Review Report –审查报告–검토 보고서– Rapport d'Evaluation

CE Documentation Review

No. 4U200319F.BGC0096

Holder: BEIFA GROUP CO., LTD
No.68, Weiliu Road, Beilun District, Ningbo, Zhejiang, 315821, China

Review goal: Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII

Product: Disposable medical mask **(no sterile)**

Model(s): KZ001, KZ002

Classification: Class I (no sterile)
(accordingly to the Manufacturer's declaration)

Review output: We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process.
The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

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Test Report

Customer	:	BEIFA GROUP CO., LTD
Address	:	NO.68, WEILIU ROAD, BEILUN DISTRICT, NINGBO, ZHEJIANG, 315821
Received Date	:	Mar 03, 2020
Turn Around Time	:	Mar 03, 2020 to Mar 24, 2020
Sample Description	:	MASK
Item No.	:	KZ001, KZ002
Buyer	:	N/A
Manufacturer	:	BEIFA GROUP CO., LTD

Test Specification	**Conclusion**
EN 14683:2019 Medical face masks – Requirements and test methods, Type II and Type IIR	**Pass**
Bacterial filtration efficiency (BFE)	Pass
Breathability (Differential Pressure)	Pass
Microbial Cleanliness	Pass
Synthetic Blood Penetration Resistance	Pass

********** FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S) **********

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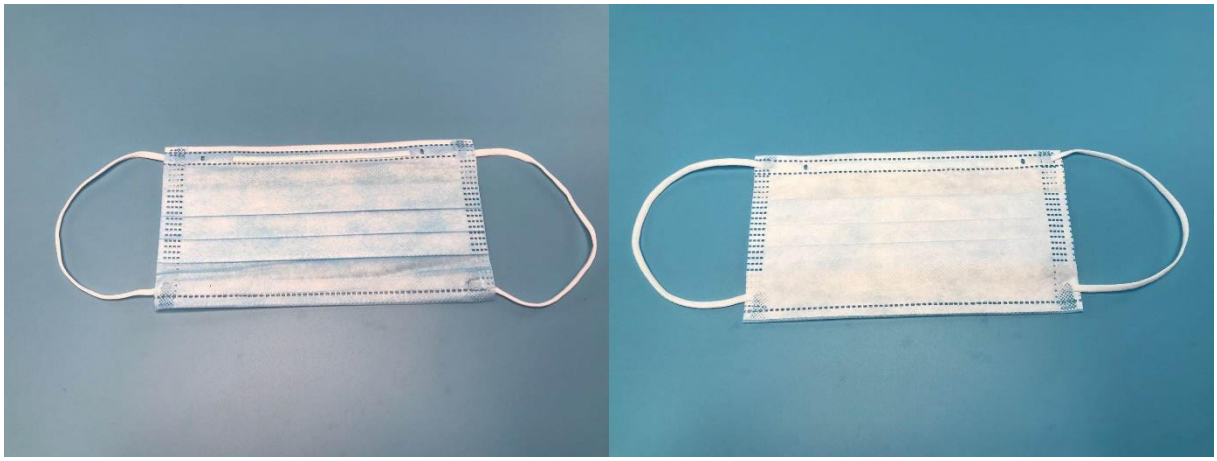
Sample Photo



Tested Component(s)			
	/	/	/
1.Mask	**2.**	**3.**	**4.**

Abbreviation

ND = Not Detected (less than RL). RL = Reporting Limit. NT = Not Tested. N/A = Not Applicable.

mg/kg = milligram per kilogram = ppm. 1 mg/kg = 0.0001%. NM = Not Meet. NC = No Comment.

R1 = Revised report with Synthetic Blood Penetration Resistance test results.

Test Result

Bacterial filtration efficiency (BFE)

Test Method	:	With reference to EN 14683:2019, the BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of Staphylococcus aureus was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 2.7 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3μm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies
Test Side	:	Inside
Test Area	:	40 cm^2
Flow Rate	:	28 Liters per minute (L/min)
Test Condition	:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Sample Dimension	:	90mm x 165mm
Positive Control	:	2,000 CFU
Negative Monitor	:	<1 CFU
MPS	:	2.7μm
Test Result	:	

Parameter	**1**	**2**	***3***	***4***	***5***
Percent BFE (%)	99.4	99.4	99.2	99.0	99.5
Limit	⩾98	⩾98	⩾98	⩾98	⩾98
Conclusion	**Pass**	**Pass**	**Pass**	**Pass**	**Pass**

Breathability (Differential Pressure)

Test Method	:	With reference to EN 14683:2019, The Differential Pressure (Delta P) test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate.
Test Side	:	Inside
Test Area	:	40 cm^2
Flow Rate	:	8 Liters per minute (L/min)
Test Condition	:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Sample Dimension	:	90mm x 165mm
Test Result	:	

Parameter	**1**	**2**	***3***	***4***	***5***
Delta P (Pa/cm^2)	17.2	17.0	17.5	17.0	17.3
Limit	<60	<60	<60	<60	<60
Conclusion	**Pass**	**Pass**	**Pass**	**Pass**	**Pass**

Microbial Cleanliness

Test Method	:	With reference to EN 14683:2019, The testing was conducted in accordance with EN 14683:2014, with the exception of approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation. When bioburden results are calculated using a software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits.
Controls/Monitors	:	Bacillus atrophaeus
Extract Fluid	:	Peptone Tween salt
Fluid Volume	:	300 mL
Extract Method	:	Orbital Shaking for 5 minutes at 250 rpm
Plating Method	:	Membrane Filtration
Agar Medium	:	Tryptic Soy Agar Sabouraud Dextrose Agar with Chloramphenicol
Recovery Efficiency	:	Exhaustive Rinse Method
Aerobic Bacteria	:	Plates were incubated 3 days at 30-35°C, then enumerated
Fungal	:	Plates were incubated 7 days at 20-25°C, then enumerated
Test Result	:	

Parameter	**1**	**2**	***3***	***4***	***5***
Weight (g)	3.1	3.1	3.1	3.1	3.1
Aerobic	<3	<3	<3	<3	<3
Fungal	<3	<3	<3	<3	<3
Total Bioburden (CFU/mask)	<6.0	<5.9	<6.0	<6.0	<5.9
Total Bioburden (CFU/g)	<2	<2	<2	<2	<2
Limit	<30 CFU/g	<30 CFU/g	<30 CFU/g	<30 CFU/g	<30 CFU/g
Conclusion	**Pass**	**Pass**	**Pass**	**Pass**	**Pass**

Synthetic Blood Penetration Resistance

Test Method	:	This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure Is to simulate an arterial spray and evaluate the effectiveness of the test article In protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method. This test method was designed to comply with ASTMF1862 and ISO 22609 {as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed In an environment with a temperature of 21 ± 5°C and a relative humidity of 85 ± 10%. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.
Tested Number	:	32 pcs
Test Side	:	Outside
Pre-Conditioning	:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions	:	19.2°C and 32% RH

Test Pressure : 120 mmHg (16.0 kPa)

Test Result :

Parameter	1-7, 9-21, 23-27, 29-32	8	22	28
Synthetic Blood Penetration	None Seen	Yes	Yes	Yes

Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ⩾29 of 32 tested articles show passing results.

Conclusion **Pass**

*****End of Report*****