

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 (Eclipse Oxygen System and FreeStyle Comfort)		
MDD Device Classification	Class IIa (MDD Appendix IX, Rule 11)		
Global Medical Device Nomenclature (GMDN) Code	31321-Portable Oxygen Concentrator		
Start of CE Marking	Eclipse Oxygen System: 14 March 2007 FreeStyle Comfort: 01 March 2018		
Technical File Reference	Eclipse: ECLIPSE-MDD-TF-01 FreeStyle Comfort: FREESTYLE COMFORT-MDD-TF-01		
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This declaration applies to all CE marked devices manufactured from date of issuance until it is either superseded by another declaration or withdrawn.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



Ted Vlahopoulos – Sr. Regulatory Specialist

Date May 15, 2024