



**LINC+ENG**  
林橙贸易

CHANGXING  
**LINCHENG**  
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STANLEY

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**CHANGXING LINCHENG TRADING CO., LTD** is the authorized distributor and sales agent of leading pharmaceutical packaging companies in China.

#### DISTINGUISHED PARTNERS



Stock Code: 603976



Stock Code: 835358

## OUR PRODUCTS FOR HEALTH INDUSTRY

### VIALS

We supply various low to medium borosilicate injection vial, antibiotic vial, oral liquid vial, ampoule vials.



### RUBBER STOPPERS

We provide all kinds of rubber stoppers: Rubber stoppers for vacuum blood collections, sampling tube, injection tube, infusion, etc.



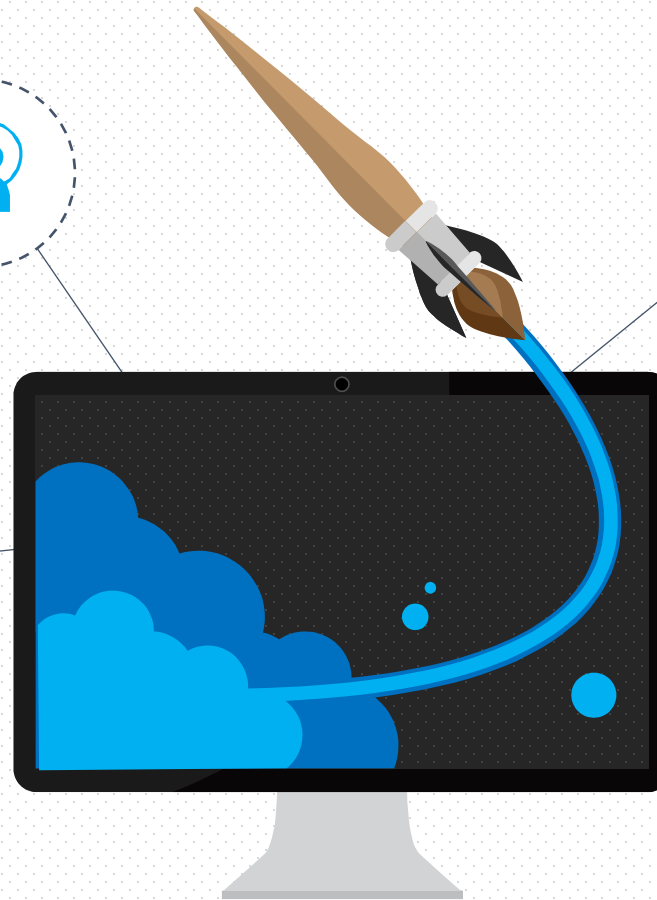
### VIAL CAPS

Aluminum-plastic vial caps, plastic vial caps, tear-off vial caps, flip-off vial caps.



### MASKS

Single-use Medical Mask (non-sterile)  
KN95 Mask, N95 Mask



# FACE MASK

## SINGLE-USE MEDICAL MASK (NON-STERILE)



Single-use Medical Mask (non-sterile)  
17.5\*9.5cm with ear loops

It is suitable for the public to wear in the indoor working environment where the personnel are relatively gathered; the general outdoor activities; and the short stay in the crowded place



GOVERNMENT REGISTRATION



ISO 13485:2016



ISO 15378:2017

# FACE MASK

## SINGLE-USE MEDICAL MASK (NON-STERILE)

河北省医疗器械与药品包装材料检验研究院  
检验报告

报告编号: 2020-Q-0576 S 共 1 页 第 1 页

| 检验项目                    | 标准条款           | 标准要求                      | 抽样方案 n/Ac | 检验结果                | 不合格品数 | 单项判定 |
|-------------------------|----------------|---------------------------|-----------|---------------------|-------|------|
| 外观                      | 2.1            | 口罩外观应整洁, 印迹完好, 表面不得有裂纹、污渍 | 3/0       | 符合要求                | 0     | 符合   |
| 结构尺寸 cm                 | 2.2            | 口罩佩戴好后, 应能罩住佩戴者的口、鼻及下巴    | 3/0       | 符合要求                | 0     | 符合   |
|                         |                | 尺寸                        |           | 17.5±0.5<br>9.5±0.5 |       |      |
| 鼻梁 cm                   | 2.3.1<br>2.3.2 | 口罩上应配有鼻梁, 鼻梁可用塑性材料制成      | 2/0       | 符合要求                | 0     | 符合   |
|                         |                | 鼻梁长度应不小于 5.0              |           | 11.7~11.9           |       |      |
| 口罩带                     | 2.4.1<br>2.4.2 | 口罩带应戴前方便                  | 3/0       | 符合要求                | 0     | 符合   |
|                         |                | 每侧口罩带与口罩体连接点处的断裂力应不小于 10N |           | 符合要求                |       |      |
| 透气阻力 Pa/cm <sup>2</sup> | 2.6            | 口罩两面进行气体交换的压力差不大于 49      | 3/0       | 45.9~49.0           | 0     | 符合   |

审核: 苏宁 检验: 郭永新

CERTIFICATE OF ANALYSIS

| TEST ITEM              | STANDARD CLAUSE | STANDARD REQUEST  | SAMPLING PLAN  | TEST RESULT          | UNQUALIFIED AMOUNT | SINGLE DECISION |
|------------------------|-----------------|---|----------------|----------------------|--------------------|-----------------|
| APPEARANCE             | 2.1             | FACE MASK APPEARANCE SHOULD BE CLEAN. SHAPE INTACT. THE SURFACE MUST NOT BE DAMAGED STAINS.                     | 3/0            | CONFORMITY           | 0                  | CONFORMITY      |
| CONSTRUCTION AND SIZE  | 2.2             | AFTER THE FACE MASK IS WORN, IT SHOULD COVER THE USER'S MOUTH.  | 3/0            | CONFORMITY           | 0                  | CONFORMITY      |
|                        |                 | SIZE  |                | 17.5-17.6<br>9.5-9.6 |                    |                 |
| NOSE STRIP             | 2.3.1<br>2.3.2  | FACE MASK SHOULD BE FITTED WITH NOSE STRIP MADE OF MALLEABLE MATERIAL.  | 3/0            | CONFORMITY           | 0                  | CONFORMITY      |
|                        |                 | NOSE STRIP LENGTH SHOULD NOT BE LESS THAN 5.0   |                | 11.7-11.9            |                    |                 |
| MASK BELT              | 2.4.1<br>2.4.2  | MASK BELT SHOULD BE EASY TO WEAR.   | 3/0            | CONFORMITY           | 0                  | CONFORMITY      |
|                        |                 | THE BREAKING FORCE AT THE CONNECTION POINT BETWEEN EACH MASK BELT AND THE MASK BODY SHOULD BE NO LESS THAN 10N. |                | CONFORMITY           |                    |                 |
| VENTILATION RESISTANCE | 2.6             | THE PRESSURE DIFFERENCE BETWEEN THE TWO SIDES OF THE MASK SHOULD NOT BE   | 3/0            | 45.9-49.0            | 0                  | CONFORMITY      |
| VERIFIER: MANJING      |                 |   | INSPECTOR: GAO |                      |                    |                 |

河北省医疗器械与药品包装材料检验研究院  
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报告编号: 2020-Q-0576 S 共 1 页 第 1 页

| 检验项目         | 标准条款 | 标准要求              | 抽样方案 n/Ac | 检验结果       | 不合格品数 | 单项判定 |
|--------------|------|-------------------|-----------|------------|-------|------|
| 细菌过滤效率 (BFE) | 2.5  | 口罩的细菌过滤效率应不小于 95% | —         | 最小值: 98.0% | —     | 符合   |
| 细菌菌落总数 CFU/g | 2.7  | ≤100              | —         | 4          | —     | 符合   |
|              |      | 不得检出              | —         | 未检出        | —     | 符合   |
| 大肠菌群         | 2.7  | 不得检出              | —         | 未检出        | —     | 符合   |
|              |      | 不得检出              | —         | 未检出        | —     | 符合   |
| 金黄色葡萄球菌      | 2.7  | 不得检出              | —         | 未检出        | —     | 符合   |
|              |      | 不得检出              | —         | 未检出        | —     | 符合   |
| 溶血性链球菌       | 2.7  | 不得检出              | —         | 未检出        | —     | 符合   |
|              |      | 不得检出              | —         | 未检出        | —     | 符合   |

审核: 高岩 检验: 郭永新

CERTIFICATE OF ANALYSIS

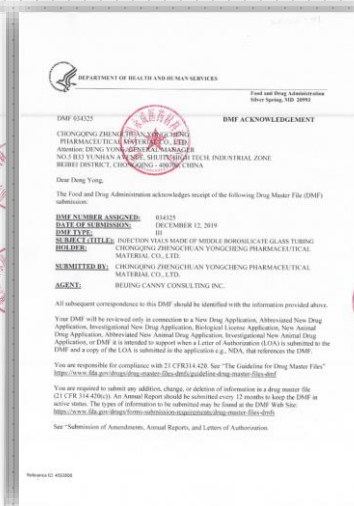
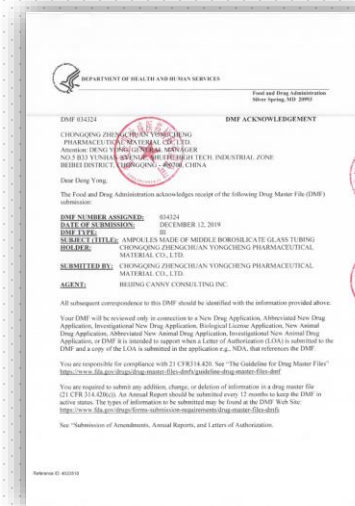
| TEST ITEM                          | STANDARD CLAUSE NO. | STANDARD REQUEST       | SAMPLING PLAN n/Ac | TEST RESULT  | UNQUALIFIED AMOUNT | SINGLE DECISION RESULT |
|------------------------------------|---------------------|------------------------|--------------------|--------------|--------------------|------------------------|
| BACTERIAL FILTRATION               | 2.5                 | ≥95%                   | —                  | MIN: 98.0%   | —                  | CONFORM                |
| TOTAL NUMBER OF BACTERIAL COLONIES | 2.7                 | SHOULD NOT BE DETECTED | —                  | 4            | —                  | CONFORMITY             |
|                                    |                     | SHOULD NOT BE DETECTED | —                  | NOT DETECTED | —                  | CONFORMITY             |
| MICROBIOLOGICAL INDICATOR          | 2.7                 | PSEUDOMONAS AERUGINOSA | —                  | NOT DETECTED | —                  | CONFORMITY             |
|                                    |                     | STAPHYLOCOCCUS AUREUS  | —                  | NOT DETECTED | —                  | CONFORMITY             |
| HEMOLYTIC STREPTOCOCCUS            | 2.7                 | SHOULD NOT BE DETECTED | —                  | NOT DETECTED | —                  | CONFORMITY             |
|                                    |                     | SHOULD NOT BE DETECTED | —                  | NOT DETECTED | —                  | CONFORMITY             |
| VERIFIER                           |                     | GAO DEYAN              | INSPECTOR          |              | SHI LIQIN          |                        |

EXAMINE REPORT

# PHARMACEUTICAL VIAL WITH VIAL CAPS OR RUBBER STOPPERS



ISO 15378



FDA DMF NO:034324 034325 034326

