EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 556743**

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 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: **2010-11-10** Date: **2020-03-20** Expiry Date: **2024-05-26**

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Supplementary Information to CE 556743

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NBOG code(s)	Device Description	Intended purpose
Class IIa		
MD 0101	Breathing circuits for respiratory therapy devices	N/A for class IIa devices
Class IIb		
MD 1102, SMD 7010	Airway clearance device that provides the following therapeutic options: • Mechanical Insufflation-Exsufflation (MI-E). • Intermittent Positive Pressure Breathing (IPPB). • Non-Invasive Ventilation (NIV) for therapeutic use.	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.

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
10 November 2010	7457882	First Issue.
30 November 2010	7611647	Reissue to include airway clearance devices within the scope.
22 October 2015	8349718	Certificate Renewal.
11 October 2017	8848664	Reissue due to change of company name.
28 February 2019	7780321	Traceable to NB 0086.
Current	9785730	Certificate renewal, Device Table added, Scope changed. Former scope: Design and manufacture of patient ventilators, airway clearance devices and their associated breathing circuits. Current scope: Design and manufacture of airway clearance devices and breathing circuits for respiratory therapy devices.