

GLOVE SPECIFICATION**SETINO**[®]

Product Specification Group Code:
 Product Code: NPF4001-4005 BLACK 3,5G
 Product name: NITRILE EXAMINATION AND PROTECTIVE GLOVES 3,5G POWDERFREE, NON STERILE, CHLORINATED
 Grade: EU Spec, Medical Grade

**NPF4001-4005
 BLACK 3.5G**

GENERAL INFORMATION:

Type: Single Use
 Marking: Gloves are not marked to designated size.
 Shape: Ambidextrous
 Material: Nitrile
 Cuff: Rolled off
 Surface: Textured at finger tip

Thickness: (single wall according to ASTM D3578, ASTM D3767)	Finger: Min. 0.07mm	Palm: Min. 0.06mm
Residual Powder: (according to EN 455-3, EN ISO 21171)	Max. 2mg/glove, PowderFree	Force at break: (according to EN 455-2)
Protein Content: (according to EN 455-3)	0. ug/g	Tensile Strength: (according to ASTM D3578, ASTM D412, ASTM D573)
Length: (according to EN 455-2)	Min. 240mm	% Elongation: (according to ASTM D3578, ASTM D412, ASTM D573)
Available Sizes & Palm Width (mm): (according to EN 455-2)	XS ≤ 80, S: 80+/-10, M:95+/-10, L:110+/-10, XL: 120+/-10	
		Before Aging: min. 6N After Aging: min 6N
		Before Aging: Min. 14Mpa After Aging: Min. 14Mpa
		Before Aging: min. 500% After Aging: min. 400%

Storage: 3 years storage life (date of expiration see on the box). Keep area cool, dry and dust free, avoid ventilation and storage close to photocopy equipment. Copper-ions discolor the glove. Protect gloves against ultraviolet light sources, as sunlight and oxidizing agents. Storage above 30°C will lead to accelerated aging and should be avoided.

STANDARDS, GUIDELINES AND QUALITY CERTIFICATION

(Every mentioned standard is used in the latest edition.)

Certification :	ISO 9001, ISO 13485, ISO 45001, ISO 14001		
Conformity to guidelines :	Medical Device Regulation (EU)2017/745 - Class I under Rule1 and Rule 5 according to Annex VIII (Subject to EU Declaration of Conformity to brand owner) Personal Protective Equipment Regulation (EU) 2016/425 - Category I or Category III (Subject to EU Type-Examination Certificate)		
Conformity to standards :	<u>Medical</u>	<u>PPE</u>	<u>PPE</u>
	EN 455	CAT I	CAT III
	ASTM D3578	EN 420	EN 420
			EN 374
			EN 16523-1
Conformity to food regulation :	1925/2004		

Please report any incidents with the products to contact@setino.com without undue delay. Our Product Safety Officers will review all information provided and might contact the original informant for further clarification