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| **Manufacturer:** | Fisher & Paykel Healthcare Ltd<br>15 Maurice Paykel Place, East Tamaki,<br>Auckland 2013, New Zealand |
| **Authorised Representative:** | Fisher & Paykel Healthcare SAS<br>10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, France |
| **Product Category:** | Respiratory Gas Delivery System and Heated Humidifier |
| **Medical Device Family:** | Airvo Series |
| **Conformity Assessment Route:** | Annex II (for class IIa and above) |
| **Validity of this declaration:** | This Declaration of Conformity, for each model listed, is valid from the start date recorded against the model and for as long as the model is listed on the DoC. When a model is no longer covered by the DoC, a discontinued date is added. |

We, the manufacturer, declare under our sole responsibility that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC concerning medical devices.
All supporting documentation is retained by the manufacturer.

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| **Notified Body (for class IIa and above):** | TÜV SÜD Product Service GmbH<br>Ridlerstr 65, D-80339 München, Germany |
| **Identification number:** | 0123 |

## Approval

| Name | Title | Signature | Date and Location |
|---|---|---|---|
| Brett Whiston<br>Author | Snr Regulatory Affairs Specialist |  | 13/Mar/2025<br>Auckland |

| REF | Description | Class | Rule | GMDN Code | Start Date | Discontinued Date |
|---|---|---|---|---|---|---|
| 6703-001 | Nonin Xpod 3012LP USB | IIb | 10 | 36554 | 17/May/2021 | |
| 900PT401 | Waterbag - 2 Pack (AIRVO) | IIa | 2 | 60662 | 04/Nov/2010 | |
| 900PT460D | HPO Dual-Input Manifold (DISS) Airvo 3 series | IIa | 2 | 65540 | 7/May/2021 | |
| 900PT460N | HPO Dual-Input Manifold (NIST) Airvo 3 series | IIa | 2 | 65540 | 7/May/2021 | |
| 900PT460S | HPO Dual-Input Manifold (SIS) Airvo 3 series | IIa | 2 | 65540 | 7/May/2021 | |
| 900PT462DN | HPO Adapter (DISS to NIST) Airvo 3 series | IIa | 2 | 65540 | 7/May/2021 | |
| 900PT500 | Breathing Tube PT100 Home 10pk | IIa | 9 | 37706 | 12/Jan/2009 | |
| 900PT500E | Heated Breathing Tube Hm Sgl | IIa | 9 | 37706 | 25/Jun/2012 | |
| 900PT501 | Breathing Tube PT100 Hosp 10Pk | IIa | 9 | 37706 | 12/Jan/2009 | |
| 900PT531 | Jnr Tube And Chamber Kit 10PK | IIa | 9 | 37706 | 29/May/2012 | |
| 900PT551 | Tube and chamber kit 10 pk | IIa | 9 | 37706 | 13/Feb/2015 | 08/Dec/18 |
| 900PT552 | Tube and chamber kit with nebulizer adapter 10 pk | IIa | 9 | 37706 | 13/Apr/2015 | 20/Aug/18 |
| 900PT560 | Heated Breathing Tube Hm | IIa | 9 | 37706 | 17/Oct/2017 | |
| 900PT560E | Heated Breathing Tube Hm Sgl | IIa | 9 | 37706 | 17/Oct/2017 | |
| 900PT561 | Heated Breathing Tube and Chamber Kit | IIa | 9 | 37706 | 22/Sep/2016 | |
| 900PT562 | Tube and Chamber Kit with Nebulizer Adapter | IIa | 9 | 37706 | 27/Mar/2018 | |
| 900PT573 | AirSpiral NIV Tube and Chamber Kit | IIa | 9 | 37706 | 13/May/2021 | |
| 900PT581 | AirSpiral Tube and Chamber Kit with Incubator/Warmer tube | IIa | 9 | 37706 | 6/May/2021 | |
| 900PT584F | AirSpiral Bubble CPAP Setup Kit for F&P Interfaces | IIa | 9 | 37706 | 6/May2021 | |
| 900PT584N | AirSpiral Bubble CPAP Setup Kit for non-F&P Interfaces | IIa | 9 | 37706 | 6/May2021 | |
| myAirSpiral | myAirvo AirSpiral Tube | IIa | 9 | 37706 | 13/May/2021 | |
| myAirvoChamber1 | Re-usable myAIRVO chamber | IIa | 2 | 60662 | 7/May/2021 | |
| myAirvoKit1 | myAIRVO AirSpiral Tube & Auto-fill Chamber Kit | IIa | 9 | 37706 | 14/Apr/2020 | |
| PT100EE | myAIRVO 2 Humidifier | IIa | 9 | 57828 | 19/Dec/2012 | |
| PT100EW | myAIRVO 2 Humidifier | IIa | 9 | 57828 | 18/Aug/2009 | |
| PT100UK | myAIRVO 2 Humidifier | IIa | 9 | 57828 | 18/Aug/2009 | |
| PT101EE | AIRVO 2 Humidifier | IIa | 9 | 57828 | 11/Nov/2010 | |
| PT101EW | AIRVO 2 Humidifier | IIa | 9 | 57828 | 24/Mar/2009 | |
| PT101UK | AIRVO 2 Humidifier | IIa | 9 | 57828 | 24/Mar/2009 | |
| PT300UK | myAirvo 3 Respiratory Support Device | IIb | 11 | 57828 | 24/May/2021 | |
| PT300EW | myAirvo 3 Respiratory Support Device | IIb | 11 | 57828 | 24/May/2021 | |

| REF | Description | Class | Rule | GMDN Code | Start Date | Discontinued Date |
|---|---|---|---|---|---|---|
| PT301UK | Airvo 3 Respiratory Support Device | IIb | 11 | 57828 | 24/May/2021 | |
| PT301EB | Airvo 3 Respiratory Support Device | IIb | 11 | 57828 | 24/May/2021 | |
| PT301EC | Airvo 3 Respiratory Support Device | IIb | 11 | 57828 | 24/May/2021 | |
| PT301EF | Airvo 3 Respiratory Support Device | IIb | 11 | 57828 | 24/May/2021 | |
| PT301EK | Airvo 3 Respiratory Support Device | IIb | 11 | 57828 | 24/May/2021 | |
| PT301EW | Airvo 3 Respiratory Support Device | IIb | 11 | 57828 | 24/May/2021 | |
| PT301IN | Airvo 3 Respiratory Support Device | IIb | 11 | 57828 | 31/May/2022 | |
| PT311UK | Airvo 3 NIV Respiratory Support Device | IIb | 11 | 65491 | 24/May/2021 | |
| PT311EB | Airvo 3 NIV Respiratory Support Device | IIb | 11 | 65491 | 24/May/2021 | |
| PT311EC | Airvo 3 NIV Respiratory Support Device | IIb | 11 | 65491 | 24/May/2021 | |
| PT311EF | Airvo 3 NIV Respiratory Support Device | IIb | 11 | 65491 | 24/May/2021 | |
| PT311EK | Airvo 3 NIV Respiratory Support Device | IIb | 11 | 65491 | 24/May/2021 | |
| PT311EW | Airvo 3 NIV Respiratory Support Device | IIb | 11 | 65491 | 24/May/2021 | |
| PT311IN | Airvo 3 NIV Respiratory Support Device | IIb | 11 | 65491 | 31/May/2022 | |
| PT321UK | Airvo 3 Junior Respiratory Support Device | IIb | 11 | 65490 | 24/May/2021 | |
| PT321EB | Airvo 3 Junior Respiratory Support Device | IIb | 11 | 65490 | 24/May/2021 | |
| PT321EC | Airvo 3 Junior Respiratory Support Device | IIb | 11 | 65490 | 24/May/2021 | |
| PT321EF | Airvo 3 Junior Respiratory Support Device | IIb | 11 | 65490 | 24/May/2021 | |
| PT321EK | Airvo 3 Junior Respiratory Support Device | IIb | 11 | 65490 | 24/May/2021 | |
| PT321EW | Airvo 3 Junior Respiratory Support Device | IIb | 11 | 65490 | 24/May/2021 | |
| PT321IN | Airvo 3 Junior Respiratory Support Device | IIb | 11 | 65490 | 31/May/2022 | |

| GMDN Code | Term |
|---|---|
| 36554 | Patient monitoring system module, pulse oximetry |
| 37706 | Ventilator breathing circuit, single-use |
| 40582 | Ventilator software |
| 57828 | Professional high-flow respiratory unit |
| 60662 | Inspiratory line humidification chamber, reusable |
| 60699 | Inspiratory line humidification chamber, single use |
| 65490 | Neonatal high-flow respiratory unit |
| 65491 | Professional BPAP/high-flow respiratory unit |

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| 65540 | Uninterrupted medical gas supply manifold |

**Addendum: Change history from 26 May 2021**

Changes to the Declaration of Conformity are in accordance with Article 120(3) of the Medical Device Regulation (EU) 2017/745 (MDR), last amended by Regulation (EU) 2023/607.

The conditions are set out in Article 120(3c) MDR and include, among others, that legacy devices must continue to comply with the MDD or AIMDD, and that there are no significant changes in the design or intended purpose of the device.

Assessment is performed with MDCG-2020-3 revision 1 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD.

| Revision | Revision Date | Change |
|---|---|---|
| AP | 4 Jun 2021 | 900PT460x GMDN code change from 35455 to 65540. 6703-001 class corrected to IIb. |
| AQ | 20 Jul 2021 | MyAirSpiral class corrected to IIa as per the other breathing tubes. |
| AR | 24 Sep 2021 | 900PT551 added stop date. |
| AS | 4 Nov 2021 | Added language variants of PT3xxUK. |
| AT | 3 Aug 2022 | PT311xx replaced ‘Acute’ with ‘NIV’ in ‘description. 900PT475 GMDN code changed from 57828 to 37331. 900PT57x and 58x class corrected to IIa as per the other breathing tubes. |
| AU | 11 Oct 2023 | 900PT475 GMDN code changed from 37331 to 40582. |
| AV | 23 Apr 2024 | 900PT475 change from ‘Airvo 3 Suite Service Application’ to ‘Fisher & Paykel Healthcare Device Manager’. |
| AW | 23 Sep 2024 | 900PT401 GMDN code change from 60699 to 60662.<br>Added PT301/311/321IN models for India using CE mark. |
| AX | 13 Mar 2025 | Removal of redundant models:<br>PT300(EB, EC, EE, EF, EH, EJ, EK)<br>PT301(EE, EH, EJ)<br>PT311(EE, EH, EJ)<br>PT321(EE, EH, EJ)<br>900PT475<br>myAirvoBottle1 |