

Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that:

Breas Medical AB
Företagsvägen 1
Mölnlycke
SE-435 33
Sweden

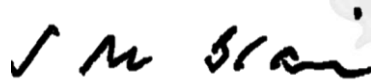
DUNS Number: 35-700-7657

Holds certificate No:

MDSAP 689358

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure [if design controls are part of the certification]; Canada - Medical Devices Regulations - Part 1- SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

Design and Development, Manufacturing, Marketing, Service and Distribution of Respiratory Therapy Devices, Respiratory Monitoring Devices and Sleep Apnea- and Humidifier Systems. Associated Stand Alone PC-Device Communication Software.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk – Medical Devices

Original Registration Date: 2019-01-30

Effective Date: 2019-02-06

Expiry date: 2022-01-20

Page: 1 of 2



BSI Group America Inc. is an MDSAP authorized auditing organization

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

Managed by: 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	Registered Activities
Breas Medical AB Företagsvägen 1 Mölnlycke SE-435 33 Sweden DUNS Number: 35-700-7657	Design and Development, Manufacturing, Marketing, Service and Distribution of Respiratory Therapy Devices, Respiratory Monitoring Devices and Sleep Apnea- and Humidifier Systems. Associated Stand Alone PC-Device Communication Software.
Breas Medical, Inc. 16 Esquire Road North Billerica Massachusetts 01862 USA DUNS Number: 07-929-6736	Design and Development, Manufacturing, Marketing, Service and Distribution of Respiratory Therapy Devices, Respiratory Monitoring Devices and Sleep Apnea- and Humidifier Systems. Associated Stand Alone PC-Device Communication Software.



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