

METACURE SURGICAL GLOVES (M) SDN. BHD.

(Company Registration No. 202101029622)

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**PRODUCT STANDARD SPECIFICATIONS,
PERFORMANCE & CONFORMANCE (PSPC)****KLEENHANDS LATEX EXAMINATION GLOVES – PRE-POWDERED**

Kleenhands powdered latex examination gloves serve to provide protection from unwanted or potentially dangerous substances for both healthcare professionals and patients.

These gloves are designed to provide maximum protection while still being economically affordable.

The all purpose gloves are dusted with USP Grade constarch for easy donning and doffing.

Product Description

| | | | |
|------------------------|---|------------------------|--|
| Type | Pre-powdered Latex Examination Gloves- Disposable | | |
| Material | Natural Rubber Latex (NR) | | |
| Color | Natural White, Off White | | |
| Design and Features | Ambidextrous, beaded cuff, smooth, finger textured, and palm textured | | |
| Donning Aid | Complies with USP Absorbable Dusting Powder | | |
| Product Classification | FDA: 80LYY-880.6250 | MDD: Class I | |
| Powder Content | Max. 15 milligram/dm ² | | |
| Protein Content | Max. 200 microgram/dm ² | | |
| Size Available | XS, S, M, L, XL, XXL | | |
| Storage Conditions | Product shall be stored under room conditions, avoid direct sunlight | | |
| Shelf Life | Product shall have a shelf life of 5 years from the date of manufacture with the above storage conditions | | |
| Packing Style | 100 pieces per inner box, 10 or 20 inners per carton | | |
| Performance Standard | ASTM D-3578 | EN 455-Part 1, 2 and 3 | |

Physical Dimension - 4 mils, 240 mm/9"

| Size | | XS | S | M | L | XL | XXL |
|-----------------|--------|-----------|---------|---------|---------|---------|---------|
| Ave width (mm) | | 78±2 | 85±5 | 95±5 | 106±5 | 113±5 | 120±5 |
| Ave weight (gm) | | 4.0±1.0 | 4.5±1.0 | 5.0±1.0 | 5.5±1.0 | 6.0±1.0 | 6.5±1.0 |
| Length (mm) | | Min 240 | | | | | |
| Thickness (mm) | Cuff | 0.07±0.02 | | | | | |
| | Palm | 0.09±0.02 | | | | | |
| | Finger | 0.10±0.03 | | | | | |

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| Physical Properties – ASTM | | | | |
|----------------------------|-----------------------------------|-------------------------|----------------------------------|-------------------------|
| Parameters | Before Aging | | After Aging | |
| | Tensile Strength (MPa) | Elongation at break (%) | Tensile Strength (MPa) | Elongation at break (%) |
| MSGSB Result | 18 - 22 | 650 - 750 | 14 - 18 | 500 - 700 |
| ASTM Requirement | Min 18 | Min 650% | Min 14 | Min 500% |
| | | | | |
| Physical Properties – EN | | | | |
| Parameters | Before Aging | | After Aging | |
| | Force at Break (N) | | Force at Break (N) | |
| MSGSB Result | 9.0 - 11.0 | | 6.0 - 9.0 | |
| EN Requirement | Min 9 N | | Min 6 N | |
| | | | | |
| Chemical Analysis | | | | |
| Requirement | Protein Content | | Powder Content | |
| | Pre-powdered | | Pre-powdered | |
| MSGSB Result | 100 - 160 | | Below 12 | |
| ASTM Requirement | Max 200 microgram/dm ² | | Max 15 milligram/dm ² | |
| | | | | |
| Performance | | | | |
| 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 | |