

EC Certificate - Full Quality Assurance System

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

No.**CE 703694**

Issued To:

**Vyair 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****...making excellence a habit.™**

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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.

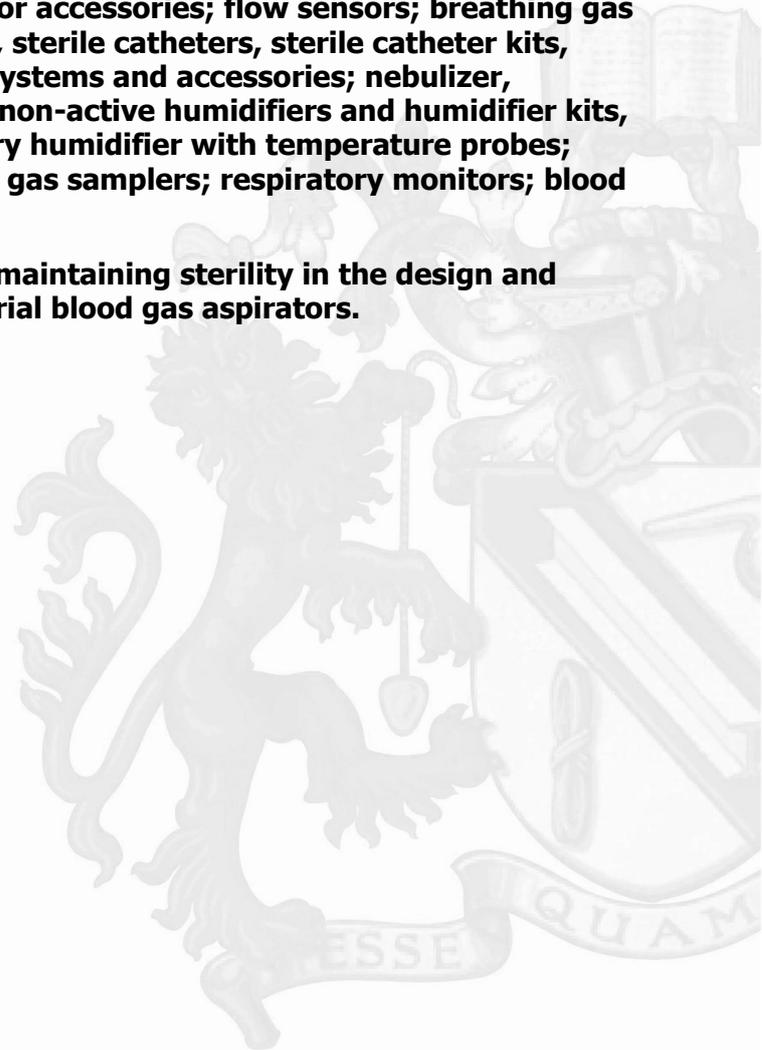
This certificate was issued electronically and is bound by the conditions of the contract.

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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Supplementary Information to CE 703694

Issued To:

Vyaire Medical, Inc.
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GMDN code	Device Description	Intended purpose
Class IIb		
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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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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NBOG code(s)	Device Description	Intended purpose
Class IIa		
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

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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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26125 N. Riverwoods Blvd
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Subcontractor:	Service(s) supplied
ACUTRONIC Medical Systems AG Fabrik im Schiffli 8816 Hirzel Switzerland	Design Manufacture
Amsino Medical (Shanghai) Co. Ltd Building #1-3, 16, Lane 355, Huazhe Road, Songjiang Export Processing Zone 201613 Shanghai People's Republic of China	ETO Sterilization Manufacture Packaging
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	Manufacture Packaging

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Subcontractor:	Service(s) supplied
Carclo Technical Plastics 1141 West Grant Road Tucson Arizona 85705 USA	Manufacture
Carclo 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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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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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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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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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
Respirationics 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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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	Manufacture
Sterigenics Radiation Technologies, LLC 7695 Formula Place San Diego California 92121 USA	Radiation (E Beam Sterilization)
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	Radiation (Gamma Sterilization)

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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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Subcontractor:	Service(s) supplied
Viomedex Limited Unit 13 Swan Barn Business Centre Old Swan Lane Hailsham BN27 2BY United Kingdom	Manufacture
Vyair Medical, Inc. 7227 W. Harry St Wichita Kansas 67209 USA	Manufacture
Vyair Medical, Inc. 7080 W Pueblo Dr Wichita Kansas 67209 USA	Manufacture

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Subcontractor:	Service(s) supplied
Vyair Medical, Inc. 7070 W Pueblo Dr Wichita Kansas 67209 USA	Manufacture
Vyair Medical, Inc. 510 Technology Drive Irvine California 92618 USA	Design
Vyair Medical, Inc. 1100 Bird Center Drive Palm Springs California 92262 USA	Manufacture

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Subcontractor:	Service(s) supplied
Vyair 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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Date	Reference Number	Action
08 May 2019	9757619	First Issue. New certificate for 'Vyair 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. Carclo Technical Plastics Co. Ltd., 1141 West Grant Road, Tucson, Arizona 85705, USA with Manufacture as Service.

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	<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 Mnaufacture as Servicce.</p> <p>Respironics Novamatrix, LLC, 1010 Murry Ridge Ln., Murrysville, PA 15668, USA with Manufacture as Service.</p> <p>Shenzen Vital Signs – KTL Medical Instrument Co. Ltd., Building 3, No. 88 North Jiaoyu Road, Gaoqiao Industrial Park Pingdi, Longgang District Shenzen, 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> <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>
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		<p>WILAmEd GmbH, Aurachhohne, 5-7, 91126 Kammerstein, Germany with Manufacture as Service.</p> <p>Removal of following subcontractors: 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>
10 February 2020	3252452	<p>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.</p>
Current	3342933	<p>Added alternate subcontractor for E Beam Sterilization Synergy Health AST, LLC, address: 3200 Lakeville Hwy, Suite #120, Petaluma, California, 94954 USA.</p> <p>Changed subcontractor name from Sterigenics US, LLC to Sterigenics Radiation Technologies, LLC for site address 7695 Formula Place, San Diego, California 92121 USA.</p>