

**CHART Inc.**

2200 Airport Industrial Drive Suite 500

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	Caire Inc. 2205 Airport Industrial Drive Ball Ground, Ga 30107 USA	
Repair Facilities/Final Configuration/Ten Year Retest	Chart Italy S.r.l. Via 10 Canada 35127 Padova, ITALY	Chart Biomedical GmbH Essener strasse 68 42327 Wuppertal, Germany
	Chart France 3, rue Etienne COLLOMBET ZAC du MOUNDRAN 31470 FONSORBES, FRANCE	(Repair only) Chart Biomedical Limited Unit 2---Wokingham, RG41 ZPL United Kingdom
TPED/MDD Representative	MPS Medical Product Service GmbH Borngasse 20 35619 Braunsfels, Germany	
Product Families	Portable Liquid Oxygen Units (Stroller, Sprint, Spirit, Helios, Companion) Base Liquid Oxygen Units (Liberator, Helios, Companion)	
MDD Equipment Classification	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This declaration applies to all CE marked devices manufactured from date of issuance until it is either superseded by another declaration or withdrawn.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

MDD Notified Body:	APRAGAZ (0029) Vilvoordesesteeweg, 156 Chaussée de Vilvorde, 156 1120 Brussels, Belgium
Start of Pi marking Start of CE Marking	Effective 30 November 2001 Effective 12 February 1998

To the best of my knowledge, the information above is accurate and was in effect from June 10, 2011 thru July 6, 2011. This applies to all listed products above manufactured within the effective dates.

Ted Vlahopoulos – Sr. Regulatory Specialist

08-11-2023

Signature

Name (Print) / Title

Date (DD-MM-YYYY)

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

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Attachment A

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