



## USER INFORMATION (EXAM DUOTONE NITRILE)

<b>a. Intended Use</b>	<p>These gloves are intended for single use only and act as a protective barrier when worn by healthcare personnel to prevent contamination against dangerous chemicals and micro-organisms between healthcare personnel and patient’s body, fluids, waste or environment.</p>
<b>b. Donning &amp; Doffing:</b>	<p><b><u>Donning:-</u></b>          Before donning gloves, it is recommended that hands be washed thoroughly using antiseptic soap then dried according to best-practice procedures. Gently insert fingers into the cuff of the glove and pull the cuff over the wrist.</p> <p><b><u>Doffing:-</u></b>          Use your gloved hand to grasp the outside edge of the glove near your wrist and pull glove away from your hand turning it inside out as you remove. Roll the removed glove into the palm of your hand that is still gloved. Next, slide fingers of ungloved hand under the wrist of the remaining glove making sure you do not touch the outside of the glove. Peel off the second glove. Never touch the outside of the glove with a bare hand. Discard gloves into proper trash receptacle. Wash your hands thoroughly using antiseptic soap according to best- practice procedure.</p>
<b>c. Precautions for Use:</b>	<p>Before use, inspect for any defects or imperfections. If in doubt, discard the gloves and select a new pair.</p> <p><b>If gloves are to be used with chemicals:</b></p> <ul style="list-style-type: none"> <li>Check with chemical permeation guides to ensure these gloves are suitable for the intended purpose.</li> <li>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.</li> <li>Gloves that have been in contact with chemicals should be removed and disposed of as quickly as possible following use.</li> <li>Ensure chemicals or residuals cannot enter via the cuff and come in contact with skin.</li> <li>These gloves should not be used in applications which require mechanical and/or thermal protection.</li> <li>Discontinue use immediately if signs of tearing, swelling or degradation appear.</li> </ul>
<b>d. Ingredients/Hazardous ingredients</b>	<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><b>e. Storage:</b></p>	<p>The product is to be 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"> <li>• The storage place shall not contain any equipment that generates ozone.</li> <li>• The product shall not be stored in direct contact with metals.</li> <li>• The expiry date indicated on the package or labelling based on product shelf life is valid for properly stored products.</li> <li>• Sterility is assured only if the pouch-seal is intact and not broken. (For sterile gloves only)</li> </ul>
<p><b>f. Disposal</b></p>	<p>Dispose of the device in accordance with the local laws and regulations applicable in the country.</p>
<p><b>g. Composition</b></p>	<p>Gloves are manufactured from synthetic latex (Nitrile). The gloves may be coated with a surface material to assist in donning.</p>
<p><b>h. Limitations/Cautions/Warnings:</b></p>	<ul style="list-style-type: none"> <li>• This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.</li> <li>• The chemical resistance data have been assessed under laboratory conditions from samples taken from the palm only and relates only to the chemical tested. Results can be different if the chemical is used in a mixture.</li> <li>• It is recommended to check that the gloves are suitable for the intended use. The conditions at the workplace may differ from the conditions depending on temperature, abrasion, and degradation.</li> <li>• Before usage, inspect gloves for any defects or imperfections.</li> <li>• Protective gloves may provide less resistance to dangerous chemicals 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.</li> <li>• Penetration resistance data have been assessed under laboratory conditions and relates only to the tested specimen.</li> <li>• For single use only.</li> <li>• This glove does not protect against mechanical risks.</li> <li>• This glove is not intended for use in the direct or primary x-ray beam.</li> <li>• This product is to be stored in cartons during transportation.</li> <li>• Sterile, as long as the peel pouch is sealed and undamaged surgically only.</li> <li>• The gloves are a device subject to wear, so far frequent replacement is recommended particularly where imperfections are observed.</li> </ul>

	<ul style="list-style-type: none"> <li>• Wear gloves with dry, clean hands.</li> <li>• In rare cases, transient skin reactions and hypersensitivity reactions may occur. In case of reaction, discontinue use.</li> <li>• If more information is required, please contact your local distribution in the first instance. More information can be obtained from <a href="http://www.wrpworld.com">www.wrpworld.com</a>.</li> </ul>				
<p><b>i. Conformity and Performance</b></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 &amp; ISO 16604:2004, CE2797; CE Class I 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><b>j. Caution</b></p>	<div style="border: 1px solid black; padding: 5px;"> <p> <b>CAUTION</b></p> <p><b>This product to be stored in carton during transportation.</b></p> </div>				
<p><b>k. Legal Manufacturer and Representative</b></p>	<table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <p> <b>WRP Asia Pacific Sdn Bhd</b> 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 <a href="mailto:inquiry@wrpworld.com">inquiry@wrpworld.com</a></p> </td> <td style="width: 50%; vertical-align: top;"> <p> &amp; 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 <a href="mailto:office@remesco.com">office@remesco.com</a></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 <a href="mailto:mail@obelis.net">mail@obelis.net</a></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: <a href="mailto:info@obelis.ch">info@obelis.ch</a></p> </td> </tr> </table>	<p> <b>WRP Asia Pacific Sdn Bhd</b> 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 <a href="mailto:inquiry@wrpworld.com">inquiry@wrpworld.com</a></p>	<p> &amp; 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 <a href="mailto:office@remesco.com">office@remesco.com</a></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 <a href="mailto:mail@obelis.net">mail@obelis.net</a></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: <a href="mailto:info@obelis.ch">info@obelis.ch</a></p>
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<p><b>Tested in accordance with ISO 374-5:2016</b></p>  <p><b>VIRUS</b></p>	<p><b>Tested Against Viruses</b></p> <p>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><b>ISO 374-1:2016/ Type B</b></p>  <p><b>KPT</b></p>	<p><b>Tested in accordance with EN ISO 374-1: 2016+A1: 2018 Type B</b></p>	<p><b>EN 16523-1:2015 + A1:2018 Permeation Level</b></p>	<p><b>EN ISO 374-4:2019 Degradation</b></p>
	40% Sodium Hydroxide (K)	6	-10.8%
	30% Hydrogen Peroxide (P)	3	28.4%
	37% Formaldehyde (T)	5	16.3%
<p>EN ISO 374-4:2019 Degradation results indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.</p>			

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






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

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

+++ Inspection Level AQL <1.5

Declaration of conformity is available at our website [www.wrpworld.com](http://www.wrpworld.com)

Symbol Used on the Packaging			
	Medical Device		Designed to protect against chemical risks according to EN ISO 374-1/Type B
	Medical Device Regulation (EU) 2017/745		Designed to protect against microorganism risks according to EN ISO 374-5
	Personal Protective Equipment of Complex Design Category III, in compliance with European Regulation (EU) 2016/425		Medical products handle with care
	CE marking		Store this way up
	UKCA marking		Allergen type IV
	Single-use only		Latex free
	Keep dry		UA Conformity mark with identification number of the national conformity assessment body
	Keep away from sunlight		For food use
	Temperature limits 10° – 40°C		Unique device identifier
	Recycle		Manufacturer
	Triman		Lot number

Symbol Used on the Packaging			
	Authorized representative in the European Community		Date of Manufacture
	Authorized representative in Switzerland		Expiration date
	Authorized representative in UK		