CONFORM CU ORIGINALUL

CAIRE®

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	CAIRE Medical Italy Srl Via 10 Canada 35127 Padova, Italy	CAIRE Medical Ltd. Unit 6- Ashville Way Wokingham, Berkshire RG41 2PL United Kingdom
Repair, distribution & order fulfilment, final configuration	CAIRE Medical Germany GmbH Arnold-Höveler-Strasse 2, 40764 Langenfeld. Germany	
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 (Eclipse Oxygen System, NewLife Intensity 10, NewLife Elite, VisicnAire, Saros 4000, Companion 5, 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	Eclipse Oxygen System: 14 March 2007 NewLife Intensity 10: 08 October 2008 NewLife Elite: 22 April 2019 VisionAire: 02 June 2008 FreeStyle Comfort: 01 March 2018 Saros 4000: 05 March 2020 Companion 5: 05 March 2020	

This declaration applies to all CE marked devices manufactured from date of issuance until it is either superseded by another declaration or withdrawn.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

12/10/23
Date

QRF-003-002E Rev L

Digitally signed by Sarco Alexandru
Date: 2024.05.29 13:34:11 EEST
Reason: MoldSign Signature
Location: Moldova

GMED
GROUPE LNE

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ATTESTATION / *CERTIFICATE* **N° 31275 rev. 14**
Délivrée à Paris le 10 février 2021
Issued in Paris on February 10th, 2021

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

CAIRE Inc.
2200 Airport Industrial Drive, Suite 500
BALL GROUND, GA 30107 UNITED STATES

Catégorie du(des) dispositif(s) / *Device(s) category*

Systèmes d'oxygène liquide et leurs composants à utiliser avec des produits de santé à domicile en thérapie respiratoire et concentrateurs d'oxygène

Liquid oxygen systems and their components for use in home healthcare products for respiratory therapy and oxygen concentrators

Voir document complémentaire GMED / See GMED additional document
n° 37985

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé T001040, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced T001040, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date :* **February 10th, 2021 (included)**
Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

GMED_b2p3_new2020-V0-04-

GMED - 31275 rev. 14
Modifie le certificat 31275-13

GMED SAS GMED SAS GMED GROUPE LNE

DocuSigned by:
Beatrice Lys
EF338DA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

GMED
GROUPE LNE

Document complémentaire GMED n° 37985 rev. 0
GMED additional document n° 37985 rev. 0
Dossier(s) / *File(s)* N° T001040

Délivré à Paris le 09/02/2021
Issued in Paris on 02/09/2021

Ce document complémentaire GMED n° 37985 rev. 0 atteste de la validité du certificat CE n° 31275 rev.14 au regard des informations listées ci-dessous.

This GMED additional document N° 37985 rev. 0 attests to the validity of CE certificate n° 31275 rev.14 with regard to the information listed below.

Fabricant / *Manufacturer:*

CAIRE Inc.
2200 Airport Industrial Drive, Suite 500
Ball Ground, GA 30107 USA

Identification des dispositifs / *Identification of devices*

Description du Dispositif Médical *Medical Device Description*	**Classe du Dispositif Médical** *Medical Device Class*
VisionAire	**IIa**
Newlife Family	
Eclipse	
Spirit	
Helios Range	
Sprint/Stroller	
Liberator	
Freestyle Comfort	
Flowmeter, SureFlow	
Saros 4000	
Companion 5	

Les produits couverts par ce certificat sont référencés sur la liste des produits par le GMED en date du 25 Mai 2020.

The products covered by this certificate are listed on the product list authenticated by GMED on May 25, 2020

GMED 0459

GMED - N° 37985 rev. 0

GMED

DocuSigned by:
Beatrice Lys
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On behalf of the President
Béatrice LYS
Technical Director

GMED
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Document complémentaire GMED n° 37985 rev. 0
GMED additional document n° 37985 rev. 0
Dossier(s) / *File(s)* N° T001040

Délivré à Paris le 09/02/2021
Issued in Paris on 02/09/2021

Sites couverts et Activités / *Locations and Activities*

Sites / *Locations*	**Activités** / *Activities*
CAIRE Inc. 2200 Airport Industrial Drive, Suite 500 Ball Ground, GA 30107 USA	**Siége social & conception** *Headquarters & design*
CAIRE Inc. 2205 Airport Industrial Drive Ball Ground, GA 30107 USA	**Fabrication & contrôle final** *Manufacturing & final control*
CAIRE Medical Technology (Chengdu) co., Ltd. No. 48 Qingma Rd, South Section, Chengdu Modem Industrial Park Pidu district, Chengdu, Sichuan 611730 China	**Fabrication & contrôle final** *Manufacturing & final control*
CAIRE Medical Germany GmbH Arnold-Höveler Strasse 2 40764 Langenfeld Gerrnany	**Fabrication & contrôle final** *Manufacturing & final control*

GMED 0459

GMED - N° 37985 rev. 0

GMED 541

DocuSigned by:
Beatrice Lys
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On behalf of the President
Béatrice LYS
Technical Director