Airon

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
751 North Drive
Unit 6
Melbourne, Florida 32934 USA

Authorized Representative:
Emergo Europe
Molenstraat 15,
2513 BH The Hague
The Netherlands

1 March 2017
Melbourne, Florida, USA

G. Eric Gjerde
President & CEO
Airon Corporation

MDD – Product List

Products included in the Certificate No: 41315697-01
Issued to: **Airon Corporation**
751 North Drive, Unit 6
Melbourne, FL 32934
USA

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Mobile Ventilators	pNeuton Ventilator Model S 20001	IIb	No		*
	pNeuton Ventilator Model S 20002	IIb	No		*
	pNeuton Ventilator Model A 20051	IIb	No		*
	pNeuton Ventilator Model A 20052	IIb	No		*
	pNeuton Ventilator Model Mini 20031	IIb	No		June 21, 2011
CPAP Systems	MACS CPAP System 20201	IIb	No		*
	MACS epic CPAP System 20301	IIb	No		Dec 18, 2015
Patient breathing circuits	Patient circuit, disposable, adult/ pediatric 1.8 m 58001	IIa	No		*
	Patient circuit, disposable, adult/ pediatric with CPAP mask, headstrap 1.8 m 58011	IIa	No		*
	Patient circuit, disposable, adult/ pediatric with CPAP mask, filter, headstrap 1.8 m 58021	IIa	No		*
	Patient circuit, disposable, adult/ pediatric 2.4 m 58051	IIa	No		*
	Patient circuit, reusable, adult/ pediatric 1.8 m 58301	IIa	No		*

Intertek Semko AB
Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00, Fax +46 8 750 60 30, www.sweden.intertek-etlsemko.com
Registered in Sweden: No SE556024059901, Registered office: As address

MDD – Product List

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	Patient circuit, disposable, neonatal 58031	IIa	No		June 21, 2011
	Patient circuit, disposable, pediatric 58035	IIa	No		June 21, 2011

* Product added before June 21, 2011.

Signed date: March 1, 2017
Valid from: March 2, 2017

Intertek Semko AB
Notified Body MDD

Bob Andersson
Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

Intertek Semko AB is a Notified Body according to the Directive 93/42/EEC on medical devices, with identification number 0413.

Intertek Semko AB
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