PS-NPFFT-EXA-USAW50 Rev: 0 (January 2012)

PRODUCT SPECIFICATION Nitrile Powderfree Examination Gloves (Finger Textured)

SECTION I: PRODUCT DESCRIPTION

1. 1 Type Nitrile Examination Glove, **Powderfree**, Non-sterile

1. 2 Material 100% Synthetic Nitrile Latex

1. 3 Color (Pigment) • Blue • Black

1. 4 Design and Feature Ambidextrous, **finger 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 D6319-00a ⁶³
2.2	Physical Properties	S2	4.0	ASTM D6319-00a ^{c3}
2.3	Freedom from Holes (Water Tight Test)	GI	2.5	FDA 1000MIL Test Method ASTM D6319-00a ^{c3}
2.4 (i) (ii)	Visual Defects: Major Visual Minor Visual	GI	1.5 2.5	In-house practice
2.5 (i) (ii) (iii)	Packaging Defects: Regulatory Visual Critical (incl. Gloves Counting)	GI GI S2	** 4.0 4.0	In-house practice
2.6	Powderfree Residue	N=5	-	ASTM D6319-00a ⁶³ ASTM D6124-06
2.7	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 S M L XL	76 +/- 3 84 +/- 3 94 +/- 3 105 +/- 3 113 +/- 3
Thickness (mm) *single wall	All Sizes	Finger: 0.12 -0.14 (5 mil) Palm: 0.08-0.09 (3.6 mil)

3.2 Physical Properties

5	Standard		
Description	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 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 weight per Dispenser).

3.6 Powderfree Residue Maximum 2 mg per glove

3.7 Protein Content Not Available

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