UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

No. **UKCA 746268**

Issued To: **Breas Medical AB**
Företagsvägen 1
Mölnlycke
SE-435 33
Sweden

In respect of:

Design, manufacture and final inspection of:
-Respiratory Therapy Devices
-Respiratory Monitoring Devices
-Sleep Apnea Devices
-Non-Sterile Respiratory Accessories
-Software Devices

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2021-05-07** Date: **2023-11-10** Expiry Date: **2028-11-09**

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NBOG Code(s)	Device Name	Intended purpose per IFU
Class IIb		
MD 1102	Vivo 55	The Vivo 55 (with or without the SpO_2 and CO_2 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 10kg. The Vivo 55 with the SpO_2 sensor is intended to measure functional oxygen saturation of arterial hemoglobin (%SpO_2) and pulse rate. The Vivo55 with the CO_2 sensor is intended to measure CO_2 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.
MD 1102	Vivo 65	The Vivo 65 (with or without the SpO_2 and CO_2 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. The Vivo 65 with the SpO_2 sensor is intended to measure functional oxygen saturation of arterial haemoglobin (%SpO_2) and pulse rate. The Vivo 65 with the CO_2 sensor is intended to measure CO_2 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.

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NBOG Code(s)	Device Name	Intended purpose per IFU
Class IIb		
MD 1102	Vivo 45, Nippy 4	Vivo 45/Nippy 4 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 apnoea. Vivo 45/Nippy 4 is intended for spontaneously breathing patients.
MD 1102	Vivo 45LS, Nippy 4+	The Vivo 45 LS/Nippy 4+ ventilators (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 Vivo 45LS/Nippy 4+ ventilators are applicable for paediatric through adult patients weighing more than 5 kg (11 lbs.) The Vivo 45LS/Nippy 4+ with the SpO2 is intended to measure functional oxygen saturation of arterial haemoglobin (%SpO2) and pulse rate. The Vivo 45LS/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 non-invasive ventilation. The Vivo 45LS/Nippy 4+ are not intended to be used as an emergency transport or critical care ventilator.

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NBOG Code(s)	Device Name	Intended purpose per IFU
Class IIb		
MD 1102	Vivo 1 , Vivo 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 apnoea. Vivo 1 and 2 are intended for spontaneously breathing patients.
MD 1102	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 apnoea. Vivo 3 is intended for spontaneously breathing patients.
MD 1111	Vivo 50/55/60/65 PC Software	The PC Software is intended to be used for follow-up on patient's ventilator treatment. The Software may indicate possible events that could require further clinical investigation. The Vivo PC Software is intended to be used in institutions, hospitals and clinics by trained clinical personnel, physicians, home care and service personnel. The Vivo PC Software can also be used for Remote Monitoring of ongoing treatment.
MD 1111	Vivo 30/40 PC Software	The Vivo 30/40 PC software setting values is designed to communicate with a Vivo 30 or Vivo 40 medical device, extracting data, or monitoring the device in real time. The PC software can also download device log files via cable or a CF card and manipulate patient information in patient archives.

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NBOG Code(s)	Device Name	Intended purpose per IFU
Class IIb		
MD 1111	Vivo 1/2/3/45/45LS/Nippy 4/4+ PC Software	The PC Software is intended to be used for follow-up on patient's ventilator treatment. The Software may indicate possible events that could require further clinical investigation. The Vivo PC Software is intended to be used in institutions, hospitals and clinics by trained clinical personnel, physicians, home care and service personnel. The Vivo PC Software can also be used for Remote Monitoring of ongoing treatment.
MD 1111	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 settings. EveryWare does not alter the intended use of connected medical devices or provide functions to automate diagnosis or therapy.

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NBOG Code(s)	Device Name	Intended purpose per IFU
Class IIa		
MD 1102	Z1, Respiratory Therapy Devices for continuous and automatic positive airway pressure (CPAP/APAP)	N/A for class IIa
MD 0101 MD 1102	Breathing circuits and ventilator accessories	N/A for class IIa
MD 1111	Z1 Mobile App intended to control the CPAP/APAP and monitor sleep quality.	N/A for class IIa

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UKCA Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
2021-05-07	3405761	First Issue; Traceable to CE 683722
2021-09-29	3540823	Re-issuing of certificate. Changes in device table. Amended device table, Class IIb devices analytically listed and intended purpose amended per device/device groups and Class IIa device names provided. Withdraw of Class IIb humidifiers as they were an accessory to withdrawn devices Vivo 30/40 devices.
2022-06-22	3696968	Removal of subcontractors i3TEX AB and Inission Boras AB. Administrative update to dates of prior history entries.
Current	30000657	Renewal of certificate. Alignment of scope wording. Correction to intended purpose for Nippy 4+. Addition of EveryWare device. Removal of significant subcontractor pages.

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