

CAIRE Inc.

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: CAIRE Inc.

2200 Airport Industrial Dr, Suite 500

Ball Ground, GA, 30107 USA

Manufacturing Facilities Address: CAIRE Inc. 2800 Airwest Blvd

2000 Airport Industrial Drive

Ball Ground, GA 30107 Plainfield, IN 46168

USA

Repair Facilities: 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

Repair/Final configuration and 10 year

Retest Facility

Chart BioMedical GmbH

Essener strasse 68

42327 Wuppertal Germany

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 35221-Base Liquid Oxygen Units (GMDN) Code:

This declaration applies to all CE marked devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.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 amendment 2007/47/EC (latest accepted revision) Certificate Number: 10/US/2021

And the following **Standard**:

1. **EN – ISO 13485 (latest accepted 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



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To the best of my knowledge, the information above is accurate and was in effect from June 06, 2010, thru to Sept 20, 2010. This applies to all listed products above manufactured within the effective dates.

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		Ted Vlahopoulos	Mar 20, 2024	
Signature	_	Name(Print)	Date	
	See Attachm	ent A for Model(s), Serial Number(s)), and Invoice/Order Number(s)	
Model(s)	Serial Number(s)	Invoice	Invoice/Order Number(s)	

Attachment A