

**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 6, Ashville way Wokingham RG41 2PL UK
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	
TPED Equipment Classification	Category 2	
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This declaration applies to all CE marked devices manufactured from date of issuance until it is either superseded by another declaration or withdrawn.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

This Declaration also applies to the closed cryogenics oxygen receptacle made according to the Transportable Pressure Equipment Directive (2010/35/EC) and covered by the following certificates:

Type Approval according to: 1.8.7.2 of ADR 2011: 10/US/2021

Surveillance of the Applicants in-house inspections: 1.8.7.6 of ADR 2011: 09/US/1952

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

To the best of knowledge, the information above is accurate and was in effect from July 7, 2011 thru Dec 20, 2012. This applies to all products listed above manufactured within the effective dates.

Signature

Ted Vlahopoulos – Sr. Regulatory Specialist
Name (Print) / Title

08-11-2023
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)