CE/MDD TEST REPORT

Product Name:	Medical masks
Brand Name:	[redacted]
Model Number:	[redacted]
Prepared For:	[redacted]
Address:	[redacted]
Prepared By:	Youbest Testing Technology Co., Ltd.
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Report No.:	YB200324144WY-MDD-B1

TEST RESULT CERTIFICATION

[redacted]

Address [redacted]

Manufacturer [redacted]

Address [redacted]

EUT : Medical masks

Brand Name: : [redacted]

Model Number : [redacted]

Date of Receipt: : March 16, 2020

Test Date : March 16-23, 2020

Date of Report : March 24, 2020

Test Standard : EN 14683:2005

Surgical masks - Requirements and test methods

Comment : Based on the performed tests on submitted samples, the results comply with the Medical Devices Directive 93/42/EEC

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Reviewer(Supervisor): Jack Li

Approved(Manager): Eric Sang

This test report is based on a single evaluation of one sample of above mentioned products. It is not permitted to be duplicated in extracts without written approval of Youbest Testing Technology Co., Ltd.

EN 14683:2005			
Clause	**Requirement-Test**	**Result-Remark**	**Verdict**
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
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

EN14683:2005			
Clause	**Requirement-Test**	**Result-Remark**	**Verdict**
	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
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	Metal strip fixing	P

	contours)		
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

EN 14683:2005			
Clause	**Requirement-Test**	**Result-Remark**	**Verdict**
	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 Microbial cleanliness (cfu/g) ≤ 30	
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
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

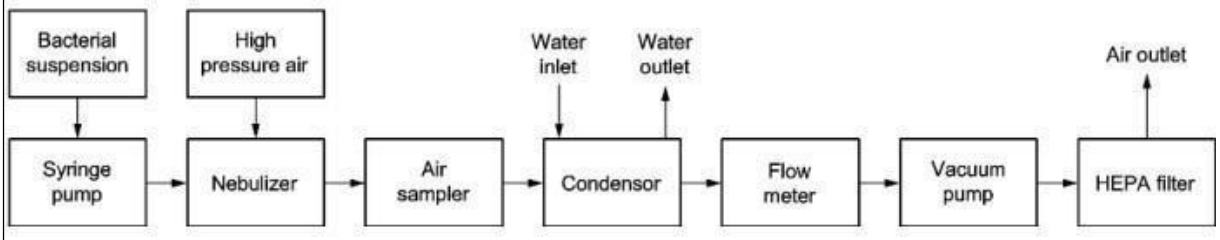
5.2.6	Biocompatibility According to the definition and classification in EN ISO 10993-1, a medical face mask is a surface device with limited contact. The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1 and determine the applicable toxicology testing regime. 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
EN 14683:2005			
Clause	**Requirement-Test**	**Result-Remark**	**Verdict**
	a) number of this European Standard; b) type of mask (as indicated in Table 1).		
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

Test data

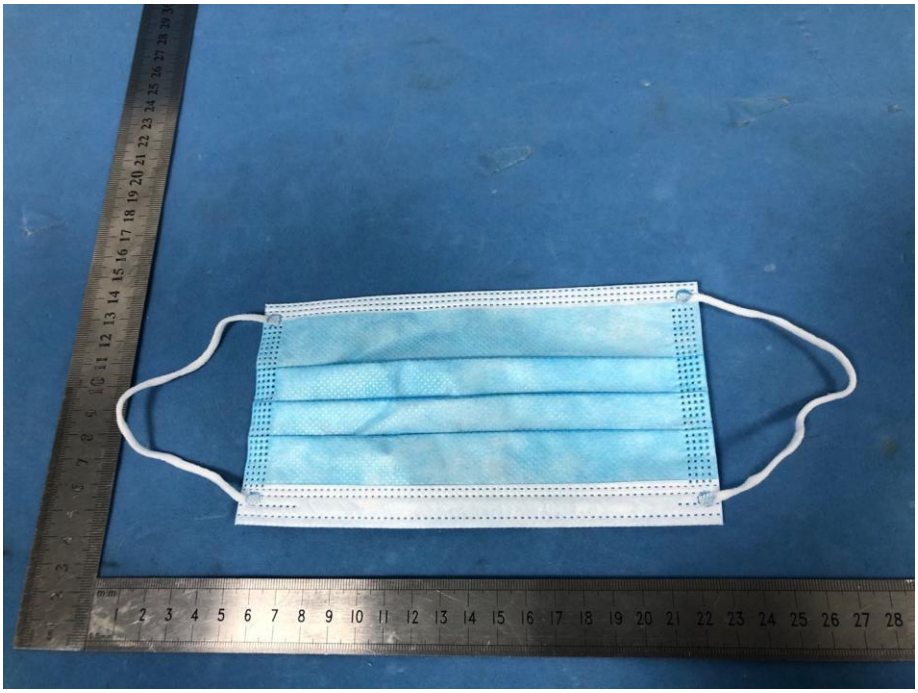
Ambient temperature: 24 ℃ Relative Humidity (RH): 32%					
Sample	Items	Limits(%)	Initial filtration efficiency(%)	Loading filter efficiency(%)	Conclusion
Non- temperature conditioning samples					
#1	Filtration Efficiency	Test gas flo w single filter element 085 ± 4) l / min >80	95.3	95.2	PASS
#2			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 flo w single filter element 0 95 ± 4) l / min >80	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
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	Thetotal gas resistance of each sample should be ≤	152		PASS
#18			154		PASS
#19			158		PASS

Documentation				
#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	Expiratory resistance	The total gas resistance of each sample should be ≤ 250Pa	92	PASS
#29			91	PASS
#30			89	PASS
#31			92	PASS
#32			93	PASS
#33			91	PASS
#34			90	PASS
Note:		Temperature conditions 24 hours at 38 ℃ and 85% At 70 ℃ for 24 hours 24 hours at -30 ℃		

Principle of BFE test apparatus



Annex：Technical Information



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