

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Breas Medical AB
Företagsvägen 1
Mölnlycke
SE-435 33
Sweden

Holds Certificate Number:

MD 686623

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN 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: 2018-03-07

Latest Revision Date: 2021-06-02

Effective Date: 2019-05-24

Expiry Date: 2022-02-28

Page: 1 of 2



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Certificate No: **MD 686623**

Location

Breas Medical AB
Företagsvägen 1
Mölnlycke
SE-435 33
Sweden

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.

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

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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Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

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