

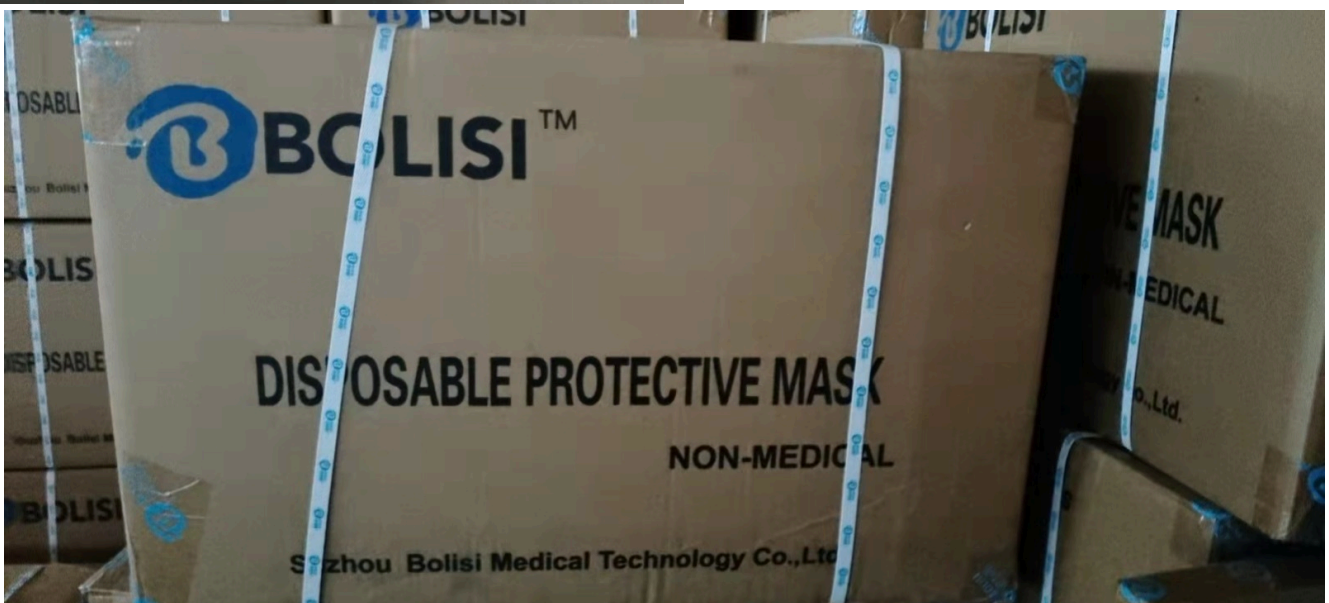
BOLISI KN95 MASK

MASK ITEM: INDIVIDUAL PACKED

KN95 MASK PER CASE: 1200 MASKS

BOX: 20 MASKS

MASKS "60 BOXES" PER CASE



510(k) Premarket Notification

FDA Home Medical Devices Databases



510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

New Search		Back To Search Results
Device Classification Name	Mask, Surgical	
510(K) Number	K210244	
Device Name	Disposable Medical Face Mask	
Applicant	Suzhou Bolisi Medical Technology Co., Ltd Baijiaqiao Industrial Community, Yangshe Town Zhangjiagang, CN 215000	
Applicant Contact	Hong Xu	
Correspondent	Shanghai Mind-Link Business Consulting Co., Ltd. Room A08, Floor 14th, No 699, Jiaozhou Road, Jingan District Shanghai, CN 200040	
Correspondent Contact	Ryan Li	
Regulation Number	878.4040	
Classification Product Code	FXX	
Date Received	01/29/2021	
Decision Date	07/12/2021	
Decision	Substantially Equivalent (SESE)	
Regulation Medical Specialty	General & Plastic Surgery	
510k Review Panel	General Hospital	
Summary	Summary	
Type	Traditional	
Reviewed By Third Party	No	
Combination Product	No	



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CNAS L7901

检验检测报告

TEST REPORT



STFWT20203590

Product Name

Multi-effect protective mask (C type)

Trust Unit

Suzhou Bolisi Medical Technology Co., Ltd.

Manufacturer

Suzhou Bolisi Medical Technology Co., Ltd.

Test Category

Entrusted Test



江苏省特种安全防护产品质量监督检验中心
JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS



Test Report

STFWT20203590

Page 1 of 5

Product Name	Multi-effect protective mask (C type)	Specification Type	General size
		Trademark	Bolisi, AAA
Trust Unit	Suzhou Bolisi Medical Technology Co., Ltd.	Tel	0512-58257080
Manufacturer	Suzhou Bolisi Medical Technology Co., Ltd.	Sample Grade	KN95
Sample Quantity	50 units	Sample Receiving Date	2020-03-07
Test Category	Entrusted Test	Serial Number	—
Samples Conditions	Meet the testing requirements		
Document and Decide Accordance	GB 2626-2006 《Respiratory protective equipment-Nor-powered air-purifying particle respirator》		
Test Conclusion	<p>The samples were tested, the items tested meet the requirements of GB 2626-2006 standard for KN95 level.</p>		
Remarks	<p>The test item marked "--" means that no single evaluation or no single evaluation conditions are met. The test conclusion of this report is only for the items inspected and does not mean that the uninspected items or functions meet the requirements. This report is responsible for samples only.</p>		



Approver

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Examiner

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Majortester

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Testing Results

STFWT20203590

Page 2 of 5

Serial	Test Items	Unit	Requirement	Results	Individual Judgment																														
1	General requirements	—	<p>Materials:</p> <p>a) Materials in direct contact with the face should be harmless to the skin.</p> <p>(b) The filter material shall be harmless to humans.</p> <p>(c) The material used shall have sufficient strength to withstand breakage or deformation during its normal service life.</p> <p>Structure:</p> <p>(a) should not be susceptible to structural damage and the design, composition and installation of the components should not pose any hazard to the user.</p> <p>(b) The headband should be designed to be adjustable and easy to wear and remove, should securely fasten the mask to the face and should be worn without visible compression or pain, and the headband design of the replaceable half mask and full mask should be replaceable.</p> <p>(c) Should have as small Carbon dioxide content of the inhalation air and a large field of view as possible.</p> <p>(d) The disposable mask shall be constructed to ensure a close fit to the face and shall be free from deformation during its service life.</p>	<p>Materials:</p> <p>a) That is not susceptible to structural damage and the design, composition and installation of the components do not pose any hazard to the user.</p> <p>b) The headband is designed to be adjustable for easy wearing and removal, to hold the mask securely to the face, and to be worn without significant compression or pressure pain.</p> <p>c) Has a smaller Carbon dioxide content of the inhalation air and a larger field of view.</p> <p>d) The disposable mask constructed to ensure a close fit to the face and free from deformation during its service life.</p>	—																														
2	Visual inspection	—	The surface shall be free from breakage, deformation and other obvious defects, the material and construction of the components shall be able to withstand normal conditions of use and the temperature, humidity and mechanical shocks that may be encountered, the headband shall be adjustable and the headband design of the replaceable mask shall be replaceable. Parts should not be dislodged, damaged or deformed after pre-treatment with temperature and humidity.	Meet the requirements.	Qualified																														
3	Respiratory resistance	Pa	Total inhalation resistance should not exceed 350 and total exhalation resistance should not exceed 250 for each sample.	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2"></th> <th style="text-align: center;">Sample No</th> <th style="text-align: center;">MV</th> </tr> </thead> <tbody> <tr> <td rowspan="4" style="text-align: center;">Total inspiratory resistance</td> <td style="text-align: center;">Unpretreated</td> <td style="text-align: center;">21[#]</td> <td style="text-align: center;">120.4</td> </tr> <tr> <td></td> <td style="text-align: center;">22[#]</td> <td style="text-align: center;">119.2</td> </tr> <tr> <td style="text-align: center;">Temperature and humidity treatment</td> <td style="text-align: center;">25[#]</td> <td style="text-align: center;">117.6</td> </tr> <tr> <td></td> <td style="text-align: center;">26[#]</td> <td style="text-align: center;">121.1</td> </tr> <tr> <td rowspan="4" style="text-align: center;">Total exhalation resistance</td> <td style="text-align: center;">Unpretreated</td> <td style="text-align: center;">23[#]</td> <td style="text-align: center;">95.2</td> </tr> <tr> <td></td> <td style="text-align: center;">24[#]</td> <td style="text-align: center;">79.9</td> </tr> <tr> <td style="text-align: center;">Temperature and humidity treatment</td> <td style="text-align: center;">27[#]</td> <td style="text-align: center;">82.1</td> </tr> <tr> <td></td> <td style="text-align: center;">28[#]</td> <td style="text-align: center;">84.4</td> </tr> </tbody> </table>			Sample No	MV	Total inspiratory resistance	Unpretreated	21 [#]	120.4		22 [#]	119.2	Temperature and humidity treatment	25 [#]	117.6		26 [#]	121.1	Total exhalation resistance	Unpretreated	23 [#]	95.2		24 [#]	79.9	Temperature and humidity treatment	27 [#]	82.1		28 [#]	84.4	Qualified
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4	Field of vision	—	Lower field of vision $\geq 60^\circ$	62°	Qualified																														
5	Carbon dioxide content of the inhalation air	—	CO ₂ volume fraction should be no greater than 1%.	0.6%	Qualified																														

Testing Results

STFWT20203590

Page 3 of 5

Serial	Test Items	Unit	Requirement	Results		Individual Judgment		
				Sample No	MV			
6	Filter efficiency /% (NaCl particulate matter)	—	KN90: ≥ 90.0 KN95: ≥ 95.0 KN100: ≥ 99.97	Unpretreated	1#	Initial	99.2	Qualified
						Loaded	99.0	
					2#	Initial	99.3	
						Loaded	99.1	
					3#	Initial	99.2	
						Loaded	99.0	
					4#	Initial	99.3	
						Loaded	99.1	
					5#	Initial	99.2	
						Loaded	99.0	
					6#	Initial	99.3	
						Loaded	99.1	
					7#	Initial	99.3	
						Loaded	99.1	
					8#	Initial	99.2	
						Loaded	99.0	
					9#	Initial	99.2	
						Loaded	99.0	
					10#	Initial	99.3	
						Loaded	99.1	
11#	Initial	99.2						
	Loaded	99.0						
12#	Initial	99.4						
	Loaded	99.1						
13#	Initial	99.0						
	Loaded	98.9						
14#	Initial	99.2						
	Loaded	99.0						
15#	Initial	99.1						
	Loaded	98.9						
7	Headband	—	Each headband, buckle and other adjusting parts of the mask should not slip or break when subjected to a 10N tension for 10s.	Unpretreated 21# Each headband, buckle and other adjusting parts of the mask did not slip or break after being subjected to 10N of tension for 10s. After pretreatment: 22# Each headband, buckle and other adjusting parts of the mask did not slip or break after being subjected to 10N tension for 10s.	Qualified			

Testing Results

STFWT20203590

Page 4 of 5

Serial	Test Items	Unit	Requirement	Results	Individual Judgment			
8	exhalation valve cover	---	The exhalation valve cover is subjected to 10N axial tension for 10s, there should be no slippage, fracture and deformation.	Without exhalation valve ,Not applicable	---			
9	exhalation valve air tightness	---	Each sample shall be free from one of the following conditions.(a) When the pumping flow rate has reached 500 mL/min, the system negative pressure is less than 1180 Pa.(b) The time for the expiratory valve to return to atmospheric pressure is less than 20s.	Without exhalation valve , Not applicable	---			
10	Leakage/% (Total Inward Leakage of Disposable Mask)	---	filter material level	Based on Til of each action (i. e. 10 persons and 5 actions) , TIL of at least 46 actions in 50 actions	Unpretreated	16 [#]	There are 47 actionss with a TIL less than 11.	Qualified
			KN95	<11		17 [#]	There are 47actionss with a TIL less than 11.	
						18 [#]	There are 47actionss with a TIL less than 11.	
						19 [#]	There are 47actionss with a TIL less than 11.	
						20 [#]	There are 47actionss with a TIL less than 11.	
					21 [#]	There are 47 actionss with a TIL less than 11.		
			Temperature and humidity treatment	22 [#]	There are 47 actionss with a TIL less than 11.			
				23 [#]	There are 47actionss with a TIL less than 11.			
				24 [#]	There are 47 actionss with a TIL less than 11.			
				25 [#]	There are 47 actionss with a TIL less than 11.			
				16 [#]	There were 9 people with a TIL less than 8.			
			filter material level	Total Inward Leakage for at least 8 out of 10 subjects when evaluated on a total person basis	Unpretreated	17 [#]	There were 9 people with a TIL less than 8.	
			KN95	<8		18 [#]	There were 9 people with a TIL less than 8.	
						19 [#]	There were 9 people with a TIL less than 8.	
						20 [#]	There were 9 people with a TIL less than 8.	
21 [#]	There were 9 people with a TIL less than 8.							
22 [#]	There were 9 people with a TIL less than 8.							
Temperature and humidity treatment	23 [#]	There were 9 people with a TIL less than 8.						
	24 [#]	There were 9 people with a TIL less than 8.						
	25 [#]	There were 9 people with a TIL less than 8.						

Testing Results

STFWT20203590

Page 5 of 5

Serial	Test Items	Unit	Requirement	Results	Individual Judgment
11	Flammability	—	The parts exposed to the flame should not burn after being removed from the flame; if they do, the renewal time should not exceed 5s.	Unpretreated 1 [#] , 2 [#] The parts of the specimen exposed to the flame did not burn after being removed from the flame. After pretreatment: 3 [#] , 4 [#] The parts of the specimen exposed to the flame did not burn after being removed from the flame.	Qualified
12	Connect and connect parts	—	Replaceable type filter element and masks, breathing tube and filter element and mask all connections and links between parts, in 10 n under axial tension and lasts 10 s, should not appear slippage, fracture or deformation.	Disposable mask, Not applicable	—

Test sample picture



The following blank

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地址：江苏省泰州市高港区临港经济园临港大道 166 号

Add: Lingang Road 166, Lingang Economic Park , Gaogang, Taizhou.Jiangsu

电话 (Tel): 0523-86989959

0523-86989939

邮编 (Post): 225300

网址 (Web): www.jstfzx.com

邮箱 (E-mail): 1735889887@qq.com

监督电话 (Complain Tel): 0523-86989901

