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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

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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

Verify the validity with the QR code

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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: Sobell Zoe

Date: **April 30,2020**

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

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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.

Authorized Signer: Sobell Zoe

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

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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.

ilac-MRA ANAB ACCREDITED TESTING LABORATORY

Sean Shepherd electronically approved for	22 Jul 2020 19:27 (+00:00)
Study Director Curtis Gerow	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.

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Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

ZHEJIANG SHAOHUA MEDICAL EQUIPMENT CO., LTD

West floor 1, building 2, Beiyuan Science Park, No. 968, Xuefeng West Road, Beiyuan street, Yiwu City, ZHEJIANG, 322000, CHINA

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

HEALREG SERVICE INC

Owner/Operator Number: 10066235

Device Listing#: See annex

HEALREG SERVICE INC 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. HEALREG SERVICE INC 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. HEALREG SERVICE INC 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, HEALREG SERVICE INC is not affiliated with the U.S. Food and Drug Administration.

FDA

Chief engineer
Issued: April 1, 2020
Expiration Date: December 31, 2020

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Fiscal Year 2020
CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Owner/Operator Number: 10066235

Listing No.	Code	Device Name	Proprietary Names	Activities
D383480	KHA	MASK, SCAVENGING	TYPE C DAILY PROTECTIVE MASK SH-ZK12	Manufacturer

END OF THE ANNEX

John Hao
Chief engineer
Issued: April 1, 2020
Expiration Date: December 31, 2020