

# EC Certificate - Full Quality Assurance System

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

**No.****CE 703694****Issued To:**

**Vyaire Medical, Inc.**  
**26125 N. Riverwoods Blvd**  
**Mettawa**  
**Illinois**  
**60045**  
**USA**

In respect of:

**See certificate scope page.**

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: **2019-10-29**

Date: **2021-04-19**

Expiry Date: **2024-05-26**

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Page 1 of 4

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.

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.

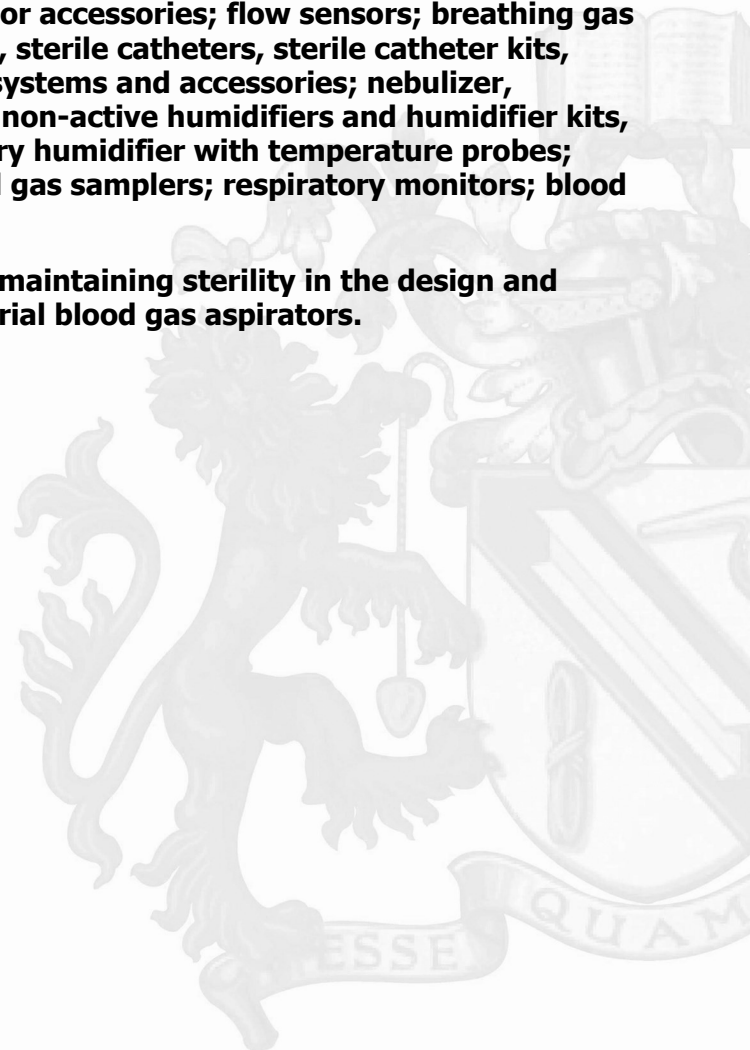
A member of BSI Group of Companies.

Certificate No: CE 703694

## Certificate Scope:

**Design and Manufacture of: masks (nasal and full face), non-invasive ventilation masks, invasive and non-invasive ventilator, oxygen and aerosol masks, tracheostomy masks, nasal masks, nasal prongs, nasal prongs used for respiratory therapy; airway connectors and adapters, oxygen tubing and cannulae, drainage bags, non-sterile adaptors for respiratory therapy, inspiration lines, IPPB manifolds; anaesthesia circuits, patient breathing circuits, heated and non-heated breathing circuits; ventilator accessories; flow sensors; breathing gas mixers/blenders; sterile Meconium Suction Device, sterile catheters, sterile catheter kits, closed suction catheter kit, sterile airway suction systems and accessories; nebulizer, nebulizer kits and nebulizer caps; bacterial filters; non-active humidifiers and humidifier kits, autofill humidification chambers, heated respiratory humidifier with temperature probes; manual resuscitation devices; sterile arterial blood gas samplers; respiratory monitors; blood warmers with sterile accessories**

**Those aspects of Annex II related to securing and maintaining sterility in the design and manufacture of endotracheal tube stylets and arterial blood gas aspirators.**

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Page 2 of 4

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## Supplementary Information to CE 703694

Issued To:

**Vyaire Medical, Inc.**  
**26125 N. Riverwoods Blvd**  
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**60045**  
**USA**

GMDN code	Device Description	Intended purpose
<b>Class IIb</b>		
47616	IV Fluid & Blood warmer and controller	Intended for warming blood, blood products and intravenous solutions prior to administration
44225	Microblender	Provide an accurate air/oxygen mixture of gas directly to a patient by way of a mask or cannulas or to a ventilator for subsequent delivery to the patient.
36554	SpO2 Monitoring	Continuous non-invasive monitoring of functional oxygen saturation of arterial haemoglobin and pulse rate
46822	Capnostat CO2 sensor	To provide carbon dioxide monitoring to a host monitoring system during anesthesia / recovery, in the intensive care unit (ICU), and in Emergency Medicine/Transport or Respiratory care.
12050	Heated humidifier with temperature probes	To add moisture to, and to warm, the breathing gases for administration to patient.
40582, 36849	Ventilator accessories, sensors	Non-invasive single patient use, and reusable Breathing circuit gas-flow sensor, reusable
36289	Ventilator	Continuous or intermittent ventilatory for the care of the individuals who require mechanical ventilation.

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## Supplementary Information to CE 703694

Issued To:

**Vyair Medical, Inc.**  
**26125 N. Riverwoods Blvd**  
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**Illinois**  
**60045**  
**USA**

NBOG code(s)	Device Description	Intended purpose
<b>Class IIa</b>		
MD 0101	Non-active devices for anaesthesia, emergency and intensive care.	N/A
MD 0102	Non-active devices for infusion.	N/A
MD 1101	Devices for extra-corporal circulation infusion and haemopheresis	N/A
MD 1102	Respiratory devices, devices including autofill humidification chamber and active breathing circuits	N/A

First Issued: **2019-10-29**Date: **2021-04-19**Expiry Date: **2024-05-26**

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Page 4 of 4

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# EC Certificate - Full Quality Assurance System

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

## List of Significant Subcontractors

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

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 Date: **2021-04-19**  
 Issued To: **Vyaire Medical, Inc.**  
**26125 N. Riverwoods Blvd**  
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**60045**  
**USA**

Subcontractor:	Service(s) supplied
ACUTRONIC Medical Systems AG Fabrik im Schiffli 8816 Hirzel Switzerland	<b>Design</b> <b>Manufacture</b>
Amsino Medical (Shanghai) Co. Ltd Building #1-3, 16, Lane 355, Huazhe Road, Songjiang Export Processing Zone 201613 Shanghai People's Republic of China	<b>ETO Sterilization</b> <b>Manufacture</b> <b>Packaging</b>
AOK Tooling Limited 101 and 1 Building, 2 Building, 3 Building, 4 Building, 5 Building, No. 8, of Long Tian No. 3 Road, Long Tian Community, Long Tian Street, Pingshan District, Shen Zhen Guangdong, China	<b>Manufacture</b> <b>Packaging</b>

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**60045**  
**USA**

### Subcontractor:

### Service(s) supplied

Carlo Technical Plastics  
 1141 West Grant Road  
 Tucson  
 Arizona  
 85705  
 USA

**Manufacture**

Carlo Technical Plastics (Taicang) Co., Ltd.  
 No. 8 Xixin Road  
 Chengxiang zhen  
 Taicang City  
 Jiangsu Province  
 China

**Manufacture**

ChinaMed Products (China) Ltd.  
 Xintang Industrial Park  
 Jiaotang Town  
 Gaoyao District  
 Zhaoqing City  
 Guangdong Province  
 526113  
 People's Republic of China

**Manufacture**

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**60045**  
**USA**

### Subcontractor:

### Service(s) supplied

Dongguan Bao Kang Dian Zi Ke Ji Ltd.  
 Yin Yang Industrial Estate  
 Zhangmutou  
 Dongguan  
 Guangdong  
 523620  
 P.R. China

**Control of Sterilization  
 Manufacture**

Emergo Europe  
 Prinsessegracht 20  
 The Hague 2515 AP  
 The Netherlands

**EU Representative**

GaleMed (Xiamen) Co.,Ltd.  
 Amoy Export Processing Zone 39  
 Section3, Haijing East Road  
 Fujian Province  
 361026  
 China

**Design  
 Manufacture**

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**USA**

### Subcontractor:

### Service(s) supplied

GaleMed Corporation  
 No. 87, Li-Gong 2nd Road  
 Wu-Jia  
 I-Lan 268  
 Taiwan

**Design**  
**Manufacture**

Hadimec AG  
 Alte Bruggerstrasse 32  
 5506 Mägenwil  
 Switzerland

**Manufacture**

Healthcare Technology  
 International Ltd.  
 15/F., Block B, Veristrong  
 Industrial Centre  
 36 Au Pui Wan Street, Fotan  
 Hong Kong

**Control of Sterilization**  
**Manufacture**

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**USA**

**Subcontractor:****Service(s) supplied**

Hsiner Co., Ltd.  
No. 312, Jhongshan Rd.,  
Shengang District,  
Taichung City  
Taiwan

**Design**  
**Manufacture**

Pacific Hospital Supply Co., Ltd.  
4F, No 160 Daye Rd  
Beitou District  
Taipei 112  
Taiwan

**Design**  
**ETO Sterilization**  
**Manufacture**

Phillips-Medisize Costa Mesa, LLC  
3545 Harbor Blvd., Suite 150  
Costa Mesa  
California 92626  
USA

**Manufacture**

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**USA**

### Subcontractor:

### Service(s) supplied

Productos Urologos de Mexico  
 S.A. de C.V  
 Cerrada Via de la Produccion No 85  
 Parque Industrial Mexicali III  
 Baja California, CP 21397  
 Mexico

**Manufacture**

Respironics Novamatrix, LLC  
 5 Technology Dr.  
 Wallingford  
 Connecticut  
 06492  
 USA

**Manufacture**

Shenzhen JPY Ion-Tech Co., Ltd.  
 No. 68, Dongsheng Road  
 Luohu District  
 Shenzhen City  
 518019 Guangdong  
 China

**Radiation (Gamma Sterilization)**

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**60045**  
**USA**

Subcontractor:	Service(s) supplied
Shenzhen Vital Signs-KTL Medical Instrument Co. Ltd. Buidling 3, No. 88 North Jiaoyu Road Gaoqiao Industrial Park Pingdi Longgang District Shenzhen 518117 Guangdong P.R. China	<b>Manufacture</b>
Sterigenics Radiation Technologies, LLC 7695 Formula Place San Diego California 92121 USA	<b>Radiation (E Beam Sterilization)</b>
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	<b>Radiation (Gamma Sterilization)</b>

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**Illinois**  
**60045**  
**USA**

Subcontractor:	Service(s) supplied
Synergy Health AST, LLC 9020 Activity Road, Suite D San Diego, California 92126 USA	Radiation (E Beam Sterilization)
Synergy Health AST, LLC 3200 Lakeville Highway #120 Petaluma California 94954 USA	Radiation (E Beam Sterilization)
Vincent Medical (Dong Guan) Manufacturing Co, Ltd. 45-46 ShaBu Industrial Zone Qiao Long District Tang Xia Town Dong Guan City Guandong Province P.R. China	ETO Sterilization Manufacture

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**60045**  
**USA**

### Subcontractor:

### Service(s) supplied

Viomedex Limited  
 Unit 13  
 Swan Barn Business Centre  
 Old Swan Lane  
 Hailsham  
 BN27 2BY  
 United Kingdom

**Manufacture**

Vyaire Medical, Inc.  
 510 Technology Drive  
 Irvine  
 California  
 92618  
 USA

**Design**

Vyaire Medical, Inc.  
 1100 Bird Center Drive  
 Palm Springs  
 California  
 92262  
 USA

**Manufacture**

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**USA**

### Subcontractor:

### Service(s) supplied

Vyaire Medical, Inc.  
 26125 N. Riverwoods Blvd  
 Mettawa  
 Illinois  
 60045  
 USA

**Regulatory Compliance**

Western/Scott Fetzer Co.  
 875 Bassett Rd  
 Westlake  
 Ohio  
 44145  
 United States

**Manufacture**

WILamed GmbH  
 Aurachhöhe 5-7  
 91126 Kammerstein  
 Deutschland

**Manufacture**

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## Certificate History

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**USA**

Date	Reference Number	Action
08 May 2019	9757619	First Issue. New certificate for 'Vyaire Medical, Inc.' traceable to CE 550406.
17 January 2020	9787413	Renewal. Amsino Medical: change of zip code to 201613. AOK Tooling: address details updated. Availmed: address details updated. Galemed: address details updated. Hsiner: address details updated. Pacific Hospital Supply: addition of zip code 112.
07 February 2020	3146941	Administrative change to reference number.
15 July 2020	3166272	Renewal and merger of CE 703691 into CE 703694. Update of product table. Addition of following subcontractors: Accutronic Medical Systems AG, Fabrik im Schiffli, 8816 Hirzel, Switzerland with Design and Manufacture as Service. Carclo Technical Plastics (Taicang) Co., Ltd. , No. 8 Xixin Road, Chengxiang Zhen, Taicang City, Jiangsu Province, China with Manufacture as Service.

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Page 1 of 5

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Date	Reference Number	Action
		<p>Carclo Technical Plastics Co. Ltd., 1141 West Grant Road, Tucson, Arizona 85705, USA with Manufacture as Service.</p> <p>Dongguan Bao Kang Dian Zi Ke Ji Ltd., Yin Yang Industrial Estate, Zhangmutou, Dongguan, Guangdong, 523620 P.R China with Manufacture and Control of Sterilization as Service.</p> <p>Galemed (Xiamen) Co. Ltd., Amoy Export Processing Zone, 39 Section 3, Haijing East Road, Fujian Province 361026, China with Manufacture as Service.</p> <p>Hadimec AG, Alte Bruggerstrasse 32, 5506 Mägenwil, Switzerland with Manufacture as Service.</p> <p>Philips-Medisize Costa Mesa, LLC, 3545 Harbour Blvd., Costa Mesa, CA 92626, USA with Manufacture as Service.</p> <p>Respironics Novamatrix, LLC, 1010 Murry Ridge Ln., Murrysville, PA 15668, USA with Manufacture as Service.</p> <p>Shenzhen Vital Signs – KTL Medical Instrument Co. Ltd., Building 3, No. 88 North Jiaoyu Road, Gaoqiao Industrial Park Pingdi, Longgang District Shenzhen, 518117 Guangdong P.R. China with Manufacture as service.</p> <p>Viomedex Ltd., Unit 13, East Sussex, BN21 2BY, UK with Manufacture as Service.</p>

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Page 2 of 5

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Date	Reference Number	Action
		<p>Vyaire Medical Inc., 510 Technology Dr., Irvine, CA 92618, USA with Design and Manufacture as Service.</p> <p>Vyaire Medical formally trading as Carefusion, 1100 Bird Center Drive, Palm Springs, California 92262 USA with Manufacture as Service.</p> <p>Western/Scott Fetzer Co., 875 Bassett Road, Westlake, OH 44145, USA with Manufacture as Service.</p> <p>WILAmed GmbH, Aurachhohne, 5-7, 91126 Kammerstein, Germany with Manufacture as Service.</p> <p>Removal of following subcontractors:</p> <p>Availmed S.A. de C.V., C. Industrial Lt. 001 Mz.105 No. 20905 Int. A Col. Cd. Industrial, Tijuana, Baja Californnia, C.P. 22444, Mexico.</p> <p>Vyaire Medical Inc., 22745 Savi Ranch Parkway, Yorba Linda, California 92887, USA.</p> <p>Addition of Packaging as Service to Amsino Medical (Shanghai) Co. Ltd.</p> <p>Change of name details: Zhaoqing ChinaMed Products Company Limited to ChinaMed Products (China) Ltd.</p>

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Date	Reference Number	Action
10 February 2020	3252452	Added invasive and non-invasive ventilator to scope, GMDN code 36289 for ventilator, and added the following three new sites under Vyaire Medical, Inc.: 7070 W Pueblo Dr, Wichita, Kansas 67209 USA; 7080 W Pueblo Dr, Wichita, Kansas 67209 USA; and 7227 W. Harry St, Wichita, Kansas 67209 USA.
19 April 2021	3342933	Added alternate subcontractor for E Beam Sterilization Synergy Health AST, LLC, address: 3200 Lakeville Hwy, Suite #120, Petaluma, California, 94954 USA.  Changed subcontractor name from Sterigenics US, LLC to Sterigenics Radiation Technologies, LLC for site address 7695 Formula Place, San Diego, California 92121 USA.

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Date	Reference Number	Action
<b>Non-significant changes approved after the 26<sup>th</sup> May 2021 as per the Transitional Provisions of MDR Article 120.3</b>		
29 April 2022	3637219	Removed - the following subcontractors are removed from the certificate: Vyaire Medical, Inc. 7227 W. Harry St, Wichita, Kansas 67209 USA Vyaire Medical, Inc. 7080 W Pueblo Dr, Wichita, Kansas 67209 USA Vyaire Medical, Inc. 7070 W Pueblo Dr, Wichita, Kansas 67209 USA Removed - the device Capnostat CO2 sensor is removed from the scope and the device table of this certificate

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29 April 2022

Vyaire Medical, Inc.  
26125 N. Riverwoods Blvd  
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Illinois  
60045  
USA

To whom it may concern,

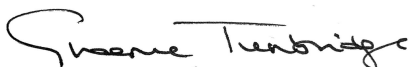
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26<sup>th</sup> May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 703694	93/42/EEC Annex II excluding Section 4	3637219	<p>Removed - the following subcontractors are removed from the certificate:</p> <p>Vyaire Medical, Inc. 7227 W. Harry St, Wichita, Kansas 67209 USA</p> <p>Vyaire Medical, Inc. 7080 W Pueblo Dr, Wichita, Kansas 67209 USA</p> <p>Vyaire Medical, Inc. 7070 W Pueblo Dr, Wichita, Kansas 67209 USA</p> <p>Removed - the device Capnostat CO2 sensor is removed from the scope and the device table of this certificate</p>

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Graeme Tunbridge  
Senior Vice President, Medical Devices