

## DECLARATION OF CONFORMITY

Manufacturer's Name/Address: Caire, Inc.  
Chart Bio-Medical Division  
3505 County Road 42 West  
Burnsville, MN 55306-3803 USA

Manufacturing Facility Name/Address: Caire, Inc.  
Chart Bio-Medical Division  
3505 County Road 42 West  
Burnsville, MN 55306-3803 USA

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

Product Families: Portable Liquid Oxygen Units  
Base Liquid Oxygen Units

MDD Equipment Class: Class IIa, MDD appendix II

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: 02/US/424-0-REV 0)
- 2.) Appendix II of the **Medical Devices Directive 93/42/EC**  
(Certificate Number: 02/US/485-0-REV 0)

and the following Standard:

- 1.) **EN – ISO 13485 (2001)**  
(Certificate Number: 02/US/512-0-REV 0)

Notified Body: APRAGAZ (0029)  
Vilvoordesesteeweg, 156  
B-1120 Brussels, Belgium

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

To the best of my knowledge, the information above is accurate and was in effect from Dec 13, 2002, thru to Dec 20, 2004. This applies to all noted products manufactured within the effective dates.



Signature: \_\_\_\_\_

Date: Jan 11, 2022  
\_\_\_\_\_

Name (Print): Ted Vlahopoulos  
\_\_\_\_\_  
Manufacturer's Representative

3505 County Road 42 West, Burnsville, MN 55306-3803  
Ph/952-882-5000, Fax/952-882-5172  
MVE Biological Customer Service 888-683-2796, CAIRE Customer Service 800-482-2473 (Toll Free, USA)