#### **Product : Powder Free Nitrile Examination Gloves**

### Brand : nitrylex<sup>\*</sup> sterile, proHAND<sup>\*</sup>PF NITRILE

RANGE OF SIZES	:	Small, Medium, Large & X-Large
PPE REFERENCE	:	This disposable medical device is made up of synthetic rubber latex which is ambidextrous, intended to be used for conducting medical examination, diagnostic and therapeutic procedures, provides barrier against potentially infectious materials and other contaminants.

REGULATORY REQUIREMENT: Regulation (EU) 2016/425 PICTOGRAMS :

Sl. No **Pictograms Description of Pictograms** CE 0598 is the identification number of SGS notified body € 0598 1. SGS Fimko Oy, Takomotie 8, FI-00380 Helsinki, Finland. It refers to the Instruction for use as per EN 420 : 2003 + EN 420:2003 + A1.2009 A1.2009 Protective gloves -Status/Performance level General Requirements 2. Sizing Small, Medium, Large & X-Large Performance Level 5 Dexterity pH Value Pass Low chemical resistance pictogram for gloves EN 16523-1:2015 Resistance to Permeation by Status/ Performance level **Chemicals** Class 1 n-Heptane 3. Class 6 Sodium Hydroxide 40% Hydrogen Peroxide 30% Class 1 Formaldehyde 37% Class 2

Sl. No	Pictograms	Description of Pictograms						
		It refers to the Instruction for use as per EN 420 : 2003 + A1.2009						
		Protective gloves – General Requirements	Status/Perform	Status / Performance level				
		Sizing	Small, Medium, Large	Large & X-				
	EN 374-1:2016 / Type C	Dexterity	Performance	Level 5				
		pH Value	Pass					
	J II	Tested for protection against liquid penetration and Micro organism						
4.	JKPT	Resistance to Penetration	Status / Perfor level	rmance				
		Air Leakage	Pass					
		Water Leakage	Pass					
	EN 274 2-2014	Resistance to Permeation         by Chemicals         n-Heptane       Sodium Hydroxide 40%         Hydrogen Peroxide 30%       Formaldehyde 37%	Status / Perfo level Class 1 Class 1 Class 1 Class 2	prmance				
	EN 374-2:2014	Tested for protection agains organism	st liquid penetratio	n and Micro				
5.	LEVEL 2	Resistance to Penetration	Status / Perform level	nance				
		All Leakage	Pass					
		Desister as to desire detined	Pass					
6		Kesistance to degradation by Chemicals.						
	EN 374- 4 : 2013	Resistance to Degradation by Chemicals	Observation	Result in %				
		n-Heptane	Slight swelling	45.9				
		Sodium Hydroxide 40%	No Change	-5.5				
		Hydrogen Peroxide 30%	Slight swelling	31.1				
		Formaldehyde 37%	Slight swelling	21.4				

Sl. No	Pictograms	Description of Pictograms						
		It refers to the Instruction for use as per EN 420 : 2003 + A1.2009						
		Protective gloves – General Reauirements				Status/Performance level		
	EN 374-5-2016	Sizing				Small, Medium, Large & X- Large		
			Dexteritu			Performance Level 5		
	A		pH Value			<u> </u>	Pass	
	(322)	Tested fo	r protection	າລອ	ainst lie	nuid nene	etration a	nd Micro
		organism	i protectioi	ug	amstin	fuid perk		ite micro
7.	VIRUS				[			
		Resistance to			Stat	Status / Performance level		
		Penetration				P		
		Air Leakage				Puss Dass		
		Protection against virus:						
		Test Article Number	Concentration (PFU/mL)	Cor (F	PFU/mL)	Assay Titer (PFU/mL)	Visual Penetration	Test Result
		1-3	1.6 x 10 <sup>8</sup>	1	.3 x 10 <sup>8</sup>	<1 <sup>a</sup>	None Seen	Pass
		Negative Contro Positive Control	I 1.6 x 10° 1.6 x 10 <sup>8</sup>	1	.3 x 10° .3 x 10 <sup>8</sup>	<1" TNTC <sup>b</sup>	None Seen Yes	Acceptable Acceptable
		<sup>a</sup> A value of <1 plaque forming unit (PFU)/mL is reported for assay plates showing no plaques. <sup>b</sup> TNTC = PFUs were too numerous to count.						es.
8.	EN 388	Sl. No.	Mechanical characteristics		cal stics	Status / Performance level		
		<i>a</i> )	Abrasion Resistance		ince	pe Performance Level ()		
		h)	Blade cut Resistance		ince	Performance Level 0		
		c)	Tear Resistance			Performance Level 0		
		<i>d</i> )	Puncture Resistance			Performance Level 0		
9.	The user information r	nentioned	in our label	ls				

Recommended use of the gloves :

- 1) Do not resterilize.
- 2) The product contains Synthetic Rubber Latex.
- 3) Dry hands thoroughly before donning.
- 4) Do not use package is damaged or wet.
- 5) Risk of reuse: Do not reuse, reuse can cause cross infection and compromise safety.
- 6) Storage information :

Keep away from Sunlight.

Store in cool dry place, away from direct light & Ozone.

- 7) "Gloves shall not be worn where there is a risk of entanglement by moving parts of machines" is needed.
- 8) Dexterity performance level is 5.
- 9) Intended Usage : To be worn on hands usually in surgical settings\patient examinations to provide barrier against potentially infectious fluids and other contaminants.
- 10) Expiration Period : 3 years
- 11) The results do not reflect the actual duration of protection in the workplace due to other factors influencing the performance, such as temperature, abrasion, degradation etc.

#### **Glove Opening and Donning Procedure**

- (a) Remove the Walleted gloves (inner wrapper) from the Pouch (outer wrapper).
- (b) Open the Walleted glove to see "Left" and "Right" compartment.
- (c) Pinch back upper and lower flaps of the inner wrapper.
- (d) Using the middle flaps, open the wrapper touching only the 1 inch margin for safety.
- (e) Be sure wrapper does not close over gloves after opening to avoid contamination.
- (f) Using the thumb and the first two fingers of the non-dominant hand, pinch the cuff of the folded edge of the glove cuff for the dominant hand, touching only the inside surface of the glove.
- (g) Slide dominant hand in to the gloves keeping hand point downwards and pull up to wrist.
- (h) Using the glove hand insert the 4 fingers under the cuff of the other glove and pull the glove up to the arm.
- (i) Adjust the gloves as necessary.

### **Glove Removal Procedure:**

- (a) Take hold of the first glove at the wrist.
- (b) Fold it over and peel it back, turning it inside out as it goes. Once the glove is off, hold it with your gloved hand.
- (C) To remove the other glove, place your bare fingers inside the cuff without touching the glove exterior. Peel the glove off from the inside, turning it inside out as it goes. Use it to envelope the other glove.

### <u>Warnings:</u>

Sl. No	Pictograms	Description of Pictograms
1.	EN 374-1:2016/ Type C L J K PT	This information does not reflect the actual duration of protection in the work place and the differentiation between mixtures and pure chemicals. The Chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400mm – where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture' It is recommended to check that the gloves are suitable for the intended use because the conditions at the work place may differ from the type test depending on temperatures, abrasion and degradation When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc., may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves. Before usage, inspect the gloves for any defect or imperfections. For Single use only.
2.	EN 374-5:2016	The Penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.