

PRODUCT SPECIFICATION

Latex Powderfree Polymer Examination Glove (Textured)

SECTION I: PRODUCT DESCRIPTION

- 1.1 Type Latex Examination Glove, **Powderfree**, **Polymer on-line**, Non-sterile
- 1.2 Material Natural High Grade Rubber Latex
- 1.3 Color • Off white to yellow
- 1.4 Design and Feature Ambidextrous, **textured**, beaded cuff
- 1.5 Powder No powder lubricant added
- 1.6 Storage Condition The gloves shall maintain their properties when stored in a dry condition. Avoid direct sunlight.
- 1.7 Shelf-Life The gloves shall have shelf life of 5 years from the date of manufacture with the above storage condition.
- 1.8 Packing Style 100 pcs gloves x 10 dispensers x 1 carton
- 1.9 Size Marking The size of gloves shall be marked in the check box on every carton with black ink.

SECTION II: PERFORMANCE REQUIREMENTS

(Sampling Plan – ISO 2859 Single Normal)

| # | Characteristics | Inspection Level | Acceptable Quality Level | Reference Standard |
|-------|---------------------------------------|------------------|--------------------------|--|
| 2.1 | Dimensions | S2 | 4.0 | ASTM D3578-05 |
| 2.2 | Physical Properties | S2 | 4.0 | ASTM D3578-05 |
| 2.3 | Freedom from holes (Water Tight Test) | GI | 2.5 | ASTM D3578- 05 FDA 1000MIL Test Method ASTM D5151-06 |
| 2.4 | Visual Defects: | | | |
| (i) | - Major Visual | GI | 2.5 | In-house practice |
| (ii) | - Minor Visual | | 4.0 | |
| 2.5 | Packaging Defects: | | | |
| (i) | Regulatory | GI | ** | In-house practice |
| (ii) | Visual | GI | 4.0 | |
| (iii) | Critical (incl. Gloves Counting) | S2 | 4.0 | |
| 2.6 | Powderfree Residue | N=5 | - | ASTM D3578-05 ASTM D6124-06 |
| 2.7 | Protein Content | N=3 | - | ASTM D3578-05 ASTM D5712-05 ^{e1} |
| 2.8 | Mix Size / Mix Glove / Mix Hand | Not Allowed | | |

**Unacceptable at any level

SECTION III: PERFORMANCE SPECIFICATION

3.1 Dimensions

| Description | Size | Standard |
|--------------------------------|-----------|---|
| Length (mm) | All Sizes | Min 240 |
| Palm Width (mm) | XS | 76 +/- 3 |
| | S | 84 +/- 3 |
| | M | 94 +/- 3 |
| | L | 105 +/- 3 |
| | XL | 113 +/- 3 |
| Thickness (mm) *single wall | All Sizes | Finger: 0.13 +/- 0.02 (5 mil) (Typical value: 0.12 – 0.15) Palm: 0.11 +/- 0.02 (4.3mil) (Typical value: 0.10 – 0.12) |

3.2 Physical Properties

| Description | Standard | |
|-------------------------|---------------------------------------|---------------------------------------|
| | Before Aging | After Aging |
| Elongation at break (%) | Min 650 (Typical value: 650 – 750) | Min 500 (Typical value: 500 – 650) |
| Tensile Strength (MPa) | Min 18 (Typical value: 18 – 24) | Min 14 (Typical value: 14 – 18) |

3.3 Freedom from holes

The sample size and allowable number of non-conforming gloves in the samples shall be determined in accordance to Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements.

3.4 Visual Inspection

The sample size and allowable number of non-conforming gloves in the samples for both major and minor defects shall be determined in accordance to Sampling Plan ISO 2859-1 Single Normal using Inspection and acceptable quality level as stated in Section II: Performance Requirements.

3.5 Packaging Defects

The Sample size and allowable number of non-conforming in sample for regulatory, visual and critical packaging defects shall be determined in accordance to Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements (Gloves Counting = 100 pcs by weight per Dispenser).

3.6 Powderfree Residue

Maximum 2 mg per glove

3.7 Protein Content

Maximum 100 g per dm²