Declaration of Conformity
MDD, RoHS 3

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. I/F, Building 4, No 670 Haifa Road, Chengdu Cross-Strait Science and Technology Industrial Development Park, Wenjiang District, Chengdu, Sichuan Province, 611138 China
Repair Facilities	CAIRE Medical Italy Srl Via 10 Canada 35127 Padova, Italy	
Repair, distribution & order fulfilment	CAIRE Medical Germany GmbH Arnold-Höveler-Strasse 2, 40764 Langenfeld. Germany	
Notified Body	SGS Belgium NV (1639) Noorderlaan 87 BE-2023 Antwerton Belgium	GMED SAS (0459) – Certificate Only. 1, rue Gaston Boissier 75015 PARIS France
Authorized Representative	Medical Product Service GmbH (MPS) Borngasse 20 35619 Braunfels, Germany	Accumed Sagl Viale Serfontana 10 CH-6834 Morbio Inferiore, Switzerland
Product Families	Oxygen Concentrators (NewLife Intensity 10, NewLife Elite, VisionAire and Companion 5)	
MDD Device Classification	Class IIa (MDD Appendix IX, Rule 11)	
Global Medical Device Nomenclature (GMDN) Code	12873- Stationary Oxygen Concentrators	
Start of CE Marking	NewLife Intensity 10: 08 October 2008 NewLife Elite: 22 April 2019 VisionAire: 02 June 2008 Companion 5: 05 March 2020	
Technical File Reference	NewLife Intensity 10: NEWLIFE-MDD-TF-02 NewLife Elite: NEWLIFE-MDD-TF-03 VisionAire: VISIONAIRE-MDD-TF-02 Companion 5: COMPCONC-MDD-TF-02	
Effective Date	May 15, 2024	
Expiration Date	Dec 31, 2028	

This declaration applies to all CE marked devices manufactured from date of issuance until it is either superseded by another declaration or withdrawn.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

- **Council Directive 93/42/EEC, Medical Devices Directive (Annex II, excluding section 4) including Amendment 2007/47/EC, and Article 120 Transitional provisions under MDR (2017/745) as revised by EU regulation 2023/607. GMED SAS Certificate No° 31275 rev. 14, Expiry Date: May 26, 2024, is hereby extended by confirmation letter reference CLNB1639-WW/MC/625801 from SGS.**
- **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**

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Ted Vlahopoulos – Sr. Regulatory Specialist

Date: May 15, 2024