

EC Certificate - Full Quality Assurance System

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

No. CE 562232
Issued To: **Broncus Medical, Inc.**
125 Nicholson Lane
San Jose
California
95134
USA

In respect of:

The design and manufacture of virtual bronchoscopic navigation software, and sterile devices and aspiration needles for interventional pulmonology.

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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **28 June 2010**

Date: **22 July 2016**

Expiry Date: **27 June 2020**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 562232**
Date: **22 July 2016**
Issued To: **Broncus Medical, Inc.**
125 Nicholson Lane
San Jose
California
95134
USA

Subcontractor:	Service(s) supplied
Medical Consulting Plus P.O. Box 3112 6202 NC Maastricht Netherlands	EU Representative
Smart World LLC, dba Steri-Tek 48225 Lakeview Blvd. Fremont California 94538 USA	Sterilization
Vention Medical Advanced Components (MN), LLC 7125 Northland Terrace North Suite 200 Minneapolis Minnesota 55428 USA	Manufacture

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125 Nicholson Lane
San Jose
California
95134
USA

Subcontractor:

Service(s) supplied

Vention Medical Design and
Development, Inc.
610 Palomar Avenue
Sunnyvale
California 94085
USA

Design
Development
Manufacture

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 562232**
 Date: **22 July 2016**
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Date	Reference Number	Action
28 June 2010	7522489	First Issue
09 July 2012	7858459	Certificate reissue due to change of legal manufacturer name from 'Broncus Technologies, Inc.' to 'Broncus Medical, Inc.'
30 July 2013	8023978	Certificate reissue due to upgrade to Annex II and addition to scope of, 'design and' and 'and sterile needles for bronchoscopic aspiration'. 'NUTEK Corporation' added as a sub-contractor for Sterilization.
29 July 2014	8194064	Change of scope From: The design and manufacture of virtual bronchoscopic navigation software and sterile needles for bronchoscopic aspiration. To: The design and manufacture of virtual bronchoscopic navigation software, sterile needles for bronchoscopic aspiration and LungPoint tools. Addition of 'Vention Medical Design and Development, Inc. 610 Palomar Avenue, Sunnyvale, California, 94085, USA' as significant subcontractor for design, development and manufacture.
19 May 2015	8292994	Certificate renewal

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Date	Reference Number	Action
22 July 2016	8487607	Certificate reissue due to: <ul style="list-style-type: none"> • Change in legal manufacturer address from '1400 N. Shoreline Boulevard, Building A-8, Mountain View, California, 94043' to '125 Nicholson Lane, San Jose, California, 95134' • Addition of 'Vention Medical Advanced Components (MN), LLC, 7125 Northland Terrace North, Suite 200, Minneapolis, MN 55428, USA' as significant subcontractor for manufacture. • Addition of 'Smart World LLC, dba Steri-Tek, 48225 Lakeview Blvd., Fremont, California 94538, USA' as significant subcontractor for sterilization. • Removal of 'Nutek Corporation, 1005 Whipple Road, Hayward, CA 94544, USA' as significant subcontractor for sterilization. • Change of scope from 'The design and manufacture of virtual bronchoscopic navigation software, sterile needles for bronchoscopic aspiration and LungPoint tools.' to 'The design and manufacture of virtual bronchoscopic navigation software, and sterile devices and aspiration needles for interventional pulmonology.'