CAIRE®

Declaration of Conformity
MDD, TPED, RoHS 2

CE 0459

Legal Manufacturer / 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	CAIRE Medical Italy Srl Via 10 Canada 35127 Padova, ITALY	CAIRE Medical Germany GmbH Arnold-Höveler-Strasse 2, 40764 Langenfeld. Germany
	CAIRE Medical Ltd. Unit 6, Ashville way Wokingham RG41 2PL UK	
Notified Body	TPED: Apragaz (0029) Chaussée de Vilvorde, 156 Vilvoordesesteenweg 156 B-1120 Brussels, Belgium	MDD: Laboratoire national d'essais/ G-MED (0459) 1, rue Gaston Boissier 75724 PARIS Cedex 15, France
TPED/MDD 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 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	Helios base: 11 November 2008 Helios portable 30 November 2001 Stroller, Sprint, Spirit, Liberator: 13 December 2002	
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This declaration applies to all CE marked devices manufactured from date of issuance until it is either superseded by another declaration or withdrawn.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 and its CAIRE approved critical components meets the essential requirements and conforms to the following, as certified by Apragaz, NB 0029 and LNE/G-MED, NB 0459.

- **Council Directive 93/42/EEC, Medical Devices Directive and Amendment 2007/47/EC Annex II, Clause 3** (Certificate 31275)
- **EN-ISO 13485:2016, Quality Management Systems** (Certificate 31276)
- **EU Medical Device Regulations (2017/745) Article 120 Transitional Provisions as of May 26, 2020**

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(2019):** Certificate 09/US/1952

N P Maloy

Neal Maloy, Director – Quality and Regulatory

3/9/2020

Date