

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Breas Medical AB**  
Företagsvägen 1  
Mölnlycke  
SE-435 33  
Sweden

Facility ID Number: F000105

Holds Certificate No: **MDSAP 689358**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

**Brazil:** RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

**Canada:** Medical Devices Regulations - Part 1 - SOR 98/282

**Japan:** MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

\_\_\_\_\_  
Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-01-30

Effective Date: 2025-01-21

Expiry Date: 2028-01-20



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 3

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Certificate No: **MDSAP 689358**

## Registered 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.



Original Registration Date: 2019-01-30

Effective Date: 2025-01-21

Expiry Date: 2028-01-20

Page: 2 of 3

This certificate remains the property of BSI and shall be returned immediately upon request.  
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To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 689358**

Location

Breas Medical AB  
Företagsvägen 1  
Mölnlycke  
SE-435 33  
Sweden  
Facility ID Number: F000105

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.

Breas Medical, Inc.  
16 Esquire Road  
North Billerica  
Massachusetts  
01862  
USA  
Facility ID Number: F001827

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: 2019-01-30

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Page: 3 of 3

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