

Declaration of Conformity – Directive 2014/53/EU F&P Airvo 3

Manufacturer:	Fisher & Paykel Healthcare Ltd 15 Maurice Paykel Place, East Tamaki Auckland 2013, New Zealand
Authorised Representative:	Fisher & Paykel Healthcare SAS 10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, France
Product Category:	Heated Humidifiers
Medical Device Family:	Airvo 3 RRN0007
Conformity Assessment Route:	Internal Production Control
Notified Body:	Not applicable
EU-Type examination Certification:	Not applicable
Validity of this declaration:	This Declaration of Conformity, for each model listed, is valid from the start date recorded against the model and for as long as the model is listed on the DoC. When a model is no longer covered by the DoC, it is transferred to a Discontinued Medical Devices list and an end date recorded against it.

We, the manufacturer, declare under our sole responsibility that the stated medical devices meet the provisions of the Council Directive 2014/53/EU and the essential requirements set out in article 3 of the Directive have been demonstrated.

Product Standards Applied:	IEC 60601-1 :2005 +A1 :2012 EN 62479:2010 EN 301 489-1 v2.2.3 2019-11 EN 301 489-52 v1.1.0 2016-11 EN 301 908-1 V13.1.1 (2019-11) EN 55032:2012 EN 55035:2017
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Doc. No: REG-1398

Revision: A

REF	Product Description
PT300UK	myAirvo 3 Humidifier
PT301UK	Airvo 3
PT311UK	Airvo 3 Acute
PT321UK	Airvo 3 Junior

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Approval

Name	Title	Signature	Date
Atul Deo Author	Quality Systems Engineer		25/May/2021