



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 13485:2003 (reference no.: 9434-5, issued on 1 March 2007, expiry 28 February 2019) 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
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Unit 6
Melbourne, Florida 32934 USA

Authorized Representative: Emergo Europe
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2514 AP The Hague
The Netherlands

7 June 2017
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)
	20031	pNeuton Ventilator Model Mini	IIb (Rule 9)
	20051	pNeuton Ventilator Model A	IIb (Rule 9)
	20052	pNeuton Ventilator Model A	IIb (Rule 9)
CPAP Systems	20201	MACS CPAP System	IIb (Rule 9)
	20301	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	IIa (Rule 2)
	58035	Patient circuit, Child/Pediatric, disposable, 15mm ID	IIa (Rule 2)
	58051	Patient circuit, disposable, adult/pediatric 2.4m long	IIa (Rule 2)
	58301	Patient circuit, reusable adult/pediatric 1.8m 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 hose, 0.9m long, yellow	I (Rule I)
	21065	High pressure medical hose, 2.4m long, yellow	I (Rule I)
	21067	Hose, oxygen, 2.4m 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 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	Hose, oxygen, 0.5m ISO white, DISS one end only, MRI compatible	I (Rule I)
	21087	High pressure medical hose, 0.5m long, ISO black w/white striping, DISS connector on one end	I (Rule I)
	21088	Hose, oxygen, 3.0m ISO white, DISS one end only, MRI compatible	I (Rule I)
	21089	High pressure medical 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 15.241ong	I (Rule I)
	21036	Remote Alarm Cable, male/female ends 30.48 long	I (Rule I)
	21040	Bracket, pole mount, MACS	I (Rule I)
	21041	Bracket, bed rail mount, MACS	I (Rule I)