

Product : Powder Free Nitrile Examination Gloves



Brand : nitrylex® sterile , proHAND® 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										
1.		CE 0598 is the identification number of SGS notified body SGS Fimko Oy, Takomotie 8, FI-00380 Helsinki, Finland.										
2.	EN 420:2003 + A1.2009 	It refers to the Instruction for use as per EN 420 : 2003 + A1.2009 <table border="1"> <thead> <tr> <th><i>Protective gloves - General Requirements</i></th> <th><i>Status/Performance level</i></th> </tr> </thead> <tbody> <tr> <td><i>Sizing</i></td> <td><i>Small, Medium, Large & X-Large</i></td> </tr> <tr> <td><i>Dexterity</i></td> <td><i>Performance Level 5</i></td> </tr> <tr> <td><i>pH Value</i></td> <td><i>Pass</i></td> </tr> </tbody> </table>	<i>Protective gloves - General Requirements</i>	<i>Status/Performance level</i>	<i>Sizing</i>	<i>Small, Medium, Large & X-Large</i>	<i>Dexterity</i>	<i>Performance Level 5</i>	<i>pH Value</i>	<i>Pass</i>		
<i>Protective gloves - General Requirements</i>	<i>Status/Performance level</i>											
<i>Sizing</i>	<i>Small, Medium, Large & X-Large</i>											
<i>Dexterity</i>	<i>Performance Level 5</i>											
<i>pH Value</i>	<i>Pass</i>											
3.	EN 16523-1 : 2015	Low chemical resistance pictogram for gloves <table border="1"> <thead> <tr> <th><i>Resistance to Permeation by Chemicals</i></th> <th><i>Status/Performance level</i></th> </tr> </thead> <tbody> <tr> <td><i>n-Heptane</i></td> <td><i>Class 1</i></td> </tr> <tr> <td><i>Sodium Hydroxide 40%</i></td> <td><i>Class 6</i></td> </tr> <tr> <td><i>Hydrogen Peroxide 30%</i></td> <td><i>Class 1</i></td> </tr> <tr> <td><i>Formaldehyde 37%</i></td> <td><i>Class 2</i></td> </tr> </tbody> </table>	<i>Resistance to Permeation by Chemicals</i>	<i>Status/Performance level</i>	<i>n-Heptane</i>	<i>Class 1</i>	<i>Sodium Hydroxide 40%</i>	<i>Class 6</i>	<i>Hydrogen Peroxide 30%</i>	<i>Class 1</i>	<i>Formaldehyde 37%</i>	<i>Class 2</i>
<i>Resistance to Permeation by Chemicals</i>	<i>Status/Performance level</i>											
<i>n-Heptane</i>	<i>Class 1</i>											
<i>Sodium Hydroxide 40%</i>	<i>Class 6</i>											
<i>Hydrogen Peroxide 30%</i>	<i>Class 1</i>											
<i>Formaldehyde 37%</i>	<i>Class 2</i>											

Sl. No	Pictograms	Description of Pictograms																								
4.	<p>EN 374-1:2016 / Type C</p> <p>JKPT</p>	<p>It refers to the Instruction for use as per EN 420 : 2003 + A1.2009</p> <table border="1"> <thead> <tr> <th><i>Protective gloves - General Requirements</i></th> <th><i>Status / Performance level</i></th> </tr> </thead> <tbody> <tr> <td><i>Sizing</i></td> <td><i>Small, Medium, Large & X-Large</i></td> </tr> <tr> <td><i>Dexterity</i></td> <td><i>Performance Level 5</i></td> </tr> <tr> <td><i>pH Value</i></td> <td><i>Pass</i></td> </tr> </tbody> </table> <p>Tested for protection against liquid penetration and Micro organism</p> <table border="1"> <thead> <tr> <th><i>Resistance to Penetration</i></th> <th><i>Status / Performance level</i></th> </tr> </thead> <tbody> <tr> <td><i>Air Leakage</i></td> <td><i>Pass</i></td> </tr> <tr> <td><i>Water Leakage</i></td> <td><i>Pass</i></td> </tr> </tbody> </table> <p>Low chemical resistance pictogram for gloves</p> <table border="1"> <thead> <tr> <th><i>Resistance to Permeation by Chemicals</i></th> <th><i>Status / Performance level</i></th> </tr> </thead> <tbody> <tr> <td><i>n-Heptane</i></td> <td><i>Class 1</i></td> </tr> <tr> <td><i>Sodium Hydroxide 40%</i></td> <td><i>Class 6</i></td> </tr> <tr> <td><i>Hydrogen Peroxide 30%</i></td> <td><i>Class 1</i></td> </tr> <tr> <td><i>Formaldehyde 37%</i></td> <td><i>Class 2</i></td> </tr> </tbody> </table>	<i>Protective gloves - General Requirements</i>	<i>Status / Performance level</i>	<i>Sizing</i>	<i>Small, Medium, Large & X-Large</i>	<i>Dexterity</i>	<i>Performance Level 5</i>	<i>pH Value</i>	<i>Pass</i>	<i>Resistance to Penetration</i>	<i>Status / Performance level</i>	<i>Air Leakage</i>	<i>Pass</i>	<i>Water Leakage</i>	<i>Pass</i>	<i>Resistance to Permeation by Chemicals</i>	<i>Status / Performance level</i>	<i>n-Heptane</i>	<i>Class 1</i>	<i>Sodium Hydroxide 40%</i>	<i>Class 6</i>	<i>Hydrogen Peroxide 30%</i>	<i>Class 1</i>	<i>Formaldehyde 37%</i>	<i>Class 2</i>
<i>Protective gloves - General Requirements</i>	<i>Status / Performance level</i>																									
<i>Sizing</i>	<i>Small, Medium, Large & X-Large</i>																									
<i>Dexterity</i>	<i>Performance Level 5</i>																									
<i>pH Value</i>	<i>Pass</i>																									
<i>Resistance to Penetration</i>	<i>Status / Performance level</i>																									
<i>Air Leakage</i>	<i>Pass</i>																									
<i>Water Leakage</i>	<i>Pass</i>																									
<i>Resistance to Permeation by Chemicals</i>	<i>Status / Performance level</i>																									
<i>n-Heptane</i>	<i>Class 1</i>																									
<i>Sodium Hydroxide 40%</i>	<i>Class 6</i>																									
<i>Hydrogen Peroxide 30%</i>	<i>Class 1</i>																									
<i>Formaldehyde 37%</i>	<i>Class 2</i>																									
5.	<p>EN 374-2:2014</p> <p>LEVEL 2</p>	<p>Tested for protection against liquid penetration and Micro organism</p> <table border="1"> <thead> <tr> <th><i>Resistance to Penetration</i></th> <th><i>Status / Performance level</i></th> </tr> </thead> <tbody> <tr> <td><i>Air Leakage</i></td> <td><i>Pass</i></td> </tr> <tr> <td><i>Water Leakage</i></td> <td><i>Pass</i></td> </tr> </tbody> </table>	<i>Resistance to Penetration</i>	<i>Status / Performance level</i>	<i>Air Leakage</i>	<i>Pass</i>	<i>Water Leakage</i>	<i>Pass</i>																		
<i>Resistance to Penetration</i>	<i>Status / Performance level</i>																									
<i>Air Leakage</i>	<i>Pass</i>																									
<i>Water Leakage</i>	<i>Pass</i>																									
6.	<p>EN 374- 4 : 2013</p>	<p>Resistance to degradation by Chemicals.</p> <table border="1"> <thead> <tr> <th><i>Resistance to Degradation by Chemicals</i></th> <th><i>Observation</i></th> <th><i>Result in %</i></th> </tr> </thead> <tbody> <tr> <td><i>n-Heptane</i></td> <td><i>Slight swelling</i></td> <td><i>45.9</i></td> </tr> <tr> <td><i>Sodium Hydroxide 40%</i></td> <td><i>No Change</i></td> <td><i>-5.5</i></td> </tr> <tr> <td><i>Hydrogen Peroxide 30%</i></td> <td><i>Slight swelling</i></td> <td><i>31.1</i></td> </tr> <tr> <td><i>Formaldehyde 37%</i></td> <td><i>Slight swelling</i></td> <td><i>21.4</i></td> </tr> </tbody> </table>	<i>Resistance to Degradation by Chemicals</i>	<i>Observation</i>	<i>Result in %</i>	<i>n-Heptane</i>	<i>Slight swelling</i>	<i>45.9</i>	<i>Sodium Hydroxide 40%</i>	<i>No Change</i>	<i>-5.5</i>	<i>Hydrogen Peroxide 30%</i>	<i>Slight swelling</i>	<i>31.1</i>	<i>Formaldehyde 37%</i>	<i>Slight swelling</i>	<i>21.4</i>									
<i>Resistance to Degradation by Chemicals</i>	<i>Observation</i>	<i>Result in %</i>																								
<i>n-Heptane</i>	<i>Slight swelling</i>	<i>45.9</i>																								
<i>Sodium Hydroxide 40%</i>	<i>No Change</i>	<i>-5.5</i>																								
<i>Hydrogen Peroxide 30%</i>	<i>Slight swelling</i>	<i>31.1</i>																								
<i>Formaldehyde 37%</i>	<i>Slight swelling</i>	<i>21.4</i>																								

Sl. No	Pictograms	Description of Pictograms																																						
7.	<p>EN 374-5:2016</p> <p>VIRUS</p>	<p>It refers to the Instruction for use as per EN 420 : 2003 + A1.2009</p> <table border="1"> <thead> <tr> <th><i>Protective gloves - General Requirements</i></th> <th><i>Status/Performance level</i></th> </tr> </thead> <tbody> <tr> <td><i>Sizing</i></td> <td><i>Small, Medium, Large & X-Large</i></td> </tr> <tr> <td><i>Dexterity</i></td> <td><i>Performance Level 5</i></td> </tr> <tr> <td><i>pH Value</i></td> <td><i>Pass</i></td> </tr> </tbody> </table> <p>Tested for protection against liquid penetration and Micro organism</p> <table border="1"> <thead> <tr> <th><i>Resistance to Penetration</i></th> <th><i>Status/Performance level</i></th> </tr> </thead> <tbody> <tr> <td><i>Air Leakage</i></td> <td><i>Pass</i></td> </tr> <tr> <td><i>Water Leakage</i></td> <td><i>Pass</i></td> </tr> </tbody> </table> <p>Protection against virus:</p> <p>Results:</p> <table border="1"> <thead> <tr> <th>Test Article Number</th> <th>Pre-Challenge Concentration (PFU/mL)</th> <th>Post-Challenge Concentration (PFU/mL)</th> <th>Assay Titer (PFU/mL)</th> <th>Visual Penetration</th> <th>Test Result</th> </tr> </thead> <tbody> <tr> <td>1-3</td> <td>1.6 x 10⁸</td> <td>1.3 x 10⁸</td> <td><1^a</td> <td>None Seen</td> <td>Pass</td> </tr> <tr> <td>Negative Control</td> <td>1.6 x 10⁸</td> <td>1.3 x 10⁸</td> <td><1^a</td> <td>None Seen</td> <td>Acceptable</td> </tr> <tr> <td>Positive Control</td> <td>1.6 x 10⁸</td> <td>1.3 x 10⁸</td> <td>TNTC^b</td> <td>Yes</td> <td>Acceptable</td> </tr> </tbody> </table> <p>^a A value of <1 plaque forming unit (PFU)/mL is reported for assay plates showing no plaques. ^b TNTC = PFUs were too numerous to count.</p>	<i>Protective gloves - General Requirements</i>	<i>Status/Performance level</i>	<i>Sizing</i>	<i>Small, Medium, Large & X-Large</i>	<i>Dexterity</i>	<i>Performance Level 5</i>	<i>pH Value</i>	<i>Pass</i>	<i>Resistance to Penetration</i>	<i>Status/Performance level</i>	<i>Air Leakage</i>	<i>Pass</i>	<i>Water Leakage</i>	<i>Pass</i>	Test Article Number	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Visual Penetration	Test Result	1-3	1.6 x 10 ⁸	1.3 x 10 ⁸	<1 ^a	None Seen	Pass	Negative Control	1.6 x 10 ⁸	1.3 x 10 ⁸	<1 ^a	None Seen	Acceptable	Positive Control	1.6 x 10 ⁸	1.3 x 10 ⁸	TNTC ^b	Yes	Acceptable
<i>Protective gloves - General Requirements</i>	<i>Status/Performance level</i>																																							
<i>Sizing</i>	<i>Small, Medium, Large & X-Large</i>																																							
<i>Dexterity</i>	<i>Performance Level 5</i>																																							
<i>pH Value</i>	<i>Pass</i>																																							
<i>Resistance to Penetration</i>	<i>Status/Performance level</i>																																							
<i>Air Leakage</i>	<i>Pass</i>																																							
<i>Water Leakage</i>	<i>Pass</i>																																							
Test Article Number	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Visual Penetration	Test Result																																			
1-3	1.6 x 10 ⁸	1.3 x 10 ⁸	<1 ^a	None Seen	Pass																																			
Negative Control	1.6 x 10 ⁸	1.3 x 10 ⁸	<1 ^a	None Seen	Acceptable																																			
Positive Control	1.6 x 10 ⁸	1.3 x 10 ⁸	TNTC ^b	Yes	Acceptable																																			
8.	<p>EN 388</p> <p>0000</p>	<table border="1"> <thead> <tr> <th><i>Sl. No.</i></th> <th><i>Mechanical characteristics</i></th> <th><i>Status/Performance level</i></th> </tr> </thead> <tbody> <tr> <td><i>a)</i></td> <td><i>Abrasion Resistance</i></td> <td><i>Performance Level 0</i></td> </tr> <tr> <td><i>b)</i></td> <td><i>Blade cut Resistance</i></td> <td><i>Performance Level 0</i></td> </tr> <tr> <td><i>c)</i></td> <td><i>Tear Resistance</i></td> <td><i>Performance Level 0</i></td> </tr> <tr> <td><i>d)</i></td> <td><i>Puncture Resistance</i></td> <td><i>Performance Level 0</i></td> </tr> </tbody> </table>	<i>Sl. No.</i>	<i>Mechanical characteristics</i>	<i>Status/Performance level</i>	<i>a)</i>	<i>Abrasion Resistance</i>	<i>Performance Level 0</i>	<i>b)</i>	<i>Blade cut Resistance</i>	<i>Performance Level 0</i>	<i>c)</i>	<i>Tear Resistance</i>	<i>Performance Level 0</i>	<i>d)</i>	<i>Puncture Resistance</i>	<i>Performance Level 0</i>																							
<i>Sl. No.</i>	<i>Mechanical characteristics</i>	<i>Status/Performance level</i>																																						
<i>a)</i>	<i>Abrasion Resistance</i>	<i>Performance Level 0</i>																																						
<i>b)</i>	<i>Blade cut Resistance</i>	<i>Performance Level 0</i>																																						
<i>c)</i>	<i>Tear Resistance</i>	<i>Performance Level 0</i>																																						
<i>d)</i>	<i>Puncture Resistance</i>	<i>Performance Level 0</i>																																						
9.	The user information mentioned in our labels																																							

Recommended use of the gloves :

OBM ADDRESS:

**MERCATOR MEDICAL S.A
UL. H. MODRZEJEWSKIEJ 30,
31 - 327 KRAKOW, POLAND**

- 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 Walleter gloves (inner wrapper) from the Pouch (outer wrapper).
- (b) Open the Walleter 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.

Warnings:

Sl. No	Pictograms	Description of Pictograms
1.	<p>EN 374-1:2016 / Type C</p>  <p>JKPT</p>	<p>This information does not reflect the actual duration of protection in the work place and the differentiation between mixtures and pure chemicals.</p> <p>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’</p> <p>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</p> <p>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.</p> <p>Before usage, inspect the gloves for any defect or imperfections.</p> <p>For Single use only.</p>
2.	<p>EN 374-5:2016</p>  <p>VIRUS</p>	<p>The Penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.</p>