产品名称_____ 出货数量_____ 日期_____ 接收方_____
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UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1278

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Zhejiang Shaohua Medical Equipment Co., Ltd.

Floor 1, Building 6, Block A, No. E22, Xinke Road, Choujiang Street, Yiwu City, Zhejiang Province, China

are tested and evaluated according to

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Brand Name: YWSH **Model:** SH-ZK12
Filtering half mask
Classification: FFP2 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **15/08/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

UNIVERSAL

Verify the validity with the QR code

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80
UNIVERSALCERT.COM

产品名称_____ 出货数量_____ 日期_____ 接收方_____
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UNIVERSAL
CERTIFICATION

NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-1278/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Zhejiang Shaohua Medical Equipment Co., Ltd.

Floor 1, Building 6, Block A, No. E22, Xinke Road, Choujiang Street, Yiwu City, Zhejiang Province, China

Continues to fulfil the requirements of

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial No	Date	Issuing NB No
YWSH / SH-ZK12	FFP2 NR	2163-PPE-1278	15.08.2020	2163

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **15/08/2020** and will be valid for one year, until **14/08/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

UNIVERSAL

Verify the validity with the QR code

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80
UNIVERSALCERT.COM

产品名称_____ 出货数量_____ 日期_____ 接收方_____
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DEKRA Testing and Certification GmbH
Standort Essen
Persönliche Schutzausrüstungen

Adlerstraße 29
45307 Essen, Germany

Tel +49.201.52319-0
Fax +49.201.52319-401
E-Mail CPA@dekra.com

Prüfbericht / *Test report*
No. 3418948.10-CPA

Prüfgegenstand *Testsubject*	Corona SARS-CoV-2 Atemschutzmaske *Corona SARS-CoV-2 respiratory protective mask*
Modell *Type*	Nicht-medizinische Atemschutzmaske
Hersteller *Manufacturer*	Zhejiang Shaohua Medical Equipment Co., Ltd West floor 1, building 2. Beiyuan Science Park, No. 968, Xuefeng West Road, Beiyuan street, Yiwu City, Zhejiang Province, China
Prüfgrundlage *Test requirement*	Prüfgrundsatz für Corona SARS-Cov-2 Pandemie Atemschutzmasken Rev. 2 vom 02.06.2020 *Testing principle for Corona SARS-CoV-2 pandemic respiratory masks rev. 2 of 2020-06-02*
Prüfergebnis *Test result*	Die Pandemie Atemschutzmaske entspricht **nicht** den Corona SARS-CoV-2 Prüfanforderungen *The pandemic respiratory protective mask does **not** meet the Corona SARS-CoV-2 test requirements.*
Datum *Date of issue*	24.06.2020

Dieser Bericht besteht aus 20 Seiten. *This report consists of 20 pages.*
Eine auszugsweise Veröffentlichung dieses Berichtes bedarf der Zustimmung der DEKRA Testing and Certification GmbH. Juristisch bindend ist ausschließlich die deutsche Fassung dieses Berichtes.
Publication of extracts of this report requires agreement of DEKRA Testing and Certification GmbH. We confirm the correctness of the translation of the German original. In the case of arbitration however only the German wording shall be valid and binding.

DEKRA Testing and Certification GmbH, Handwerkstraße 15, 70565 Stuttgart
Zertifizierungsstelle *Certification Body*: Dinnendahlstraße 9, 44809 Bochum
Telefon +49.234.3696-400, Fax +49.234.3696-401, DTC-Certification-body@dekra.com

产品名称_____ 出货数量_____ 日期_____ 接收方_____
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中国认可
国际互认
检测
TESTING
CNAS L0599

Test Report **SL52025256510501TX** **Date: June 10,2020**

ZHEJIANG SHAOHUA MEDICAL EQUIPMENT CO., LTD
WEST FLOOR 1, BUILDING 2, BEIYUAN SCIENCE PARK, NO. 968, XUEFENG WEST ROAD, BEIYUAN STREET, YIWU CITY, ZHEJIANG PROVINCE

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A) Face mask
Style No.	:	SH-ZK12;SH-ZK12-NZDF;SH-ZK12-WZDF;SH- ZK12-NZ;SH-ZK12-WZ
Sample Color	:	(A)White
Manufacturer	:	ZHEJIANG SHAOHUA MEDICAL EQUIPMENT CO., LTD
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	May 06, 2020
Testing Period	:	May 08, 2020 - Jun 10, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Conclusion:

Sample No.	Recommendation Level
(A)	FFP1 NR

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

3rd Building,No.889,Yishan Road,Xuhui District,Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e sgs.china@sgs.com

产品名称_____ 出货数量_____ 日期_____ 接收方_____
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ЕВРАЗИЙСКИЙ ЭКОНОМИЧЕСКИЙ СОЮЗ
ДЕКЛАРАЦИЯ О СООТВЕТСТВИИ

Заявитель, Общество с ограниченной ответственностью «СТАНДАРТСЕРТИФИКАЦИЯ», уполномоченное изготовителем лицо

Основной государственный регистрационный номер: 5177746302290, Место нахождения и адрес места осуществления деятельности: Российская Федерация, Москва, 115547, улица Михневская, дом 15, квартира 35, номер телефона: +74957447714, адрес электронной почты: 1346446@gmail.com

в лице Генерального директора Данжеева Юрия Арсалановича

заявляет, что Средства индивидуальной защиты от общих производственных загрязнений: маски лицевые типа KN95 с клапаном, модель SH-ZK12, торговой марки YWSH, класс защиты FFP2

изготовитель «Zhejiang Shaohua Medical Equipment Co., Ltd.», Место нахождения и адрес места осуществления деятельности: West floor 1, building 2, Beiyuan Science Park, No. 968, Xuefeng West Road, Beiyuan street, Yiwu City, Zhejiang Province, Китай.
Продукция изготовлена в соответствии с нормативной документацией производителя.
Код ТН ВЭД ЕАЭС 6307909800. Серийный выпуск

соответствует требованиям
ТР ТС 019/2011 «О безопасности средств индивидуальной защиты»

Декларация о соответствии принята на основании
Протокола испытаний № СТ20-43-05 от 20.05.2020 года, выданного Испытательной лабораторией Общества с ограниченной ответственностью «СЕРТ ТЕСТ», аттестат аккредитации № НРК RU.04ПИН0.21ТМ03 от 01.09.2017 года, расположенной по адресу: Российская Федерация, Москва, 117393, улица Гарибальди, дом 10, корпус 3.
Схема декларирования 1д

Дополнительная информация
Условия хранения и сроки годности продукции указаны в прилагаемой к продукции товаросопроводительной документации и/или на упаковке каждой единицы продукции.

Декларация о соответствии действительна с даты регистрации по 19.05.2025 включительно.

(подпись) М.П. Данжеев Юрий Арсаланович (Ф.И.О. заявителя)

Регистрационный номер декларации о соответствии: ЕАЭС N RU Д-CN.PA01.B.42269/20
Дата регистрации декларации о соответствии: 20.05.2020

产品名称 出货数量 日期 接收方

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Verification of Compliance

No.:E04302013C

Application Name:	Zhejiang shaohua medical equipment co. LTD
Address:	West floor 1, building 2, beiyuan science park, 968 xuefeng west road, beiyuan street, yiwu city, zhejiang province
Manufacturer Name:	Zhejiang shaohua medical equipment co. LTD
Address:	West floor 1, building 2, beiyuan science park, 968 xuefeng west road, beiyuan street, yiwu city, zhejiang province
Product Name:	Non-Medical KN95 Daily Protected Mask
Trade Mark:	N/A
Model No.:	SH-ZK12
Standard:	EN149:2001+A1:2009
Date of Issue:	Apr 30.2020

Relate to CE Directive(s): R 2016/425 (Personal Protective Equipment)

Remark:This document has been issue 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 EUTLAB.The conformity mark above can be affixed on the product(s) accordingly to the EUTLAB regulation about its release and its use.

Additional information and clarification about the Marking:The manufactuer is reponsible 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 EUTLAB Voluntary Mark for the certification of products.

CE

Authorized Signer: Sobrell Zou

Date: April 30,2020

Europen Test Lab.Inc Http:www.eutlab.com

产品名称 出货数量 日期 接收方
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Verification of Compliance

No.:E04272010C

Application Name:	Zhejiang shaohua medical equipment co. LTD
Address:	West floor 1, building 2, beiyuan science park, 968 xuefeng west road, beiyuan street, yiwu city, zhejiang province
Manufacturer Name:	Zhejiang shaohua medical equipment co. LTD
Address:	West floor 1, building 2, beiyuan science park, 968 xuefeng west road, beiyuan street, yiwu city, zhejiang province
Product Name:	KN95
Trade Mark:	N/A
Model No.:	SH-ZK12
Standard:	EN149:2001+A1:2009
Date of Issue:	Apr 27.2020

Relate to CE Directive(s): R 2016/425 (Personal Protective Equipment)

Remark:This document has been issue 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 EUTLAB.The conformity mark above can be affixed on the product(s) accordingly to the EUTLAB regulation about its release and its use.

Additional information and clarification about the Marking:The manufactuer is reponsible 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 EUTLAB Voluntary Mark for the certification of products.

CE

Authorized Signer: Sobell Zou

Date: April 27,2020

Europen Test Lab.Inc Http:www.eutlab.com

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美国NIOSH检测报告

Nelson Labs.
A Sotera Health company

Sponsor:
Yoly Zhu
Zhejiang Shaohua Med. Equipment Co. Ltd.
Floor 1, Building 6, Zone a
Yiwu Shuangchuang Street No E22
Shanghai,
CHINA

Determination of Inhalation and Exhalation Resistance for Air-Purifying Respirators Final Report

Test Article:	Respiratory Protective Mask SH-ZK12
Study Number:	1304401-S01
Study Received Date:	28 May 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0145 Rev 05
Deviation(s):	None

Summary: This procedure was performed to evaluate the differential pressure of non-powered air-purifying particulate respirators in accordance with 42 CFR Part 84.180. The air exchange differential or breathability of respirators was measured for inhalation resistance using NIOSH procedure TEB-APR-STP-0007 and exhalation resistance with NIOSH procedure TEB-APR-STP-0003. The differential pressure technique is a simple application of a basic physical principle employing a water manometer differential upstream and downstream of the test material, at a constant flow rate.

According to 42 CFR Part 84.64, pretesting must be performed by all applicants as part of the application process with NIOSH. Results seen below are part of that pretesting and must be submitted to and accepted by NIOSH for respirator approval.

The inhalation resistance criteria as stated in 42 CFR Part 84.180 is an initial inhalation not exceeding 35 mm water column height pressure. The test articles submitted by the sponsor conform to this NIOSH criterion for airflow resistance.

The exhalation resistance criteria as stated in 42 CFR Part 84.180 is an initial exhalation not exceeding 25 mm water column height pressure. The test articles submitted by the sponsor conform to this NIOSH criterion for airflow resistance.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

ilac-MRA ANAB ACCREDITED TESTING LABORATORY

Robert Dieker electronically approved for Curtis Gerow
Study Director

19 Jun 2020 15:10 (+00:00)
Study Completion Date and Time

产品名称_____ 出货数量_____ 日期_____ 接收方_____
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美国NIOSH检测报告

Nelson Labs
A Sotera Health company

Study Number 1304401-S01
Determination of Inhalation and Exhalation Resistance for Air-Purifying Respirators Final Report

Results:

Test Article Number	Inhalation Resistance (mm H_2O)	Exhalation Resistance (mm H_2O)
1	11.3	11.0
2	11.3	8.3
3	11.3	10.8

Test Method Acceptance Criteria: The resistance measurement for the reference plate must be within ± 3 standard deviations of the mean established in the control chart.

Procedure: A complete respirator was mounted to a test fixture comprised of a metal plate with an approximate 3.5 inch diameter hole in the center to allow airflow to reach the mask. The sample holder was assembled by placing a Plexiglas collar around the test fixture and topping with another metal disc with a 3.5 inch opening in the center. The sample holder is held tightly together with clamps and connected to an air source. The manometer is attached to the sample holder by a connection port on the Plexiglas collar.

Before testing, the manometer was zeroed and the back pressure in the sample holder checked and verified to be acceptable. Resistance measurements were taken with a manometer capable of measuring at least 6 inches of water. For inhalation testing, a negative airflow (vacuum) was applied. For exhalation testing, a positive airflow (compressed air) was used. Airflow was passed through the sample holder at approximately 85 ± 2 liters per minute (L/min).

Nelson Labs
A Sotera Health company

Sponsor:
Yoly Zhu
Zhejiang Shaohua Medical Equipment Co., Ltd.
Floor 1, Building 6, Zone a
Yiwu Shuangchuang Street, #E22,
Shanghai,
CHINA

Sodium Chloride (NaCl) Aerosol Test Final Report

Test Article:	Respiratory Protective Mask SH-ZK12
Study Number:	1304402-S01
Study Received Date:	28 May 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0014 Rev 09
Deviation(s):	None

Summary: This procedure was performed to evaluate particulate filter penetration as specified in 42 CFR Part 84 and TEB-APR-STP-0059 for requirements on a N95 respirator. Respirators were conditioned then tested for particle penetration against a polydispersed, sodium chloride (NaCl) particulate aerosol. The challenge aerosol was dried, neutralized, and passed through the test article at a concentration not exceeding 200 mg/m^3. The initial airflow resistance and particle penetration for each respirator was determined.

According to 42 CFR Part 84.64, pretesting must be performed by all applicants as part of the application process with NIOSH. Results seen below are part of that pretesting and must be submitted to and accepted by NIOSH for respirator approval.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Sean Shepherd electronically approved for Curtis Gerow
Study Director

22 Jul 2020 19:27 (+00:00)
Study Completion Date and Time

Results: The NIOSH N95 filter efficiency as stated in 42 CFR Part 84.181 is a minimum efficiency for each filter of ≥95% (≤5% penetration). The test articles submitted by the sponsor conform to the NIOSH N95 criteria for filter efficiency.

Test Article	Corrected[a] Initial Airflow Resistance (mm H_2O)	Maximum Particle Penetration (%)	Filtration Efficiency (%)
1	16.0	.252	99.748
2	15.2	.406	99.594
3	16.7	.358	99.642
4	16.9	0.552	99.448
5	17.5	0.505	99.495
6	14.7	0.373	99.627
7	14.9	0.425	99.575
8	18.5	0.320	99.680
9	18.6	0.343	99.657
10	14.5	0.730	99.270
11	16.5	0.595	99.405
12	14.4	0.382	99.618
13	17.8	0.485	99.515
14	17.6	0.456	99.544
15	14.4	0.616	99.384
16	16.4	0.204	99.796
17	16.1	0.426	99.574
18	15.6	0.514	99.486
19	15.6	0.477	99.523
20	19.2	0.644	99.356

[a] The final airflow resistance value for each test article was determined by subtracting out the background resistance from the system.

Test Method Acceptance Criteria: The filter tester must pass the "Tester Set Up" procedure. The airflow resistance and particle penetration of the reference material must be within the limits set by the manufacturer.

Filter Test Procedure: Prior to testing, respirators were taken out of their packaging and placed in an environment of 85 ± 5% relative humidity (RH) and 38 ± 2.5°C for 25 ± 1 hours.

The filter tester used in testing was a TSI® CERTITEST® Model 8130 Automated Filter Tester that is capable of efficiency measurements of up to 99.999%. It produces a particle size distribution with a count median diameter of 0.075 ± 0.020 microns (µm) and a geometric standard deviation not exceeding 1.86 µm. The mass median diameter was approximately 0.26 µm, which is generally accepted as the most penetrating aerosol size. The reservoir was filled with a 2% NaCl solution and the instrument allowed a minimum warm-up time of 30 minutes. The main regulator pressure was set to 75 ± 5 pounds per square inch (psi). The filter holder regulator pressure was set to approximately 35 psi. The NaCl aerosol generator pressure was set to approximately 30 psi and the make-up airflow rate was set to approximately 70 liters per minute (L/min).

The NaCl concentration of the test aerosol was determined in mg/m^3 by a gravimetric method prior to the load test assessment. An entire respirator was mounted on a test fixture, placed into the filter holder, and the NaCl aerosol passed through the outside surface of the test article at a continuous airflow rate of 85 ± 4 L/min. In accordance with NIOSH policy, three respirators were challenged until 200 ± 5 mg of NaCl had contacted each test article. Based upon the load pattern of NIOSH Type 2, the initial penetration reading of the remaining 17 respirators was recorded.

产品名称_____ 出货数量_____ 日期_____ 接收方_____
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151111260099

检 验 报 告

TEST REPORT

Scan is following us

Scan checks for authenticity

W202025076E

浙江省轻工业品质量检验研究院

Zhejiang Light Industrial Products Inspection and Research Institute

产品名称_____ 出货数量_____ 日期_____ 接收方_____
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Zhejiang Light Industrial Products Inspection and Research Institute

Test report

Number:W202025076E

Name of Customer	Zhejiang Shaohua Medical Equipment Co., Ltd	Address	West floor 1, building 2, Beiyuan Science Park, No. 968, Xuefeng West Road, Beiyuan street, Yiwu City, Zhejiang Province
Manufacturer	Zhejiang Shaohua Medical Equipment Co., Ltd	Address	West floor 1, building 2, Beiyuan Science Park, No. 968, Xuefeng West Road, Beiyuan street, Yiwu City, Zhejiang Province
Sample information	Name of sample: KN95 MASK (built-in bridge of nose) Characteristics of sample: White Trademark of sample: --- Specification/model: SH-ZK12 Level: --- Category of safety specification: --- Art. No.: --- ----------		
Above-mentioned information by Customer-supplied			
The sent way of sample	Courier	Sample quantity	30 pieces
Receiving Date of Sample	2020/06/10	Test Category	Entrusted inspection
Date of Testing	2020-06-10~2020-06-14		
RatingRequirements	GB 2626-2019		

Test Summary:

See the attached page for the results.

浙江省轻工业品质量检验研究院 检验检测专用章

Test Seal

Date of Approval: 2020-06-17

Remarks	

Approved by:

产品名称_____ 出货数量_____ 日期_____ 接收方_____
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Test report

Number:W202025076E

ITEM	STANDARD (KN95)	RESULT	RATING
1. FILTER EFFICIENCY(NaCl PARTICLE) (GB 2626-2019 6.3)(%)			
- Before pretreatment:	≥95.0	1#: 99.9 2#: 99.8 3#: 99.8 4#: 99.8 5#: 99.8 6#: 99.7 7#: 99.7 8#: 99.7 9#: 99.7 10#: 99.9	PASS
-After pretreatment:	≥95.0	1#: 99.8 2#: 99.8 3#: 99.9 4#: 99.9 5#: 99.8	
2. RESPIRATORY RESISTANCE (GB 2626-2019 6.5 6.6)(Pa)			
-EXPIRATORY RESISTANCE (Before pretreatment)	≤210	1#: 140 2#: 145	PASS
-EXPIRATORY RESISTANCE (After pretreatment)	≤210	1#: 112 2#: 107	PASS
-INSPIRATORY RESISTANCE (Before pretreatment)	≤210	1#: 160 2#: 166	PASS
-INSPIRATORY RESISTANCE (After pretreatment)	≤210	1#: 120 2#: 118	PASS

产品名称_____ 出货数量_____ 日期_____ 接收方_____
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Test Report

EN 149:2001+A1:2009

For

Product Name :KN95

Model :SH-ZK12

Report No. :E04272010

Date of Issue :4.27.2020

Prepared For

Zhejiang shaohua medical equipment co. LTD

West floor 1, building 2, beiyuan science park, 968 xuefeng west road, beiyuan street, yiwu city, zhejiang province

Prepared By

Europen Test Lab.Inc

STATUS CENTER, 81,ATHINAS AV.VOULIAGMENI GR-16671,ATHENS, GREECE

Remark: This document 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 EUTLAB. The manufacturer is responsiblefor the CE Marking process, and if necessary, must refer to a Notified Body.

产品名称_____ 出货数量_____ 日期_____ 接收方_____
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Test Report

EN 149:2001+A1:2019 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles-Requirements,Testing,Marking

Report reference No.	E04272010
Test by	Sam
Review by.....	Ray
Approved by(+ Signature).....	Yemig
Date of Issue	Apr.27,2020
Contents.....	Total 12 pages

Application

Name	Zhejiang shaohua medical equipment co. LTD
Address	West floor 1, building 2, beiyuan science park, 968 xuefeng west road, beiyuan street, yiwu city, zhejiang province

Manufacturer

Name	Zhejiang shaohua medical equipment co. LTD
Address	West floor 1, building 2, beiyuan science park, 968 xuefeng west road, beiyuan street, yiwu city, zhejiang province

Test Item

Description.....	KN95
Brand Name	N/A
Model.....	SH-ZK12

Test Specification

Standard	EN 149:2001+A1:2009
Test Procedure.....	CE
Procedure deviation.....	N/A
Non-Standard test method	N/A

Test Report Form/Blank test report

Test Report From No.....	E149-A2
TRF originator	EUTLAB

Testing Laboratory

Name	Europen Test Lab.Inc
Address	STATUS CENTER, 81,ATHINAS AV.VOULIAGMENI GR-16671,ATHENS, GREECE
Test Location.....	Same as above

Testing

Date of receipt of test item.....	Apr.20,2020
Date(s) of performance of test	Apr.20,2020--Apr.27,2020

Test case verdicts

Test case does not apply to the test object..... :	N(/A)
Test item meet the requirement..... :	P(ass)
Test item does not meet the requirement..... :	F(ail)

General remarks

This test report shall not be reproduced except in full without the written approval of the testing laboratory.
The test results presented in this report relate only to the item tested. "(see remark #)" refers to a remark appended to the report. "(see appended table)" refers to a table appended to the report.
Throughout this report a comma is used as the decimal separator.
When determining the test result, measurement uncertainty has been considered.

Note:
This report shall not be altered, increase and deleted.
The results relate only to the items tested.
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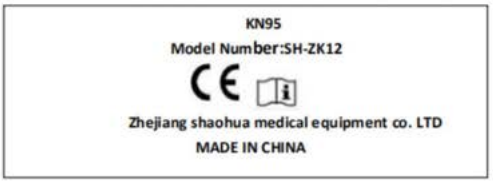
Should any objections to the test reports occurred, should submit it to the Company within ten days since the issuing of the report, Fail to accept .

Summary of testing

All tests were found satisfactory in accordance with Personal Protective Equipment (PPE) - (EU) 2016/425

Copy of Marking Plate



EN 149:2001+A1:2009			
Clause	**Requirement - Test**	**Result**	**Verdict**
5	Classification		P
	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices:	Complied with standard, see appended.	P
	-FFP1		N
	-FFP2		P
	-FFP3		N

5.1	Bacterial filtration efficiency (BFE)	Sample 1: 95.9% Sample 2: 95.8% Sample 3: 95.8% Sample 4: 95.0% Sample 5: 95.1% Sample 6: 95.2%	P
5.2	Breathability	Sample 1: 28.4Pa/cm ^{2} Sample 2: 29.0Pa/cm ^{2} Sample 3: 26.8Pa/cm ^{2} Sample 4: 26.4Pa/cm ^{2} Sample 5: 28.1Pa/cm ^{2} Sample 6: 27.7Pa/cm ^{2}	P
5.3	Microbial cleanliness (Bioburden)	Sample 1: 17cfu/g Sample 2: 21cfu/g Sample 3: 20cfu/g Sample 4: 21cfu/g Sample 5: 19cfu/g Sample 6: 17cfu/g	P

6	Designation		P
	Particle filtering half masks meeting the requirements of this European Standard. Year of publication, classification	2020; FFP2 NR D	P

7	Requirements		P
7.1	In all tests all test samples shall meet the requirements	Complied see bellow	P
7.2	Nominal values and tolerances		P
	Unless otherwise specified, the values stated in this European Standard are expressed as normal values.	Actual using value is clear	P

EN 149:2001+A1:2009			
Clause	**Requirement - Test**	**Result**	**Verdict**
7.3	Visual inspection		P
	The visual inspection shall also include the marking and the information supplied by the manufacturer.	Clear marking is provided,see sample body	P
7.4	Packaging		P
	Masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use	Distinct design and warning are made on packaging,see sample body	P
7.5	Material		P
	Materials used shall be suitable to withstand handling and wear over the period. Any material from the filter media released shall not constitute a hazard or nuisance for the wearer	Comfortable wearing, when releasing no hazards is produced	P
7.6	Cleaning and disinfecting		N
	The materials used shall withstand the cleaning and disinfecting	Single-use equipment	N
7.7	Practical performance		P
	The particle filtering half mask shall undergo practical performance tests under realistic conditions.	Complied, see bellow test	P
7.8	Finish of parts	Soft equipment	N
	Parts likely to come into contact with the wearer shall have no sharp edges or burrs		N
7.9	Leakage		P
7.9.1	Total inward leakage		P
	The laboratory tests shall wearer to protect with high probability against the potential hazard to be expected.	Enough safe condition is provide	P
	Exercise results for total inward leakage shall be not greater than 25% for FFP1,11% forFFP2,5% for FFP3	FFP2, See below test table	P
7.9.2	Penetration of filter material		P
	Meet the requirements of Table 1	FFP2 Sodium chloride test: 3.5% Paraffin oil test: 3.3%	P
7.10	Compatibility with skin		P
	Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	Have no irritation or adverse effect to skin and health	P

EN 149:2001+A1:2009			
Clause	**Requirement - Test**	**Result**	**Verdict**
7.11	Flammability	Have no such hazard	P
	The material used shall not present a danger for the wearer and shall not be of highly flammable nature.		P
7.12	Carbon dioxide content of the inhalation air		P
	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).	<1.0%	P
7.13	Head harness		P
	Head harness shall be designed so that mask can be donned and removed easily.	The design is considered	P
	Head harness shall be adjustable or self- adjusting and sufficiently robust to hold the mask firmly in position.	Non-adjustable	N
7.14	Field of vision		P
	The field of vision is acceptable if determined so in practical performance tests.	Clear field of vision when wearing	P
7.15	Exhalation valve(s)	No exhalation valve(s)	N
	A particle filtering half mask may have one or more exhalation valve(s) and shall function correctly in all orientations.		N
	If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device		N
	Exhalation valve(s) shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.		N
	Exhalation valve housing is attached to the faceblank, and withstand axially a tensile force of 10 N applied for 10 s.		N
7.16	Breathing resistance		P
	The breathing resistances apply to valved and valveless and shall meet the requirements	Complied, see below test table	P
7.17	Clogging		N
7.17.1	General	Single-use device	N
	For single-use devices dogging test is an optional test.		N
	Devices designed to be resistant to dogging, shown by a slow increase		N
	specified breathing resistances not be exceeded before the required dust load of 833mg·h/m³		N

EN 149:2001+A1:2009			
Clause	**Requirement - Test**	**Result**	**Verdict**
7.17.2	Breathing resistance		N
7.17.2.1	Valved particle filtering half masks		N
7.17.2.2	Valveless particle filtering half masks		N
	After clogging the inhalation and exhalation resistances shall not exceed - FFP1: 3 mbar - FFP2: 4 mbar - FFP3: 5 mbar		N
	at 95 l/min continuous flow.		N
7.17.3	Penetration of filter material		N
	All types claimed to meet the clogging requirement shall also meet the penetration requirements given in 7.9.2 after the treatment.		N
7.18	Demountable parts		N
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand	No any such par	N

EN 149:2001+A1:2009			
Clause	**Requirement - Test**	**Result**	**Verdict**
8.1	General		P
	No special measuring devices and methods are specified, commonly used devices and methods shall be used.	Common methods	P
8.2	Visual inspection		P
	The visual inspection is carried out appropriate by the test house prior to laboratory or practical performance tests	Considered	P
8.3	Conditioning		P
8.3.1	Simulated wearing treatment		P
	A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke.	25 cycles/min 2,0 l/stroke.	P
	For testing, a saturator is incorporated in the exhalation line between the breathing machine andthe dummy head	a saturator incorporated by breathing machine and the dummy head	P
	The spilling out of the dummy's mouth and contaminating the particle filtering half mask the head shall be incline	Incline considered	P
8.3.2	Temperature conditioning		P
	Expose masks to the following thermal cycle:	Complied	P
	a) for 24 h to a dry atmosphere of (70 ± 3) °C;		P
	b) for 24 h to a temperature of (-30 ± 3) °C;		P
	Allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing.	5h	P

9	Marking		P
9.1	Packaging		P
	The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.	Complied, clearly marked	P
9.1.1	The name, trademark or other means of identification of the manufacturer or supplier.	See user manual	P
9.1.2	Type-identifying marking.		P
9.1.3	Classification: FFP1, FFP2. FFP3.		P
9.1.4	The number and year of publication of this European Standard.	See above	P

EN 149:2001+A1:2009			
Clause	**Requirement - Test**	**Result**	**Verdict**
9.1.5	At least the year of end of shelf life.	2 years	P
9.1.6	The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b	English used	P
9.1.7	The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.	See user manual	P
9.1.8	The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D".		P
9.2	Particle filtering half mask		P
	Complying with this European Standard shall be clearly and durably marked with the following:		P
9.2.1	The name, trademark or other means of identification of the manufacturer or supplier.		P
9.2.2	Type-identifying marking.		P
9.2.3	The number and year of publication of this European Standard.	See above	P
9.2.4	The symbols FFP1, FFP2 or FFP3 according to class.	FFP2	P
9.2.5	If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the class designation (see 9.2.4).		P
9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.		P

10	Information to be supplied by the manufacturer		P
10.1	Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.	English	P

EN 149:2001+A1:2009			
Clause	**Requirement - Test**	**Result**	**Verdict**
10.3	The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on - application/limitations; - the meaning of any colour coding; - checks prior to use; - donning, fitting; - use; - maintenance (e.g. cleaning, disinfecting), if applicable; - storage; - the meaning of any symbols/pictograms used of the equipment.	See user manual	P
10.4	The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.	Clearly considered	P
10.5	Warning shall be given against problems likely to be encountered, for example: - fit of particle filtering half mask (check prior to use); - it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal; - air quality (contaminants, oxygen deficiency); - use of equipment in explosive atmosphere.	See user manual	P
10.6	The information shall provide recommendations as to when the particle filtering half mask shall be discarded.		P

Table 8.5	Leakage test				P
Item	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Test subject walk (km/h)	6	6	6	6	6
Particle size distribution(μ m)	0.08-1.5	0.08-1.5	0.08-1.5	0.08-1.5	0.08-1.5
NaCl flow rate (L/min)	98-101	98-101	98-101	98-101	98-101
NaCl concentration before mask (mg/m^3)	7.9-83	7.9-83	7.9-83	7.9-83	7.9-83
NaCl concentration after mask (mg/m^3)	0.49	0.48	0.48	0.49	0.49
Note: Test ark volume is 2m 3 Test result total inward Leakage is 6.1%<11%					

EN 149:2001+A1:2009						
Clause	**Requirement - Test**	**Result**				**Verdict**
Table 8.9-1		**Inhalation breathing resistance test at 30 L/min**				**P**
Item		Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)		30	30	30	30	30
Maximum resistance (mbar)		0,60	0.62	0.61	0.61	0.62
Note: Maximum permitted resistance <0.7 mbar						

Table 8.9-2	**Inhalation breathing resistance test at 95 L/min**				**P**
Item	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)	95	95	95	95	95
Maximum resistance (mbar)	1.94	1.95	1.92	1.93	1.94
Note: Maximum permitted resistance <2.4 mbar					

Table 8.9-3	**Inhalation breathing resistance test at 160 L/min**				**P**
Item	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)	160	160	160	160	160
Maximum resistance (mbar)	2.20	2.22	2.21	2.19	2.21
Note: Maximum permitted resistance <2.4 mbar					