BIO PROMEDICAL

MASCARILLA 3 PLIEGUES

DESCRIPCIÓN	
Marca	CHANGZHOU UNIVERSAL
Modelo	3 Pliegues
Material	tela no tejida
Color	Celeste
Tamaño de mascarilla	17.5x9.5cm
Peso de mascarilla	3.5Gr+/-
Tamaño de caja	20.5x10.5x6.5cm
Vida útil	2 años
Certificaciones	FDA CE

MANUEL DE USO

1.- El lado de color más oscuro de la máscara suele ser el lado frontal. Coloque un elástico alrededor de cada oreja y cubra su boca y nariz con la mascarilla.

2.- Tire de la parte inferior de la máscara sobre su boca y mentón para mostrar un espacio de respiración en 3D.

3.- Moldea a la forma de tu nariz, del lado de la máscara que tiene un borde flexible rígido para sellar tu nariz del aire contaminado.

ATENCIÓN Y ADVERTENCIA

* El producto es desechable solamente, se debe destruir después del uso.
* No lo use si el empaque está dañado.
* Usar con precaución en caso de alergia a las telas no tejidas.
* Por favor consulta las instrucciones antes del uso.
* Fecha de producción, número de lote, revise en los sellos.
* Periodo de validez: 2 años.
* Norma operativa: GB/T32610-2016.

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Certificate Of Registration

Changzhou Universal Medical Equipment Co., Ltd
No.6,Xinxi Road,Xinbei District, Changzhou, Jiangsu, China
Has Completed With The U.S. Food And Drug Administration Pursuant To 21 CFR Part 807: Establishment Registration And Device Listing

Owner/Operator No.:10065199

Listing Number	Code No.	Proprietary Name	Model
D380895	LYU	Disposable mask Disposable medical mask KN95 mask	17.5cm*9.5cm, KN95 mask

Huawin 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. Huawin makes no other representations or warranties, nor does this certificate make 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. Huawin assumes no liability to any person or entity in connection with the foregoing.

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. Huawin is not affiliated with the U.S. Food and Drug Administration.

FDA

HUAWIN TESTING & CERTIFICATION CO. APPROVED

Manager: Cary Su
Issue date: Mar. 28, 2020
Expire Date: Dec. 31, 2020

Shenzhen Huawin Testing Certificaton Co., Ltd.
Add: 7F, U Center, No.743, Zhoushi Road, Bao'an, Shenzhen, China
Http://www.huawinlab.com E-mail: info@huawinlab.com

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Certificate Number: HW20200312054S
Personal Protective Equipment Regulation (EU) 2016/425

Certificate Of Compliance

Applicant	:	Changzhou universal medical equipment Co., Ltd
Address	:	No. 6, Xinxi road, Xinbei District, Changzhou City, Jiangsu Province, China
Manufacturer	:	Changzhou universal medical equipment Co., Ltd
Address	:	No. 6, Xinxi road, Xinbei District, Changzhou City, Jiangsu Province, China
Product	:	Disposable mask
Model	:	175mm*95mm

The submitted products have been tested by us with the following standard(s) and found to be in compliance with the listed European Directives.

EN 149: 2001+A1:2009

The test results apply only to the particular sample tested and to the specific tests carried out. Technical Report and documentation are at the Holder's disposal.
This certificate applies specifically to the sample investigated in our test reference number only. The CE markings as shown below can be affixed on the product after preparation of necessary technical documentation. Other relevant Directives have to be observed.

CE

SHENZHEN HUAWIN TESTING & CERTIFICATION CO., LTD. APPROVED

Manager: Guy Su

Date: March 13, 2020

Shenzhen Huawin Testing Certification Co., Ltd.
Add: 7F, Building A, Shenye U Center, No. 743, Zhoushi Road, Bao'an District, Shenzhen, China
Http://www.huawinlab.com E-mail: info@huawinlab.com

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CMA 180011112242

CAL (2018)浙认监认字(344)号

ilac-MRA

CNAS 中国认可 国际互认 检测 TESTING CNAS L6780

检 验 报 告

TEST REPORT

Scan is following us

Scan checks for authenticity

W202010623E

浙江省轻工业品质量检验研究院

Zhejiang Light Industrial Products Inspection and Research Institute

国家纺织服装产品质量监督检验中心（浙江）

National Textiles and Garment Quality Supervision Inspection Center(Zhejiang)

BIO PROMEDICAL

Zhejiang Light Industrial Products Inspection and Research Institute
National Textiles and Garment Quality Supervision Inspection Center(Zhejiang)

Test report

Number:W202010623E

Name of Customer	Changzhou universal medcal equipment CO.,LTD	Address	NO.6 Xinxi road Xinbei District Changzhou Jiangsu
Manufacturer	---	Address	---
Sample information	Name of sample: MASK Characteristics of sample: WHITE Trademark of sample: --- Specification/model: --- Level: --- Category of safety specification: --- Art. No.: ---		
Above-mentioned information by Customer-supplied			
The sent way of sample	Courier	Sample quantity	20 pieces
Receiving Date of Sample	2020/04/25	Test Category	Entrusted inspection
Date of Testing	2020-04-25- 2020-04-28		
RatingRequirements	GB 2626-2006		

Test Summary:

See the attached page for the results.

Test Seal

Date of Approval: 2020-04-28

Remarks	1. The filter efficiency grade is not marked on the sample mark, and it is judged according to the lowest standard requirement KN90. 2. The sample is not pretreated and the result is for reference.

Approved by:

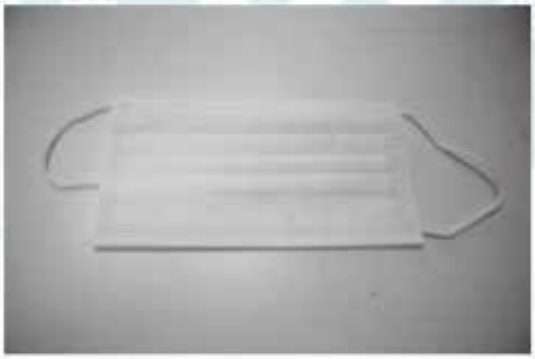
BIO PROMEDICAL

Test report

Number:W202010623E

ITEM	STANDARD	RESULT	RATING
1. FILTER EFFICIENCY(SALT MEDIUM) (GB 2626-2006 6.3)(%)			
-	≥90.0	90.1	PASS
2. RESPIRATORY RESISTANCE (GB 2626-2006 6.5 & 6.6)(Pa)			
-INSPIRATORY RESISTANCE	≤350	67	PASS
-EXPIRATORY RESISTANCE	≤250	60	PASS

Picture(s) of sample



—End of report—

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DECLARATION

1. Our organization guarantees impartiality, independence and honesty of inspection, and is responsible for the results of inspection, keeping the samples supplied by the entrusting party confidential and at the same time protecting the ownership of the samples supplied.
2. The test report will be deemed invalid without signatures of the inspector/reviewer and authorized personnel, and the red special inspection stamp of our organization.
3. The test report will be invalid if it is altered. Copies of the report are invalid without the red special inspection stamp of our organization.
4. The test results shown in this report are applicable only to the samples provided by customers.
5. All the pages of the report are integral parts of the report. Our organization will not be responsible for any misunderstanding or other results caused by using separate page(s) of the report.
6. If there is any dissent of the report, the entrusting party shall notify our organization timely. For the mandatory inspection given by governmental administration departments, and dissent about the sample being tested or test results on the report should be dealt with in accordance with national regulations.

浙江省轻工业品质量检验研究院及附设的检验中心
The Affiliated Inspection Centers

浙江省轻工业品质量检验研究院
Zhejiang Light Industrial ProductsInspectionandResearchInstitute
国家纺织服装产品质量监督检验中心（浙江）
National Textiles and Garment Quality Supervision Inspection Center(Zhejiang)
地址：浙江省杭州市江干区下沙路 300 号 6 号楼
Address：Building No.6, 300 XiaSha Road, Hangzhou, Zhejiang
联系电话：0571-85122669
Telephone：0571-85122669
E-Mail：1137907994@qq.com

国家家具产品质量监督检验中心（浙江）
National Center for Quality Supervision Inspection of Furniture(Zhejiang)
浙江省室内安全及家具产品质量检验中心
Zhejiang Center of Quality Test for Indoor Safety and Furniture Products
地址：浙江省杭州市余杭区良渚街道经一路 1 号良渚大学科技园 4 号楼
Address：Building 4 LiangZhu University Science and Technology Park, No.1, JingYi Rd, Yuhang District, Hangzhou, Zhejiang
联系电话：0571-89009556
Telephone：0571-89009556
E-Mail：2047699564@qq.com

浙江省轻工及五金产品质量检验中心
Zhejiang Center of Quality Test for Light Industry and Hardware Products
浙江省体育用品质量检验中心
Zhejiang Center of Quality Test for Sports Products
地址：浙江省杭州市西湖区天目山路 222 号 3 号楼
浙江省杭州市余杭区良渚街道经一路 1 号良渚大学科技园 3 号楼
Address：No. 222 Tianmushan Rd., Hangzhou, Zhejiang
Building 3 LiangZhu University Science and Technology Park, No.1, JingYi Rd., Hangzhou, Zhejiang
联系电话：0571-89001107
Telephone：0571-89001107
E-Mail：wujtest@126.com

国家锁具产品质量监督检验中心（浙江）
National Center for Quality Supervision Inspection of Lock(Zhejiang)
浙江省锁具产品质量检验中心
Zhejiang Center of Quality Test for Lock Products
地址：浙江省杭州市塘苗路 24 号
Address：No. 24 Tangmiao Rd., Hangzhou, Zhejiang
联系电话：0571-85027738
Telephone：0571-85027738
E-Mail：Locktest@126.com

BIO PROMEDICAL

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

CERTIFICATE

Certificate Number **UCN** : **802789216610**
Job : J29804
Date of Issue : *2020-03-25*
Certificate valid up to : *2024-03-24*

Brand Name : *See label*
Type : *Disposable mask*
Model N : *175mm*95mm*

Manufacturer : Changzhou Universal Medical Equipment Co., Ltd
Address : No. 6, Xinxi Road, Xinbei District, Changzhou City, Jiangsu Province 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 : SCC(20)-50013A-73-19	✔ 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

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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 CELAB for request of information at celab@celab.com

8. Technical construction File storage

The technical construction file is normally not stored in CELAB archives, after review of CELAB the documents were not archived in the CELAB databases. Is responsibility of the manufacturer that the documents is available for law requirements. CELAB is not responsible for the storage of the technical construction file.
Note : that the technical construction files for activities related to CE marking will need to be available in Europe.

9. CE Marking General information's

All person/company/body involved on a CE marking product are responsible to perform all task indicate in the directive. Full text of directive can be found in 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.