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User manual - PROMATES nitrile black

Producer:

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Co.,Ltd.
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Authorized Representative:

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Distributor:

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PROMATES Nitrile Black

GLM2001, GLM2002, GLM2003, GLM2004, GLM2005

The following instructions should be used in conjunction with the information provided on the packaging.

Product Description:

Nitrile examination and protective gloves, powder-free, non-sterile, single-use

Product Features:

Material: nitrile
Color: black
Powdering agent: none
Surface: textured fingertips
AQL: 1.5
Cuff: evenly rolled
Shape: universal (fits right and left hands)
Quantity per package: 100 pieces
Available sizes: XS, S, M, L, XL
Shelf life: 5 years

Classification and legal standards

Gloves classified as a medical device - class I in accordance with the Regulation of the European Parliament and of the Council (EU) of April 5, 2017. [MDR] Compliance with standards: ISO 13485:2016; EN ISO 14971:2019; EN ISO 20417:2021; EN ISO 15223-1:2021; EN 455-1:2020+A2:2024; EN 455-2:2024; EN 455-3:2023; EN 455-4:2009; ISO 10993-1:2018; ISO 10993-10:2021; ISO 10993-11:2017; ISO 10993-23:2021. Gloves classified as Personal Protective Equipment - category III in accordance with Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 [PPE] Compliance with standards: EN ISO 21420, EN ISO 374-1:2016, EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013, EN ISO 374-5:2016



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Non-sterile, protective, powder-free nitrile gloves made of 100% synthetic rubber, universally shaped, and disposable. Chlorinated for ease of donning.

The gloves are characterized by high durability and flexibility, while remaining soft and comfortable, retaining their original shape well. The gloves fit both right and left hands. The extended cuff ensures easy donning, a perfect fit, a secure fit (the glove won't slip), and quick removal at the end of use. The gloves protect the user's hands against microorganisms (bacteria, fungi, and viruses) and selected chemical hazards. The testing and labeling of the gloves are in accordance with Regulation (EU) 2016/425 and applicable harmonized European Standards. The gloves should be used only as recommended in the Instructions for Use.

Food Contact

Approved for food contact in accordance with Commission Regulation (EC) No. 10/2011, Regulation (EC) No. 1935/2004, and Regulation (EC) No. 2023/2006 on Good Manufacturing Practice.

Declaration of Conformity

A copy of the Declaration of Conformity can be downloaded at www.promates.eu.

Storage Conditions

It is recommended to store the gloves at a temperature of not less than 10°C and not more than 30°C. Do not store in the immediate vicinity of heating devices, sources of ignition, or ozone. Do not store near solvents, oils, fuels, or lubricants. Protect from moisture.

Applications

These gloves are widely used in the medical sector: nursing, medical diagnostics, veterinary medicine, dentistry, and laboratory diagnostics. In the food sector: catering, gastronomy, HORECA; in the beauty sector: cosmetology, hairdressing; during cleaning work (in contact with selected chemicals) and household work.

Use and Precautions

Before use, check the gloves for defects. Disposable gloves should be used at least one pair for each patient and medical procedure. During use, gloves should be replaced immediately if they are cracked, torn, or punctured. When using gloves, use mild detergents and disinfectants that do not irritate the skin. Before putting on gloves, it is recommended to thoroughly dry the skin. After each removal of gloves, it is recommended to thoroughly wash and dry your hands, and apply a skin care cream. Keep all chemicals away from the skin, even if they are not hazardous. If a chemical penetrates the skin, wash it immediately with plenty of soap and water. Avoid gloves that are contaminated on the inside – they can cause irritation, leading to dermatitis or more serious injuries. Do not use the gloves when there is a risk of entanglement in moving machine parts. The gloves should not be used in contact with open flames or for protection against any sharp tools. The gloves are not intended for welding, for protection against electric shock, ionizing radiation, or against contact with hot or cold objects. Do not use after the expiration date. After use, dispose of the product in accordance with applicable regulations.

Hazardous Ingredients

Some gloves may contain ingredients that may cause allergies in individuals who are allergic to them, and may develop irritation and/or allergic reactions. If any symptoms occur, consult a doctor immediately.

Effectiveness level in protection against chemical hazards and microorganisms

According to a test in accordance with EU guidelines issued by SATRA Technology Europe Ltd (Notified Body No.: 2777) located at Bracetown Business Park, Clonee, County Meath, Dublin 15, Ireland. PROMATES Nitrile Black powder-free examination nitrile gloves:



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Size	Comments
XS	Type B for chemical protection. Provides protection against bacteria, fungi, and viruses.
S	Type B for chemical protection. Provides protection against bacteria, fungi, and viruses.
M	Type B for chemical protection. Provides protection against bacteria, fungi, and viruses.
L	Type B for chemical protection. Provides protection against bacteria, fungi, and viruses.
XL	Type B for chemical protection. Provides protection against bacteria, fungi, and viruses.

EN ISO 374-1:2016+A1:2018/Type B



KPT

Chemical Penetration Properties:

- Level 6 – Sodium Hydroxide 40% (K)
- Level 2 – Hydrogen Peroxide 30% (P)
- Level 4 – Formaldehyde 37% (T)

Protective Properties of the Gloves Against Bacteria, Fungi, and Viruses

- Protection against bacteria and fungi – YES
- Protection against viruses – YES

EN ISO 374-5:2016



VIRUS

NOTIFIED BODY WITH CURRENT CONFORMITY ASSESSMENT UNDER REGULATION (EU) 2016/425, ANNEX VIII (MODULE B)





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For gloves protecting against chemical risks and microorganisms, compliant with Regulation (EU) 2016/425. Annex VIII (Module B) is under the control of SATRA Technology Europe Ltd. located in Dublin (Ireland) at Bracetown Business Park, Clonee, Dublin 15D15 YN2P Ireland.

Immunity levels explained

Method	Description	Requirements	Test Results
EN 16523-1	Penetration 37% Formaldehyde	Resistance classes: 1:>10 min 2:>30 min 3:>60 min 4:>120 min 5:>240 min 6:>480 min	>120 minutes
EN 16523-1	Penetration 40% sodium solution	Resistance classes: 1:>10 min 2:>30 min 3:>60 min 4:>120 min 5:>240 min 6:>480 min	>480 minutes
EN 16523-1	Penetration 30% Hydrogen Peroxide	Resistance classes: 1:>10 min 2:>30 min 3:>60 min 4:>120 min 5:>240 min 6:>480 min	>30 minutes
EN 374-4	Degradation 37% Formaldehyde	N/A	Degradation rate 1.4%
EN 374-4	Degradacja 40% Roztwór Sodu	N/A	Degradation rate -52.7%
EN 374-4	Degradation 40% Sodium Solution	N/A	Degradation rate 19.4%
EN 374-5	Penetration of blood-borne pathogens. Protection against bacteria and fungi. Protection against viruses.	No penetration	YES YES YES
EN 420:2003+ A1:2009	Chemical harmlessness	<1mg/kg per PaH	YES
EN 420 dexterity	Dexterity	Performance level 1: 11mm 2: 9.5mm 3: 8.0mm 4: 6.5mm 5: 5.0mm	Level 5



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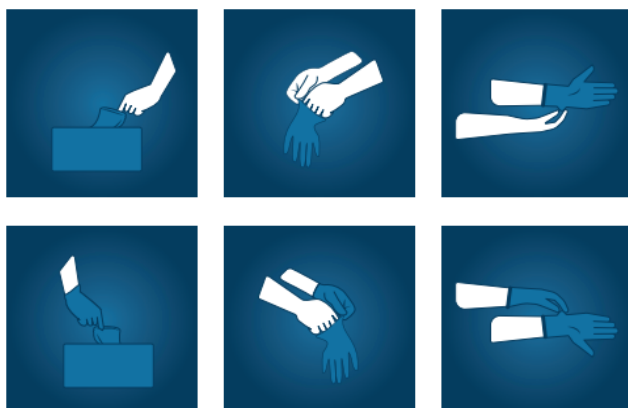
Final Remarks

The following document is intended to assist in selecting appropriate personal protective equipment. While the research and test results are intended to facilitate selection, please note that they do not simulate actual operating conditions. Responsibility for the use of a given personal protective equipment rests with the user.

If the product shows signs of wear (tearing, tears), discontinue use immediately and replace it with a new one.

The gloves do not protect against risks not listed in this document.

Gloves Donning Instructions



Instrukcja zdejmowania rękawic





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Production date



Approved for contact with food



Reference number



Medical device



Non sterile



Personal Protective Equipment



Protect from moisture



Authorized Representative



Recyclable packaging



Distributor details



Batch number assigned by the manufacturer



Compliance with EU standards



Please read the instructions for use.



Protect from sunlight and fluorescent light



Expiration date



Manufacturer's Data