

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, Senior Vice President Medical Devices

First Issued: **2016-06-14**

Date: **2021-04-30**

Expiry Date: **2023-08-01**

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Page 1 of 2

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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Supplementary Information to CE 649013

Issued To:

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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	---

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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 under 33264284.

A member of BSI Group of Companies.

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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.**
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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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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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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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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 649013**
 Date: **2021-04-30**
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 46241
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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.

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Page 1 of 1

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