

# 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

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| 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     |
|            |   |        | 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/cm²)          |        | When test in accorance with EN 14683:2019 Annex C, Minimum value ≤40Pa/cm²   | 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\*\*\*\*\*