

## PRODUCT SPECIFICATION

### Powder-Free Nitrile Exam Gloves

Medical Device License a: 111315

Product: Non-Sterile, Ambidextrous, Finger-Textured Surface, Powder Free, Nitrile Exam Gloves, Latex Free

Color: Black

Product Code: 4101S / 4102M / 4103L / 4104XL / 4105XXL

Grade : AQL 1.5

Standard: ASTM D6319 and ASTM D6978 Chemotherapy Drugs Test

Thickness: 6 mil



| No                       | Test                   | Particular                                                                                                                                     |                         | Specification          | In-house Inspection Level / AQL |
|--------------------------|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------------------|---------------------------------|
| 1                        | Dimension (mm)         | Width                                                                                                                                          | Extra Small             | 75 ± 5                 | S2/AQL 4.0                      |
|                          |                        |                                                                                                                                                | Small                   | 85 ± 5                 |                                 |
|                          |                        |                                                                                                                                                | Medium                  | 95 ± 5                 |                                 |
|                          |                        |                                                                                                                                                | Large                   | 106 ± 5                |                                 |
|                          |                        |                                                                                                                                                | Extra Large             | 116 ± 5                |                                 |
|                          |                        |                                                                                                                                                | Extra Extra Large       | 125 ± 5                |                                 |
|                          |                        | Length                                                                                                                                         |                         | Min. 240               |                                 |
|                          |                        | Thickness (Single Wall)                                                                                                                        | Cuff (25 ± 5 from bead) | Min. 0.09              |                                 |
| Palm (center of palm)    | Min. 0.11              |                                                                                                                                                |                         |                        |                                 |
| Finger (13 ± 3 from tip) | Min. 0.15              |                                                                                                                                                |                         |                        |                                 |
| 2                        | Physical Properties    | Unaged (ASTM)                                                                                                                                  | Tensile Strength (MPa)  | Min. 18                | S2/AQL 4.0                      |
|                          |                        |                                                                                                                                                | Elongation at Break (%) | Min. 500               |                                 |
|                          |                        | Unaged (EN)                                                                                                                                    | Force at Break (N)      | Min. 6.0               | N = 13 (Median Value)           |
|                          |                        |                                                                                                                                                | Aged (ASTM)             | Tensile Strength (MPa) | Min. 14                         |
|                          |                        | Elongation at Break (%)                                                                                                                        |                         | Min. 400               |                                 |
|                          |                        | Aged (EN)                                                                                                                                      | Force at Break (N)      | Min. 6.0               | N = 13 (Median Value)           |
| 3                        | Freedom from Holes     |                                                                                                                                                |                         |                        | GI/AQL 1.5                      |
| 4                        | Visual Defects (Major) | Dirt ≥1mm², Sticky Pleat ≥5mm, Visible Hole (Non-Inflated), Discoloration, Mix Surface, Incomplete Beading, Wrong Orientation, Deformed Gloves |                         |                        | GI/AQL 2.5                      |
| 5                        | Visual Defects (Minor) | Lump <2mm², Dirt <1mm², Sticky Pleat <5mm, Poor Beading                                                                                        |                         |                        | GI/AQL 4.0                      |