

# 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, 21 CFR 821

Please see scope page.

For and on behalf of BSI:

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Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-01-30

Effective Date: 2026-06-26

Expiry Date: 2028-01-20



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 689358**

## Registered Scope:

Design and development, Manufacture, Servicing and Distribution of Respiratory Therapy and Monitoring Devices; Airway Clearance 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.



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This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

America Headquarters: BSI Group America Inc. 1950 Opportunity Way, Suite 900, Reston, VA 20190.  
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 689358**

Location	Registered Activities
Breas Medical AB Företagsvägen 1 Mölnlycke SE-435 33 Sweden Facility ID Number: F000105	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.
Breas Medical Ltd Units A1-A2 The Bridge Business Centre Timothy's Bridge Road Stratford Enterprise Park Stratford-Upon-Avon CV37 9HW United Kingdom Facility ID Number: F008677	Design and development, Manufacture, Servicing and Distribution of Airway Clearance Devices.
Breas Medical Ltd 33 Timothy's Bridge Road Stratford Upon Avon Warwickshire CV37 9NQ United Kingdom Facility ID Number: F008677	Manufacture of Airway Clearance Devices.

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