



SHIJIAZHUANG HONGRAY GROUP

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

PRODUCT SPECIFICATION SHEET

GLOVE SPECIFICATION

Product Specification Group Code: **NPF4001-4005, XS-XL**

Product Name: Nitrile Examination Glove, Powder Free, Non-sterile, Medical Grade, M/5.0g, Black

GENERAL INFORMATION

Type: Single-use disposable examination glove

Shape: Ambidextrous

Material: Synthetic Nitrile Latex

Cuff: Rolled cuff

Surface: Full Textured

Thickness:

Single wall according to ASTM D6319, ASTM D3767	Palm: Min. 0.09mm	Finer: Min. 0.11mm
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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. $\geq 6.0N$ After Aging: Med. $\geq 6.0N$
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Length: (according to EN 455-2)	XS-XL: Med. $\geq 240mm$
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Tensile Strength: (according to ASTM D 6319, ASTM D412, ASTM D573)	Before Aging: Min. 14Mpa After Aging: Min. 14Mpa
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Elongation %: (according to ASTM D 6319, ASTM D412, ASTM D573)	Before Aging: Min. 500% After Aging: Min. 400%
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Available Sizes & Palm width (mm): (according to EN 455-2)

XS: 70 \pm 10 S: 80 \pm 10 M: 95 \pm 10 L: 110 \pm 10 XL: 120 \pm 10
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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)
Conformity to standards:	Medical EN455 ASTM D6319

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