

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

**Breas Medical AB**

Företagsvägen 1  
Mölnlycke  
SE-435 33  
Sweden

Holds Certificate Number:

FM 703971

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

Design and Development, Manufacture, Servicing and Distribution of Respiratory Therapy and Monitoring Devices; Sleep Apnea Devices; and related Non-Sterile Accessories including Humidifiers, Breathing Circuits, Patient Interfaces, Tubing and Filters; Sensors; Batteries, Electrical Connection and Power Supply Equipment; Signal processing, Control, Networking and Alarm Devices; Transport and Storage Equipment; and Software Devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2017-01-26

Latest Revision Date: 2025-01-06

Effective Date: 2025-01-21

Expiry Date: 2028-01-20

Page: 1 of 2



...making excellence a habit.™

Certificate No: FM 703971

Location

Breas Medical AB  
Företagsvägen 1  
Mölnlycke  
SE-435 33  
Sweden

Breas Medical, Inc.  
16 Esquire Road  
North Billerica  
Massachusetts  
01862  
USA

Registered Activities

Design and Development, Manufacture, Servicing and Distribution of Respiratory Therapy and Monitoring Devices; Sleep Apnea Devices; and related Non-Sterile Accessories and Software Devices.

Design and Development, Manufacture, Servicing and Distribution of Respiratory Therapy and Monitoring Devices; Sleep Apnea Devices; and related Non-Sterile Accessories and Software Devices.



Original Registration Date: 2017-01-26

Latest Revision Date: 2025-01-06

Effective Date: 2025-01-21

Expiry Date: 2028-01-20

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)

Information and Contact:

BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780  
BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.  
Americas Headquarters: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA