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YHUK Product Certificate Document

Type I Surgical Mask

Date: 2020/04/25



中国认可
国际互认
检测
TESTING
CNAS L10314



No:200035641

APPLICANT: Guangzhou Shunyi nonwoven Co., Ltd
ADDRESS: No. 232, Shabei village business street
City, Guangdong Province

APPLICANT PROVIDED SAMPLE DESCRIPTION:

VERI

VERI

TEST REPORT 检验检测报告



广州检验检测认证集团有限公司
Guangzhou Inspection Testing and Certification Group Co., Ltd.
广州广检纺织服装服饰检测研究院有限公司
Guangzhou Guangjian Textile Garment and Accessories Testing and Research Institute Co., Ltd.
国家纺织品服装服饰产品质量检验中心(广州)
National Quality Inspection and Testing Center for Textile Garment and Accessories(Guangzhou)
国家皮革制品质量检验中心(广东)
National Quality Inspection and Testing Center for Leather Products (Guangdong)

TEST REPORT



No:200035641

VERIFICATION WEBSITE: www.gttc.net.cn

VERIFICATION CODE: RROF-6230-54



ISSUE DATE:2020-03-16

APPLICANT: Guangzhou Shunyi nonwoven Co.,Ltd
ADDRESS: No.232,Shabei village business street,JIEKOU street,Conghua District,Guangzhou City,Guangdong Province

APPLICANT PROVIDED SAMPLE DESCRIPTION:

FIFTY(50) PIECES OF DISPOSABLE PROTECTIVE MASK

COLOUR: LIGHT BLUE

DATE RECEIVED/DATE TEST STARTED: 2020-03-14

CONCLUSION:

FORMALDEHYDE CONTENT	M
EXTRACTABLE HEAVY METALS	M
COLIFORM GROUP	M
TOTAL AMOUNT OF BACTERIAL COLONY	M
TOTAL AMOUNT OF FUNGUS COLONY	M
PSEUDOMONAS AERUGINOSA	M
STAPHYLOCOCCUS AUREUS	M
HEMOLYTIC STREPTOCOCCUS	M
BREAKING STRENGTH OF MASK STRING AND JUNCTION BETWEEN MASK STRING AND MASK BODY	M
VISUAL FIELD	M

NOTE: "M" -MEET THE STANDARD'S REQUIREMENT "F" -FAIL TO MEET THE STANDARD'S REQUIREMENT
"----" -NO COMMENT

REMARK:

THE DECISION INDICATORS ARE DERIVED FROM THE GROUP STANDARD REQUIRED BY CLIENT (T/CTCA 7-2019).OUR INSPECTION CAPACITY AUTHORIZED BY CMA AND CAL COVERS THE INSPECTION ITEMS T/CTCA 7-2019.

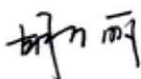
ALL THE TESTED ITEMS ARE TESTED UNDER THE STANDARD CONDITION (EXCEPT FOR INDICATION).

COPIES OF THE REPORT ARE VALID ONLY RE-STAMPED.

THE EXPERIMENT WAS CARRIED OUT AT No.1, ZHUJIANG ROAD, PANYU DISTRICT, GUANGZHOU, GUANGDONG, P. R. CHINA.

APPROVED BY:

WanLi Hu ENGINEER




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FORMALDEHYDE CONTENT

(GB/T 2912.1-2009, WATER EXTRACTION METHOD)
(GB/T 2912.1-2009 MOD ISO 14184-1:1998)

NOT DETECTED

REQUIREMENT
 ≤ 20 mg/kg
(T/CTCA 7-2019)

REMARK: DETECTION LIMIT 20mg/kg

EXTRACTABLE HEAVY METALS (mg/kg)

(GB/T 17593.2-2007)

As NOT DETECTED
(DETECTION LIMIT:0.20)
Cu NOT DETECTED
(DETECTION LIMIT:0.06)
Cr NOT DETECTED
(DETECTION LIMIT:0.12)
Pb NOT DETECTED
(DETECTION LIMIT:0.16)
Cd NOT DETECTED
(DETECTION LIMIT:0.01)
Co NOT DETECTED
(DETECTION LIMIT:0.02)
Ni NOT DETECTED
(DETECTION LIMIT:0.05)
Sb NOT DETECTED
(DETECTION LIMIT:0.09)

REQUIREMENT
 ≤ 0.2
 ≤ 25.03
 ≤ 1.0
 ≤ 0.2
 ≤ 0.1
 ≤ 1.0
 ≤ 1.0
 ≤ 30.0
(T/CTCA 7-2019)

COLIFORM GROUP

(GB 15979-2002 ANNEX B)

NOT DETECTED

REQUIREMENT
MUST NOT BE DETECTED
(T/CTCA 7-2019)

TOTAL AMOUNT OF BACTERIAL COLONY (CFU/g)

(GB 15979-2002 ANNEX B)

< 20

REQUIREMENT
 ≤ 200
(T/CTCA 7-2019)

TOTAL AMOUNT OF FUNGUS COLONY (CFU/g)

(GB 15979-2002 ANNEX B)

< 20

REQUIREMENT
 ≤ 100
(T/CTCA 7-2019)

PSEUDOMONAS AERUGINOSA

(GB 15979-2002, ANNEX B)

NOT DETECTED

REQUIREMENT
MUST NOT BE DETECTED
(T/CTCA 7-2019)

STAPHYLOCOCCUS AUREUS

(GB 15979-2002, ANNEX B)

NOT DETECTED

REQUIREMENT
MUST NOT BE DETECTED
(T/CTCA 7-2019)



TEST REPORT

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HEMOLYTIC STREPTOCOCCUS

(GB 15979-2002, ANNEX B)

NOT DETECTED

REQUIREMENT
MUST NOT BE DETECTED
(T/CTCA 7-2019)

BREAKING STRENGTH OF MASK STRING AND JUNCTION BETWEEN MASK STRING AND MASK BODY

(YY 0469-2011 5.4)

PASS

REQUIREMENT
≥10N
(T/CTCA 7-2019)

VISUAL FIELD(°)

(GB 2890-2009 6.8)

60

REQUIREMENT
≥60
(T/CTCA 7-2019)

——End of Report——

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APPLICATION FOR MEDICAL DEVICES DIRECTIVE

On Behalf of

Guangzhou Shunyi Nonwoven Co., Ltd.

Mask

Model: SY45

Prepared For : Guangzhou Shunyi Nonwoven Co., Ltd.

**No. 232, Shabei Village Business Street,
Jiekou Street, Conghua District, Guangzhou
City, Guangdong Province**

Date of Test : Feb. 26-29, 2020
Date of Report : Mar. 02-03, 2020
Report Number : EPTC-SY-S2002370

MDD Report EN 14683: 2019 Surgical masks – Requirements and test methods	
Testing laboratory	Guangzhou Inspection and Certification Group Co., Ltd.
Address	No. 1 Zhujiang Road, Panyu District, Guangzhou City
Testing location	No. 1, Qiling Hebin West Road, Shiling Town, Huadu District, Guangzhou City
Report Number	No. 200035642
Applicant	Guangzhou Shunyi Nonwoven Co., Ltd.
Address	No. 232, Shabei Village Business Street, Jiekou Street, Conghua District, Guangzhou City, Guangdong Province
Standard	EN 14683: 2019
Procedure deviation	N.A.
Type of test object	MASK
Trademark	N.A.
Model/type reference	SY45
Manufacturer	Guangzhou Shunyi Nonwoven Co., Ltd.
Address	No. 232, Shabei Village Business Street, Jiekou Street, Conghua District, Guangzhou City, Guangdong Province

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

Reported by : Mark
 Signature

March 03, 2020
 Date

Mark Zhang / Project Engineer
 Name and Title

Approved by : Eliza
 Signature

March 03, 2020
 Date

Eliza Chen / Manager
 Name and Title



General remarks:	
<p>"(see remark #)" refers to a remark appended to the report.</p> <p>"(see appended table)" refers to a table appended to the report.</p> <p>Throughout this report a comma is used as the decimal separator.</p> <p>The test results presented in this report relate only to the object tested.</p> <p>This report shall not be reproduced except in full without the written approval of the testing laboratory.</p>	<p>Attached with:</p> <p>A. 1 page of photo documentation</p>

Artwork of Marking Label

<p>MASK Model No.: SY45 Standard: EN 14683 Type I Guangzhou Shunyi Nonwoven Co., Ltd. No. 232, Shabei Village Business Street, Jiekou Street, Conghua District, Guangzhou City, Guangdong Province</p>	
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Marking on the packaging bag

EN 14683			
Cl.	Requirement – Test	Result	Verdict

4.	Classification		P
	Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant, The 'R' signifies splash resistance.	Type I	P

5.	Requirements		P
5.1	General		P
5.1.1	Materials and construction	Not disintegrate, split or tear during intended use	P
5.1.2	Design		P
	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides		P
	Medical face mask may have different shapes and constructions as well as additional features such as a face shield(to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).		N
5.2	Performance requirements		P
5.2.1	General		P
	All tests shall be carried out on finished products or samples cut from finished products.		P
5.2.2	Bacterial filtration efficiency (BFE)	98.6%	P
5.2.3	Breathability	34.7Pa	P
5.2.4	Splash resistance	Not required	P

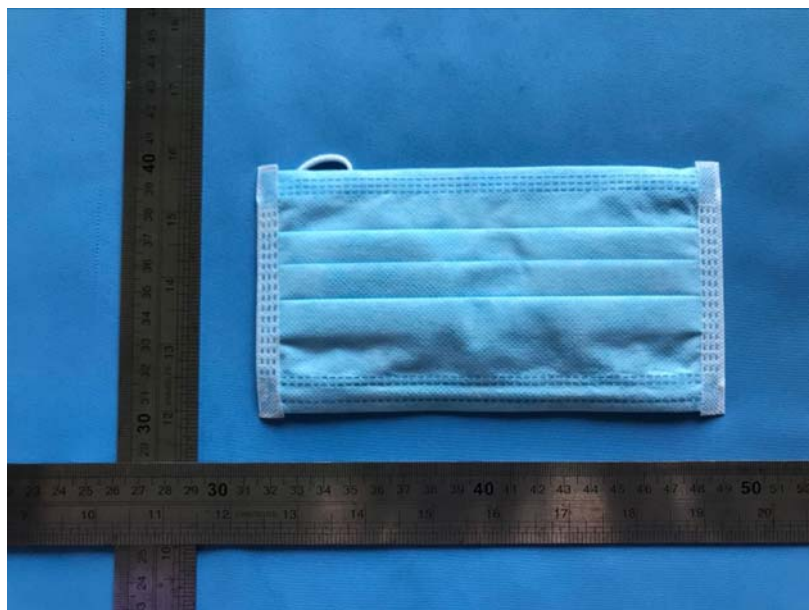
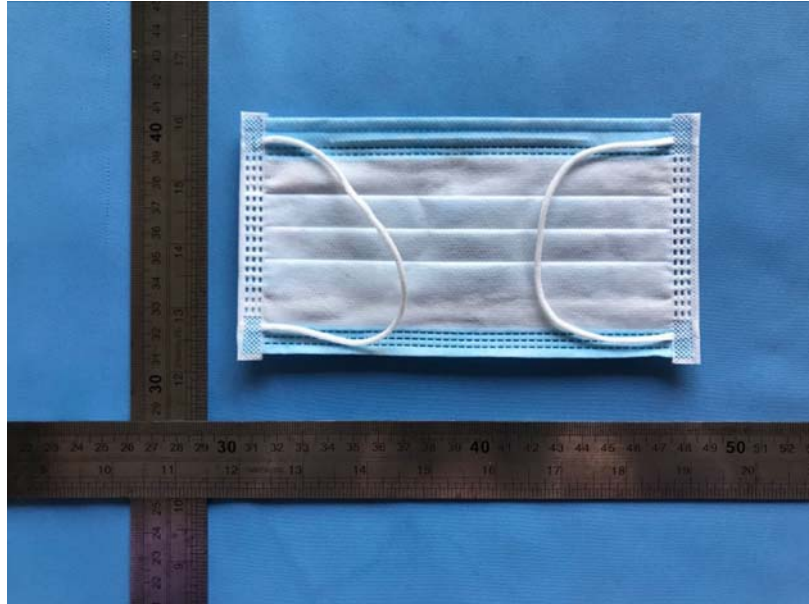
EN 14683			
Cl.	Requirement – Test	Result - Remark	Verdict
5.2.5	Microbial cleanliness (Bioburden)	18cfu/g	P
5.2.6	Biocompatibility	classification in EN ISO 10993-1,	P
5.2.7	Summary of performance requirements		P

6.	Marking, labelling and packaging		P
	Annex I, §13, of the medical Devices Directive (93/42/EEC) or Annex I §23, of the Medical Device Regulation(EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied.	See packaging	P
	The following information shall be supplied:		-
	a) number of this European Standard;	EN14683	P
	b) type of mask(as indicated in Table1).	Type I	P
	ENISO 15223-1: 2016 and EN1041: 2008+A1: 2013 should be considered.		N

Appendix 1

The whole views of 'Mask'

Model: SY45



-----END OF REPORT-----

Declaration of Conformity

Registration No.: EPTC-SY-S2002370

Issue date: March 03, 2020

In accordance with the following Applicable Directives:

The medical devices directive 93/42/EEC

The device, as described herewith, was tested pursuant to applicable test procedure and complies with the requirements of:

EN 14683: 2019

Applicant:

**Guangzhou Shunyi Nonwoven Co., Ltd.
No. 232, Shabei Village Business Street, Jiekou Street,
Conghua District, Guangzhou City, Guangdong
Province**

Product:

MASK

Model Number:

SY45

The tests were performed in normal operation mode. The test results apply only to the particular sample tested and to the specific tests carried out.

This certificate applies specifically to the sample investigated in our test reference number only.

The CE markings as shown below can be affixed on the product after preparation of necessary technical documentation.

Other relevant Directives have to be observed.



Authorized by: _____

Eliza Chen



Eport Compliance Laboratory Limited

[Http: //www.eportsz.com](http://www.eportsz.com)