Declaration of Conformity
MDD, TPED, RoHS 3

CE 0459

Legal Manufacturer / Address:	CAIRE Inc. 2200 Airport Industrial Dr, Suite 500 Ball Ground, GA 30107 USA		
Manufacturing/Repair	CAIRE Inc. 2205 Airport Industrial Drive Ball Ground, GA 30107 USA		
Repair Facilities/Final Configuration/TenYear Retest	CAIRE Medical Italy Srl Via 10 Canada 35127 Padova, ITALY	CAIRE Medical Germany GmbHArnold-Höveler-Strasse 2, 40764 Langenfeld Germany	
Distribution & order fulfilment	CAIRE Medical Germany GmbH Arnold-Höveler-Strasse 2, 40764 Langenfeld Germany		
Notified Body	TPED: Apragaz A.S.B.I. (0029) Chaussée de Vilvorde, 1561120 Bruxelles, Belgium	SGS Belgium NV (1639) Noorderlaan 87 BE-2023 Antwerton Belgium	MDD: GMED SAS (0459) – Certificate Only 1, rue Gaston Boissier 75015 PARIS,France
TPED/MDD Authorized Representative	Medical Product Service GmbH (MPS) Borngasse 20 35619 Braunfels, Germany	Accumed Sagl Viale Serfontana 10 CH-6834 Morbio Inferiore, Switzerland	
Product Families	Portable Liquid Oxygen Units (Stroller, Sprint, Spirit, HELiOS)Base Liquid Oxygen Units (Liberator, HELiOS)		
MDD Device Classification	Class IIa, MDD Appendix IX, Rule 11		
Global Medical Device Nomenclature(GMDN) Code:	35910-Portable Liquid Oxygen Units 35221-Base Liquid Oxygen Units		
Universal Medical Device Nomenclature System (UMDNS) Code:	16-853 – Individual Liquid Oxygen Units		
Start of CE Marking	Helios base U36. U46, 36, 46: 11 November 2008 Helios portable 300, 850: 30 November 2001 Hi Flow Stroller, Stroller, Sprint, Spirit 300, 600, 1200, Liberator 20, 30, 37, 45. 60: 13 December 2002		
Start of Pi marking45, 6060	Helios base U36, U46, 36, 46: 11 November 2008 Helios portable 300, 850: 30 November 2001 Hi Flow Stroller, Stroller, Sprint, Spirit 300, 600, 1200, Liberator 20, 30, 37, 45, 60: 13 December 2002		
Technical File Reference	Sprint/Stroller: SPRINT/STROLLER-MDD-TF-01 Spirit: SPIRIT-MDD-TF-01 HELiOS: HELIOS-MDD-TF-01 Liberator: LIBERATOR-MDD-TF-01		
Effective Date	May 15, 2024		
Expiration Date	Dec 31, 2028		

This declaration applies to all CE marked devices manufactured from date of issuance until it is either supersededby another declaration or withdrawn. I, the undersigned, hereby declare the equipment specified above and its CAIRE approved critical components meets the essential requirements as certified by Apragaz A.S.B.I., NB 0029 and conforms to the following:

- **Council Directive 93/42/EEC, Medical Devices Directive (Annex II, excluding section 4) including Amendment 2007/47/EC, and Article 120 Transitional provisions under MDR (2017/745) as revised by EU regulation 2023/607. GMED SAS Certificate No° 31275 rev. 14, Expiry Date: May 26, 2024, is hereby extended by confirmation letter reference CLNB1639-WW/MC/625801 from SGS.**
- **EN ISO 13485:2016, Quality Management Systems (Certificate 31276)These devices also conform to the following Directive(s):**
- **Council Directive 2011/65/EU, Restriction of hazardous substances; Directive (EU) 2015/863,amending Annex II to 2011/65/EU**
- **Closed cryogenics oxygen receptable made according to the Transportable Pressure EquipmentDirective 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 (2023):** Certificate: 09/US/1952

Date: May 15, 2024

Ted Vlahopoulos – Sr. Regulatory Specialist
CAIRE Inc.
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Ball Ground, GA 30107