By Royal Charter

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
Effective Date: 2019-01-21
Latest Revision Date: 2021-02-20
Expiry Date: 2022-01-20

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Certificate No: **FM 703971**

Location	Registered Activities
Breas Medical AB Företagsvägen 1 Mölnlycke SE-435 33 Sweden	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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