EU Quality Management System Certificate

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

MDR 727515 R001

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: **2026-06-05**

Starting Validity Date: **2026-06-10**

Expiry Date: **2031-06-09**

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Device Schedule: Class III and Class IIb devices

Class IIb under Rule 12	Intended purpose
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.
Class IIb	**Intended purpose**
Ventilator Treatment Software	For remote monitoring and follow up of patient treatment.

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

Device(s)	Risk Classification
Humidifying Systems and Heated Patient Circuits	Class IIa
Accessories, Non-Heated Patient Circuits and Breathing Masks	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.
2025-11-10	30559114	Restricted – Removal of Breathing Masks. Removal of subcontractor for manufacture of Breathing Masks.
2026-01-20	30590865	Supplemented – Addition of Airway Clearance Devices. Amended - Restructure of device schedule to list device groups instead of device names.
2026-04-09	30685019	Supplemented – Addition of Breathing Masks. Addition of subcontractor for manufacture of Breathing Masks.
Current	30533786	Re-issued – Certificate renewal

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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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
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