



Certificate of Compliance

No. 01 [REDACTED]

Technical Construction File no. TPS [REDACTED]

Certificate's
Holder:[REDACTED]
Co., Ltd[REDACTED]
Area ShanghaiCertification ECM
Mark:Product:
Model(s):KN95 respirator (Not Sterile)
HX-KN95-001

Verification to:

Standard:
EN 149: 2001+A1:2009related to CE Directive(s):
R 2016/425 (Personal Protective Equipment)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:



The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 27 March 2020**Expiry date: 26 March 2025**Reviewer
Technical expert
Amanda Payne


Approver
ECM Service Director
Luca Bedonni

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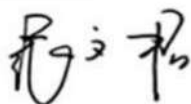
Shanghai Textile Group Testing & Standard Co., Ltd

No.:20 [REDACTED]

TEST REPORT

Sample	KN95 RESPIRATOR		Test Type	Entrusted Test
Specification	/		Brand	/
Entrusting Party	Name	[REDACTED] Co.Ltd.		
	Address	[REDACTED] Shanghai, China	Tel.	/
Name of the Relevant Party	/		Sample acquisition method	Express
No. of Lot	HX-KN95-001		Number of the Entrusted Sample(s)	1pc (80pcs)
Description of the sample(s)/Description	The sample(s) are not abnormality. White respirator		Delivery Time of the Entrusted Sample(s)	2020-03-19
Standard	GB 15979-2002 GB 2626-2006			
Testing Date	2020-03-19		to	2020-3-26
Result	See the summary page of test results for details		 Issuing Date 2020-03-30	
Remark: The determination on conformance in this report is only based on the test results regardless of the uncertainty of the results.				

Approved by



Prepared by



TEST REPORT

No:2

BatchNumber:

Summary of test results						
No.	Items	Unit	Requirement	Test Results	Pass/Failure	
1	Expiratory resistance	Untreated sample	Pa	≤ 250	1#41 2#41	Pass
		Sample after pretreatment	Pa	≤ 250	1#48 2#47	Pass
2	Inspiratory resistance	Untreated sample	Pa	≤ 350	1#35 2#31	Pass
		Sample after pretreatment	Pa	≤ 350	1#47 2#50	Pass
3	Filter efficiency	Untreated sample	%	≥ 95.0	1#99.86 2#99.31 3#99.60 4#99.52 5#99.66 6#99.73 7#99.45 8#99.40 9#99.39 10#99.65	Pass
		Sample after pretreatment	%	≥ 95.0	1#98.55 2#99.29 3#99.46 4#99.21 5#99.17	Pass
4	Head harness	Untreated sample	/	Pull to 10N, lasting for 10s, no slippage and fracture	Pull to 10N, lasting for 10s, no slippage and fracture	Pass
		Sample after pretreatment	/	Pull to 10N, lasting for 10s, no slippage and fracture	Pull to 10N, lasting for 10s, no slippage and fracture	Pass


No:20W

No:2

BatchNumber:

Summary of test results					
No.	Items	Unit	Requirement	Test Results	Pass/Failure
5	<i>Total bacterial colonies</i>	CFU/g	≤ 200	40	Pass
	<i>Coliform group</i>	/	Forbidden	Not detected	Pass
	<i>Pseudomonas aeruginosa</i>	/	Forbidden	Not detected	Pass
	<i>Staphylococcus aureus</i>	/	Forbidden	Not detected	Pass
	<i>Hemolytic streptococcus</i>	/	Forbidden	Not detected	Pass
	<i>Total number of fungal colonies</i>	CFU/g	≤ 100	36	Pass
Remark:/					
The following is blank.					

TEST REPORT

Test Description	
Sample's Characteristics	
Stick Samples	
Note	<hr/>

██████████ Co., Ltd

Introduction to KN95 face mask.

██████████ was founded in 2020, when the COVID 19 bursted and caused a globe urgent need for face mask.

At this special period, ██████████ built a mask production line, explored technologies, delved into craft, just for your high quality health secure. ██████████ embrace kindness in every production and quality testing process, thus contribute efforts to the fight against the COVID 19.

██████████有限公司

KN95口罩介绍

██████████品牌成立于2020年新冠肺炎爆发之时，全球口罩需求紧迫之际，██████████有限公司为抗击疫情，共克时艰，迅速设立口罩生产线，努力钻研技术，不断改进工艺，只为给您提供高质量的健康安全保障。我们怀着素心柔意在每一道生产工序，和质检流程中层层把关，严格要求，为抗击疫情贡献自己的一份力量。



Start from zero
explore technology, delve into craft
provide high -quality health security for you

一切从零开始
探索技术 钻研工艺
只为您提供高质量的健康保障

引进全自动化口罩生产机器

Introduce full automatic mask machine

全自动化口罩机产量标准

50000只/班次



注重细节 品质保障

Emphasize details

Quality security



超声点焊 牢固防脱
多重质检工序层层把关

Ultrasonic welding Breaking proof
Multiple quality testing process



FDA certification
CE is under certifying now

获得美国 FDA 注册证书 欧盟国际 CE 认证中

FDA, short for the Food and drug Administration, is responsible for ensuring the safety of foods, cosmetics, drugs, biologics, medical devices, and radiological products produced or imported in the United States. It was one of the first federal agencies whose primary function was consumer protection

美国食品和药物管理局 (Food and Drug Administration) 简称 FDA, FDA 的职责是确保美国本国生产或进口的食品、化妆品、药物、生物制剂、医疗设备 and 放射产品的安全。它是最早以保护消费者为主要职能的联邦机构之一。



The 3rd Party Certificate of FDA Medical Device Registration

Note:

This file is Not being issued by FDA. It is a 3rd party, produce it, intended to facilitate customer display & transmit the following contents, FDA registered Facility/Owner/Operator & FDA listing information. These, are excerpted from database at www.fda.gov.



Establishment

CHINA [REDACTED] CO., LTD SHANGHAI

Registration Number / FEI Number*:

* First Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Status: Active

Date of Registration Status: 2020

Owner/Operator

CHINA 201209 [REDACTED] CO., LTD SHANGHAI

Owner/Operator Number: [REDACTED]

Official Correspondent

Contact Name: Maria Ma Division Manager
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CHINA, 201209
Tel: +86-21-5138390-8 E-mail: maria@huaxiang.biz

U.S. Agent

Contact Name: Grace Liu
Address: 839 FM 1489 Road, Brookshire, Texas 77423 U.S.A.
Phone: (281) 600-8227 E-mail: grace.liu@bbja.com

Devices Listing Information

Proprietary Name	Product Codes	Device Class	Listing Number	Establishment Operations
Mask	LYU	1	D37****	Manufacturer

⚠ Please careful protect your Listing Number.

Professional FDA Registration Services, by Shanghai Global Testing Services Co., Ltd.

More details on the website: <http://www.gts-lab.com>

Need help? Contact us, SFT, at +86(021) 33637666 & info@gts-lab.com

FDA CERTIFICATE NUM: [REDACTED]

执行标准：GB2626-2006

Standards: GB2626-2006

Protection upgrade

comfortable fit
3D cut

Droplets/particulate/pollen
filtration efficiency $\geq 95\%$

防护
升级

佩戴
舒适
立体剪裁

飞沫 | 颗粒物 | 花粉
95%
过滤效率 \geq



Health protector Surou patron
KN95 protective mask

健康卫士 · 素柔守护
KN95 防护口罩



防护升级 | 有效过滤 健康呼吸

protection upgrade Effective filtration
Healthy breathing

中层超细熔喷布材料

超细熔喷纤维强力吸
附**细菌**、**病毒**、**粉尘**
烟雾等小颗粒物

Middle Layer ultrafine meltblown fabric material
Ultrafine meltblown fabric can strongly adsorb
small particles such as bacteria, viruses and dust
smoke.

Comfortable, skin-friendly and breathable.
isolate droplets and minor dust efficiently
The inner layer soft non-woven fabric.

舒适亲肤透气，有
效阻隔口腔鼻腔飞
沫，细微粉尘

内层柔软无纺布



宽版可塑金属鼻夹

立体剪裁，更贴合更舒适

Wide plastic metal nose clip 3D
cut, comfortable fit

外层防护无纺布

有效隔离

大颗粒物

outer layer non-woven fabric
isolating efficiency big particulate

20枚盒装

20pcs/box





180011112242



(2018)国认监认字(244)号



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



浙江省轻工业产品质量检验研究院

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)



Test report

Number: W██████████

page 1/2

Name of Customer	██████████ Co., Ltd	Address	██████████ ██████████ Shanghai, China
Manufacturer	---	Address	---
Sample information	Name of sample: KN95 MASK Characteristics of sample: White Trademark of sample: --- Specification/model: --- Level: KN95 Category of safety specification: --- Art. No.: --- -----		
Above-mentioned information by Customer-supplied			
The sent way of sample	Sent by customer	Sample quantity	30 pieces
Receiving Date of Sample	2020/04/21	Test Category	Entrusted inspection
Date of Testing	2020-04-21- 2020-04-21		
Rating Requirements	GB 2626-2006		
Test Summary: See the attached page for the results.			
		 Test Seal Date of Approval: 2020-04-22	
Remarks	The sample is not pretreated and the result is for reference.		

Approved by: 曹丽勤

产品质量
检验检测专用章

Test report

Number:W[REDACTED]

page2/2

ITEM	STANDARD (KN95)	RESULT	RATING
1. FILTER EFFICIENCY(SALT MEDIUM) (GB 2626-2006 6.3)(%)			
-	≥ 95.0	99.3	PASS
2. RESPIRATORY RESISTANCE (GB 2626-2006 6.5 & 6.6)(Pa)			
-INSPIRATORY RESISTANCE	≤ 350	142	PASS
-EXPIRATORY RESISTANCE	≤ 250	111	PASS

Picture(s) of sample



—End of report—



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 Products Inspection and Research Institute
国家纺织服装产品质量监督检验中心（浙江）
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E-Mail: 1137907994@qq.com

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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
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Zhejiang Center of Quality Test for Light Industry and Hardware Products
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Zhejiang Center of Quality Test for Sports Products
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浙江省锁具产品质量检验中心
Zhejiang Center of Quality Test for Lock Products
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联系电话：0571-85027738
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Complaint Tel: 0571-85023552

