

**TOP GLOVE SDN. BHD.**

## PRODUCT SPECIFICATION

### Latex Powdered Examination Glove Smooth

**SECTION I: PRODUCT DESCRIPTION**

1. 1	Type	Latex Examination Glove, Powdered, Non sterile
1. 2	Material	Natural High Grade Rubber Latex
1. 3	Color	Natural
1. 4	Design and Feature	Ambidextrous, smooth, beaded cuff
1. 5	Powder	Inside absorbable cornstarch USPXX1
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 D3578-19
2.2	Physical Properties	S2	4.0	ASTM D3578-19
2.3	Freedom from Holes Air Pump Test	GI	1.5	In house practice
2.4	Visual Defects:			
i	Major Visual	GI	2.5	In house practice
ii	Minor Visual		4.0	
2.5	Packaging Defects:			In house practice
i	Regulatory	GI	**	
ii	Visual	GI	4.0	
iii	Critical (incl. Gloves Counting)	S2	4.0	
2.6	Powder Amount	N=2	N/A	ASTM D3578-19 ASTM D6124-06 (2017)
2.7	Mix Size / Mix Glove / Mix Hand	Not	Allowed	

\*\*Unacceptable at any level

**TOP GLOVE SDN. BHD.****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: 0.10 +/- 0.02 Typical value: 0.08 to 0.11  Palm: 0.10 +/- 0.02 Typical value: 0.08 to 0.10

## 3.2 Physical Properties

Description	Standard	
	Before Aging	After Aging
Elongation at Break, %	Min 650 Typical value: 650 to 750	Min 500 Typical value: 500 to 700
Tensile Strength, MPa	Min 18 Typical value: 18 to 22	Min 14 Typical value: 14 to 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 Defects

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 the samples 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 count per Dispenser.

## 3.6 Powder Amount

Maximum 10 mg per dm<sup>2</sup>

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