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: 41315697-02, 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. **Expiration is 26 May 2024.**

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.: 0085627-01, issued on 3 January 2019, expiry 13 January 2025) 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
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

10 February 2023
Melbourne, Florida, USA

G. Eric Gjerde
President & CEO
Airon Corporation