



SHIJIAZHUANG HONGRAY GROUP

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

PRODUCT SPECIFICATION SHEET

GLOVE SPECIFICATION

Product Specification Group Code: **NPF3001-3005, XS-XL**

Product Name: Nitrile Examination Glove, Powder Free, Chlorinated, Non-sterile, Medical Grade/PPE Grade, M/3.5g

GENERAL INFORMATION

Type: Single-use disposable examination or protective glove

Shape: Ambidextrous

Material: Synthetic Nitrile Latex

Cuff: Rolled cuff

Surface: Textured at Finger Tip

Thickness:

Single wall according to ASTM D6319, ASTM D3767 Palm: Min. 0.06mm Finer: Min. 0.08mm

Residual Powder:
(according to EN 455-3) Max. 2.0mg/glove

Force at break:
(according to EN 455-2) Before Aging: Med. $\geq 6.0N$
After Aging: Med. $\geq 6.0N$

Length:
(according to EN 455-2) XS-XL: Med. $\geq 240mm$

Tensile Strength:
(according to ASTM D 6319,
ASTM D412, ASTM D573) Before Aging: Min. 14Mpa
After Aging: Min. 14Mpa

Elongation %:
(according to ASTM D 6319,
ASTM D412, ASTM D573) Before Aging: Min. 500%
After Aging: Min. 400%

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

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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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 D6319	PPE CAT III EN ISO21420 EN ISO374 EN 16523-1
Conformity to food regulation:	AP (2004) 4, (EU) No 10/2011	

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