Appendix E
Certifications

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 063744 0018 Rev. 01

Manufacturer:

Xiamen Compower Medical Tech. Co., Ltd.
Unit 301, No.16, Xianghong Road
Xiang'an Torch Industrial Zone
361101 Xiamen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Silicone/SEBS/PVC Manual Resuscitators (Including Mask, Positive End-Expiratory Pressure Valve, Oxygen Tube, Reservoir Bag, Mouth opener, Oropharyngeal Airway, Manometer), Resuscitation Mask, Continuous Positive Airway Pressure Mask/Non-invasive Ventilation Mask, Simple Oxygen Mask, Venturi Mask, Non-Rebreathing Mask, Aerosol Mask w/Nebulizer, Breathing Circuit (Including Mask, Elbow Connector, Y Piece, Corrugate Tubing, Collapsible Tubing, Water Trap, Straight Connector, HMEF), Anesthesia Circuit (Including Mask, Elbow Connector w/Luer Port & Cap, Y Piece, Corrugate Tubing, Collapsible Tubing, Straight Connector, Breathing Bag, Bacterial Filter, Gas Sampling Line), Anesthesia Mask, Breathing Filter for Single Use

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH1917614

Valid from: 2019-08-26
Valid until: 2022-09-30

Date, 2019-08-26

Stefan Preiß
Head of Certification/Notified Body

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 063744 0018 Rev. 01

Facility(ies):

Xiamen Compower Medical Tech. Co., Ltd.
Unit 301, No.16, Xianghong Road, Xiang'an Torch Industrial Zone,
361101 Xiamen, PEOPLE'S REPUBLIC OF CHINA

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q6 063744 0017 Rev. 01

Holder of Certificate: **Xiamen Compower Medical Tech. Co., Ltd.**
Unit 301, No.16, Xianghong Road
Xiang'an Torch Industrial Zone
361101 Xiamen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Xiamen Compower Medical Tech. Co., Ltd.
Unit 301, No.16, Xianghong Road, Xiang'an Torch Industrial Zone,
361101 Xiamen, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Production and Distribution of Manual Resuscitators with Accessories, Resuscitation Mask, Pneumatic Splint, Continuous Positive Airway Pressure Mask/Non-invasive Ventilation Mask, Simple Oxygen Mask, Venturi Mask, Non-Rebreathing Mask, Aerosol Mask w/Nebulizer, Breathing Circuit,Anesthesia Circuit, Nose Clip, Anesthesia Mask, Breathing Filter for Single Use**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1917614

Valid from: 2019-10-01
Valid until: 2022-09-30

Date, 2019-08-26

Stefan Preiß
Head of Certification/Notified Body

A4 / 07.17

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Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Our Ref: CA014885

Mr Eric Banagan
LifeVac Europe Limited
Carnanton
King Street
Combe Martin
Devon
EX34 0AD
United Kingdom

MHRA
151 Buckingham Palace Road
London
SW1W 9SZ
United Kingdom

www.gov.uk/mhra

16 June 2015

Dear Mr Eric Banagan,

MEDICAL DEVICES REGULATIONS 2002: REGULATION 19
Registration of Persons Placing General Medical Devices on the Market

Thank you for informing the Competent Authority of your company's details and for supplying the medical device information.

Your registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of "medical device", and that you have classified it/them as falling within Regulation 13 taking into account the intended purpose(s) and mode(s) of action. In accepting your registration, I should make clear that the Competent Authority does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations. Neither does this letter represent any form of accreditation, certification or approval by the UK Competent Authority.

Your registration is based upon your declaration on the RG2 form and means that:

For Manufacturers of Class I medical devices, Assemblers, and Sterilisers

You should now be operating under the Medical Devices Directive and the above Regulations for the products you asked us to register, by fully complying with the essential requirements, CE marking those products or labelling them as such.

For Manufacturers of Custom-made devices and Custom Made Active Implantable

You should be ready to claim compliance with the Directive and Regulations and should be manufacturing custom-made devices in accordance with their requirements.

If you stop placing devices on the market or if you are not complying with the Regulations you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the regulations.

The information you provided has been recorded against the reference number shown at the top of this letter, which we ask you to quote in all future correspondence and communications.

Please inform us of the following chargable changes:

- the company information e.g. name and address
- additional generic groups of devices (not individual products within an existing generic group)

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/discontinuation of a device from your registration record, change of contact person, postcode, telephone number and/or email address, for which payment of our statutory fee does not apply. Though, you are required to provide these non-chargeable changes in writing we will not provide an updated letter of registration. As the updated information does not affect your regulatory obligations or the information published on our Public Access Registration Database (PARD).

Thank you for registering the following generic groups of devices:

Class I Devices:
Airway Devices/Monitoring Equipment And Accessories

Custom Made Devices:
None

Products Covered By Article 12:
None

Confidentiality

Please note that in accordance with Directive 2007/47/EC as of 21st March 2010 information on the registration of persons responsible for placing devices on the market will no longer be treated as confidential and the Competent Authority will provide third parties with information on the name and address of manufacturers and authorised representatives and their devices that have been registered. However the names of individuals, their telephone numbers and email addresses will remain confidential unless you have chosen to trade using personal details. This change only applies to medical devices and does not affect In Vitro Diagnostic devices registration, which remain confidentiality under Article 19 of the In Vitro Diagnostic Directive 98/79EC.

If your company name or that of a manufacturer that you represent is based on an individual's personal name it will be published unless you inform the MHRA that you would like the company name to remain confidential.

Likewise, if your company address or that of a manufacturer that you represent is the personal home address of an individual it will be published unless you inform the MHRA that you would like the company address to remain confidential.

Should you have any queries regarding your registration please do not hesitate in contacting us.

Yours sincerely

Barbara Clarke
Regulatory Affairs Administrator
Tel: 020 3080 7318
Fax: 020 3118 9809
Email: barbara.clarke@mhra.gsi.gov.uk

LIFEVAC EUROPE LTD
2014-2015

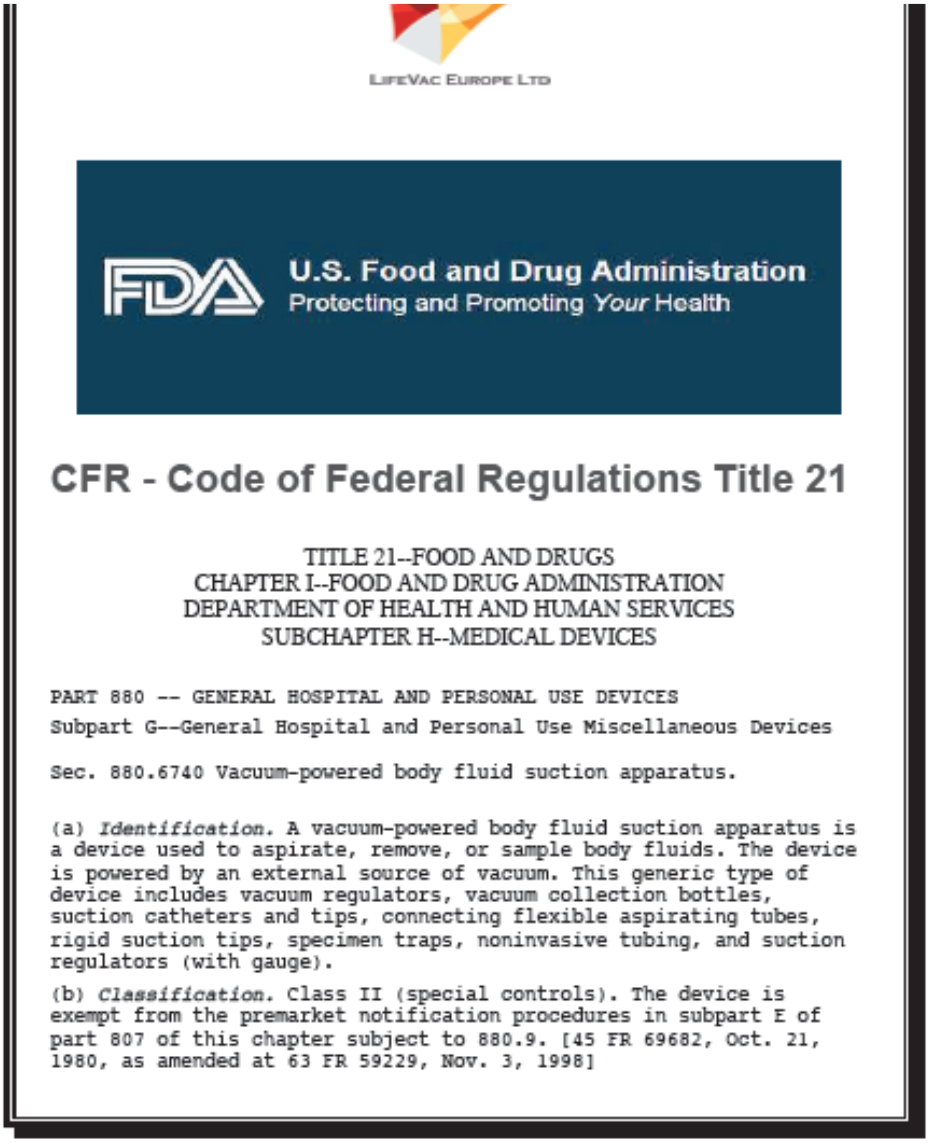
Certificate of Registration

This certificates that:

LifeVac Corp.
83 Rome Street
Farmingdale, NY 11735

Is registered with the U.S. Food and Drug Administration pursuant to section 305 of the United States Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107-188, such registration having been verified as currently effective on the date hereof by Registrar Corp.

U.S. FDA Registration No.: 3011053282



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U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

CFR - Code of Federal Regulations Title 21

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 880 -- GENERAL HOSPITAL AND PERSONAL USE DEVICES

Subpart G--General Hospital and Personal Use Miscellaneous Devices

Sec. 880.6740 Vacuum-powered body fluid suction apparatus.

(a) *Identification.* A vacuum-powered body fluid suction apparatus is a device used to aspirate, remove, or sample body fluids. The device is powered by an external source of vacuum. This generic type of device includes vacuum regulators, vacuum collection bottles, suction catheters and tips, connecting flexible aspirating tubes, rigid suction tips, specimen traps, noninvasive tubing, and suction regulators (with gauge).

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 880.9. [45 FR 69682, Oct. 21, 1980, as amended at 63 FR 59229, Nov. 3, 1998]