

USER INFORMATION (EXAMINATION EDUOTONE NITRILE)

a. Intended Use:

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.

b. Doffing & Donning:

Before application of gloves, it is recommended to carry out antiseptic processing of hands. To use depending on the enclosed manipulations and procedures.

- 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.

BE SURE TO WASH YOUR HANDS AFTER REMOVING THE GLOVES!

c. Precaution for Use:

Before use, inspect for any defects or imperfections. If in doubt, discard the gloves and select a new pair.

If gloves are to be used with chemicals:

- 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:

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.

e. Storage:

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.

- 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)

f. Disposal

Dispose of the device in accordance with the local laws and regulations applicable in the country.

g. Composition

Gloves are manufactured from synthetic latex (Nitrile). The gloves are coated with a surface material to assist the user putting the gloves on.


h. Limitation/Caution/Warning


- 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.
- 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.

i. Conformity and Performance

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 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.

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

ISO 374-1:2016/ Type B  KPT	Tested in accordance with EN ISO 374-1: 2016+A1: 2018 Type B	EN 16523-1:2015 + A1:2018 Permeation Level	EN ISO 374-4:2019 Degradation
	40% Sodium Hydroxide (K)	6	-9.4%
	30% Hydrogen Peroxide (P)	3	29.7%
	37% Formaldehyde (T)	5	35.3%

EN ISO 374-4:2019 Degradation results indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

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		
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

Caution



CAUTION

This product to be stored in carton during transportation.

Symbols



Legal Manufacturer and Representative

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