

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

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

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-01-30

Effective Date: 2024-01-25

Expiry Date: 2025-01-20



BSI Group America Inc. is an MDSAP recognised auditing organization

Certificate No: **MDSAP 689358**

Location

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

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

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.



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