmask för PAP-behandling) – small U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1MU	F&P Solo™ Nasal (näsmask för PAP-behandling) – medium U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1LU	F&P Solo™ Nasal (näsmask för PAP-behandling) – large U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1WU	F&P Solo™ Nasal (näsmask för PAP-behandling) – bred U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1SML U	F&P Solo™ Nasal (näsmask för PAP-behandling) – small small U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1SSU	F&P Solo™ Nasal (näsmask för PAP-behandling) – large large U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1MMU	F&P Solo™ Nasal (näsmask för PAP-	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Sc1 1	-

	behandling) – medium medium U						
SLN1LLU	F&P Solo™ Nasal (näsmask för PAP-behandling) – SML U	94200124SOLONM001BF	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SU	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – small U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1MU	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – medium U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1LU	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – large U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SML U	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – SML U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SSU	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – small small U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1MMU	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – medium medium U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1LLU	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – large large U	94200124SOLOPM001C5	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1SSL	F&P Solo™ Nasal (näsmask för PAP-behandling) – small SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1MSL	F&P Solo™ Nasal (näsmask för PAP-behandling) – medium SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Sc1 1	-

SLN1LSL	F&P Solo™ Nasal (näsmask för PAP-behandling) – large SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1WSL	F&P Solo™ Nasal (näsmask för PAP-behandling) – bred SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1SMLS	F&P Solo™ Nasal (näsmask för PAP-behandling) – SML SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SSL	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – small SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1MSL	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – medium SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1LSL	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – large SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SMLS	F&P Solo™ Pillows (PAP-behandlingsmask med näskuddar) – SML SL	94200124SOLOPMSL0187	R030101	-	Ila	Rule 2 Sc1 1	-

Turkish Türkçe

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

Bu AB Uygunluk Beyanı, yalnızca üreticinin sorumluluđu kapsamında yayınlanmıştır.

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

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

**Diđer Mevzuat**

- 1) Elektrikli ve elektronik ekipmanlarda (RoHS) belirli tehlikeli maddelerin kullanımının kısıtlanmasına ilişkin 2015/863 ile deđiştirilen 2011/65/AB Direktifi.  
4. Maddede belirtilen gereksinimlerin karřılandığı kanıtlanmıştır.
- 2) 2014/53/AB Radyo Ekipmanları Direktifi (RED).  
Üretici olarak, belirtilen tıbbi cihazların Konsey Direktifi 2014/53/AB hükümlerini karřıladığını yalnızca kendi sorumluluđumuz 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	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MU	F&P Vitera™ Tam Yüz PAP Terapi Maskesi – Orta U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LU	F&P Vitera™ Tam Yüz PAP Terapi Maskesi – Büyük U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1SSU	F&P Vitera™ Tam Yüz PAP Terapi Maskesi – Küçük/Küçük U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MMU	F&P Vitera™ Tam Yüz PAP Terapi Maskesi – Orta/Orta U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1LLU	F&P Vitera™ Tam Yüz PAP Terapi Maskesi – Büyük/Büyük U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
VIT1MLU	F&P Vitera™ Tam Yüz PAP Terapi Maskesi – Orta/Büyük U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
SLN1SU	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Küçük U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
SLN1MU	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Orta U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-
SLN1LU	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Büyük U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Scl 1	-

REF	Ticari Ad	Temel UDI-DI	EMDN	Ortak Spesifikasyonlar	Sınıf	Kural	Diğer Mevzuat
SLN1WU	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Geniş U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 ScI 1	-
SLN1SML U	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – SML U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 ScI 1	-
SLN1SSU	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Küçük Küçük U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 ScI 1	-
SLN1MMU	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Orta Orta U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 ScI 1	-
SLN1LLU	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Büyük Büyük U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 ScI 1	-
SLP1SU	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – Küçük U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 ScI 1	-
SLP1MU	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – Orta U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 ScI 1	-
SLP1LU	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – Büyük U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 ScI 1	-
SLP1SML U	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – SML U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 ScI 1	-
SLP1SSU	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – Küçük Küçük U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 ScI 1	-

REF	Ticari Ad	Temel UDI-DI	EMDN	Ortak Spesifikasyonlar	Sınıf	Kural	Diđer Mevzuat
SLP1MMU	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – Orta Orta U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1LLU	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – Büyük Büyük U	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1SSL	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Küçük SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1MSL	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Orta SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1LSL	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Büyük SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1WSL	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – Geniş SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLN1SML SL	F&P Solo™ Nasal (Nazal PAP Terapi Maskesi) – SML SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1SSL	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – Küçük SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1MSL	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – Orta SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-
SLP1LSL	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – Büyük SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 Sc1 1	-

REF	Ticari Ad	Temel UDI-DI	EMDN	Ortak Spesifikasyonlar	Sınıf	Kural	Diđer Mevzuat
SLP1SML SL	F&P Solo™ Pillows (Nazal Yastıklı PAP Terapi Maskesi) – SML SL	94200124VITERAFFM01PH	R030101	-	Ila	Rule 2 ScI 1	-