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 747726**

Issued To: **Breas Medical Ltd**
Units A1-A2
The Bridge Business Centre
Timothy's Bridge Road
Stratford Enterprise Park
Stratford-upon-Avon
CV37 9HW
United Kingdom

In respect of:

Design and manufacture of airway clearance devices and breathing circuits for respiratory therapy 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: **2021-08-17** Date: **2025-06-09** Expiry Date: **2029-05-26**

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Supplementary Information to UKCA 747726

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Device code	Device Description	Intended purpose
Class IIb		
MD 1102	Airway clearance device	Airway clearance device assists patients in loosening, mobilizing and clearing secretions, as well as promoting lung volume recruitment. IPPB mode and NIV mode must only be used noninvasively.
Class IIa		
MD 0101	Breathing circuits	--

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UKCA Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
2021-08-17	3414254	First Issue; Traceable to CE 556743.
2024-04-22	30129109	Certificate Renewal.
Current	30448167	Change of device name "NIPPY Clearway 2" to device group "Airway clearance device".

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