

## pNeuton Ventilator Technical File

### Airon Corporation

#### Declaration of Conformity – Medical Devices

We hereby declare that the distributed CE marked products, specified in the annexed product list, are covered by the “**EC Marking of Conformity Certificate**”, **reference number: 41315697, issued on 1 March 2007 and delivered by Intertek Semko AB, Krista, Sweden, Notified Body Identification Number 0413**, and conform to the required technical documentation, in accordance with Annex VII of the “EC-Directive”, 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 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 Annex II of the EC-Directive**. The conformity of the production quality assurance set out in Annex II, is described in the said 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, issued on 1 March 2007) and delivered by Intertek Semko**.

This Declaration of Conformity covers “**Respiratory Equipment**” 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  
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6 March 2007  
Melbourne, Florida, USA

  
G. Eric Gjerde  
President & CEO  
Airon Corporation