Declaration of Conformity
MDD, TPED, RoHS 2

CE 0029

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
	(Repair only) Chart Biomedical Limited Unit 6, Ashville way Wokingham RG41 2PL UK	
Notified Body	Apragaz (0029) Chaussée de Vilvorde, 156 Vilvoordesesteenweg 156 B-1120 Brussels, Belgium	
TPED/MDD Representative	Medical Product Service GmbH (MPS) 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 Classification	Class IIa, MDD Appendix IX, Rule 11	
Global Medical Device Nomenclature (GMDN) Code:	35910-Portable Liquid Oxygen Units 35221-Base Liquid Oxygen Units	
Start of CE Marking	Effective 12 February 1998	
Start of Pi marking	Effective 30 November 2001	

This declaration applies to all CE marked devices manufactured from date of issuance until it is either superseded by another declaration or withdrawn.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 meets the essential requirements and conforms to the following, as certified by Apragaz, NB 0029.

Council Directive 93/42/EEC, Medical Devices Directive and Amendment 2007/47/EC Annex II, Clause 3 (Certificate 10/US/2021)

EN-ISO 13485: 2012, Quality Management Systems (Certificate 05/US/920)

These devices also conform to the following Directive(s):

Council Directive 2011/65/EU, Restriction of hazardous substances

Closed cryogenics oxygen receptable made according to the Transportable Pressure Equipment Directive 2010/35/EU and covered by the following certificates:
Surveillance of the Applicants in-house inspections: 1.8.7.3 & 1.8.7.4 of ADR(2015): Certificate 09/US/1952

To the best of my knowledge, the information above is accurate and was in effect from July 29, 2015, thru to June 13, 2016. This applies to all listed products above manufactured within the effective dates.

Ted Vlahopoulos-Sr. Regulatory Specialist 11-01-2023

Signature **Name/Title** **Date (DD-MM-YYYY)**

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

Attachment A

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