

# EC Certificate

## FULL QUALITY ASSURANCE SYSTEM

### Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

**Certificate Number**  
41315697-01

**Initial Certification Date**  
March 1, 2007

**Certificate Valid from**  
March 2, 2017

**Certificate Expiry Date**  
March 1, 2022

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

*The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.*

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

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#### Organization:

## Airon Corporation

751 North Drive, Unit 6, Melbourne, FL 32934, USA

#### Product Category:

- Mobile Ventilators
- CPAP Systems
- Patient Breathing Circuits

For further identification of the products covered, see the MDD product list/product schedule.



Akcred. nr 1003  
ISO/IEC 17021

March 01, 2017

Signed date



Bob Andersson, Certification Authority MDD  
Intertek Semko AB, Kista, Sweden