

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Breas Medical AB
Företagsvägen 1
Mölnlycke
SE-435 33
Sweden

Holds Certificate No:

FM 703971

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2017-01-26

Latest Revision Date: 2021-02-20

Effective Date: 2019-01-21

Expiry Date: 2022-01-20

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Certificate No: **FM 703971**

Location

Breas Medical AB
Företagsvägen 1
Mölnlycke
SE-435 33
Sweden

Breas Medical, Inc.
16 Esquire Road
North Billerica
Massachusetts
01862
USA

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
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