

Suite 500

2200 Airport Industrial Drive Ball Ground, GA 30107

Phone: 770.721.7700 Fax: 770.721.7701

www.chart-ind.com

## DECLARATION OF CONFORMITY

Business Unit Name/Address: Ball Ground, GA, 30107 USA

Manufacturing Facilities Address: CAIRE Inc. CAIRE Inc.

2000 Airport Industrial Drive 2800 Airwest Blvd Ball Ground, GA 30107 Plainfield, IN 46168

USA USA

Repair/Final Configuration Facilities

Address:

Chart Italy S.r.l. Chart Biomedical Limited

Via 10 Canada Unit 2---Maxdata Centre, Downmill Rd

35127 Padova Italy Bracknell, Berkshire, RG12 1QC

United Kingdom

TPED/MDD Representative: MPS

Medical Product Service GmbH

Borngasse 20

35619 Braunfels, Germany

Product Families: Portable Liquid Oxygen Units (Stroller, Sprint, Spirit, Helios, Companion)

Base Liquid Oxygen Units (Liberator, Helios, Companion)

MDD Equipment Class: Class IIa, MDD Appendix IX, Rule 11

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This declaration applies to all CE marked devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.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 B1+D of the European Council Directive 99/36 EC for Transportable Pressure Equipment Directive latest revision (Certificate Number: 05/US/919)

2. Appendix II of the **Medical Devices Directive 93/42/EC latest revision** (Certificate Number: 10/US/2021) And the following <u>Standard</u>:

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

Notified Body: APRAGAZ (0029)

Vilvoordesesteenweg, 156 Chaussée de Vilvorde, 156 1120 Brussels, Belgium

Start of Pi Marking: 30 November 2001 Start of CE Marking: 12 February 1998

To the best of my knowledge, the information above is accurate and was in effect from Mar 12, 2010, thru to June 5, 2010. This applies to all listed products above manufactured within the effective dates.

1803 Wakefoules		
	Ted Vlahopoulos	Mar 20, 2024
Signature	Name(Print)	Date

See Attachment A for Model(s), Serial Number(s), and Invoice/Order Number(s)



## CAIRE Inc.

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## Attachment A

Model(s)	Serial Number(s)	Invoice/Order Number(s)