

FLEXITECH SDN. BHD.

PRODUCT SPECIFICATION
Nitrile Cleanroom Glove Finger Textured

SECTION I: PRODUCT DESCRIPTION

1. 1	Type	Nitrile Cleanroom Glove, Non sterile
1. 2	Material	100% Synthetic Nitrile
1. 3	Particle Count	Class 100, < 1500 counts / cm ² (particle sizes ≥ 0.5µm)
1. 4	Color	White
1. 5	Design and Feature	Ambidextrous, finger textured, beaded cuff
1. 6	Powder	No powder lubricant added
1. 7	Storage Condition	The gloves shall maintain their properties when stored in a dry condition. Avoid direct sunlight.
1. 8	Shelf Life	The gloves shall have shelf life of 5 years from the date of manufacture with the above storage condition.
1. 9	Packing Style	100 pcs gloves x 10 polybags x 1 carton
1. 10	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 D6319-19
2.2	Physical Properties	S2	4.0	ASTM D6319-19
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:			
i	Regulatory	GI	**	In-house practice
ii	Visual	GI	4.0	
iii	Critical incl. Gloves Counting	S2	4.0	
2.6	Powder Free Residue	N=5	N/A	ASTM D6319-19 ASTM D6124-06 (2017)
2.7	Mix Size / Mix Glove / Mix Hand	Not Allowed		

**Unacceptable at any level

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#	Characteristics	Inspection Level	Acceptable Quality Level	Reference Standard	
2.8	Liquid Particle Count	N=3	N/A	IEST- RPCC005	
2.9	Extractable Ionic Content	N=1	N/A	IEST- RPCC005	
3.0	Fourier Transform Infrared, FTIR	N=1	N/A	IEST- RPCC005	
3.1	Total Non Volatile Residue , NVR	C100	N=1	N/A	IEST- RPCC005

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 : 0.12 +/- 0.02 Typical value: 0.11 to 0.13 Palm : 0.08 +/- 0.02 Typical value: 0.08 to 0.09

3.2 Physical Properties

Description	Standard	
	Before Aging	After Aging
Elongation at Break, %	Min 500 Typical value: 500 to 600	Min 400 Typical value: 400 to 500
Tensile Strength, MPa	Min 14 Typical value: 14 to 18	Min 14 Typical value: 14 to 18

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3.3 Liquid Particle Count
Refer to Section I : Product Description 1.3 Particle Count

3.4 Extractable Contents, Ionic

EXTRACTABLE CONTENTS, IONIC	CLASS 100 SPECIFICATION
Silicone	None
Amide	None
Phthalates	None
Fluoride, F ⁻	< 0.010 µg/cm ²
Chloride, Cl ⁻	< 0.300 µg/cm ²
Bromide, Br ⁻	< 0.050 µg/cm ²
Nitrate, NO ₃ ⁻	< 0.300 µg/cm ²
Phosphate, PO ₄ ³⁻	< 0.015 µg/cm ²
Sulfate, SO ₄ ²⁻	< 0.050µg/cm ²
Lithium, Li ⁺	< 0.001 µg/cm ²
Sodium, Na ⁺	< 0.100 µg/cm ²
Ammonium, NH ₄ ⁺	< 0.100 µg/cm ²
Potassium, K ⁺	< 0.100 µg/cm ²
Magnesium, Mg ²⁺	< 0.010 µg/cm ²
Calcium, Ca ²⁺	< 0.200 µg/cm ²

3.5 Total Non Volatile Residue, NVR

Description	Standard
Class 100	<2.5 µg/cm ²

3.6 Fourier Transform Infrared, FTIR
No silicone and amide detected

3.7 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.

3.8 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.

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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, Gloves Counting=100 pcs by count per polybag.

3.10 Powder Free Residue

Maximum 2 mg per glove

Prepared by:
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