

# 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: 2022-02-27

Effective Date: 2022-02-27

Expiry Date: 2025-01-20

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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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