

MATANG MANUFACTURING SDN BHD (172443-V)

Lot 10, Kawasan Perindustrian Serkam,
Mukim Serkam,
77300 Melimau,
Jasin, Melaka

PRODUCT SPECIFICATION

PRODUCT : ALOE VERA TEXTURED POWDER FREE LATEX EXAMINATION GLOVE

PRODUCT DESCRIPTION

PRODUCT TYPE : Textured Powder Free Latex Examination Gloves
STERILITY : Non-sterile
INTENDED USE : Medical Activities
MDD 93/42/EEC STATUS : Class I Medical Device
ORIENTATION : Ambidextrous
CUFF : Beaded end
COLOUR : Natural color
BASIC MATERIAL : Natural Rubber Latex
STORAGE CONDITION : Keep in Dry Cool Place, Avoid Ozone
SHELF LIFE : The gloves shall have shelf life of 3 years from the date of manufacturing with the above storage condition.
PACKAGING : 100 pieces per box, 10 boxes per case

GLOVE DIMENSION

SIZE	X-SMALL	SMALL	MEDIUM	LARGE	X-LARGE	TOLERANCE
Overall Length (mm)						
ASTM D 3578-05	220	220	230	230	Not Spec	min
EN 455-02:00	med ≥ 240	med ≥ 240	med ≥ 240	med ≥ 240	med ≥ 240	-
Matang Manufacturing	240	240	240	240	240	min
Width (mm)						
ASTM D 3578-05	60 – 80	70 – 90	85 – 105	101 – 121	Not Spec	-
EN 455-02:00	≤ 80	70 - 90	85 - 105	100 - 120	≥ 110	-
Matang Manufacturing	74 – 79	80 – 89	90 - 99	100 – 109	110 - 117	-
Thickness(mm) *single layer						
Palm (centre of palm)						
ASTM D 3578-05	0.08	0.08	0.08	0.08	0.08	min
EN 455-02:00	Not Spec	Not Spec	Not Spec	Not Spec	Not Spec	-
Matang Manufacturing	0.08	0.08	0.08	0.08	0.08	min
Finger(13 ± 3mm from tip)						
ASTM D 3578-05	0.08	0.08	0.08	0.08	0.08	min
EN 455-02:00	Not Spec	Not Spec	Not Spec	Not Spec	Not Spec	-
Matang Manufacturing	0.10	0.10	0.10	0.10	0.10	min

GLOVE PERFORMANCE

Tensile Properties	UNAGED		AGED (7 days @ 70° C)	
Specifications	ASTM D 3578-05	EN 455-2:00	ASTM D 3578-05	EN 455-2:00
Force at break (min), N	-	med ≥ 9	-	med ≥ 6
Tensile Strength (min), MPa	18	-	14	-
Elongation @ break (min), %	650	-	500	-

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TYPE : ALOEVERA TEXTURED POWDER FREE LATEX EXAMINATION GLOVE

QUALITY PERFORMANCE REQUIREMENT

Items	Standard Reference	Inspection Level	Acceptance Criteria
<u>Freedom from Holes</u>	ASTM D 3578-05 EN 455-1:00 Matang Manufacturing	G-1 G-1 G-1	AQL 2.5 AQL 1.5 AQL 1.5
<u>Visual Inspection:</u> <u>Major defect</u> <u>Minor defect</u>	In-house practice	G-1 G-1	AQL 2.5 AQL 4.0
<u>Dimensions</u>	ASTM D 3578-05 EN 455-2:00	S-2 N=13	AQL 4.0 Median value must comply
<u>Physical Properties</u>	ASTM D 3578-05 EN 455-2:00	S-2 N=13	AQL 4.0 Median value must comply
<u>Powder Free Residue</u>	ASTM D 3578-05	N = 5	Max: 2 mg/glove
<u>Protein Content</u>	ASTM D 3578-05	N = 3	Max: 50 µg/dm ²

LIST OF CHEMICALS INGREDIENTS

1. High Ammonia Latex
2. Zincdiethyldithiocarbamate (ZDEC)
3. Zincdibutyldithiocarbamate (ZDBC)
4. Zinc Oxide
5. Sulphur
6. Titanium Dioxide
7. Stabilizer
8. Antioxidant
9. Calcium Nitrate Ca(NO₃)₂
10. Calcium Carbonate (CaCO₃)