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## DECLARATION OF CONFORMITY

Business Unit Name/Address: Caire, Inc.  
2200 Airport Industrial Dr, Suite 500  
Ball Ground, GA, 30107 USA

Manufacturing Facilities Address: Caire, Inc. Chart BioMedical Ltd.  
2000 Airport Industrial Drive Unit 2 – Maxdata Centre, Downmill Rd  
Ball Ground, GA 30107 Bracknell, Berkshire, RG12 1QC  
USA United Kingdom

TPED/MDD Representative: MPS  
Medical Product Service GmbH  
Borngasse 20  
35619 Braunfels, Germany

Product Families: Portable Liquid Oxygen Units  
Base Liquid Oxygen Units

MDD Equipment Class: Class IIa, MDD appendix II

Global Medical Device Nomenclature 35910-Portable Liquid Oxygen Units  
(GMDN) Code: 35221-Base Liquid Oxygen Units

This declaration applies to all CE marked devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn. I, the undersigned, hereby declare the equipment specified above, is in accordance with the following Directives:

1. Module D1 of the **European Council Directive 99/36 EC for Transportable Pressure Equipment Directive** (Certificate Number: 05/US/919)
2. Appendix II of the **Medical Devices Directive 93/42/EC** (Certificate Number: 05/US/920)

And the following Standard:

1. **EN – ISO 13485** (Certificate Number: 05/US/920)

Notified Body: APRAGAZ (0029)  
Vilvoordesesteeweg, 156  
Chaussée de Vilvorde, 156  
1120 Brussels, Belgium

Start of Pi Marking: 13 December 2002  
Start of CE Marking: 12 February 1998

Model(s): N/A Serial Number(s): N/A Invoice Number /Order Number: N/A

***To the best of my knowledge, the information above is accurate and was in effect from Jan 09, 2009, thru to Mar 11, 2010. This applies to all listed products above manufactured within the effective dates.***



Signature: \_\_\_\_\_  
Position: Quality or CSR or Operations or Regulatory  
Ted Vlahopoulos  
Name (Print): \_\_\_\_\_

Date: Mar 20, 2024