

## METACURE SURGICAL GLOVES (M) SDN. BHD.

(Company Registration No. 202101029622)

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### PRODUCT STANDARD SPECIFICATIONS, PERFORMANCE & CONFORMANCE (PSPC)

#### KLEENHANDS NITRILE EXAMINATION GLOVES – POWDER-FREE

Kleenhands powder-free nitrile examination gloves are made from high quality nitrile, a synthetic copolymer; Acrylonitrile Butadiene, and are latex free, making them suitable for healthcare professionals and patients who experience Type 1 Allergic Reactions to natural rubber latex products.

These gloves have a low level of chemical residue, which in turn reduces the incidence of contact dermatitis (Type IV Allergic Reactions).

The unique formulation makes the gloves soft, ensuring flexibility and a comfortable fit.

The micro-textured surface provides an excellent grip.

#### Product Description

|                               |  |
|-------------------------------|--|
| <b>Type</b>                   | Nitrile Examination Glove- Disposable  |
| <b>Material</b>               | Nitrile Butadiene Rubber (NBR)   |
| <b>Color</b>                  | Natural White, Blue, Black   |
| <b>Design and Feature</b>     | Ambidextrous, beaded cuff, palm textured, finger textured  |
| <b>Donning Aid</b>            | Chlorinated / Polymer Coated   |
| <b>Product Classification</b> | FDA: 80LYY-880.6250 MDD: Class I   |
| <b>Powder Content</b>         | Max. 2.0 milligram/glove   |
| <b>Protein Content</b>        | N/A  |
| <b>Size Available</b>         | S, M, L, XL  |
| <b>Storage Condition</b>      | Product shall be stored under room condition, avoid direct sunlight                                    |
| <b>Shelf Life</b>             | Product shall have shelf life of 5 years from the date of manufacture with the above storage condition |
| <b>Packing Style</b>          | Fully Packed   |
| <b>Performance Standard</b>   | ASTM D-6319 EN 455-Part 1, 2 and 3   |

#### Physical Dimension - 3 mils, 240 mm / 9"

| Size                   | S             | M          | L       | XL      |
|------------------------|---------------|------------|---------|---------|
| <b>Ave width (mm)</b>  | 80±10         | 90±10      | 105±10  | 115±10  |
| <b>Ave weight (gm)</b> | 3.2±0.3       | 3.5±0.3    | 3.8±0.3 | 4.2±0.3 |
| <b>Length (mm)</b>     | Min 240       |            |         |         |
| <b>Thickness (mm)</b>  | <b>Cuff</b>   | 0.040±0.02 |         |         |
|                        | <b>Palm</b>   | 0.070±0.02 |         |         |
|                        | <b>Finger</b> | 0.080±0.02 |         |         |

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PERFORMANCE & CONFORMANCE (PSPC)****KLEENHANDS NITRILE EXAMINATION GLOVES – POWDER-FREE**

| <b>Physical Properties - ASTM</b> |                                 |                         |                         |                         |                         |                       |
|-----------------------------------|---------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-----------------------|
| Parameters                        | Before Aging                    |                         |                         | After Aging             |                         |                       |
|                                   | Tensile Strength (MPa)          | Elongation at break (%) | Modulus at 500% (MPa)   | Tensile Strength (MPa)  | Elongation at break (%) | Modulus at 500% (MPa) |
| MSGSB Result                      | 18 - 28                         | 650 - 750               | Max 2.8                 | 14 - 18                 | 500 - 650               | Max 2.8               |
| ASTM Requirement                  | Min 14                          | Min 650%                | Max 2.8                 | Min 14                  | Min 500%                | N/A                   |
| <b>Physical Properties - EN</b>   |                                 |                         |                         |                         |                         |                       |
| Parameters                        | Before Aging                    |                         | After Aging             |                         |                         |                       |
|                                   | Force at Break (N)              | Elongation at break (%) | Force at Break (N)      | Elongation at break (%) |                         |                       |
| MSGSB Result                      | 9.0 - 11.0                      | N/A                     | 6.0 - 10.0              | N/A                     |                         |                       |
| EN Requirement                    | Min 9 N                         | N/A                     | Min 6 N                 | N/A                     |                         |                       |
| <b>Chemical Analysis</b>          |                                 |                         |                         |                         |                         |                       |
| Requirement                       | Protein Content                 |                         | Powder Content          |                         |                         |                       |
|                                   | Powder Free                     |                         | Powder Free             |                         |                         |                       |
| MSGSB Result                      | N/A                             |                         | Below 2.0               |                         |                         |                       |
| ASTM requirement                  | N/A                             |                         | Max 2.0 milligram/glove |                         |                         |                       |
| <b>Performance</b>                |                                 |                         |                         |                         |                         |                       |
| Inspection                        | Related Defects                 | Inspection Level        |                         | AQL                     |                         |                       |
| Watertight Test                   | Holes                           | 0>                      |                         | 1.5                     |                         |                       |
| Visual Inspection                 | Major Defects                   |                         |                         | 2.5                     |                         |                       |
|                                   | Minor Defects                   |                         |                         | 4.0                     |                         |                       |
| Physical Properties               | Tensile Strength and Elongation | S-2                     |                         | 4.0                     |                         |                       |
| Physical Dimension                | Measurement                     | S-2                     |                         | 4.0                     |                         |                       |