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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 649013**

Issued To: **Pulmodyne, Inc.**
2055 Executive Dr.
Indianapolis
Indiana
46241
USA

In respect of:

The manufacture of anesthesia/respiratory devices & accessories

Those aspects of manufacture related to metrology of disposable pressure manometer and CO2 indicator

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack

Digitally signed by Durdun Margareta
Date: 2023.09.29 16:24:30 EEST
Reason: MoldSign Signature
Location: Moldova

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-06-14** Date: **2021-04-30** Expiry Date: **2023-08-01**

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Supplementary Information to CE 649013

Issued To:

Pulmodyne, Inc.
2055 Executive Dr.
Indianapolis
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46241
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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0101	Filters & HME	---
MD 0101	Respiratory mask	---
MD 0101	CPAP device	---
MD 0101	Tracheostomy device	---
Class Im		
MD 0101	Disposable Pressure Manometer (DPM)	---
MD 0101	FENEM CO2 indicator	---

First Issued: **2016-06-14** Date: **2021-04-30** Expiry Date: **2023-08-01**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No: **CE 649013**

Date: **2021-04-30**

Issued To: **Pulmodyne, Inc.**
2055 Executive Dr.
Indianapolis
Indiana
46241
USA

Subcontractor:	**Service(s) supplied**
Centurion Medical Products Corporation 301 Catrell Drive Howell Michigan 48843 USA	**ETO Sterilization**
Combat Medical Systems, LLC 5555 Harrisburg Industrial Park Dr. Harrisburg North Carolina 28075 USA	**Manufacture**

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No: **CE 649013**

Date: **2021-04-30**

Issued To: **Pulmodyne, Inc.**
2055 Executive Dr.
Indianapolis
Indiana
46241
USA

Subcontractor:	Service(s) supplied
Engineered Medical Systems Malaysia Sdn. Bhd. 993, Lorong Perindustrian Bukit Minyak 11, Taman Perindustrian Bukit Minyak, 14100 Simpang Ampat, Pulau Pinang Malaysia	**Manufacture**
Engineered Medical Systems, Inc. 2055 Executive Drive Indianapolis Indiana 46241 USA	**Manufacture**
QNET, BV Kanstraat 19 5076 NP Haaren The Netherlands	**EU Representative**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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Certificate No: **CE 649013**

Date: **2021-04-30**

Issued To: **Pulmodyne, Inc.**
2055 Executive Dr.
Indianapolis
Indiana
46241
USA

Subcontractor:	Service(s) supplied
Sterigenics US, LLC 1148 Porter Avenue Haw River North Carolina 27258 USA	**Radiation (Gamma Sterilization)**
Synergy Sterilisation Kulim (M) Sdn. Bhd Lot 71, Kulim Industrial Estate Kulim Kedah 09000 Malaysia	**ETO Sterilization**

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 649013**

Date: **2021-04-30**

Issued To: **Pulmodyne, Inc.**
2055 Executive Dr.
Indianapolis
Indiana
46241
USA

Date	Reference Number	Action
14 June 2016	8471341	First issue. Transfer from another Notified Body.
27 July 2018	8957538	Certificate Renewal.
21 February 2019	8650590	Traceable to NB 0086.
10 April 2020	3165091	Addition of Filters & HME. Addition of supplementary device table. Addition of critical subcontractor Synergy Sterilisation Kulim (M) Sdn. Bhd. Address change for Engineered Medical Systems Malaysia (Jalan Perindustrian Bukit Minyak 18). Removal of subcontractor Engineered Medical Systems Malaysia (1124, Jalan Perindustrian).
Current	3346837	Removal of Tracheostomy tube from supplementary device table. Addition of critical subcontractors Combat Medical Systems, LLC and Sterigenics US, LLC.