

PRODUCT NUMBER	7540	
DESCRIPTION OF PRODUCT	<ul style="list-style-type: none"> <li>Material: Nitrile Butadiene Rubber (NBR); Latex Free (The gloves do not contain natural rubber latex.)</li> <li>Type of gloves: Disposable gloves for Single use only</li> <li>Sterile: Non Sterile</li> <li>Powder: Free</li> <li>Shape: Ambidextrous</li> <li>Sizes: XS(5-6), S(6-7), M(7-8), L(8-9), XL(9-10), XXL(10-11)</li> <li>Packaging: 100 pcs/dispenser box</li> </ul>	
For Medical Device	TYPE	Examination glove for medical use
	DIRECTIVE/ CLASS/ CATEGORY	MEDICAL DEVICE DIRECTIVE (MDD) 93/42/EEC, CLASS I PERSONAL PROTECTIVE EQUIPMENT (PPE) REGULATION (EU) 2016/425, CAT. III
PERFORMANCE LEVEL	EN 455-1, EN 455-2, EN 455-3 and EN 455-4	
	EN 420 :2003+A1:2009 Dexterity Level 5 (Min.1 - Max.5)	
	EN ISO 374 Against chemical risks Complies with EN ISO 374 on requirements for protective gloves against chemical risks	
	EN ISO 374-5:2016 <b>ISO 374-5</b> 	Penetration (Min. 1 - Max.3) Level 3 Inspection level G-1 AQL: < 0.65
	EN ISO 374-1:2016 <b>ISO 374-1/Type C</b> 	Permeation (Min. 0 - Max.6) J: n-Heptane - CAS No. 142-85-5 Level 6 K: 40% Sodium hydroxide - CAS No. 1310-73-2 Level 6 L: 96% Sulphuric acid - CAS No. 7664-93-9 Level 0
	EN 374-4:2013	Degradation J: n-Heptane - CAS No. 142-85-5 49.5% K: 40% Sodium hydroxide - CAS No. 1310-73-2 -55.0% L: 96% Sulphuric acid - CAS No. 7664-93-9 100%
	EN 388:2016 <b>EN 388:2016</b>  1000X	EN 388:2016 Against Mechanical risks Abrasion / Cut / Tear / Puncture / Cut EN ISO 13997 : 1 / 0 / 0 / 0 / X
APPLICATIONS	<p>Patient examination gloves are disposable devices intended for medical purposes that are worn on the examiner's hands or fingers to prevent contamination between patient and examiner in medical examination condition.</p> <p>The glove can contact intact skin, or body orifice for transient use, or oral cavity as far as the pharynx, ear canal up to the ear drum or nasal cavity for short term.</p> <p>In addition, the gloves are intended for use to protect the examiner from the chemical attack up to the above mentioned performance level. The glove is not intended to be able to contact with all chemicals or matters such as open fire, hot or cold objects, or use for protection against any sharp tools or for welding, for protection against electric shock, ionization radiation.</p>	
CERTIFICATE ISSUED BY NOTIFIED BODY	<ul style="list-style-type: none"> <li>Type examination certificate (EN ISO 374-1:2016, EN 374-2:2014, EN 374-4:2013, EN ISO 374-5:2016, EN 420:2003+A1:2009, EN 388:2016) has been issued by CENTEXBEL TEXTILE COMPETENCE CENTRE Notified Body No. 0493 under the PPE Regulation (EU) 2016/425.</li> <li>CE certificate for CAT. III under Module D has been issued by the SGS Fimko Oy, Notified Body No. 0598 under the PPE Regulation (EU) 2016/425.</li> </ul>	
FOR FOOD	REGULATION	EU Regulation 1935/2004
	APPLICATIONS	Contact with Food
STORAGE	<ul style="list-style-type: none"> <li>Store at 5°C to 40°C in the original packaging, in a dry and well ventilated area.</li> <li>Keep away from the light, heat and ozone.</li> <li>Do not store in direct vicinity of solvents, oils, fuel and lubricants.</li> <li>Opened boxes will result in decreased shelf life and compromised efficiency.</li> </ul>	
SHELF LIFE	With proper storage the physical properties of the gloves are retained for five years after the manufacture. The expiry date is given on the packaging.	

CONTRAINDICATION		<ul style="list-style-type: none"> <li>Do not use beyond the APPLICATIONS and PERFORMANCE LEVEL.</li> <li>Avoid that chemical substance is entered inside a glove through the cuff.</li> <li>Do not reuse. Single use only. If reused, user and/or patient may be contaminated and/or may not be protected.</li> <li>Discard glove after having used for a patient. Do not use the same glove for another patient.</li> <li>Discard glove when the outer surface of glove contacted something other than a patient.</li> <li>Avoid using glove if the inside of it is dirty before use or during use, as they may cause irritation leading to skin inflammation or serious injury or lose cleanliness.</li> </ul>																																	
PRECAUTION		<ul style="list-style-type: none"> <li>Check whether defects or other imperfections exist or not before use and during use. If the glove has dirt, hole, scratch, tear, discoloration, deformation or thinned-out portion, exchange to new glove.</li> <li>In the case of allergic reaction, medical aid should be sought immediately.</li> <li>Gloves contain zinc-dibutyldithiocarbamate and zinc-diethyldithiocarbamate. Do not use in the case of hypersensitivity to these substances. Medical aid should be sought immediately.</li> <li>Permeation performance information does not reflect the actual duration of protection in the workplace due to other factors that may influence the performance.</li> <li>In the case any chemical substance penetrates or contact to the wearer's hand, it should be rinsed off immediately with large amount of water and soap. Medical aid should be sought immediately.</li> </ul>																																	
INSTRUCTION	BEFORE USE	Wash and/or disinfect the hands and wear gloves.																																	
	DURING USE	Gloves may not meet the minimum length requirements of EN 420:2003+A1:2009 as they are designed to stretch upon donning.																																	
	AFTER USE	Dispose used gloves according to national and local regulations.																																	
FOR FOOD CONTACT			<ul style="list-style-type: none"> <li>Gloves labelled with a pictogram indicating contact with food.</li> <li>There are some restrictions when this glove is used for contact with foodstuffs.</li> <li>To know which restrictions apply and for which specific foodstuffs this glove can be used, make sure the SHOWA EU Regulatory Compliance Statement of 7540 on WEB.</li> </ul>																																
COMPANY PROFILE	Manufacturer		SHOWA GLOVE Co. 565 Tohori, Himeji, Hyogo 670-0802 Japan																																
	Authorized representative		Emergo Europe B.V. Prinsessegracht 20, 2514 AP, Hague, The Netherlands																																
	Importer/Distributor EU		SHOWA International (Netherland) B.V. WTC Tower I, Strawinskylaan 1817, 1077 XX Amsterdam, The Netherlands																																
	US		SHOWA 579 Edison Street, Menlo, GA 30731, USA																																
	Canada		SHOWA 2507 Macpherson Street, Magog, Quebec J1X 0E6 Canada																																
	Australia		SHOWA 32 Sargents Road, Minchinbury, NSW 2770, Australia																																
	WEB. ADDRESS	<b>www.showagroup.com</b> The EU declaration of conformity can be obtained at the WEB.																																	
	COUNTRY OF ORIGIN	Made in Malaysia																																	
DESCRIPTION OF SYMBOL MARK ON THE LABEL		<table border="1"> <tr> <td></td> <td>Re-Order Number</td> <td></td> <td>Lot. Number</td> <td></td> <td>Consult Instructions for Use</td> </tr> <tr> <td></td> <td>Do Not Reuse</td> <td></td> <td>Caution</td> <td></td> <td>Use-by Date</td> </tr> <tr> <td></td> <td>Temperature Limitation</td> <td></td> <td>Keep Away from Sunlight</td> <td></td> <td>Keep Dry</td> </tr> <tr> <td></td> <td>Non Sterile</td> <td></td> <td>Manufacturer</td> <td></td> <td>European Authorized Representative</td> </tr> <tr> <td></td> <td>Latex Free</td> <td></td> <td></td> <td></td> <td></td> </tr> </table>					Re-Order Number		Lot. Number		Consult Instructions for Use		Do Not Reuse		Caution		Use-by Date		Temperature Limitation		Keep Away from Sunlight		Keep Dry		Non Sterile		Manufacturer		European Authorized Representative		Latex Free				
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