

GMP MEDICARE SDN. BHD.**PRODUCT SPECIFICATION****Nitrile Powder Free Disposable Gloves Finger Textured****SECTION I: PRODUCT DESCRIPTION**

1. 1	Type	Nitrile Disposable Glove, Powder Free, Online Single Chlorinated, Non sterile
1. 2	Material	100% Synthetic Nitrile Latex
1. 3	Color	Marlin Blue
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 D6319-10
2.2	Physical Properties	S2	4.0	ASTM D6319-10
2.3	Freedom from Holes Air Pump Test	GI	4.0	In house practice
2.4 i ii	Visual Defects: Major Visual Minor Visual	GI	6.5 6.5	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	Powder Free Residue	N=5	N/A	ASTM D6319-10 ASTM D6124-06 (2017)
2.7	Mix Size / Mix Glove / Mix Hand	Not Allowed		

**Unacceptable at any level

GMP MEDICARE 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: 0.10 to 0.12 Palm : 0.07 +/- 0.02 Typical value: 0.07 to 0.08

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 550
Tensile Strength, MPa	Min 14 Typical value: 14 to 18	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 Free Residue

Maximum 2 mg per glove

Prepared by:
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