

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

**Vyaire Medical, Inc.**  
26125 N. Riverwoods Blvd  
Mettawa  
Illinois  
60045  
USA

Holds Certificate Number:

FM 555355

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, Development, Production and Service of blood warmers, continuous and non-continuous ventilators and accessories, continuous positive airway pressure systems and accessories, nitric oxide delivery systems, nitrogen oxide-nitrogen dioxide analyzers, respiratory monitors, gas blenders, flow sensors, patient breathing circuits, carbon monoxide washout systems, anesthetic agent washout systems, pulmonary function diagnostic systems, cardio-pulmonary diagnostic systems, plethysmograph, sleep diagnostic systems, ventilation kits including nCPAP generator kit, inspiration lines, anesthesia circuits, nasal masks, endotracheal tube stylets, oral airways and nasal prongs, including molded components for these devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2009-10-01

Latest Revision Date: 2023-12-19

Effective Date: 2024-01-03

Expiry Date: 2027-01-02

Page: 1 of 2



...making excellence a habit.™

Certificate No: FM 555355

Location	Registered Activities
Vyair Medical, Inc. 26125 N. Riverwoods Blvd Mettawa Illinois 60045 USA	Legal manufacturer and servicing respiratory equipment designed, manufactured, and distributed by sites included in this certificate: Palm Springs, Minneapolis, and Mexicali.
Productos Urológos de Mexico S.A.de C.V Cerrada Via de la Produccion No.85 Parque Industrial Mexicali III Baja California Baja California CP 21397 Mexico	Productions and Distribution of Masks, Cannulas, Tubing, Connectors, Adapters, Catheters, Nebulizers and Nebulizer Kits, Nebulizer Caps, Humidifiers and Humidifier Kits, Drainage Bags, Solution Feed Sets, Breathing Circuits, Inspiratory Lines, Filters, Thermometers, IPPB Manifolds, including molded components for these devices, Scrub Care Surgical Brushes, Prep Trays, and Preoperative Skin, manual resuscitation devices, and Anaesthesia, Ventilator, Endotracheal Tube Stylets, Oral Airways and Respiratory Circuits.
Vyair Medical Inc. 510 Technology Drive Irvine California 92618 USA	The design of Blood Warmers, Ventilators, Continuous Positive Airway Pressure (CPAP) Systems, Gas Blenders, Accessories, Cardiopulmonary diagnostics, Sleep Diagnostics, Oximeter Products, Medicinal Gas and Vacuum Valves with Aerosol Generators (adapters), Breathing Masks and Respiratory Care equipment.
Vyair Medical Inc. 1100 Bird Center Drive Palm Springs California 92262 USA	The manufacture, distribution and servicing of blood warmers and respiratory equipment, including continuous and non-continuous life support ventilators and related accessories.

Original Registration Date: 2009-10-01

Latest Revision Date: 2023-12-19

Effective Date: 2024-01-03

Expiry Date: 2027-01-02

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Issuing Body: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

Contact Office: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA.