
















USER INFORMATION (EXAM NITRILE STERILE)

a. Intended Use:	<p>These gloves are intended for single use only and acts as protective barrier when worn by healthcare personnel to prevent contamination between healthcare personnel and patient’s body, fluids, waste, or environment against dangerous chemicals and micro-organisms.</p>
b. Doffing & Donning:	<p>Before application of gloves, it is recommended to carry out antiseptic processing of hands. To use depending on the enclosed manipulations and procedures.</p> <ul style="list-style-type: none"> Gently put the glove on your hand, and gently straighten the cuff of the glove on your hand up to your wrist. By your other hand lightly straighten the glove to fit your hand. To remove the gloves, make a flap on the left glove with the fingers of your right hand, touching only the outside of the glove, remove the glove from your left hand, flipping it from outside to inside by holding the cuff. Hold it in your right hand, grab the right glove with your left hand for the cuff from inside, remove the glove with your right hand, twisting it upside down: the left-hand glove will be in the middle of the right hand, throw the gloves into the trash. Do not reuse. <p>BE SURE TO WASH YOUR HANDS AFTER REMOVING THE GLOVES!</p>
c. Precaution for Use:	<p>Before use, inspect for any defects or imperfections. If in doubt, discard the gloves and select a new pair.</p> <p>If gloves are to be used with chemicals:</p> <ul style="list-style-type: none"> Consult the subsequent user instruction to ensure these gloves are suitable for the intended purpose. Keep all chemicals away from direct skin contact, even if thought to be harmless. If contact occurs, wash the affected area immediately and seek assistance, contacting a suitable, qualified professional. Gloves that have been in contact with chemicals should be removed and disposed of as quickly as possible following use. Ensure chemicals or residuals cannot enter via the cuff and come in contact with skin. These gloves should not be used in applications which require mechanical and/or thermal protection. Discontinue use immediately if signs of tearing, swelling or degradation appear.
d. Ingredients/Hazardous ingredients:	<p>This product contains synthetic latex (Nitrile). Some gloves may contain ingredients which are known to be a possible cause of allergies to sensitive individuals, including irritation and/or allergic reactions. If this occurs, seek appropriate medical advice immediately.</p>

<p>e. Storage:</p>	<p>The product is kept away from direct sunlight and fluorescent light and is to be stored in an environment with a temperature of 10°C - 40°C.</p> <ul style="list-style-type: none"> • The storage place shall not contain any equipment that generates ozone. • The product shall not be in direct contact with metals. • Avoid contact with oil-based antiseptic phenols or their derivatives, greases, petroleum jelly, petroleum spirit, paraffin or other related compounds. • The expiry date indicated on the package or labelling based on product shelf life is valid for the properly stored product. • Sterility is assured provided that the pouch-seal is intact and not broken. (For sterile gloves only)
<p>f. Disposal</p>	<p>Dispose of the device in accordance with the local laws and regulations applicable in the country.</p>
<p>g. Composition</p>	<p>Gloves are manufactured from synthetic latex (Nitrile). The gloves are coated with a surface material to assist the user putting the gloves on.</p>
<p>h. Limitation/Caution/Warning</p>	<ul style="list-style-type: none"> • This information does not reflect the actual duration of protection in the workplace 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 400 mm – 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 workplace may differ from the type test depending on temperature, abrasion and degradation. • Before usage, inspect the gloves for any defects or imperfections. • The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only. • When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by 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. • For single use only. • The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen. • This product is to be stored in a carton during transportation.

	<ul style="list-style-type: none"> • The glove is a device subject to wear, so frequent replacement is recommended and, in all cases, where imperfections are observed. Visit our website for more information on the lifetime in use of the device. • Wear gloves with dry, clean hands. • In rare cases, transient skin reactions and hypersensitivity reactions may occur. In case of reaction, discontinue use. • If more information is required, please contact your local distributor in the first instance. More information can be obtained from the following link www.wrpworld.com or by contacting the WRP technical team quoting the product article number. 				
<p>i. Conformity and Performance</p>	<p>Personal Protective Equipment of Complex Design Category III, in compliance with European Regulation (EU) 2016/425, Regulation 2016/425 on personal protective equipment, as amended to apply in GB, tested to EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018 Type B, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016 & ISO 16604:2004, CE2797; CE Class I Sterile Medical Device, in compliance with MDR (EU) 2017/745, tested to EN 455-1:2020, EN 455-2:2015, EN 455-3:2023, EN 455-4:2009, and ASTM D6319.</p>				
<p>j. Caution</p>	<div style="border: 1px solid black; padding: 5px;"> <p> CAUTION</p> <p>This product to be stored in carton during transportation.</p> </div>				
<p>k. Legal Manufacturer and Representative</p>	<table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <p> WRP Asia Pacific Sdn Bhd 1 4 7 8 1 7 V</p> <p>Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi 43900 Sepang, Selangor Darul Ehsan, Malaysia Phone +60-3-8706-1486 Email inquiry@wrpworld.com</p> </td> <td style="width: 50%; vertical-align: top;"> <p> & Importer in the EU <i>Remesco Handelsges.m.b.H.</i> Muthgasse 36/19, A-1190 Vienna, Austria Phone +43-1-328-50-88 Email office@remesco.com</p> </td> </tr> <tr> <td style="vertical-align: top;"> <p> <i>Obelis UK Ltd</i> Sandford Gate, Oxford OX4 6LB, UK Phone +32 (0) 2 732 5954 Fax. +32 (0) 2 732 6003 Email mail@obelis.net</p> </td> <td style="vertical-align: top;"> <p> <i>OBELIS SWISS GmbH</i> Ruessenstrasse 12 6340 Baar / ZG Switzerland Tel: +41 41 544 15 26 Fax: +41 41 544 15 27 Email: info@obelis.ch</p> </td> </tr> </table>	<p> WRP Asia Pacific Sdn Bhd 1 4 7 8 1 7 V</p> <p>Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi 43900 Sepang, Selangor Darul Ehsan, Malaysia Phone +60-3-8706-1486 Email inquiry@wrpworld.com</p>	<p> & Importer in the EU <i>Remesco Handelsges.m.b.H.</i> Muthgasse 36/19, A-1190 Vienna, Austria Phone +43-1-328-50-88 Email office@remesco.com</p>	<p> <i>Obelis UK Ltd</i> Sandford Gate, Oxford OX4 6LB, UK Phone +32 (0) 2 732 5954 Fax. +32 (0) 2 732 6003 Email mail@obelis.net</p>	<p> <i>OBELIS SWISS GmbH</i> Ruessenstrasse 12 6340 Baar / ZG Switzerland Tel: +41 41 544 15 26 Fax: +41 41 544 15 27 Email: info@obelis.ch</p>
<p> WRP Asia Pacific Sdn Bhd 1 4 7 8 1 7 V</p> <p>Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi 43900 Sepang, Selangor Darul Ehsan, Malaysia Phone +60-3-8706-1486 Email inquiry@wrpworld.com</p>	<p> & Importer in the EU <i>Remesco Handelsges.m.b.H.</i> Muthgasse 36/19, A-1190 Vienna, Austria Phone +43-1-328-50-88 Email office@remesco.com</p>				
<p> <i>Obelis UK Ltd</i> Sandford Gate, Oxford OX4 6LB, UK Phone +32 (0) 2 732 5954 Fax. +32 (0) 2 732 6003 Email mail@obelis.net</p>	<p> <i>OBELIS SWISS GmbH</i> Ruessenstrasse 12 6340 Baar / ZG Switzerland Tel: +41 41 544 15 26 Fax: +41 41 544 15 27 Email: info@obelis.ch</p>				

<p>Tested in accordance with ISO 374-5:2016</p>  <p>VIRUS</p>	<p>Tested Against Viruses The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.</p>
	<p>Protection against bacteria and fungi - Pass</p>
	<p>Protection against viruses - Pass</p>

<p>ISO 374-1:2016/ Type B</p>  <p>KPT</p>	<p>Tested in accordance with EN ISO 374-1: 2016+A1: 2018 Type B</p>	<p>EN 16523-1:2015 + A1:2018 Permeation Level</p>	<p>EN ISO 374-4:2019 Degradation</p>
	40% Sodium Hydroxide (K)	6	-5.7%
	30% Hydrogen Peroxide (P)	2	30.1%
	37% Formaldehyde (T)	6	11.7%
<p>EN ISO 374-4:2019 Degradation results indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.</p>			

<p>EN ISO 374-1:2016+A1:2018 Type B Permeation levels based on breakthrough times as follows:</p>						
<p>Performance Level</p>						
0	1	2	3	4	5	6
<p>Minimum breakthrough Time (min)</p>						
>0	>10	>30	>60	>120	>240	>480









<p>Tested in accordance with EN ISO 374-2:2019</p>		
7.2	Air Leak	N/A
7.3	Water Leak	PASS

Performance Level	AQL	Inspection Level
LEVEL 3	<0.65	G1
LEVEL 2	<1.5	G1
LEVEL 1	<4.0	S4

+++ Inspection Level AQL <1.5

Declaration of conformity is available at our website www.wrpworld.com

Symbol Used on the Packaging	
	Medical Device
	Medical Device Regulation (EU) 2017/745
	Personal Protective Equipment of Complex Design Category III, in compliance with European Regulation (EU) 2016/425
	CE marking
	UKCA marking
	Single-use only
	Keep dry
	Keep away from sunlight
	Temperature limits 10° – 40°C
	Recycle
	Triman
	Sterilized by irradiation
	Single sterile barrier system with protective packaging inside
	Designed to protect against chemical risks according to EN ISO 374-1/Type B
	Designed to protect against microorganism risks according to EN ISO 374-5
	Medical products handle with care
	Store this way up
	Allergen type IV
	Latex free
	UA Conformity mark with identification number of the national conformity assessment body
	1 pair of gloves per pouch
	50 pairs of gloves per dispenser

Symbol Used on the Packaging			
	Authorized representative in the European Community		Lot number
	Authorized representative in Switzerland		Date of Manufacture
	Authorized representative in UK		Expiration date
	Manufacturer		Unique device identifier