



# Shandong INTCO Medical Products CO., LTD

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## Nitrile Examination Disposable Gloves Product Specification

| <b>Type</b>                           | Disposable Blue Nitrile Gloves, Powder free, Non Sterile, Ambidextrous |              |                            |                    |                 |                         |  |                     |                         |             |                               |             |                |  |
|---------------------------------------|--|--------------|----------------------------|--------------------|-----------------|-------------------------|--|---------------------|-------------------------|-------------|-------------------------------|-------------|----------------|--|
| <b>Grade</b>                          | Exam   |              | <b>Surface</b>             |                    |                 | Finger texture          |  |                     | <b>Glove Length(mm)</b> |             | 240±10                        |             |                |  |
| <b>Material</b>                       | NBR  |              | <b>Packing</b>             |                    |                 | 100pcs/box, 10boxes/ctn |  |                     | <b>Weight(g)</b>        |             | 3.5±0.3 (Medium Size)         |             |                |  |
|                                       |  |              |                            |                    |                 |                         |  |                     | <b>Powder Level</b>     |             | ≤2mg/glove ASTM D6124         |             |                |  |
| Product                               | Color  | Size         | Weight                     | Physical Dimension |                 |                         |  |                     | Physical Property       |             |                               |             |                | Appearance AQL                         |
|                                       |  |              |                            | Length (mm)        | Palm Width (mm) | Cuff Thickness (mm)     | Finger Thickness (mm)  | Palm Thickness (mm) | Tensile Strength(N)     |             | Elongation                    |             | Water Test AQL |  |
|                                       |  |              |                            |                    |                 |                         |  |                     | Before Aging            | After Aging | Before Aging                  | After Aging |                |  |
| Disposable Powder Free Nitrile Gloves | Blue   | S            | 3.0g±0.3                   | 240±10             | 80±10           | 0.05±0.03               | 30.10±0.03   | 30.08±0.03          | 6                       | 6           |                               |             |                | Critical AQL1.5 Major AQL2.5 Minor 4.0 |
|                                       |  | M            | 3.5g±0.3                   |                    | 95±10           |                         |  |                     |                         |             |                               |             |                |  |
|                                       |  | L            | 3.8g±0.3                   |                    | 110±10          |                         |  |                     |                         |             |                               |             |                |  |
|                                       |  | XL           | 4.0g±0.3                   |                    | 115±10          |                         |  |                     |                         |             |                               |             |                |  |
| No.                                   | sort   |              | Critical defects           |                    |                 |                         | Major defects  |                     |                         |             | Minor defects                 |             |                |  |
| 1                                     | torn   | big tearing  | √                          |                    |                 |                         | -  |                     |                         |             | -                             |             |                |  |
|                                       |  | scratch      | ≥3mm                       |                    |                 |                         | ≥2mm   |                     |                         |             | -                             |             |                |  |
|                                       |  | visible hole | ≥3mm                       |                    |                 |                         | ≥3mm   |                     |                         |             | -                             |             |                |  |
| 2                                     | dirt   | greasy dirt  | ≥3mm, serious              |                    |                 |                         | 1-2mm, visible   |                     |                         |             | <2mm, slightly                |             |                |  |
|                                       |  | yellow dirt  | √                          |                    |                 |                         | -  |                     |                         |             | -                             |             |                |  |
| 3                                     | black spots, impurities  |              | uncountable                |                    |                 |                         | ≥3mm or 0.5-3mm, >3/side   |                     |                         |             | 0.5-3mm, ≤3/side              |             |                |  |
| 4                                     | beading  |              | broken; torn; none-beading |                    |                 |                         | impurity; knot; black; bright PU ≥ 3mm; inward ≥ 10mm; minuteness (≤ |                     |                         |             | inward < 10mm; thin 0.5-0.8   |             |                |  |
| 5                                     | sticky   |              | -                          |                    |                 |                         | sticky cuff severely   |                     |                         |             | slightly                      |             |                |  |
| 6                                     | Extreme color variation  |              | entirely, severely         |                    |                 |                         | finger, cuff, severely   |                     |                         |             | cuff, slightly, inconspicuous |             |                |  |
| 7                                     | Bad smell  |              | -                          |                    |                 |                         | severely irritating smell  |                     |                         |             | slight odor                   |             |                |  |
| 8                                     | Embedded foreign particles   |              | insect, hair, etc.         |                    |                 |                         | -  |                     |                         |             | -                             |             |                |  |

We have established the Quality management system in accordance with ISO9001 and ISO 13485 standards

The certification which we have is 510K, CE certification, ISO9001 ISO13485

Sampling Procedures according to the standard of ISO2859, Inspection Level for physical dimensions and force /elongation at break is according to S-2, water test according to S-4