

Klinion Latex Exam Gloves Powder Free	Document number: 1206	
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### Particulars:

Standard:	Reference:
Specification	E2TD – Textured – Double Coated – Powder Free – Non Sterile
Packing Code Recommendations	01US
Standards conform to	EN 455 part 1 and 3
FDA 510(K) Notification no.:	510 K001529
Certification of Manufacture	ISO 9001:2008 certified by BSI Malaysia: FM 512209
Certification of Medical Manufacture	ISO 13485:2003 certified by BSI Malaysia: MD 512207

### Sampling Plan:

Defects:	Inspection Level:	AQL
Pinholes	Gen. Ins. Level I	1.5
Visual defects (major)	Gen. Ins. Level I	2.5
Visual defects (minor)	Gen. Ins. Level I	4.0
Physical Dimensions	N = 13	Median Value must comply
Physical Properties	N = 13	Median Value must comply

Major: Deformed glove – Dirt  $\geq 1\text{mm}^2$  – Discoloration – Double dipping – Folded finger – Incomplete beading – Lump  $\geq 2\text{mm}$  – Mixed Size – Mixed surface – Pigment – Powder mark – Residue beading – Roll cuff – Stain – Sticky  $\geq 5\text{mm}$  – Thin spot – Weak point – wet look – wrong orientation – yellowish  
Minor: Lump  $< 2\text{mm}$  – Dirt  $< 1,0\text{mm}^2$  – Sticky  $< 5\text{mm}$  – Blister – Poor Beading  
Powder  $< 2,0\text{mg/gloves}$

### Physical Dimensions in mm and Properties:

Size	Length Min.	Width Of Palm	Thickness Min.		
			Finger	Palm	Cuff
Xsmall	240	75 $\pm$ 5	0.10	0.10	0.08
Small	240	85 $\pm$ 5	0.10	0.10	0.08
Medium	240	95 $\pm$ 5	0.10	0.10	0.08
Large	240	106 $\pm$ 5	0.10	0.10	0.08
Xlarge	240	116 $\pm$ 5	0.10	0.10	0.08
Elongation				500% Min.	400% Min.
Shelf Life 3 Years		Protein $< 50\text{ }\mu\text{g/dm}^2$	Average Weight: 6.0 $\pm$ 0.2 gram M Size		

### 01US – Packing Details and External Dimensions in mm for 240 mm gloves:

Dimensions LxWxH in mm:	Packing per Unit:	Stacking per Unit:
Dispenser 243x123x74	5 layer of 20 pieces	100 pieces
Export Carton 380x253x253	Dispenser flat in Carton	10x100 pieces
20ft Container 5900x2340x2340	Carton 15 length 9 width 9 height	1,215 Cartons
40ft Container 12060x2340x2340	Carton 31 length 9 width 9 height	2,510 Cartons

### Percetakan Konta Sdn Bhd - Packing Material & Print Specification:

Dispenser:	Properties:
Thickness	0.59 mm
Weight of material	450 g/m <sup>2</sup>
Raw material base	Duplex Board / Grey Back
Type of printing ink used	Oil based offset ink
Type of lacquer / varnish used	Water based, Solvent Based
Export Carton:	Properties:
Thickness	3 mm
Weight of material	400 g/m <sup>2</sup>
Box quality Gram M <sup>2</sup> / Liner	200/150/200
Type of printing ink used	Water base