Declaration of Conformity
MDD, RoHS 2

CE 0459

Legal Manufacturer / Address	CAIRE Inc. 2200 Airport Industrial Dr, Suite 500 Ball Ground, GA 30107, USA	
Manufacturing/Repair Facilities	CAIRE Inc. 2205 Airport Industrial Drive Ball Ground, GA 30107 USA	CAIRE Medical Technology (Chengdu) Co., Ltd. No. 48 Qingma Road, South Section Chengdu Modern Industrial Park Pidu district, Chengdu 611730, Sichuan China
Repair Facilities	CAIRE Medical Italy Srl Via 10 Canada 35127 Padova, Italy	CAIRE Medical Ltd. Unit 6- Ashville Way Wokingham, Berkshire RG41 2PL United Kingdom
Repair, distribution & order fulfilment, final configuration	CAIRE Medical Germany GmbH Arnold-Höveler-Strasse 2, 40764 Langenfeld. Germany	
Notified Body	Laboratoire national d'essais/ G-MED (0459) 1, rue Gaston Boissier 75724 PARIS Cedex 15 France	
Authorized Representative	Medical Product Service GmbH (MPS) Borngasse 20 35619 Braunfels, Germany	
Product Families	Oxygen Concentrators (Eclipse Oxygen System, NewLife Intensity 10, NewLife Elite, VisionAire, Saros 4000, Companion 5, and FreeStyle Comfort)	
MDD Device Classification	Class IIa (MDD Appendix IX, Rule 11)	
Global Medical Device Nomenclature (GMDN) Code	12873- Stationary Oxygen Concentrators 31321-Portable Oxygen Concentrator	
Start of CE Marking	Eclipse Oxygen System: 14 March 2007 NewLife Intensity 10: 08 October 2008 NewLife Elite: 22 April 2019 VisionAire: 02 June 2008 FreeStyle Comfort: 01 March 2018 Saros 4000: 05 March 2020 Companion 5: 05 March 2020	

This declaration applies to all CE marked devices manufactured from date of issuance until it is either superseded by another declaration or withdrawn.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 LNE/G-MED, 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)
- **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**

Neal Maloy, Director – Quality and Regulatory

March 31, 2020
Date