CAIRE®

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. 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	
Repair, 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	GMED SAS (0459) 1, rue Gaston Boissier 75015 PARIS France	
Authorized Representative	Medical Product Service GmbH (MPS) Borngasse 20 35619 Braunfels, Germany	
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 1, 2021	
Expiration Date	May 26, 2024	

This declaration applies to all CE marked devices manufactured from date of issuance until it is either superseded by another declaration or withdrawn.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 GMED SAS, NB 0459.

- **Council Directive 93/42/EEC, Medical Devices Directive (Annex II, excluding section 4) and Amendment 2007/47/EC, Article 120 Transitional provisions under MDR (2017/745)** (GMED SAS Certificate No° 31275 rev. 14, Expiry Date: May 26, 2024)
- **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**

Edward Kim, Vice President – Engineering and Regulatory