## Certificate US24/00000346

The management system of



2200 Airport Industrial Drive, Suite 500, Ball Ground, GA 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 and liquid oxygen products for home care oxygen therapy respiration systems.

This certificate is valid from 21 August 2024 until 31 August 2026 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 21 August 2024

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.

Jorothan M. Hell

Authorised by Jonathan Hall Global Head - Certification Services

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SG

# Certificate US24/00000346, continued **CAIRE, Inc.**



## ISO 13485:2016 EN ISO 13485:2016

Issue 1

#### Sites

CAIRE, Inc.

2200 Airport Industrial Drive, Suite 500, Ball Ground, GA 30107 United States of America Headquarters, design, QMS and regulatory function, customer services of oxygen concentrators and liquid oxygen products

#### CAIRE, Inc

495 Brown Industrial Parkway, Canton, GA 30114, United States of America Service, repair and distribution for oxygen concentrators and liquid oxygen products.

#### CAIRE Inc.

2205 Airport Industrial Drive, Suite 500, Ball Ground, GA 30107, United States of America Manufacturing, purchasing, service and distribution of oxygen concentrators and liquid oxygen products.

#### CAIRE Medical Technology Co., Ltd.

Bldg 4, No. 670, Haifa Rd., Chengdu Cross-Strait Science & Technology 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.







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