

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 Number:

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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-01-26

Latest Revision Date: 2022-09-15

Effective Date: 2022-01-21

Expiry Date: 2025-01-20

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Certificate No: FM 703971

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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