CE certificates (CE 认证）

CELAB®
Via Maira snc
04100 Latina
Italy
celab@celab.com

CERTIFICATE

Certificate Number **UCN**	: **802759487332**
Job	: J29230
Date of Issue	: *2020-03-21*
Certificate valid up to	: *2024-03-20*
Brand Name	: *Leihuo*
Type	: *Protective masks*
Model N	: *LH-KN95*

Manufacturer : Dongguan Leihuo Medical Device Co., Ltd.
Address : Dongshan Yongshenglu N0.47 Room 101, Qishi, Dongguan, Guangdong China

Standard Used : EN 14683:2005

Conclusion :
After inspection of the technical documentation issued by the customer, and in his request, we express our opinion that the product meets the technical requirement of the following directives and standards:
93/42/EEC Medical devices (MDD)

This opinion is only valid for the directive, the equipment and configuration described, in conjunction with the test data detailed above and with compliance with all applicable legal requirement for the product .
The following manufacturer documents was inspected:

Presence of Declaration of conformity template	✔ OK
Presence of test report using standards as indicated in the declaration of conformity Test report reference : HTT202003147LR	✔ OK
Presence of CE symbol in the product label.	✔ OK
Presence of instruction manual	✔ OK
Use of valid Harmonized standard in the declaration of conformity	✔ OK
Presence of product description in the technical construction file	✔ OK

Check the authenticity of this certificate and related information before use in the web site www.celab.com introducing the UCN number in the 'Check document authenticity' area. You will see copy of this certificate and regulation on certificate use. This document is released only for scope allowed by laws- Do not use this document without full understanding of regulation.

Massimiliano Bertoldi
General Manager – CELAB
www.celab.com

FDA certificates (FDA认证)

Fiscal Year 2020

CERTIFICATION OF FDA REGISTRATION

This certifies that:

DONGGUAN LEIHUO MEDICAL DEVICE CO., LTD.
Dongshan Yongshenglu No.47 Room 101, Qishi
Dongguan, Guangdong, 523500, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

Shenzhen CCT Testing Technology Co., Ltd.

Owner/Operator Number: 10063202

Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D375637	KHA	MASK, SCAVENGING	KN95 Mask, Disposable Mask

CCT will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. CCT makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. CCT assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, CCT is not affiliated with the U.S. Food and Drug Administration.

Chief engineer
Issued: 03/18/2020
Expiration Date:12/31/2020

Shenzhen CCT Testing Technology Co.,Ltd.
W: www.fda-test.com E: fda@fda-test.com
T: 400-8788-298 T: 86-755-36916737

Web: http://www.fda.gov Tel: 1-888-INFO-FDA (1-888-463-6332) e-mail: webmail@oc.fda.gov

Annex : Regulation for Voluntary Certification Activities

1. Release of certificate

These certificates are issued on a voluntary basis on request of manufacturer.
The certificate is released for product after inspection of the documentation relative to the technical construction file.
This Certificate is released only after that, is opinion of a CELAB approved technician, that the technical construction file (test reports, documentations, instruction manuals) demonstrate that the essential requirements indicated in the directives himself was covered.
Note: the technical requirement are related to the physical propriety of a product and his production process and not the legal requirements of directives.
When the opinion is positive, the certificate is released.
The inspection provided by CELAB is not relative to: The product; The production; The law requirements; The work performed or that will be performed by Notified Bodies.
The Inspection cover ONLY the following aspects (where applicable):

- Presence of declaration of conformity;
- Presence of test report as indicated in the certificate;
- Presence of CE symbol in the product label template;
- Presence of Instruction manual;
- Use of actual harmonized standards as for EU official Journal;
- Presence of production description in the technical construction file.

2. Validity of certificate

All certificate have 4 years of validity. After such time the certificate will not be any more valid.

3. Withdraw of certificate

The certificate are withdraw if there is a reasonable justification that the product do not comply with the requirement of a directive, or when this agreement was not addressed.

4. Responsibility of manufacturer

As many directives require use of a Notified Body, in such case is responsibility of producer or his representative in Europe to follow all applicable directives requirement and contact.
This regulation will always be consigned together with the certificate and is a part of them, use of the certificate without text of this regulation is not allowed or accepted.
Is responsibility to the manufacturer to comply with CE marking law prescriptions.

5. Responsibility of CELAB

CELAB take no responsibility on product tested except that, in case of advice from market, CELAB will investigate on such compliant and, if found acceptable, the certificate will be withdraw.
CELAB is not responsible for the product, the production, the importing, the distribution, the sales, the advertisement, the technical assistance, the consulting or as EU mandatories.
Certificate is the result of technical opinion, given as a private owned company. There is no any warranty that the product will comply with all requirements of directives or a law.
CELAB is not responsible for CE marking of the product indicated in the certificate.

6. Responsibility of user of certificate

Is responsibility of the user of the certificate to comply with all laws requirements. Only as a general reference, the user of certificate will need to get copy of test-report from his supplier and be responsible for technical construction file. User of the certificate take full legal responsibility on such use.
Such certificate are not legal requirements except when used between private company as a specific contract agreement between them.
User of certificate need to full comply with applicable requirements indicated in such directives. User of certificate are not allowed to induce the market on a different destination of use of the certificate different from what stated in this agreement. Use of certificate of conformity is restricted to expert in CE Marking field that can fully understand scope of this certificate and is not for general public.
This certificate cannot be publicized in a misuses or in a way that It can confuse general public. The user of the certificate will Always do not use the certificate for customs control or public authority requirement control.

7. Scope of the certificate.

The ONLY Scope of this kind of certificate is :

- Allow the manufacturer to demonstrate to a customer that a product was tested without need to give him test reports (if both accepted by manufacturer and by the customer);
- Allow a private customer to have an evidence that an independent 3th part have inspected the documentation on voluntary basis.

The certificate provide an added value for manufacturer in situation where the manufacturer don't want to provide to his customer the test reports (if not required by law).
Such certificate will need to be used only as demonstration that a sample of a product was really tested between companies that recognize this agreement. Such certificate are not required by law (as they are voluntary certificate), and are intended to be used between private company for commercial issue. These certificate where not to be used to demonstrate conformity of the product to authority or for government control. The certificate are not an authorization by CELAB to put the CE marking on the product.
The Certificate is not a legal requirement for CE marking activities. Is the opinion of CELAB that manufacture can provide the CE marking in the product IF he comply with all prescription of the directives. The Certificate is not a declaration of conformity or an attestation of conformity. Note that some directive require use of Notified Body, the certificate of conformity and the certificate of compliance are NOT related to Notified Body work and are not related to law requirements.
The certificate is a Technical Opinion issued by CELAB to the manufacturer of the product where, after review of document issued by manufacturer, CELAB certify his opinion regarding the conformity between the product and the prescription of the standard and/or the technical requirement of the directive.
The certificate where not issued in the role or the task of Notified Body or accredited testing laboratory or accredited certification body. Warning : do not confuse this certificate with certificates issued by notified bodies. In case of doubt on using this certificate, do not use it and consult a consultant or expert or contact
European Union Web Site : http://ec.europa.eu/growth/index_en
We recommend to search in such web site full information about CE marking related directives.

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Massimiliano Bertoldi
General Manager – CELAB

www.celab.com

Respirez, vous êtes bien protégés !
Breathe easy, we've got you covered !
Mit Valmy, sind Sie gut geschützt !

DÉCLARATION UE DE CONFORMITE – SPIREOR
EU DECLARATION OF CONFORMITY- SPIREOR

SAS VALMY INDUSTRIES, dont le siège social et l'usine se situent Rue Benjamin Franklin, 42300 MABLY-FRANCE, déclare sous sa seule responsabilité que les EPI neufs décrits ci-après :
SAS VALMY INDUSTRIES, which has its head office and factory Rue Benjamin Franklin, 42300 Mably-France, declares under its sole responsibility that the following PPE:

- Masques de protection respiratoire classes FFP1, FFP2 et FFP3, format pliable gamme SPIREOR – références VSP152TF, VSP252TF et VSP352TF
  Respiratory protective masks FFP1, FFP2 and FFP3, folded, SPIREOR range - part numbers VSP152TF, VSP252TF and VSP352TF
- Masques de protection respiratoire de classes FFP1, FFP2 et FFP3, format coquille gamme SPIREOR – références VSPX111A, VSPX252A et VSPX353
  Respiratory protective masks FFP1, FFP2 and FFP3, cupstyle, SPIREOR range - part numbers VSPX111A, VSPX252A and VSPX353

Sont conformes aux dispositions du règlement sur les EPI 2016/425 et à la norme nationale EN149 :2001 + A1 :2009 ;
Are in conformity with the PPE Regulation 2016/425 and with the harmonized standard EN149 :2001 + A1 :2009.

Sont identiques aux EPI ayant fait l'objet des attestations CE délivré par APAVE SUD EUROPE Numéro 0082, CS60193 – 13322 MARSEILLE CEDEX 16 – France.
Are identical to the PPE EC Certificated supplied by APAVE SUD EUROPE Number 0082, CS60193 – 13322 MARSEILLE CEDEX 16 – France.

Référence/*Part Number*	**Numéro d'attestation CE/*EC Certificate***
VSP152TF	0082/2061/079/10/15/0275
VSP252TF	0082/2061/079/10/15/0276
VSP352TF	0082/2061/079/10/15/0277
VSPX151A	0082/2061/079/07/17/0452
VSPX252A	0082/2061/079/07/17/0453
VSPX353	0082/2061/079/07/17/0454

Sont soumis à la procédure d'évaluation de la conformité Module D du règlement 2016/425, sous le contrôle de l'organisme notifié APAVE SUD EUROPE Numéro 0082, CS60193 – 13322 MARSEILLE CEDEX 16 – France.
Are subject to the conformity assessment procedure based on quality assurance of the production process Module D under the surveillance of the notified body APAVE SUD EUROPE Number 0082, CS60193 – 13322 MARSEILLE CEDEX 16 – France.

Mably, 18/04/2019

Amélie ARBOUR
Responsable RH et Qualité/ HR and Quality Manager

France - SAS VALMY INDUSTRIES au capital de 100 000€ - N° TVA: FR60 832 864 714 - APE/NAF 1419Z - info@valmy.eu
Siège Social & Usine - «La Demi-Lieue» - Rue Benjamin Franklin - 42300 MABLY - France - Tel. +33(0)4 77 23 11 21 - Fax. +33 (0)4 77 72 54 57
United Kingdom & Ireland - Valmy SAS Ltd - VAT No GB 358 746 410 - uk-sales@valmy.eu
Units 21 & 23 Scott Road Off Park Avenue - LUTON - Beds - LU3 3BF - United Kingdom - Tel: +44(0)1582 563 600 - Fax. + 44(0)1582 563 323

FULL SUPPORT®

Protection and Safety without Compromise

EU DECLARATION OF CONFORMITY

PPE: Particulate Respirators (filtering half masks)

This declaration of conformity is issued under the sole responsibility of the manufacturer:

Full Support Healthcare Ltd, Harrowden Court, 66-80 Huxley Close, Wellingborough, Northamptonshire, NN8 6AB. United Kingdom.

Product Model / Description:

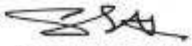
FSM7 - FFP2 NR Valved Particulate Respirator – duckbill
FSM9 - FFP3 NR Valved Particulate Respirator – cone
FSM10 - FFP2 NR Particulate Respirator – duckbill
FSM11 - FFP2 NR Particulate Respirator – cone
FSM12 - FFP2 NR Valved Particulate Respirator – cone
FSM14 - FFP3 NR Valved Particulate Respirator – duckbill
FSM15 - FFP3 NR Particulate Respirator – cone
FSM16 - FFP3 NR Particulate Respirator – duckbill
FSM17 - FFP3 NR D Valved Particulate Respirator – Custom-Fit
FSM18 - FFP3 NR D Particulate Respirator – Custom-Fit

The above models are:

- in conformity with the provisions of **Personal Protective Equipment (PPE) Regulation (EU) 2016/425** and, where such is the case, with the national standard transposing harmonized standard No. **EN149:2001+A1:2009**.
- identical to the PPE which is the subject of EU type-examination certificate of conformity No: **CE 718536.**

  BSI (**Notified Body No. 086**), Kitemark court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom, performed the EU type-examination (Module B of PPE Regulation (EU) 2016/425) and issued the above certificate.
- subject to the conformity assessment procedures set out in Module D of PPE Regulation (EU) 2016/425 (quality assurance of the production process) under surveillance of the notified body: **INSPEC International Ltd** (**Notified Body No. 0194**), 56 Leslie Hough Way, Salford M6 6AJ, Greater Manchester, United Kingdom.

Signed for and on behalf of Full Support Healthcare Ltd:



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Date: 15 October 2019

Sarah Stoute
Chief Executive Officer
Full Support Healthcare Ltd, Wellingborough UK

PPE Test Report

Application No.	:	ET16075001
Applicant	:	Jiande ChaoMei Daily Chemical Co.; Ltd.
Equipment Under Test (EUT)		
EUT Name	:	Folding Class
Model No.	:	6002A Series
Serial No.	:	6002A Series
Brand Name	:	CM朝美
Receipt Date	:	2016-07-05
Test Date	:	2016-07-05 to 2016-07-25
Issue Date	:	2016-07-25
Standards	:	EN 149: 2001.
Conclusions	:	PASS
		This report shows that the product technically complies with the Council PPE Directive **89/686/EEC** requirements.
Report by	:	Jim chen
Approved by	:	Jackwang

This test report is valid for above tested sample only and shall not be reproduced in part without written approval of the laboratory.