

<b>Legal Manufacturer / Address</b>	CAIRE Inc. 2200 Airport Industrial Dr, Suite 500 Ball Ground, GA 30107, USA	
<b>Manufacturing/Repair Facilities</b>	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
<b>Repair Facilities</b>	CAIRE Medical Italy Srl Via 10 Canada 35127 Padova, Italy	CAIRE Inc. 7736 Clairemont Mesa Blvd San Diego, CA 92111 USA
<b>Repair, distribution &amp; order fulfilment</b>	CAIRE Medical Germany GmbH Arnold-Höveler-Strasse 2, 40764 Langenfeld. Germany	CAIRE Medical Ltd. Unit 6- Ashville Way Wokingham, Berkshire RG41 2PL United Kingdom
<b>Notified Body</b>	GMED SAS (0459) 1, rue Gaston Boissier 75015 PARIS France	
<b>Authorized Representative</b>	Medical Product Service GmbH (MPS) Borngasse 20 35619 Braunfels, Germany	
<b>Product Families</b>	Oxygen Concentrators (NewLife Intensity 10, NewLife Elite, VisionAire and Companion 5)	
<b>MDD Device Classification</b>	Class IIa (MDD Appendix IX, Rule 11)	
<b>Global Medical Device Nomenclature (GMDN) Code</b>	12873- Stationary Oxygen Concentrators	
<b>Start of CE Marking</b>	NewLife Intensity 10: 08 October 2008 NewLife Elite: 22 April 2019 VisionAire: 02 June 2008 Companion 5: 05 March 2020	
<b>Technical File Reference</b>	NewLife Intensity 10: NEWLIFE-MDD-TF-02 NewLife Elite: NEWLIFE-MDD-TF-03 VisionAire: VISIONAIRE-MDD-TF-02 Companion 5: COMPCONC-MDD-TF-02	

This declaration applies to all CE marked devices manufactured from date of issuance until it is either superseded by another declaration or withdrawn.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



Edward Kim, Vice President – Engineering and Regulatory

May 10, 2021

Date