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 GmbH Arnold-Höveler-Strasse 2, 40764 Langenfeld Germany
Distribution & order fulfilment	CAIRE Medical Germany GmbH Arnold-Höveler-Strasse 2, 40764 Langenfeld Germany	CAIRE Medical Ltd. Unit 6, Ashville Way Wokingham, Berkshire RG41 2PL United Kingdom
Notified Body	TPED: Apragaz A.S.B.I. (0029) Chaussée de Vilvorde, 156 1120 Bruxelles, Belgium	MDD: GMED SAS (0459) 1, rue Gaston Boissier 75015 PARIS, France
TPED/MDD Authorized Representative	Medical Product Service GmbH (MPS) Borngasse 20 35619 Braunfels, Germany	
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: 11 November 2008 Helios portable 30 November 2001 Stroller, Sprint, Spirit, Liberator: 13 December 2002	
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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 1, 2021	
Expiration Date	May 26, 2024	

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to all CE marked devices manufactured from date of issuance until it is either supersededby another declaration or withdrawn.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 and conforms to the following, as certified by Apragaz A.S.B.I., NB 0029 and GMED SAS, NB 0459.

- **Council Directive 93/42/EEC, Medical Devices Directive (Annex II, excluding section 4) and Amendment 2007/47/EC, Article 120 Transitional provisions under MDR (2017/745)** (GMED SAS Certificate No° 31275 rev. 14, Expiry Date: May 26, 2024)
- **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

Ted Vlahopoulos – Sr. Regulatory Specialist
CAIRE Inc.
2200 Airport Industrial Drive, Suite 500
Ball Ground, GA 30107

Date: Jan 16, 2024