EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 683722**

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

In respect of:

Design and Manufacture of Respiratory Therapy Systems, Respiratory Monitoring Devices, Sleep Apnea and Humidifier Systems and associated Stand Alone PC-Device Communication Software.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2018-03-15** Date: **2021-05-21** Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 683722

Issued To:

Breas Medical AB
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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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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 ventilator is applicable for paediatric through adult patients weighing more than 5 kg (11 lbs.) and the Nippy 4+ is applicable for paediatric through adult patients weighing more than 10 kg (22 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.

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NBOG code(s)	Device Name	Intended Purpose per IFU
Class IIb		
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.
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.

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 683722**
Date:	**2021-05-21**
Issued To:	**Breas Medical AB** **Företagsvägen 1** **Mölnlycke** **SE-435 33** **Sweden**

Subcontractor:	**Service(s) supplied**
Breas Medical Ltd Units A1-A2 The Bridge Business Centre Timothy's Bridge Road Stratford Enterprise Park Stratford-upon-Avon CV37 9HW United Kingdom	**Manufacture**
Breas Medical, Inc 16 Esquire Road North Billerica Massachusetts 01862 USA	**Design** **Development** **Manufacture**
GlobalMed Inc. 155 North Murray Street Trenton Ontario K8V 5R5 Canada	**Manufacture**

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

Subcontractor:	**Service(s) supplied**
Guangzhou Schauenburg-truplast Hose Technology Ltd No. 6, Nanjiang 3rd Road Nansha District Guangzhou Guangdong 511462 P.R. China	**Manufacture**
NOTE TORSBY AB Inova Park 685 29 Torsby Sweden	**Manufacture**
Plastiflex Group NV Beverlosesteenweg 99 3583 Paal-Beringen Belgium	**Manufacture**

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Date	Reference Number	Action
15 March 2018	8855397	First issue. Transfer from another Notified Body.
12 February 2019	8900397	Traceable to NB 0086.
24 March 2020	9754972	Renewal. Change of name and address of additional site from Human Design Medical, LLC in Newton, Massachusetts to Breas Medical, Inc. North Billerica, MA in June 2018. Addition of subcontractors: Inission Boras AB Gränsvägen 6 518 40 Sjömarken, Sweden, GlobalMed Inc. 155 North Murray Street, Trenton, Ontario, K8V 5R5 Canada, Guangzhou Schauenburg-truplast Hose Technology Ltd, No. 6, Nanjiang 3rd Road, Nansha District, Guangzhou, Guangdong, 511462, P.R. China, Productos Urológos de Mexico S.A.de C.V. Cerrada Via de la Produccion No. 85 Parque Industrial Mexicali III Baja California CP 21397 Mexico, I3tex AB, Klippan 1 A, 414 51 Göteborg Sweden, Plastiflex Group NV, Beverlosesteenweg 99, 3583 Paal-Beringen, Belgium, NOTE TORSBY AB, Inova Park, 685 29 Torsby, Sweden and Breas Medical Ltd, Units A1-A2, The Bridge Business Centre, Timothy's Bridge Road, Stratford Enterprise Park, Stratford-upon-Avon, CV37 9HW. Addition of product table.

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Date	Reference Number	Action
05 April 2021	3414247	Removal of subcontractor: "Productos Urológos de Mexico S.A.de C.V, Cerrada Via de la Produccion No. 85, Parque Industrial Mexicali III, Baja California, CP 21397, Mexico"
21 May 2021	3446719	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.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
27 May 2022	3696967	Removal of subcontractors i3TEX AB and Inission Boras AB

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Inspiring trust for a more resilient world.

27th May 2022

Breas Medical AB
Företagsvägen 1
Mölnlycke
SE-435 33
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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	**Directive and Annex**	**Reference Number**	**Changes approved**
CE 683722	93/42/EEC Annex II excluding Section 4	3696967	Removal of subcontractors i3TEX AB and Inission Boras AB

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

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