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Test Report

Product:	Disposable medical mask(nonsterile)
Model /Type:	YY-L
Trademark:	Sky Screen
Applicant:	Guangdong Jinye Technology Development Co.ltd
Address:	Room 501, building 2, No. 8, qiaolonghe East Road, Tangxia Town, Dongguan City, Guangdong Province
Manufacturer	Guangdong Jinye Technology Development Co.ltd
Address:	Room 501, building 2, No. 8, qiaolonghe East Road, Tangxia Town, Dongguan City, Guangdong Province
Laboratory:	Aerospace Testing Technology (Shenzhen) Co., Ltd.
Address:	3/F, Block A1, No. 5, 8th Road, Shapu Yangyong Industrial Park, Songgang Street, Bao'an District, Shenzhen, Guangdong, China
Report Number	AST2003205048
Standard:	EN 14683:2019
Web :	http://www.ast-test.com

Tested By:_____ Date: 2020-04-03

Approved By:_____ Date: 2020-04-03

Aerospace Testing Technology (Shenzhen) Co., Ltd. AST.LAB Approved

航天检测技术（深圳）有限公司
广东省深圳市宝安区松岗街道沙浦洋涌工业区8路5号A1栋三楼
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TEST REPORT EN 14683:2019 Medical face masks —Requirements and test methods	
Report reference No.	AST2003205048
Test By	Megan
Approved By.	Thomas
Date of issue	2020-04-03
Date of test	2020-03-21 to 2020-04-03
Testing laboratory	Aerospace Testing Technology (Shenzhen) Co., Ltd.
Location	3/F, Block A1, No. 5, 8th Road, Shapu Yangyong Industrial Park, Songgang Street, Bao'an District, Shenzhen, Guangdong, China
Applican	Guangdong Jinye Technology Development Co.ltd
Address:	Room 501, building 2, No. 8, qiaolonghe East Road, Tangxia Town, Dongguan City, Guangdong Province
Standards	EN 14683:2019
Procedure deviation	N/A
Non-standard test method	N/A
Type of test product	Disposable medical mask(non sterile)
Trade mark.	Sky Screen
Model/Type designation	YY-L
TRF originator.	FHT
Copyright blank test report:	--
Test item particulars:	N/A
Test procedure	MDD Approval
Test Report Form No.	EN 14683

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)
General remarks:	
"(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. The test results presented in this report relate only to the object tested. This report shall not be reproduced except in full without the written approval of the testing laboratory. Until otherwise specified, all tests are done under normal ambient condition 25℃±10℃, Max RH: 75% and air pressure of 860 mbar to 1060 mbar.	Attached with: Attachment - A. Photo Documentation

The test samples were pre-production samples without serial numbers. This report shall not be reproduced except in full without the written approval of the testing laboratory.

This report covers YY-L.

The test result presented in this report relate only to the object tested. The samples tested comply with the requirements of this standard.

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EN 14683:2019			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
1	Scope		-
2	Normative references		-
3	Terms and definitions		-
3.1	aerosol gaseous suspension of solid and/or liquid particles		P
3.2	bacterial filtration efficiency (BFE) efficiency of the medical face mask material(s) as a barrier to bacterial penetration Note 1 to entry: The BFE test method isused to measure the bacterial filtration efficiency (BFE) of medical face mask materials.		P
3.3	biocompatibility quality of being accepted in a specific living environment without adverse or unwanted side effects		P
3.4	cleanliness freedom from unwanted foreign matter		P
3.4.1	microbial cleanliness freedom from population of viable micro-organisms on a product and/or a package		P
3.5	colony forming unit (CFU) unit by which the culturable number of micro-organisms is expressed Note 1 to entry: The culturable number is the number of micro-organisms, single cells or aggregates, able to form colonies on a solid nutrient medium.		P
3.6	differential pressure air permeability of the mask, measured by determining the difference of pressure across the mask under specific conditions of air flow, temperature and humidity		P
3.7	filter material used for mechanical and physical separation or deposition of aerosol particles (liquid or solid) from the inhaled and exhaled air		N/A
3.8	infective agent micro-organism that has been shown to cause surgical wound infections or that might cause infection in the patient, members of staff or other		P
3.9	medical face mask medical device covering the mouth and nose providing a barrier to minimize the direct transmission of infective agents between staff and patient		P
3.10	splash resistance ability of a medical face mask to withstand penetration of synthetic blood projected at a given pressure		NA

EN 14683:2019			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
3.11	surgical procedure surgical intervention penetrating skin or mucosa, performed by a surgical team under controlled environmental conditions		NA
4	Classification 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.	Type II	P
5	Requirements		P
5.1	General		P
5.1.1	Materials and construction The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric. The medical face mask shall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness	absence of particulate matter	P
5.1.2	Design 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. Medical face masks 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)	Metal strip fixing	P
5.2	Performance requirements		P
5.2.1	General All tests shall be carried out on finished products or samples cut from finished products, if applicable in their sterile state.		P
5.2.2	Bacterial filtration efficiency (BFE) When tested in accordance with Annex B, the bacterial filtration efficiency (BFE) of the medical face mask shall conform to the minimum value given for the relevant type in Table 1.	Bacterial filtration efficiency (%), 98.32 %≥ 98 %	P
5.2.3	Breathability When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1.	Differential pressure (Pa/cm^2), 19.30 Pa/cm^2< 40 Pa/cm^2	P

EN 14683:2019			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
5.2.4	Splash resistance When tested in accordance with ISO 22609 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.		N/A
5.2.5	Microbial cleanliness (Bioburden) When tested according to EN ISO 11737-1 the bioburden of the medical mask shall be ≤ 30 cfu/g tested (see Table 1). NOTE EN ISO 11737-1 specifies requirements and provides guidance for the enumeration and microbial characterisation of the population of viable microorganisms on or in a medical device, component, raw material or package. To determine the mask's bioburden according to EN ISO 11737-1, follow the procedure below: The number of masks that shall be tested is minimum 5 (five), but can be greater if necessary to allow for an AQL of 4 %.		N/A
5.2.6	Biocompatibility According to the definition and classification in EN ISO 10993-1, a medical face mask is a surface device with limited contact. The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1 and determine the applicable toxicology testing regime. The results of testing should be documented according to the applicable parts of the EN ISO 10993 series. The test results shall be available upon request. As a minimum, EN ISO 10993-5 and EN ISO 10993-10 shall be considered.		P
6	Labelling and information to be supplied		P
	The following information shall be supplied in addition: a) number of this European Standard; b) type of mask (as indicated in Table 1).	EN 14683:2019 Type II	P
Annex A	Information for users		P
	When breathing, speaking, coughing, sneezing etc., one releases smaller or larger amounts of droplets of secretions from the mucous membranes in the mouth and nose. The majority of the nuclei are between 0,5 µm and 12 µm in diameter and especially the larger droplets can contain micro-organisms from the source site. Nuclei can subsequently spread through the air to a susceptible site such as an open operating wound or sterile equipment.		P
Annex B	Method for in-vitro determination of bacterial filtration efficiency (BFE)		P

Table 1-performance requirements for medical face masks

Test	Type I [a]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥95	≥98	≥98
Differential pressure(Pa/cm^2)	<40	<40	<60
Splash resistance pressure (kPa)	Not required	Not required	≥16,0
Microbial cleanliness (cfu/g)	≤30	≤30	≤30

[a] Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements

EC Declaration

Manufacture

Guangdong Jinye Technology Development Co.ltd

Address

Room 501, building 2, No. 8, qiaolonghe East Road, Tangxia Town, Dongguan City, Guangdong Province

Description of product

Disposable medical mask(non sterile)

Model(s)

YY-L

Standards used, including number, title, issue date and other relative documents

EN 14683:2019

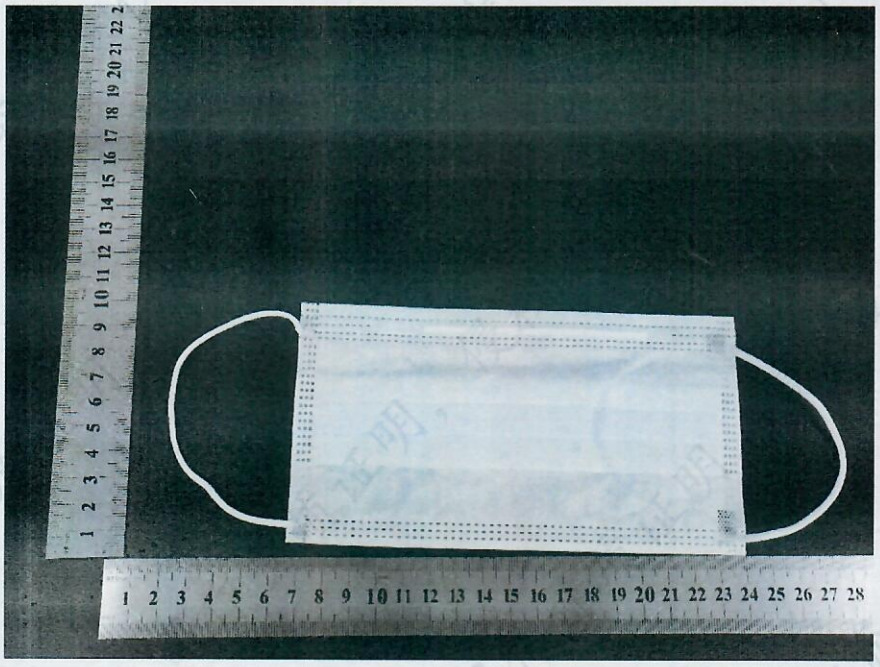
Declaration：

I declare that as the authorised representative, the above information in relation to the supply / manufacture of this product, is in conformity with the stated standards and other related documents following the provisions of the above Directives and their amendments.

Signature Of Manufacturers Authorized:

2020.04.03

Photo Documentation



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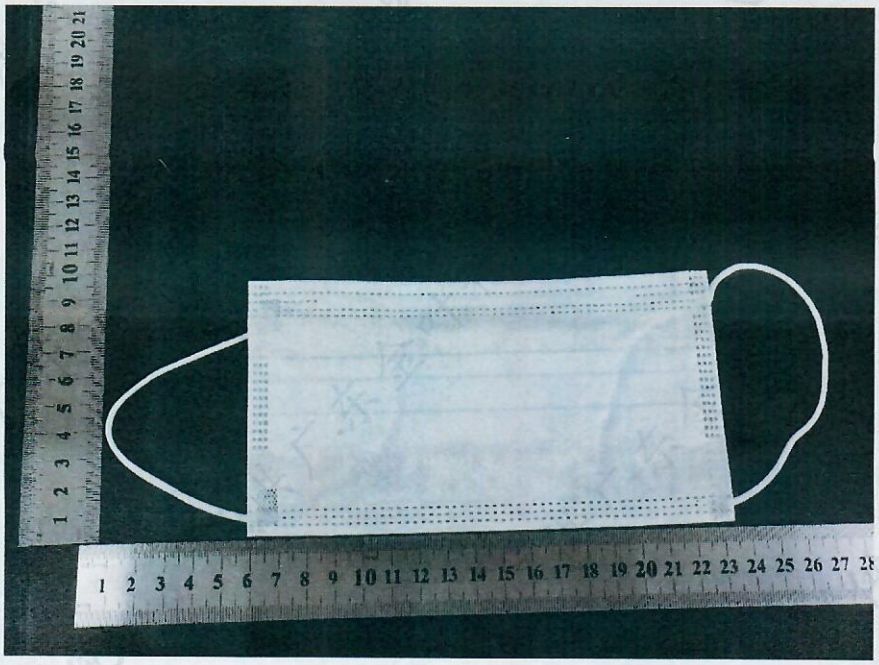

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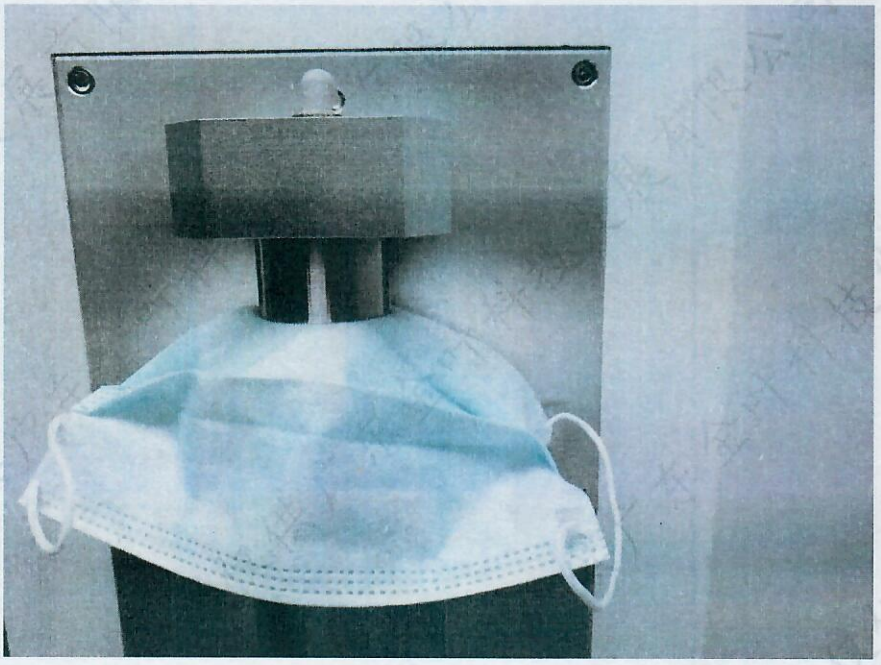
Test Photograph

1



2

End of Report

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