

# 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]

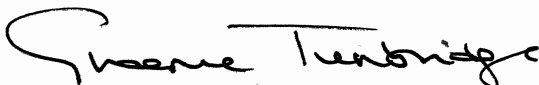
**No.** UKCA 747726  
**Issued To:** Breas Medical Ltd  
Units A1-A2  
The Bridge Business Centre  
Timothy's Bridge Road  
Stratford Enterprise Park  
Stratford-upon-Avon  
CV37 9HW  
United Kingdom

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 Medical Devices

First Issued: **2021-08-17**

Date: **2024-04-22**

Expiry Date: **2029-05-26**

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## Supplementary Information to UKCA 747726

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NBOG code(s)	Device Description	Intended purpose
<b>Class IIb</b>		
MD 1102	NIPPY Clearway 2	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.
<b>Class IIa</b>		
MD 0101	Breathing circuits	--

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## Certificate History

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Date	Reference Number	Action
2021-08-17	3414254	First Issue; Traceable to CE 556743.
Current	30129109	Certificate Renewal.

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