

**FLEXITECH SDN BHD.**

**PRODUCT SPECIFICATION**  
**Nitrile Cleanroom Glove (Textured)**

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**SECTION I : PRODUCT DESCRIPTION**

- |      |                                                           |                                                                                                                                                                                                |
|------|-----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. 1 | Type                                                      | Nitrile Clean Room Gloves                                                                                                                                                                      |
| 1. 2 | Material                                                  | 100% Synthetic Nitrile Latex                                                                                                                                                                   |
| 1. 3 | Particle Count<br>(particle sizes $\geq 0.5\mu\text{m}$ ) | <ul style="list-style-type: none"><li>o Class 100 – <math>&lt; 2,500</math> counts / <math>\text{cm}^2</math></li><li>o Class 1000 – 3,500 to 5000 counts / <math>\text{cm}^2</math></li></ul> |
| 1. 4 | Color ( Pigment )                                         | <ul style="list-style-type: none"><li>o White</li></ul>                                                                                                                                        |
| 1. 5 | Design and Feature                                        | Ambidextrous ,beaded cuff <ul style="list-style-type: none"><li>o Textured</li></ul>                                                                                                           |
| 1. 6 | Tackiness Surface                                         | <ul style="list-style-type: none"><li>o Tacky</li><li>o Non Tacky</li></ul>                                                                                                                    |
| 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 $10^{\circ}\text{C}$ to $30^{\circ}\text{C}$ .<br>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.                                                                                     |

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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 D6319-00a <sup>E3</sup>
2.2	Physical Properties	S2	4.0	In-house standard
2.3	Freedom from Holes (Air Pump Test)	G1	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	**	In-house practice
(ii)	Visual	S1	2.5	
(iii)	Critical (incl. Gloves Counting)	S1	2.5	
2.6	Protein Content	N = 5	-	ASTM D6319-00a <sup>E3</sup> 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
3.1	Total Non Volatile Residue (NVR)	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: 0.15 +/- 0.02 (Typical value: 0.12 – 0.15)  Palm: 0.14 +/- 0.02 (Typical value: 0.11 – 0.14)

3.2 Physical Properties

Description	Standard	
	Before Aging	After Aging
Elongation at break (%)	Min 500 (Typical value: 500 - 600 )	Min 400 (Typical value: 400 - 500)
Tensile Strength (MPa)	Min 14 (Typical value: 14 – 18)	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)

<b><u>EXTRACTABLE CONTENTS (IONIC)</u></b>	<b><u>CLASS 100 SPECIFICATION</u></b>	<b><u>CLASS 1000 SPECIFICATION</u></b>
Silicone	None	None
Amide	None	None
Phatalates	None	None
Fluoride ( F <sup>-</sup> )	< 0.010 µg/cm <sup>2</sup>	N/A
Chloride ( Cl <sup>-</sup> )	< 0.300 µg/cm <sup>2</sup>	N/A
Bromide ( Br <sup>-</sup> )	< 0.050 µg/cm <sup>2</sup>	N/A
Nitrate ( NO <sub>3</sub> <sup>-</sup> )	< 0.300 µg/cm <sup>2</sup>	N/A
Phosphate ( PO <sub>4</sub> <sup>3-</sup> )	< 0.015 µg/cm <sup>2</sup>	N/A
Sulfate ( SO <sub>4</sub> <sup>2-</sup> )	< 0.050µg/cm <sup>2</sup>	N/A
Lithium ( Li <sup>+</sup> )	< 0.001 µg/cm <sup>2</sup>	N/A
Sodium ( Na <sup>+</sup> )	< 0.100 µg/cm <sup>2</sup>	N/A
Ammonium ( NH <sub>4</sub> <sup>+</sup> )	< 0.100 µg/cm <sup>2</sup>	N/A
Potassium ( K <sup>+</sup> )	< 0.100 µg/cm <sup>2</sup>	N/A
Magnesium ( Mg <sup>2+</sup> )	< 0.010 µg/cm <sup>2</sup>	N/A
Calcium ( Ca <sup>2+</sup> )	< 0.200 µg/cm <sup>2</sup>	N/A

3.5 Total Non Volatile Residue (NVR )

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

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- 3.6 Fourier Transform Infrared (FTIR)  
No Silicone and no Amide detected
- 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
- 3.6 Powderfree Residue  
Maximum 2 mg per glove

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