

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:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-01-30

Effective Date: 2025-06-19

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; 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: 2025-06-19

Expiry Date: 2028-01-20

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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.

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.



Original Registration Date: 2019-01-30 Effective Date: 2025-06-19 Expiry Date: 2028-01-20

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