

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. 2000 Airport Industrial Drive Ball Ground, GA 30107 USA	CAIRE Inc. 2800 Airwest Blvd Plainfield, IN 46168 USA
Repair Facilities:	Chart Italy S.r.l. Via 10 Canada 35127 Padova Italy	Chart Biomedical Limited Unit 2---Maxdata Centre, Downmill Rd 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 Bornegasse 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 (GMDN) Code:	35910-Portable Liquid Oxygen Units 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This declaration applies to all CE marked devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.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, conforms to the:

**Medical Devices Directive 93/42/EC & latest amendment 2007/47/EC (latest accepted revision)**  
**Annex II, Clause 3 and EN-ISO 13485 (latest accepted revision)**

**EN – ISO 13485 Certificate Number: 05/US/920**

**MDD Certificate Number: 10/US/2021**

Notified Body:	APRAGAZ (0029) Vilvoordesesteeweg, 156 Chaussée de Vilvorde, 156 1120 Brussels, Belgium
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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 Sept 21, 2010 thru June 9, 2011.  
This applies to all listed products above manufactured within these effective dates.*

Signature

Ted Vlahopoulos

Name(Print)

Nov 8, 2023

Date

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

Attachment A

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