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: **2020-03-24** Expiry Date: **2024-05-26**

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Supplementary Information to CE 683722

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NBOG code	Device Name	Intended Purpose per IFU
Class IIa		
MD 1102	Respiratory Therapy Device for continuous and automatic positive airway pressure (CPAP/APAP)	N/A for class IIa
MD 0101	Breathing Circuits and ventilator accessories	N/A for class IIa
MD 1111	Mobile app intended to control the CPAP/APAP and monitor sleep quality.	N/A for class IIa

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NBOG code	Device Name	Intended Purpose per IFU
Class IIb		
MD 1102	Vivo Family and Nippy Family	The Vivo Family and Nippy Family devices are intended to provide non-invasive or invasive, long-term mechanical ventilatory support to adult and pediatric patients (weighing more than 5kg). The devices may be used continuously or intermittently by either spontaneously breathing patients or patients who are dependent on ventilatory support. The devices are intended to be used for life-supporting and non life-supporting ventilation at home, institution, hospitals or in portable applications such as wheelchairs and gurneys.
MD 1111	Vivo Family and Nippy Family Software	The Vivo Family and Nippy Family software is used for follow-up on patient's ventilator treatment.
MD 1102	Humidifiers	The Humidifier is intended to humidify the patient air during breathing therapy. It is intended for non-invasive use only.

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By Royal Charter

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List of Significant Subcontractors

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

Certificate No:	**CE 683722**
Date:	**2020-03-24**
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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Subcontractor:	**Service(s) supplied**
Guangzhou Schauenburg-truplast Hose Technology Ltd No. 6, Nanjiang 3rd Road Nansha District Guangzhou Guangdong 511462 P.R. China	**Manufacture**
i3TEX AB Klippan 1A 414 51 Göteborg Sweden	**Design** **Development**
Inission Borås AB Gränsvägen 6 518 40 Sjömarken Sweden	**Manufacture**
NOTE TORSBY AB Inova Park 685 29 Torsby Sweden	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Plastiflex Group NV Beverlosesteenweg 99 3583 Paal-Beringen Belgium	**Manufacture**
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	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 683722**

Date: **2020-03-24**

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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.
Current	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.