



SHIJIAZHUANG HONGRAY GROUP

South Tongda Rd., East Dist. Jinzhou City Hebei, 052260, China

PRODUCT SPECIFICATION SHEET

GLOVE SPECIFICATION

Product Specification Group Code: VGPF1001-1005, XS-XL

Product Name: Vinyl Examination Glove, Powder Free, Non-sterile, EU Spec, Medical Grade/PPE Grade

GENERAL INFORMATION

Type: Single-use disposable examination or protective glove

Shape: Ambidextrous

Material: Synthetic Vinyl

Cuff: Rolled cuff

Surface: Smooth

Thickness:

Single wall according to ASTM D5250, ASTM D3767	Palm: Min. 0.08mm	Finer: Min. 0.08mm
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Residual Powder: (according to EN 455-3)	Max. 2.0mg/glove
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Force at break: (according to EN 455-2)	Before Aging: Med. $\geq 3.6\text{N}$ After Aging: Med. $\geq 3.6\text{N}$
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Length: (according to EN 455-2)	XS-XL: Med. $\geq 240\text{mm}$
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Tensile Strength: (according to ASTM D 5250, ASTM D412, ASTM D573)	Before Aging: Min. 12Mpa After Aging: Min. 12Mpa
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Elongation %: (according to ASTM D 5250, ASTM D412, ASTM D573)	Before Aging: Min. 300% After Aging: Min. 300%
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Available Sizes & Palm width (mm): (according to EN 455-2)

XS: 75 \pm 5 S: 85 \pm 5 M: 95 \pm 5 L: 105 \pm 5 XL: 115 \pm 5

Storage: 3 years storage life (date of expiration see on the box). Store in a cool, dry place. Shield open box from direct sunlight, fluorescent lighting or x-rays.

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INITIALED DATE: 2021.10.25

REVISION DATE: N/A

REVISION TIMES: 0



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STANDARDS, GUIDELINES AND QUALITY CERTIFICATION

(Every mentioned standard is used in the latest edition)

Certification:	ISO 9001, ISO13485	
Conformity to guidelines:	Medical Device Regulation (EU) 2017/745: Class I under Rule 1 and Rule 5 according to Annex VIII (Subject to EU Declaration of Conformity)	
	Personal Protective Equipment Regulation (EU) 2016/425: Category III (Subject to EU Type-Examination Certificate)	
Conformity to standards:	Medical EN455 ASTM D5250	PPE CAT III EN ISO21420 EN ISO374 EN 16523-1
Conformity to food regulation:	(EU) No 10/2011	

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