By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 727515 R000

Manufacturer: Breas Medical AB

Address:
Företagsvägen 1
Mölnlycke
SE-435 33
Sweden

Single Registration Number: SE-MF-000001061

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2021-06-10**

Current Issue Date: **2025-11-10**

Starting Validity Date: **2025-11-10**

Expiry Date: **2026-06-09**

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Device Schedule: Class III and Class IIb devices

Class IIb under Rule 12	Intended purpose
Vivo 45	Vivo 45 is intended to provide non-invasive or invasive ventilation for adult or paediatric patients weighing over 10 kg (22 lbs) who require long-term support or mechanical ventilation for respiratory insufficiency or respiratory failure, with or without obstructive sleep apnea. Vivo 45 is intended for spontaneously breathing patients.
Vivo 45LS	The Vivo 45 LS ventilator (with or without the SpO2 and CO2 sensor) is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for paediatric through adult patients weighing more than 5 kg (11 lbs.) The Vivo 45LS with the SpO2 is intended to measure functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate. The Vivo 45LS with the CO2 sensor is intended to measure CO2 in the inspiratory and expiratory gas. The device is intended to be used in home, institution, hospitals and portable applications such as wheelchairs and gurneys. It may be used for both invasive and non-invasive ventilation. The Vivo 45LS is not intended to be used as an emergency transport or critical care ventilator.

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Device Schedule: Class III and Class IIb devices

Class IIb under Rule 12	Intended purpose
Vivo 1 and 2	Vivo 1 and 2 are intended to provide non-invasive ventilation for patients weighing over 10 kg (22 lbs) who require long-term support or mechanical ventilation for respiratory impairment, with or without obstructive sleep apnea. Vivo 1 and 2 are intended for spontaneously breathing patients.
Vivo 3	Vivo 3 is intended to provide non-invasive or invasive ventilation for patients weighing over 10 kg (22 lbs) who require long-term support or mechanical ventilation for respiratory insufficiency or respiratory failure, with or without obstructive sleep apnea. Vivo 3 is intended for spontaneously breathing patients
Vivo 55	The Vivo 55 (with or without the SpO2 and CO2 sensor) is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for pediatric through adult patients weighing more than 10 kg. The Vivo 55 with the SpO2 sensor is intended to measure functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate. The Vivo 55 with the CO2 sensor is intended to measure CO2 in the inspiratory and expiratory gas. The device is intended to be used in home, institution, hospitals and portable applications such as wheelchairs and gurneys. It may be used for both invasive and noninvasive ventilation.

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Device Schedule: Class III and Class IIb devices

Class IIb under Rule 12	Intended purpose
Vivo 65	The Vivo 65 (with or without the SpO2 and CO2 sensor) is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for pediatric through adult patients weighing more than 5 kg. The Vivo 65 with the SpO2 sensor is intended to measure functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate. The Vivo 65 with the CO2 sensor is intended to measure CO2 in the inspiratory and expiratory gas. The device is intended to be used in home, institution, hospitals and portable applications such as wheelchairs and gurneys. It may be used for both invasive and noninvasive ventilation.
Nippy 4	Nippy 4 is intended to provide noninvasive or invasive ventilation for adult or pediatric patients weighing over 10 kg (22 lbs) who require long-term support or mechanical ventilation for respiratory insufficiency or respiratory failure, with or without obstructive sleep apnea. Nippy 4 is intended for spontaneously breathing patients.

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Device Schedule: Class III and Class IIb devices

Class IIb under Rule 12	Intended purpose
Nippy 4+	The Nippy 4+ ventilator (with or without the SpO2 and CO2 sensor) is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for paediatric through adult patients weighing more than 5 kg (11 lbs.) The Nippy 4+ with the SpO2 is intended to measure functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate. The Nippy 4+ with the CO2 sensor is intended to measure CO2 in the inspiratory and expiratory gas. The device is intended to be used in home, institution, hospitals and portable applications such as wheelchairs and gurneys. It may be used for both invasive and noninvasive ventilation. Nippy 4+ is not intended to be used as an emergency transport or critical care ventilator.
Class IIb	**Intended purpose**
EveryWare	EveryWare securely connects compatible medical devices located at the point of patient care to the cloud and provides authorized healthcare representatives the means to manage patient and device information and settings. EveryWare does NOT alter the intended use of connected medical devices or provide functions to automate diagnosis or therapy.

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Humidifying Systems and Heated Patient Circuits	Class IIa
Accessories and Non-Heated Patient Circuits	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
2021-06-10	3171450	Issued.
2021-10-18	3540083	Re-issue of certificate. Addition of Vivo 1/2/3, Vivo 55/65, Nippy 4/4+ under device schedule.
2022-05-26	3696964	Amended – Removal of subcontractor i3TEX AB. Administrative update to dates of prior history entries.
2025-05-16	30000661	Supplemented – Addition of Heated Patient Circuits to existing group with Humidifying Systems. Addition of Accessories, Non-Heated Patient Circuits and Breathing Masks. Addition of subcontractor for manufacture of Breathing Masks.
Current	30559114	Restricted – Removal of Breathing Masks. Removal of subcontractor for manufacture of Breathing Masks.

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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