



Peha-Soft Powder Free Latex  
**Examination Gloves**

POWDER FREE



NON STERILE

## DATA SHEET CARADOC

### PEHA-SOFT POWDER FREE LATEX EXAMINATION GLOVES, NON-STERILE

Size	Product Part#	510K # / MDL #	Design and Feature	Type	Material	Color	Surface Treatment	Protein Content	Powder Free Residue (mg/glove)
XS S M L XL	145xx.100 21312	N/A	Ambidextrous, finger-textured surface (E4) and beaded cuff	Powder free and non-sterile examination gloves	Natural rubber latex	Natural (i.e. off white to yellow)	Chlorination	This latex glove contains 50 microgram or less of total extractable protein per gram	≤ 2

Dimension (mm)			Single-wall Thickness (mm)			Physical Properties (Before Aging)						
Size	Palm Width	Length	Finger	Palm	Cuff	Tensile Strength (MPa)		Elongation (%)		Force at Break (N)		pH
XS	≤ 80	Min. 240	0.19 ± 0.05	0.15 ± 0.05	Min. 0.10	Spec	Spec	Spec	Spec	Spec	Spec	7 ± 1
S	80 ± 10	Min. 240	0.19 ± 0.05	0.15 ± 0.05	Min. 0.10	Min. 21	Min. 16	Min. 700	Min. 500	≥ 6	≥ 6	
M	95 ± 10	Min. 240	0.19 ± 0.05	0.15 ± 0.05	Min. 0.10							
L	111 ± 10	Min. 240	0.19 ± 0.05	0.15 ± 0.05	Min. 0.10							
XL	≥ 110	Min. 240	0.19 ± 0.05	0.15 ± 0.05	Min. 0.10							

Packing Mode	Glove Marking	Lot # identification on Finished Goods	Recommended Shelf Life	Pre-shipment Inspection <i>*Single - Normal Sampling plan</i>	
*100 gloves (by weight per dispenser)  *10 dispensers per carton / shipping case	No Marking	Lot No. is generated online by Hartmann Lot Based Labelling Software	3 years upon manufactured date	Dimension	N=13, Median
				Physical Properties	N=13, Acceptance no.: 1, Rejection no.: 2
				1000ml Water Leak	G-I, AQL 1.5
				Protein Content	N=8
				Powder Free Residue	N=5
				Major Visual Inspection	G-I, AQL 2.5
				Minor Visual Inspection	G-I, AQL 4.0

#### PRODUCT CONFORMANCE:

- Medical Device: In compliance with European MDR (EU) 2017/745 (CE CLASS II)
- EN455 Parts 1, 2, 3 and 4

#### QUALITY ASSURANCE:

- US FDA Quality System Regulation (QSR)
- ISO9001:2015 Quality Management Systems
- ISO13485:2016 and EN ISO13485:2016 Quality Management Systems



- No unpleasant odor
- Powder free to eliminate powder-induced irritation and dermatitis
- Meets or exceeds EN455-2
- Resists permeation by a wider range of chemical than natural rubber latex of the same thickness
- Superior strength and puncture resistance
- Beaded cuff ensures easy donning and helps prevent roll down

**MEDI-KNIGHT Mediknight Glove Sdn Bhd** (421629-M)

No. 33, Lorong Sungai Puloh 10/KU6, Kawasan Perindustrian Sungai Puloh, 42100 Klang, Selangor Darul Ehsan, Malaysia

Office: +60-1-7533 8832

Email: stephen@mediknightglove.com

Distributed by: