

CERTIFICATE OF ANALYSIS

No.: Y2020030811

Product Name: Medical Face Mask

Specification: Earloop

Size	Lot No.	QTY (PCS)
<u>Earloop</u>	20200305	60

Test in accordance with: Product
Technology requirement on Medical Face
Mask

Tested by: SFDA State Food and
Drug Administration Jinan Testing And
Inspection Institute For Medical Device

Test Date: 2020-03-08---2020-03-15

CERTIFICATE OF ANALYSIS

No.: Y2020030811

List	Test Item	Requirements	Test Result					
1	Materials and Structure	Comply with the requirements of EN 14683:2019	Qualified					
2	Appearance	The surface should be smooth, and there should be no stains, mildew,	Qualified					
3	Dimensions cm	length	17.5cm*(1±10%) (15.8-19.2cm)		17.0cm	17.5cm	17.7cm	17.9cm
		wide	9.5cm*(1±10%) (8.64-10.4cm)		9.0cm	9.5cm	9.8cm	10cm
4	Joint strength of face mask straps	Mask straps should be easily worn and removed	ok	ok	ok	ok	ok	
		Do not break under 10 Newton						
5	Bacterial filtration efficiency(BFE)	When test in accordance with EN 14683:2019 Annex C, Minimum value≥95%	95.542%	96.709%	95.417%	96.12%		
6	Pressure Differential (Pa/cm ²)	When test in accordance with EN 14683:2019 Annex C, Minimum value ≤40Pa/cm ²	25	28	30	29		
7	Particle filtration efficient(PFE)	The filtration efficiency of mask should be no less than 30%	96%	90%	92%	93%		
8	Microbial cleanliness (Bioburden) CFU/g	The bioburden of the medical mask shall be ≤100CFU/g	0	0	0	0		
	Coliform		not detected					
	Pseudomonas aeruginosa		not detected					
	Staphylococcus aureu		not detected					
	Streptococcus hemolyticus		not detected					
	Fungus		not detected					
9	Flame retardation	Masks should be made of non-flammable materials and should not burn for more than 5 seconds after leaving the flame	0	0	0	0		
10	Synthetic blood penetration	After 2ml of synthetic blood is sprayed to the outer side of the mask at a pressure of 16 kpa(120mmHg), no infiltration should occur to the inner side of the mask	Qualified					
Conclusion		All test results comply with the Product Technology requirement of Disposable Medical Face Mask						

*****End of the certificate*****