

Certificate US24/00000346

The management system of

CAIRE, Inc.

2200 Airport Industrial Drive, Suite 500, Ball Ground, Georgia, 30107, United States of America

has been assessed and certified as meeting the requirements of

ISO 13485:2016

EN ISO 13485:2016

For the following activities

Design, development, manufacturing, distribution and servicing of oxygen concentrators/generators and liquid oxygen products for home care and professional uses.

This certificate is valid from 01 April 2025 until 17 December 2027 and remains valid subject to satisfactory surveillance audits.

Issue 2. Organization certified since 19 April 2024 and first certified by SGS on 21 August 2024.

Certified activities performed by additional sites are listed on subsequent pages.

L. Moran

Authorised by

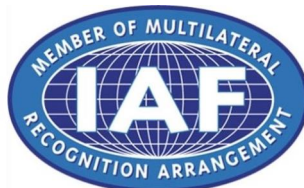
Liz Moran

Business Manager

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0)151 350-6666 - www.sgs.com



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ISO 13485:2016
EN ISO 13485:2016

Issue 2

Sites

CAIRE, Inc.
2200 Airport Industrial Drive, Suite 500, Ball Ground, Georgia, 30107, United States of America
Headquarters, Design, Regulatory, IT, Document control, Quality management, Customer service of oxygen concentrators and liquid oxygen products.

CAIRE, Inc.
495 Brown Industrial Parkway, Canton, Georgia, 30114, United States of America
Service and repair for oxygen concentrators and liquid oxygen products and distribution of their components.

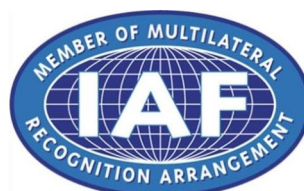
CAIRE, Inc.
2205 Airport Industrial Drive, Suite 500, Ball Ground, Georgia, 30107, United States of America
Manufacturing, Distribution, Quality inspection, product release & purchasing of oxygen concentrators and liquid oxygen products.

CAIRE Medical Technology (Chengdu) Co., Ltd.
1/F, Building 4, No. 670, Haifa Road, Chengdu Cross-Strait Science and Technology Industrial Development Park, Wenjiang District, Chengdu, Sichuan 611138, China
Manufacturing, distribution, service and repair, and customer services of oxygen concentrators and liquid oxygen products.

CAIRE Medical Italy SRL
Via Canada 10 35127 Padova, Italy
Repair and retest of oxygen concentrators and liquid oxygen products.

CAIRE Medical Germany GmbH
Arnold-Höveler Strasse 2 40764 Langenfeld Germany
Repair, retest, distribution and order fulfillment, final configuration of oxygen concentrators and liquid oxygen products.

AirSEP Corporation
260 Creekside Drive, Amherst, Buffalo, New York, 14228, United States of America
Design, manufacturing, distribution and servicing of oxygen generators and their components.



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