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	Chart Italy S.r.l. Via 10 Canada 35127 Padova, Italy	Chart Biomedical Limited Unit 6- Ashville Way Wokingham, Berkshire RG41 2PL United Kingdom
	CAIRE Inc. 12230 World Trade Drive Suite 100 San Diego, CA 92128 USA	CAIRE Inc. 260 Creekside Drive Buffalo, NY 14228 USA
Repair, distribution & order fulfilment, final configuration	Chart Biomedical GmbH Essener Strasse 68 42327 Wuppertal, 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, VisionAire,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	Effective 19 July 2002	

This declaration applies to all CE marked devices manufactured from date of issuance until it is either superseded by another declaration or withdrawn.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

These devices also conform to the following Directive(s):

Council Directive 2011/65/EU, Restriction of hazardous substances

Ted Vlahopoulos Sr. Regulatory Specialist 17/03/2025

Signature | Name and Title (Print) | Date (DD-MM-YYYY)

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

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Attachment A

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