

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

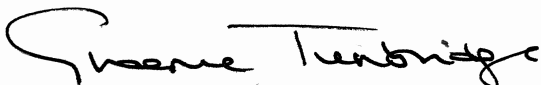
In respect of:

Design, manufacture and final inspection of:

- Respiratory Therapy Devices**
- Respiratory Monitoring Devices**
- 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 Global Regulatory & Quality

First Issued: **2021-05-07**

Date: **2026-04-09**

Expiry Date: **2028-11-09**

...making excellence a habit.™

Page 1 of 2

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

UKCA Certificate - Full Quality Assurance System

Supplementary Information to UKCA 746268

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

Device Code	Device Name	Intended purpose per IFU
Class IIb		
MD1102	Ventilators and Airway Clearance Devices	Ventilators for non-invasive or invasive, continuous or intermittent, mechanical ventilation for adult or paediatric patients. Airway Clearance Devices for clearing secretions and promoting lung volume recruitment.
MD1111	Ventilator Treatment Software	For remote monitoring and follow up of patient treatment.
Class IIa		
MD 1102	Heated Patient Circuits	N/A for Class IIa
MD 0101	Accessories, Non-Heated Patient Circuits and Breathing Masks	N/A for Class IIa

First Issued: **2021-05-07**

Date: **2026-04-09**

Expiry Date: **2028-11-09**

...making excellence a habit.™

Page 2 of 2

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

UKCA Certificate - Full Quality Assurance System

Certificate History

Certificate No: **UKCA 746268**
 Date: **2026-04-09**
 Issued To: **Breas Medical AB**
Företagsvägen 1
Mölnlycke
SE-435 33
Sweden

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.
2023-11-10	30000657	Renewal of certificate. Alignment of scope wording. Correction to intended purpose for Nippy 4+. Addition of EveryWare device. Removal of significant subcontractor pages.
2026-01-19	30590866	Addition of Airway Clearance Devices and restructure of device schedule to list device groups instead of device names.

...making excellence a habit.™

UKCA Certificate - Full Quality Assurance System

Certificate History

Certificate No: **UKCA 746268**
 Date: **2026-04-09**
 Issued To: **Breas Medical AB**
Företagsvägen 1
Mölnlycke
SE-435 33
Sweden

Date	Reference Number	Action
2026-03-23	30634029	Removal of "Sleep Apnea Devices" from the certificate scope. Removal of Class IIa devices below: CPAP/APAP Devices. CPAP/APAP and Sleep Quality Monitoring Software App.
Current	30685060	Addition of Breathing Masks. Addition of subcontractor for manufacture of Breathing Masks.

...making excellence a habit.™