YICHITA®

SN95

YICHITA YQD95H

Surgical Respirator

SN95 Surgical Respirator

Approved and cleared for use in healthcare settings under the FDA/NIOSH MOU 225-18-006

Model: YICHITA YQD95H

- 95% filter efficiency level
- Effective against particulate aerosols free of oil
- Low breathing resistance for long time wearing
- Moldable noseclip to provide better fit & seal
- Anti-fog cushioning nose foam
- FDA MSH Listed Surgical Respirator
- ASTM F2100 Level II (seperate testing reports)
  - Flammability test
  - Fluid Resistance test against 120mmHg of pressure
  - Biocompatibility test

SN95 Surgical Respirator

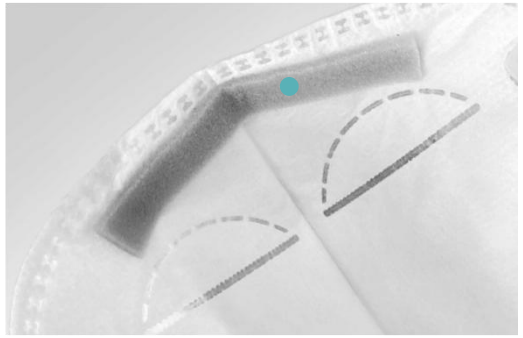
YQD95H

YICHITA®

3D facial fitting design

Exposed moldable nose clip

No welding at chin part



Comfortable anti-fog sponge nose pad

High-elastic comfortable knitted head band strap

SN95 Surgical Respirator

YQD95H

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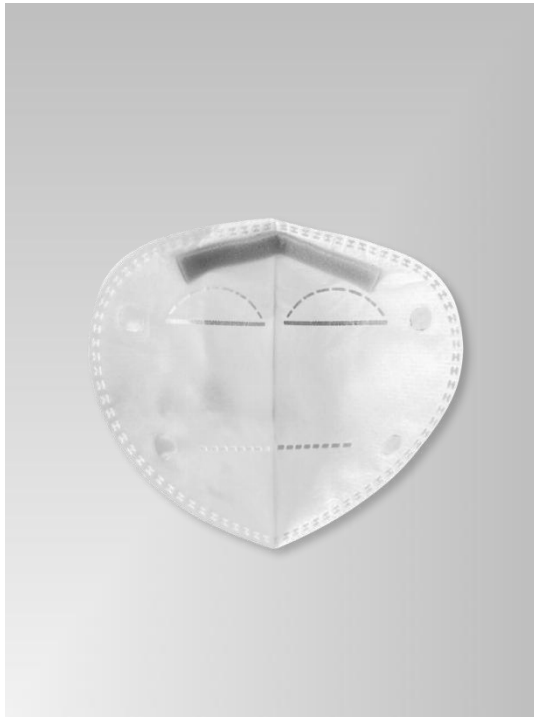


YICHITA

Reference No:US9502005

	Each Box	Each Carton
Qty.	25 pcs	36 box
Net Weight(kg)	0.188	6.75
Gross Weight(kg)	0.310	12.16
L*W*H(mm)	169*126*130	510*390*515

Container Loading	20'FT	286 ctn.(257,400 pcs)
	40'FT	598 ctn.(538,200 pcs)
	40'HQ	670 ctn.(603,000 pcs)

NIOSH Approval Letter

YICHITA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

NIOSH Reference: TN-25479
Mfr. Reference: SYIYQD95Hc

National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
626 Cochrans Mill Road
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

March 3, 2022

Shelly Chen
Regulatory Compliance Leader
Shanghai Yunqing Industrial Co., Ltd.
2nd Building 1818 Shangsu Road
Fengxian District
Shanghai, 201414
CHINA

Dear Shelly Chen:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted December 8, 2021. This request was for Surgical N95 approval of the model YQD95II air-purifying filtering facepiece respirator for protections against particulates at a N95 filter efficiency level. The complete respirator configuration is detailed on assembly matrix, file name *YQD95HAMg.xls*, revision g, dated: 28-12-2021.

This request is granted. Approvals are granted only for documentation written in the English language. It is the approval holder's responsibility to correctly translate materials desired to be produced in languages other than English. Approval number **TC-84A-9399** has been assigned. This respirator is approved and cleared for use in healthcare settings under the FDA/NIOSH MOU 225-18-006. This Surgical N95 provides protection against particulates at the N95 filter efficiency level and conforms to recognized standards for flammability, fluid resistance and biocompatibility.

The approval label is included as an attachment to this letter. The abbreviated label has been accepted as submitted. The full and abbreviated approval labels must be presented to users as approved by NIOSH, including the cautions and limitations as listed. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

Production and labeling of the approved respirator configuration can begin following receipt of this letter (the time and date of the approval action are recorded by my electronic signature, below).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that this respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84). You may market the device, subject to the general controls provisions of the Federal Food, Drug and Cosmetic Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

Sincerely,

Jeffrey A. Peterson -S

Digitally signed by Jeffrey A. Peterson -S
Date: 2022.03.03
15:17:15 -05'00'

Jeffrey Peterson
Chief, Conformity Verification and
Standards Development Branch

Enclosures

Test Summary

42 CFR 84

Approval Label

YICHITA

National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Evaluation and Testing Branch

TEST REPORT

Task Number: TN-25479

Manufacturer: Shanghai Yunqing Industrial Co., Ltd.

Prepared by: Nichole Suhon

Date: January 13, 2022

Tests Conducted by: Nichole Suhon

Respirator Tested: YQD95H

Tests Completed

Test Description	STP Number
A. Exhalation Resistance Test	TEB-APR-STP-0003
B. Inhalation Resistance Test	TEB-APR-STP-0007
C. Sodium Chloride (NaCl) N95 Test	TEB-APR-STP-0059

Overall Results

The respirator system tested met the requirements of the above procedures.

ETB-1020 Rev. 13
Page 1 of 1

Shanghai Yunqing Industrial Co.,Ltd.

2nd Buliding 1818 Shangsu Road,Fengxian Distict,Shanghai 201414

E-mail: yichita@yqgroup.vip

THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATION:

TC-	Protection[1]	Respirator	Cautions and Limitations[2]
		YQD95H	
84A-9399	Surgical/N95	X	ABCJMNOS

1. Protection

N95 - Particulate Filter (95% filter efficiency level)
Effective against particulate aerosols free of oil;
time use restrictions may apply

2. Cautions and Limitations

A - Not for use in atmospheres containing less than 19.5% oxygen.

B - Not for use in atmospheres immediately dangerous to life or health.

C - Do not exceed maximum use concentrations established by regulatory standards.

J - Failure to properly use and maintain this product could result in injury or death.

M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA and other applicable regulations.

N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.

O - Refer to User Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.

S - Special or critical User Instructions and/or specific use limitations apply. Refer to User Instructions before donning.

NIOSH N95 Test Report

YICHITA

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

NIOSH

Task Number: TN-25479 **Reference No.:** CFR 84.172
Test: Exhalation Resistance Test **STP No.:** 3
Manufacturer: Shanghai Yunqing Industrial Co., Ltd.

Filter Type: Filter Only
Item Tested: YQD95H

Sample	Maximum Allowable Resistance (MM of H2O) Exhalation	Actual Resistance (MM of H2O) Exhalation	Result
1	25	9.7	PASS
2	25	8.9	PASS
3	25	9.4	PASS

Overall Result: PASS

Comments:
Samples were tested on manometer 000283.

Was all equipment verified to be in calibration throughout all testing? (•) Yes ( ) No

Signature: Jessica L. Sikan **Date:** 1/13/2022

Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

NIOSH

Task Number: TN-25479 **Reference No.:** CFR 84.172
Test: Inhalation Resistance Test **STP No.:** 7
Manufacturer: Shanghai Yunqing Industrial Co., Ltd.
Item Tested: YQD95H

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H2O) Inhalation	Actual Resistance (MM of H2O) Inhalation	Result
1	35	11.4	PASS
2	35	10.4	PASS
3	35	11.4	PASS

Overall Result: PASS

Signature: Jessica L. Sikan **Date:** 1/13/2022

Engineering Technician

National Institute for Occupational Safety and Health
Evaluation and Testing Branch
Test Data Sheet

NIOSH

Task Number: TN-25479 **Reference No.:** CFR 84.174
Test: Sodium Chloride (NaCl) - N95 **STP No.:** 59
Manufacturer: Shanghai Yunqing Industrial Co., Ltd.
Item Tested: YQD95H

Filter	Flow Rate lpm	Initial Filter Resistance mm water gauge	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	10.5	5.00	0.141	0.174	PASS
2	85	10.9	5.00	0.125	0.139	PASS
3	85	11.3	5.00	0.128	0.144	PASS
4	85	10.3	5.00	0.156	0.178	PASS
5	85	11.7	5.00	0.166	0.189	PASS
6	85	10.4	5.00	0.133	0.143	PASS
7	85	10.8	5.00	0.141	0.172	PASS
8	85	10.7	5.00	0.138	0.155	PASS
9	85	10.6	5.00	0.191	0.223	PASS
10	85	11.6	5.00	0.120	0.133	PASS
11	85	12.2	5.00	0.207	0.238	PASS
12	85	11.9	5.00	0.165	0.185	PASS
13	85	12.1	5.00	0.188	0.227	PASS
14	85	11.4	5.00	0.141	0.174	PASS
15	85	11.0	5.00	0.135	0.165	PASS
16	85	11.8	5.00	0.115	0.140	PASS
17	85	11.6	5.00	0.221	0.249	PASS
18	85	13.4	5.00	0.820	1.983	PASS
19	85	11.5	5.00	0.127	0.141	PASS
20	85	11.2	5.00	0.123	0.141	PASS

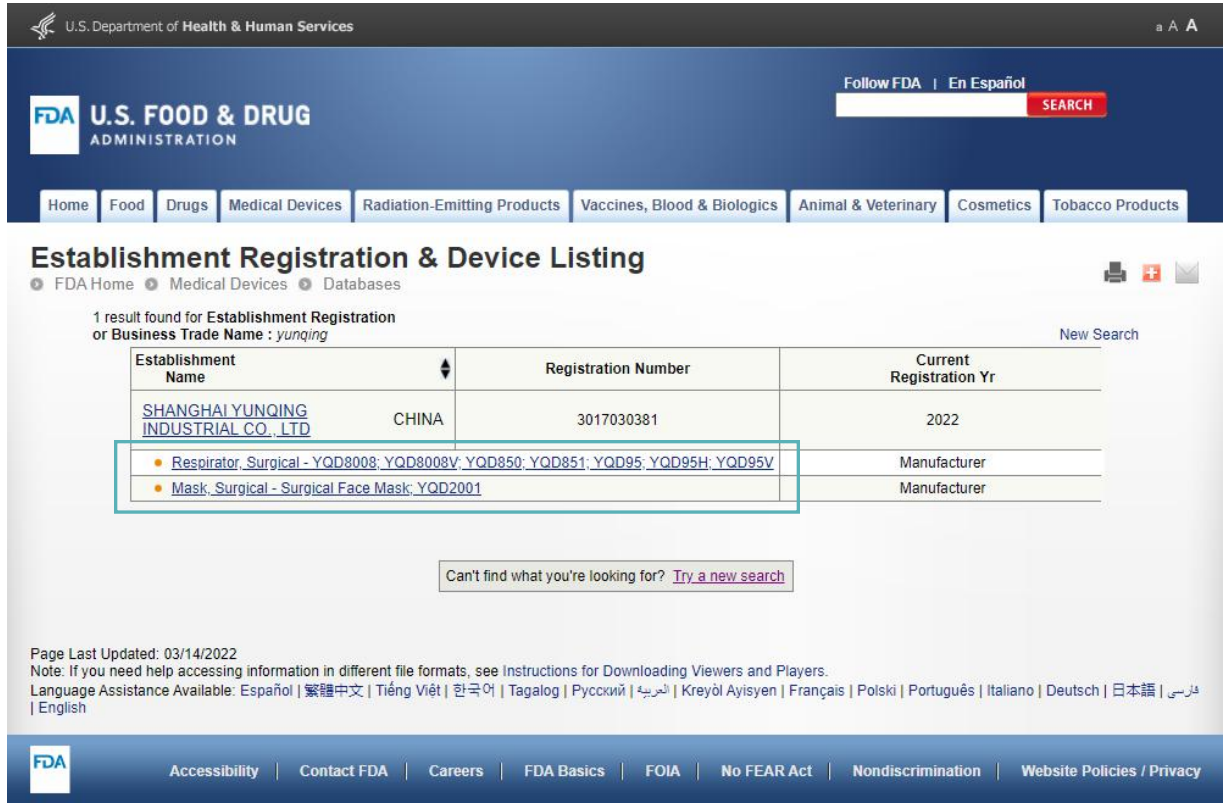
Overall Result: PASS

Signature: Jessica L. Sikan **Date:** 1/11/2022

Engineering Technician

Form revision: 1.1 2 October 2019

FDA MSH Listed Surgical Mask



FDA official website link

About Us

Founded in 2014, Shanghai YunQing Industrial Co., LTD ("YQ") is a first-class enterprise with large scale production capability that provides profession al, effective and high-quality face masks. YQ owns brands of "YICHITA" & "Miyuki" that focus on professional product line and consumer-oriented prod uct line respectively. YQ has become authorized producers for many well-known brands, the products have been widely exported to Japan, Korea, Eu rope, the United States etc.

YQ is conveniently located in Shanghai, the center of supplier chain. Our production facilities cover an area of approx. 6,000 SQM with more than 100 highly trained employees, 12 automated and 20 semi-automated production lines. Our max. production capacity can reach 300,000 masks per day with an annual output of more than 100 million masks. Our production facilities are modern and meet international requirements for environmental protection, health and safeness. YQ adopts a comprehensive management system that encompasses all aspects of our production processes. At the core of this management system is a team of highly trained quality control professionals utilizing state-of-the-art instruments (i.e. 8130 and 8130A testing apparatus) and techniques to effectively execute quality control protocols to ensure our products meet all set requirements.

Our goal is to lead the purification technology for healthy breathing. In order to develop high-quality protective masks that are more efficient, more comfortable, and more environmentally friendly, our R&D team never stops on innovation and improvement upon existing technologies and process control capabilities. As a result, we are able to provide high-quality products and services to our customers worldwide. Last but not least, we are also able to offer more customized respiratory protection products upon request.

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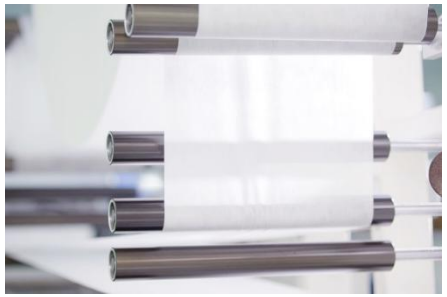

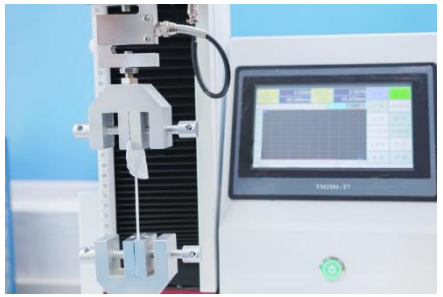

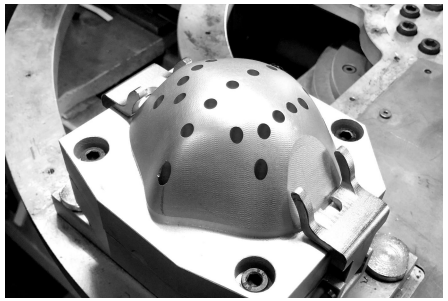

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Shanghai Yunqing Industrial Co.,Ltd

Address: 2nd building 1818 Shangsu Road,Fengxian District,Shanghai
E-mail: yichita@yqgroup.vip
www.yqgroup.vip