



SGH N95 RESPIRATOR CERTIFICATES

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Establishment Registration & Device Listing

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Proprietary Name:	FANGTIAN FT-N040 DUST MASKS
Classification Name:	RESPIRATOR, SURGICAL
Product Code:	MSH
Device Class:	2
Regulation Number:	878.4040
Medical Specialty:	General & Plastic Surgery
Registered Establishment Name:	SUZHOU FANGTIAN INDUSTRIES CO., LTD.
Owner/Operator:	Suzhou Fangtian Industries Co., Ltd.
Owner/Operator Number:	10078902
Establishment Operations:	Manufacturer

Page Last Updated: 11/16/2020

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Suzhou Fangtian Industries Co., Ltd.

Office: Xiehe Building, No.158 Jinmen Road, Suzhou City, Jiangsu, P. R. China

Factory: Xingfu South Rd, Medical Products Industrial Park, Yandu District, Yancheng, City, Jiangsu

TEL :+86-512-65586028 FAX : +86-512-65586038

THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATION:

TC-	Protection ¹	Respirator	Cautions and Limitations ²
		FT-N040	
84A-7861	N95	X	ABCJMNOF

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 percent 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's Instructions and/or maintenance manuals for information on use and maintenance of these respirators.

P-NIOSH does not evaluate respirators for use as surgical masks.

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



Task Number: TN-21589

Reference No.: CFR 84.180

Test: Exhalation Resistance Test

STP No.: 3

Manufacturer: Suzhou Fangtian Industries Co., Ltd.

Filter Type: Filter Only

Item Tested: FT-N040

Sample	Maximum Allowable Resistance (MM of H2O)	Actual Resistance (MM of H2O)	Result
	Exhalation	Exhalation	
1	25	7.3	PASS
2	25	7.7	PASS
3	25	7.9	PASS

Overall Result: PASS

Comments:

Samples were tested on manometer 000282.

Was all equipment verified to be in calibration throughout all testing?



Yes



No

Signature:

Nichole L. Petitta

Date: 8/14/2017

Engineering Technician

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



Task Number: TN-21589

Reference No.: CFR 84.180

Test: Inhalation Resistance Test

STP No.: 7

Manufacturer: Suzhou Fangtian Industries Co., Ltd.

Item Tested: FT-N040

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H ₂ O)	Actual Resistance (MM of H ₂ O)	Result
	Inhalation	Inhalation	
1	35	8.9	PASS
2	35	9.6	PASS
3	35	11.2	PASS

Overall Result: PASS

Signature:

A handwritten signature in black ink that reads "Nicholas L. Petitta".

Date: 8/14/2017

Engineering Technician

Task Number: TN-21589

Reference No.: CFR 84.180

Test: Inhalation Resistance Test

STP No.: 7

Manufacturer: Suzhou Fangtian Industries Co., Ltd.

Item Tested: FT-N040

Comments:

Samples were tested on manometer 000286.

Was all equipment verified to be in calibration throughout all testing?



Yes



No

Signature:

Nichole L. Petitta

Date: 8/14/2017

Engineering Technician

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



Task Number: TN-21589

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: Suzhou Fangtian Industries Co., Ltd.

Item Tested: FT-N040

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	10.8	5.00	0.096	0.136	PASS
2	85	11.2	5.00	0.076	0.109	PASS
3	85	10.6	5.00	0.096	0.136	PASS
4	85	12.6	5.00	0.128	0.185	PASS
5	85	10.5	5.00	0.083	0.122	PASS
6	85	13.1	5.00	0.160	0.215	PASS
7	85	10.9	5.00	0.091	0.135	PASS
8	85	12.4	5.00	0.150	0.194	PASS
9	85	11.9	5.00	0.153	0.192	PASS
10	85	11.4	5.00	0.095	0.137	PASS
11	85	13.3	5.00	0.159	0.216	PASS
12	85	12.8	5.00	0.182	0.222	PASS
13	85	12.5	5.00	0.114	0.152	PASS
14	85	13.2	5.00	0.154	0.210	PASS
15	85	11.2	5.00	0.083	0.108	PASS
16	85	12.4	5.00	0.082	0.128	PASS
17	85	12.6	5.00	0.097	0.129	PASS
18	85	13.3	5.00	0.131	0.169	PASS
19	85	13.7	5.00	0.158	0.198	PASS
20	85	11.6	5.00	0.089	0.115	PASS

Overall Result: PASS

Signature:

Nichole L. Petitta

Date: 8/17/2017

Engineering Technician

Task Number: TN-21589

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: Suzhou Fangtian Industries Co., Ltd.

Item Tested: FT-N040

Comments:

Samples 1-6 were tested on TSI 8130 machine 000332 using timer 000213. Samples 7-12 were tested on TSI 8130 machine 000333. Samples 13-20 were tested on TSI 8130 machine 000334 using timer 000215.

Was all equipment verified to be in calibration throughout all testing?



Yes



No

Signature:

Nichole L. Petitta

Date: 8/17/2017

Engineering Technician



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Shelf Life Declaration-FT-N040 N95 NIOSH - Particulate Respirator Mask

Suzhou Fangtian Industries warranties our FT-N040 N95 protective Mask product to the following confirmed shelf life.

Product	Shelf Life (from date of manufacture - DOM)
FT-N040 N95 Mask	36 months

**Shelf life is warranted for performance only. Suzhou Fangtian Industries products are manufactured in a controlled environment under controlled with no claims to sterility.*

***FT-N040 N95 Mask from date of delivery inspection, but not to exceed 36 months from date of manufacturing. This statement is valid only if stored in normal controlled conditions in their original packaging .*

For and on behalf of
SUZHOU FANGTIAN INDUSTRIES CO., LTD
苏州方天实业有限公司

Authorized Signat**re(s)

General Manager



QUALITY MANAGEMENT SYSTEM CERTIFICATE OF CONFORMITY

Yancheng Fangtian Non-woven Products Co., Ltd.

Unified Social Credit Code: 913209037938268488

South Xingfu Road, Xuefu Town, Yandu District, Yancheng, Jiangsu

224035, China

has established and applied a quality management system in conformity with

GB/T 19001-2016/ISO 9001:2015

The scope covered by the system is:

design, development and production for non-woven face masks (the product with qualification requirement shall be limited in its qualification certificate).

Audit Address: South Xingfu Road, Medical Equipment of Yandu Industrial Park, Yandu District, Yancheng, Jiangsu

Certificate Registration: 00319Q30012R2S/NJ

Duration of Validity: 2019.01.25—2022.01.24

The validity of this certificate will be maintained through annual surveillance audit.

Certification Body



Date

Jan.25, 2019



中国认可

国际互认

管理体系

MANAGEMENT SYSTEM

CNAS C003-M

Shanghai Audit Center of Quality System

No.258 Wuyi Road, Shanghai P.R.China <http://www.sac.org.cn>

This certificate information can be found at the official website (www.cnca.gov.cn) of
Certification and Accreditation Administration of the People's Republic of China (CNCA)