

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/Ten Year 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	
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	

This declaration applies to all CE marked devices manufactured from date of issuance until it is either superseded by another declaration or withdrawn.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 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** (Certificate 31275)
- **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 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



Edward Kim, Vice President – Engineering and Regulatory

July 6, 2021

Date