# Declaration of Conformity
# MDD, TPED, RoHS 2

CE 0029

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|---|---|---|
| **Business Unit Name / Address:** | CAIRE Inc.<br>2200 Airport Industrial Dr, Suite 500<br>Ball Ground, GA 30107 USA | |
| **Manufacturing Facilities** | CAIRE Inc.<br>2205 Airport Industrial Drive<br>Ball Ground, GA 30107<br>USA | |
| **Repair Facilities/Final Configuration/Ten Year Retest** | Chart Italy S.r.l.<br>Via 10 Canada<br>35127<br>Padova, ITALY | Chart Biomedical Gmbh<br>Essener strasse 68<br>42327<br>Wuppertal, Germany |
| | (Repair only)<br>Chart Biomedical Limited<br>Unit 6, Ashville way<br>Wokingham RG41 2PL UK | |
| **Notified Body** | Apragaz (0029)<br>Chaussée de Vilvorde, 156<br>Vilvoordesesteenweg 156<br>B-1120 Brussels, Belgium | |
| **TPED/MDD Representative** | Medical Product Service GmbH (MPS)<br>Borngasse 20<br>35619 Braunsfels, Germany | |
| **Product Families** | Portable Liquid Oxygen Units (Stroller, Sprint, Spirit, Helios, Companion)<br>Base Liquid Oxygen Units (Liberator, Helios, Companion) | |
| **MDD Equipment Classification** | Class IIa, MDD Appendix IX, Rule 11 | |
| **TPED Equipment Classification** | Category 2 | |
| **Global Medical Device Nomenclature (GMDN) Code:** | 35910-Portable Liquid Oxygen Units<br>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This declaration applies to all CE marked devices manufactured from date of issuance until it is either superseded by another declaration or withdrawn.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:**
**Type Approval according to: 1.8.7.2 of ADR (2013):** Certificate 10/US/2021
**Surveillance of the Applicants in-house inspections: 1.8.7.6 of ADR(2013):** Certificate 09/US/1952

***To the best of my knowledge, the information above is accurate and was in effect from June 25, 2014, thru to Aug 05, 2014. This applies to all listed products above manufactured within the effective dates***

_____ Ted Vlahopoulos / Sr. Regulatory Specialist 20/03/2024

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

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

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**Attachment A**

| Model(s) | Serial Number(s) | Invoice / Order Number (s) |
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