CE Test Report

Test Report No. :AS2020032309MDD

Type / Model Name	:	**DA1**
Filter Grade	:	**Class 1**
Product Name	:	**Mask**
Applicant	:	**SHENZHEN ANDOOR SPORTING GOODS CO., LTD.**

PPE -- TEST REPORT

Test Report No. : AS2020032309MDD	23-Mar.-2020 Date of issue

Type / Model Name : DA1

Filter Grade : Class 1

Product Name : Mask

Applicant : SHENZHEN ANDOOR SPORTING GOODS CO., LTD.

Address : Room B, Floor 5, Building 2, Houhai Industrial Park, liyuhe Industrial Zone, Loucun community, Gongming Sub-district, Guangming District, Shenzhen

Manufacturer : SHENZHEN ANDOOR SPORTING GOODS CO., LTD.

Address : Room B, Floor 5, Building 2, Houhai Industrial Park, liyuhe Industrial Zone, Loucun community, Gongming Sub-district, Guangming District, Shenzhen

Prepared By : Shenzhen AS Technology Co., Ltd.

Address : Building A3,Digital Technology Park, Gao Xin South 7# Road High-Tech Industrial Park,Nanshan District, Shenzhen,China

Test Result according to the standards listed in clause 1 test standards:	**POSITIVE**

The test report merely corresponds to the test sample.
It is not permitted to copy extracts of these test results without the written permission of the test laboratory.

Contents

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1 TEST STANDARDS

The tests were performed according to following standards:

EN 14683:2019	Medical face masks-Requirements and test methods

Technical grade

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.

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2 SUMMARY

GENERAL REMARKS:

The results of this test report are only valid for the mentioned equipment under test. The test report with all its sub-reports, e.g. tables, photographs and drawings, is copyrighted. Unauthorized utilization, especially without permission of the test laboratory, is not allowed and punishable. For copying parts of the test report, a written permission by the test laboratory is needed.

FINAL ASSESSMENT:

The test results of this report relate only to the tested sample identified in this report. Samples are tested in full accordance with EN14683:2019.

Date of receipt of test sample	:	16-03-2020
Testing commenced on	:	16-03-2020
Testing concluded on	:	23-03-2020

Tested By:

Antany/ Engineer
23-03-2020

Approved By:

Davis/Technical Manager
23-03-2020

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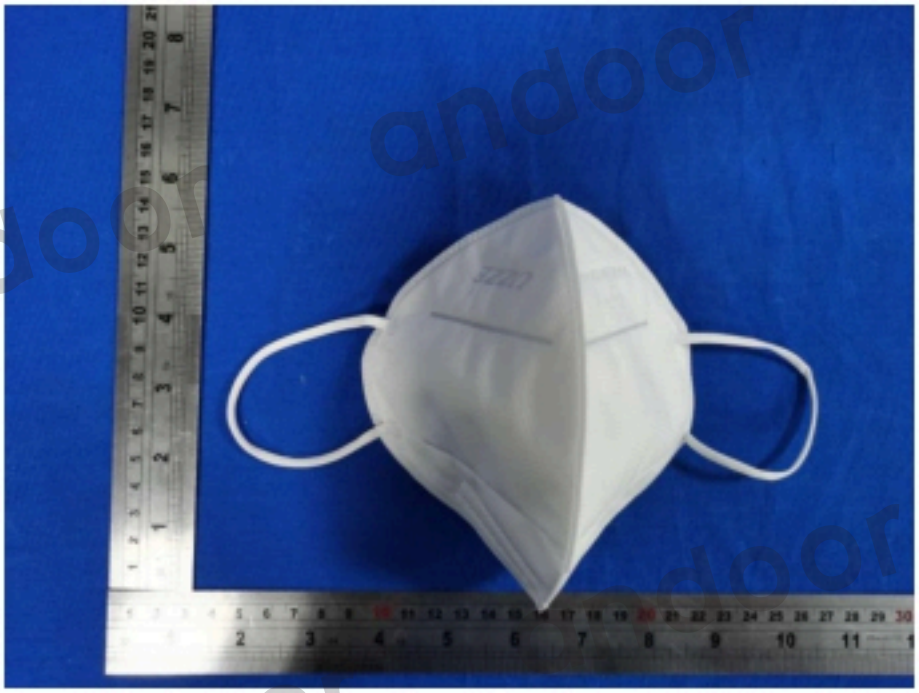
3 PRODUCT UNDER TEST

3.1 Photo documentation of the Product



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3.2 Correlation parameter

N/A

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4 TEST ENVIRONMENT

4.1 Address of the test laboratory

Shenzhen AS Technology Co., Ltd.
Building A3,Digital Technology Park, Gao Xin South 7# Road
High-Tech Industrial Park,Nanshan District, Shenzhen,
P.R.China. P.C. 518000

Subcontractor: NIL

4.2 Environmental conditions

During the measurement the environmental conditions were within the listed ranges:

Temperature:	20-25 ° C
Humidity:	55-60 %
Atmospheric pressure:	100-106 kPa

5 TEST CONDITIONS AND RESULTS

Possible test case verdicts:

- test case does not apply to the test object.....N(Not apply)

- test object does meet the requirement.....P(Pass)

- test object does not meet the requirement.....F(Fail)

Copy of marking plate:

Product Name:Mask
Model:DA1
Standard: EN 14683:2019
SHENZHEN ANDOOR SPORTING GOODS CO., LTD.
Made in China

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EN 14683:2019			
Claus	**Requirement-Test**	**Result-**	**Verdi**
1	Scope		P
2	Normative references		P
3	Terms and definitions		P
3.1	medical face mask medical device covering the mouth and nose providing a barrier to minimise the direct transmission of infective agents between staff and patient		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 is used to measure the bacterial filtration efficiency (BFE) of medical face mask materials.		P
3.3	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
3.4	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
3.5	cleanliness freedom from unwanted foreign matter		P
3.5.1	cleanliness — microbial freedom from population of viable micro-organisms on a product and/or a package		P
3.5.2	cleanliness — particulate matter freedom from particles that are contaminating a material and can be released but are not generated by mechanical impact		P
3.6	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

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EN 14683:2019			
Claus	**Requirement-Test**	**Result-**	**Verdi**
3.7	surgical procedure surgical intervention penetrating skin or mucosa, performed by a surgical team under controlled environmental conditions		P
3.8	aerosol gaseous suspension of solid and/or liquid particles, the particles having a negligible falling velocity		P
	Note 1 to entry: See EN 132. Note 2 to entry: This velocity is generally considered to be less than 0,25 m/s.		
3.9	filter material used for mechanical and physical separation or deposition of aerosol particles (liquid or solid) from the inhaled and exhaled air		P
3.10	splash resistance ability of a medical face mask to withstand penetration of synthetic blood projected at a given pressure		P
	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 I	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

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EN 14683:2019			
Claus	**Requirement-Test**	**Result-**	**Verdi**
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)	Bacterial filtration	P
	When tested in accordance with Annex B, the	efficiency (BFE),	P
	bacterial filtration efficiency (BFE) of the medical face mask shall conform to the minimum value given for the relevant type in Table 1.	≥ 95% Differential pressure (Pa/cm2) < 29.4	
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.		P
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.		P

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EN 14683:2019			
Claus	**Requirement-Test**	**Result-**	**Verdi**
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 %.		P
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:		P
	a) number of this European Standard; b) type of mask (as indicated in Table 1).		
Annex	Information for users		P

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EN 14683:2019			
Claus	**Requirement-Test**	**Result-**	**Verdi**
	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

6 Test data

Ambient temperature: 24 ℃ Relative Humidity (RH): 32%					
Sample	Items	Limits(%)	Initial filtration	Loading filter	Conclusion
Non- temperature conditioning samples					
#1	Filtration Efficiency	Test gas flow single filter element 085 ±	95.3	95.2	PASS
#2			95.2	95.2	PASS
#3			95.3	95.3	PASS
#4			95.2	95.1	PASS
#5			95.3	95.2	PASS
#6			95.3	95.2	PASS
Temperature conditioning samples					
#7	Filtration Efficiency	Test gas flow single filter element 095	95.3	95.3	PASS
#8			95.2	95.1	PASS
#9			95.3	95.2	PASS
#10			95.3	95.2	PASS
Sample	Items	Limits(%)	Data （Pa）		Conclusion

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Non- temperature conditioning samples				
#11	Inspiratory resistance	The total gas resistance of each sample should be ≤ 350Pa	141	PASS
#12			141	PASS
#13			142	PASS
#14			145	PASS
#15			141	PASS
#16			144	PASS
Temperature conditioning samples				
#17	Inspiratory resistance	The total gas resistance of each	152	PASS
#18			154	PASS
#19			158	PASS
#20		350Pa	156	PASS
#21			157	PASS
Non- temperature conditioning samples				
#22	Expiratory resistance	The total gas resistance of each sample should be ≤ 250Pa	65	PASS
#23			68	PASS
#24			85	PASS
#25			65	PASS
#26			65	PASS
#27			65	PASS
Temperature conditioning samples				
#28			92	PASS
#29			91	PASS

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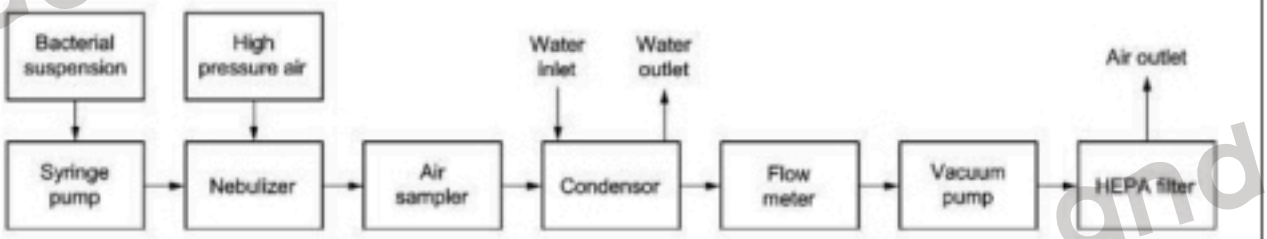
#30			89	PASS
#31			92	PASS
#32			93	PASS
#33			91	PASS
#34			90	PASS
Note:		Temperature conditions a) 24 hours at 38 ℃ and 85% b) At 70 ℃ for 24 hours c) 24 hours at -30 ℃		

Principle of BFE test apparatus



-----End of Test Report------

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