

FLEXITECH SDN. BHD.

PRODUCT SPECIFICATION
Natural Rubber Latex Clean Room Glove (Textured)

SECTION I : PRODUCT DESCRIPTION

1. 1	Type	Natural Rubber Latex Clean Room Gloves
1. 2	Material	Natural High Grade Rubber Latex
1. 3	Particle Count	<ul style="list-style-type: none">• Class 1000 – 3,500 to 5,000 counts / cm² (particle sizes $\geq 0.5\mu\text{m}$)• Class 100 – < 1,500 counts / cm² (particle sizes $\geq 0.5\mu\text{m}$)
1. 4	Color (Pigment)	<ul style="list-style-type: none">▪ Natural White
1. 5	Design and Feature	Ambidextrous ,beaded cuff <ul style="list-style-type: none">• Textured
1. 6	Tackiness Surface	<ul style="list-style-type: none">• Tacky• Non Tacky
1. 7	Powder	No powder lubricant added
1. 8	Storage Condition	The gloves shall maintain their properties when stored in a dry condition at temperature between 10° C to 30°C. Avoid direct sunlight.
1. 9	Shelf-Life	The gloves shall have shelf life of 5 years from the date of manufacture with the above storage condition.
1. 10	Packing Style	10 bags per 1liner polybags packed in a shipping carton & 1000 gloves per shipping carton

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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 (Barrier) (Air Pump Test)	GI	1.5	In-house practice
2.4	Visual Defects:			
(i)	- Major Visual	G1	2.5	In-house practice
(ii)	- Minor Visual	G1	4.0	
2.5	Packaging Defects:			
(i)	Regulatory	S1	**	
(ii)	Visual	S1	2.5	In-house practice
(iii)	Critical (incl. Gloves Counting)	S1	2.5	
2.6	Protein Content	N = 5	-	ASTM D3578-05 ASTM D5712-99
2.7	Mix Size / Mix Glove / Mix Hand	Not	Allowed	
2.8	Liquid Particle Count	N = 3	-	IEST- RPCC005
2.9	Extractable Ionic Content	N= 1	-	IEST- RPCC005
3.0	Fourier Transform Infrared (FTIR)	N = 1	-	IEST- RPCC005

**Unacceptable at any level

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SECTION III: PERFORMANCE SPECIFICATION

3.1 Dimensions

Description	Size	Standard
Length (mm)	All Sizes	300 +/- 10
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: 0.16 +/- 0.02 (Typical value: 0.14 – 0.17) Palm : 0.14 +/- 0.02 (Typical value: 0.13 – 0.16)

3.2 Physical Properties

Description	Standard	
	Before Aging	After Aging
Elongation at break (%)	Min 650 (Typical value: 650 – 800)	Min 500 (Typical value: 600 – 700)
Tensile Strength (MPa)	Min 18 (Typical value: 18 – 24)	Min 14 (Typical value: 14 – 18)

3.3 Liquid Particle Count

Refer to Section I : Product Description 1.3 Particle Count

3.4 Extractable Contents (Ionic)

<u>EXTRACTABLE CONTENTS (IONIC)</u>	<u>CLASS 100 SPECIFICATION</u>	<u>CLASS 1000 SPECIFICATION</u>
Silicone	None	None
Amide	None	None
Phatalates	None	None
Fluoride (F ⁻)	< 0.030 µg/cm ²	N/A
Chloride (Cl ⁻)	< 2.000 µg/cm ²	N/A
Bromide (Br ⁻)	< 0.030 µg/cm ²	N/A
Nitrate (NO ₃ ⁻)	< 1.000 µg/cm ²	N/A
Phosphate (PO ₄ ³⁻)	< 0.030 µg/cm ²	N/A
Sulfate (SO ₄ ²⁻)	< 1.000 µg/cm ²	N/A
Lithium (Li ⁺)	< 0.002 µg/cm ²	N/A
Sodium (Na ⁺)	< 0.150 µg/cm ²	N/A
Ammonium (NH ₄ ⁺)	< 0.150 µg/cm ²	N/A
Potassium (K ⁺)	< 0.100µg/cm ²	N/A
Magnesium (Mg ²⁺)	< 0.010 µg/cm ²	N/A
Calcium (Ca ²⁺)	< 0.200 µg/cm ²	N/A

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3.5 Total Non Volatile Residue (NVR)

Description	Standard
Class 100	<2.5 µg/cm ²
Class 1000	N/A

3.6 Fourier Transform Infrared (FTIR)
No Silicone and Amide detected

3.7 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.

3.8 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.

3.9 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.

3.10 Protein Content

Maximum 50 µg/gm

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