



Declaration of Conformity – Medical Devices

We hereby declare that the distributed CE marked products (specific Part Numbers are included as part of this document) are covered by the “**EC Marking of Conformity Certificate**”, **reference number: 41315697, issued on 1 March 2007 and delivered by Intertek Semko AB, Kista, Sweden, Notified Body Identification Number 0413**, and conform to the required technical documentation of the **Council Directive 93/42/EEC of 14 June 1993**, concerning medical devices.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within **Class IIa and IIb**, conforms to **Swedish regulation LVFS 2003:11** as the Council Directive has been transposed into national law.

This declaration is based on the application of the **Quality System approved for the manufacture and final inspection of the products concerned, in accordance with the EC-Directive**. The conformity of the production quality assurance is described in the CE Marking of Conformity Certificate, issued and delivered by Intertek Semko.

This declaration is supported by the **Quality System Certificate based on harmonized standard ISO 13485:2016 (certificate no.: 0085627, issued on 3 January 2019, expiry 2 January 2022) and delivered by Intertek Semko**.

This Declaration of Conformity covers “**Mobile Ventilators, CPAP Systems and Patient Breathing Circuits**” as specified in the Product List belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site:

Manufacturer: Airon Corporation
 751 North Drive
 Unit 6
 Melbourne, Florida 32934 USA

Authorized Representative: Emergo Europe
 Prinsessegracht 20
 2514 AP The Hague
 The Netherlands

1 February 2019
Melbourne, Florida, USA



G. Eric Gjerde
President & CEO
Airon Corporation

MDD Product List

Product Category	Part Number	Part Description	MDD Classification (Per Annex IX, Section III)
Mobile Ventilators	20001	pNeuton Ventilator Model S	IIb (Rule 9)
	20002	pNeuton Ventilator Model S	IIb (Rule 9)
	20013	pNeuton Ventilator Model S	IIb (Rule 9)
	20014	pNeuton Ventilator Model S	IIb (Rule 9)
	20031	pNeuton Ventilator Model Mini	IIb (Rule 9)
	20033	pNeuton Ventilator Model Mini	IIb (Rule 9)
	20041	pNeuton Ventilator Model Mini neo	IIb (Rule 9)
	20042	pNeuton Ventilator Model Mini neo	IIb (Rule 9)
	20051	pNeuton Ventilator Model A	IIb (Rule 9)
	20052	pNeuton Ventilator Model A	IIb (Rule 9)
	20056	pNeuton Ventilator Model A	IIb (Rule 9)
	20057	pNeuton Ventilator Model A	IIb (Rule 9)
CPAP Systems	20201	MACS CPAP System	IIb (Rule 9)
	20212	MACS CPAP System	IIb (Rule 9)
	20213	MACS CPAP System	IIb (Rule 9)
	20301	MACS epic CPAP System	IIb (Rule 9)
	20312	MACS epic CPAP System	IIb (Rule 9)
	20313	MACS epic CPAP System	IIb (Rule 9)
Patient Breathing Circuits	58001	Patient circuit, disposable, adult/pediatric with CPAP mask, headstrap 1.8m long	IIa (Rule 2)
	58011	Patient circuit, disposable, adult/pediatric with CPAP large mask, headstrap 1.8m long	IIa (Rule 2)
	58021	Patient circuit, disposable, adult/pediatric with CPAP large mask, expiratory filter, headstrap 1.8m long	IIa (Rule 2)
	58031	Patient circuit, Neonatal/Infant, disposable, 10mm ID 1.8m long	IIa (Rule 2)
	58201	Patient circuit, Neonatal/Infant, disposable, 10mm ID 2.4m long	IIa (Rule 2)
	58035	Patient circuit, Child/Pediatric, disposable, 15mm ID 1.8m long	IIa (Rule 2)
	58051	Patient circuit, disposable, adult/pediatric 2.4m long	IIa (Rule 2)
	58301	Patient circuit, reusable adult/pediatric 1.5m long	IIa (Rule 2)
Oxygen Supply Accessories	21051	Regulator, Oxygen, Pin index style, High Pressure, MRI compatible	I (Rule I)
	21052	Regulator, Medical Air, Pin index style, High Pressure, MRI compatible	I (Rule I)
	21061	High pressure Oxygen hose, 0.9m long, green	I (Rule I)

	21062	High pressure Medical Air hose, 0.9m long, yellow	I (Rule I)
	21065	High pressure Medical Air hose, 2.4m long, yellow	I (Rule I)
	21067	High pressure Oxygen hose, 2.4m long ISO white, DISS one end only, MRI compatible	I (Rule I)
	21068	High pressure Oxygen hose, 2.4m long, green	I (Rule I)
	21069	High pressure Oxygen hose, 0.9m long, green	I (Rule I)
	21070	High pressure Medical Air hose, 2.4m long, ISO black w/white striping, DISS connector on one end	I (Rule I)
	21071	Cylinder, Oxygen, USA "E" size (650 L) MRI compatible	I (Rule I)
	21072	Cylinder, Medical Air, USA "E" size (650 L) MRI compatible	I (Rule I)
	21082	High pressure Oxygen hose, 3.7m long, green	I (Rule I)
	21086	High pressure Oxygen hose, 0.5m long ISO white, DISS one end only, MRI compatible	I (Rule I)
	21087	High pressure Medical Air hose, 0.5m long, ISO black w/white striping, DISS connector on one end	I (Rule I)
	21088	High pressure Oxygen hose, 3.0m long ISO white, DISS one end only, MRI compatible	I (Rule I)
	21089	High pressure Medical Air hose, 3.0m long, ISO black w/white striping, DISS connector on one end	I (Rule I)
General Accessories	21001	Stand, Mobile, Models A, S, MRI compatible	I (Rule I)
	21005	Stand, Mobile, Mini MRI compatible	I (Rule I)
	21016	Bed rail mount, Model A	I (Rule I)
	21017	Bed rail mount, Model S	I (Rule I)
	21018	Pole mount, Mini ventilator	I (Rule I)
	21031	Remote Alarm	I (Rule I)
	21035	Remote Alarm Cable, male/female ends 15.24m long	I (Rule I)
	21036	Remote Alarm Cable, male/female ends 30.48m long	I (Rule I)
	21040	Bracket, pole mount, MACS	I (Rule I)
	21041	Bracket, bed rail mount, MACS	I (Rule I)