


Product	<p>Examination and protective nitrile gloves, powder-free, non-sterile, disposable External surface: textured at the fingertips Cuff: rolled Colour: black Shape: universal, suitable both for right and left hand Sizes: EGO2XS (5-6), EGO2S (6-7), EGO2M (7-8), EGO2L (8-9), EGO2XL (9-10) Quantity in the unit package: 100 items by weight Expiry date: 3 years (from the production date)</p>						
Classification	<p>Class I medical device - Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. Category III Personal Protective Equipment - Regulation (EU) 2016/425 of the European Parliament and of the Council of 9th March 2016</p> <table border="1"> <tr> <td>MD</td> <td>CLASS I</td> <td>EN 455-1, EN 455-2, EN 455-3, EN 455-4</td> </tr> <tr> <td>PPE</td> <td>CAT III Type B</td> <td>EN 420+A1, EN ISO 374-1, EN ISO 374-2, EN ISO 374-4, EN ISO 374-5, EN 16523-1</td> </tr> </table> <p>Declaration of Conformity available at the website www.itano.pl Notified body responsible for EU Type Examination Module B: SATRA Technology Europe Limited (2777), Bracetown Business Park, Clonee, D15 YN2P, Dublin, Ireland Notified body responsible for Module D On-going conformity assessment: BSI Group The Netherlands B.V. (2797), Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands</p>	MD	CLASS I	EN 455-1, EN 455-2, EN 455-3, EN 455-4	PPE	CAT III Type B	EN 420+A1, EN ISO 374-1, EN ISO 374-2, EN ISO 374-4, EN ISO 374-5, EN 16523-1
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PPE	CAT III Type B	EN 420+A1, EN ISO 374-1, EN ISO 374-2, EN ISO 374-4, EN ISO 374-5, EN 16523-1					
Properties / Application	<p>Disposable, non-sterile examination and protective gloves for use in the medical environment, intended to: protect the patient and user from cross-contamination, carry out medical and diagnostic tests, therapeutic activities and work with contaminated medical material. Classified as a Class I medical device and as a Personal Protective Equipment (PPE) Category III. Their design and labelling comply with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Regulation (EU) 2016/425 of the European Parliament and of the Council of 9th March 2016. It should be noted that the confirmed level of protection does not reflect actual working conditions, where other factors may affect the effectiveness of protection. Care should be taken to ensure that the gloves are used only for their intended purpose.</p>						
Storage and transportation	<p>It is recommended to store and transport the gloves in a dry place at 10-40°C and to protect them from sunlight and fluorescent light. Store the gloves not less than 1 m away from heating devices, fire sources and ozone. Do not store them in the immediate vicinity of solvents, oils, fuels, greases.</p>						
Food contact	<p>Gloves marked with a pictogram (glass and fork)  to indicate approval for contact with food . They comply with Regulation (EC) No 10/2011, Regulation (EC) No 1935/2004.</p>						
Indications for use	<p>It is recommended to wash and dry your hands thoroughly before wearing gloves. Before using the gloves, check for defects (e.g. holes, dirt). After each removal of gloves, it is recommended to wash hands thoroughly, dry them and apply a care cream. Use min. 1 pair of gloves for one patient and one procedure - disposable gloves. Gloves contaminated with blood or body fluids should be removed as medical waste. Care should be taken to ensure that chemicals do not get into the gloves through the cuff. If a chemical gets into the skin, it should be washed off immediately with plenty of soapy water. In case of puncture, breakage or tearing, change the gloves immediately during use. Avoid gloves that are dirty on the inside - they may cause irritation leading to dermatitis or more serious injuries. Do not use the gloves in contact with open fire or to protect against all sharp tools. The gloves are not designed for welding, to protect against electric shock, ionizing radiation, or cold or hot objects. Protection is limited to the hand only, the results refer to the hand part and the gloves have been tested in laboratory conditions.</p>						
Ingredients/hazardous substances	<p>Some gloves may contain ingredients that cause allergies in people who are allergic to them and who may develop contact irritation and/or allergic reactions. If an allergic reaction occurs, seek medical attention immediately.</p>						
Disposal	<p>Used gloves may be contaminated with infectious or other hazardous substances. They must be disposed of in accordance with applicable local regulations.</p>						
Incident reporting	<p>Any serious incident involving gloves must be reported to the manufacturer and to the competent authority of the Member State where the user or patient is domiciled.</p>						
Manufacturer and responsible entity	<p>Itano Sp. z o.o. ul. Szparagowa 14 52-311 Wrocław, Poland www.itano.pl</p>						
Issue number and date	<p>Rev. 3 07.09.2021</p>						

Test acc.to EN ISO 374-1:2016+A1:2018 (Type B)	Level	Test acc. to EN ISO 374-4:2019 Mean degradation (%)
40% Sodium Hydroxide (K)	6	2.8
10-13% Sodium Hypochlorite	6	23.9
50% Sulphuric Acid	6	-50.8
5% Ethidium Bromide	6	-12.0
37% Formaldehyde (T)	3	24.5
65% Nitric Acid (M)	0	98.4
50% Glutaraldehyde	6	4.5
0.1% Phenol	6	9.4
30% Hydrogen Peroxide (P)	4	32.1
70% Isopropanol	0	30.6
99% Acetic Acid (N)	0	97.9
25% Ammonium Hydroxide (O)	0	-8.0
1.5 % Methanor in water	6	-12.3
n-Heptyne (J)	0	45.7

* Permeation rate 7µg/cm2/min

Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

Measured Breakthrough Time (minutes)	>10	>30	>60	>120	>240	>480
Permeation performance level	1	2	3	4	5	6

Test acc. to: EN ISO 374-5:2016	Level
Protection against bacteria and fungi	Pass
Protection against viruses	Pass

The penetration resistance has not been assessed under laboratory conditions and relates only to the tested specimen.

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 the temperature, abrasion and degradation.

When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the 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 the chemical resistant gloves.

Before usage inspect the gloves for any defect or imperfections

The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

Gloves are packed in dispenser which is suitable for transport. Keep the gloves in the box when not in use.

When relevant, a list of substances contained in the glove which are known to cause allergies, per list in Annex G of EN ISO 21420:2020, shall be supplied on request.

Pictograms and markings on the packaging

	Single use only		Non sterile product
	The quality of the product is not guaranteed if the packaging is damaged or dirty		Protect against sunlight and fluorescent light
	Protect the product from moisture		Store product at 10°-40° C
	Protect the product from ozone		It is recommended that you read the product's user manual
EN ISO 374-5:2016 	Protection against microorganisms - viruses, bacteria, and fungi	EN ISO 374-1:2016/Type B 	Type B chemical resistant gloves
	Product suitable for contact with food		100 gloves by weight
	Available product sizes. Colour coded size, appropriate to the product in the package.		Series no.
	Expiry date		Production date
	Manufacturer, responsible entity		Indications related to recycling of the immediate packaging of the product
	Medical device	CE 2777	CE mark with the number of the Notified Body



How to correctly put on and take off gloves

Before putting gloves on carefully wash your hands with water and soap for at least 20 seconds

Putting on



1

Take a glove from the package



2

Grab its wrist part and slide your hand in smoothly



3

Put on the first glove



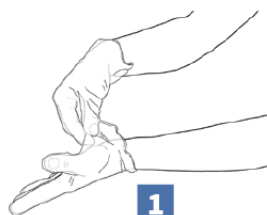
4

Take the other glove from the package with your bare hand



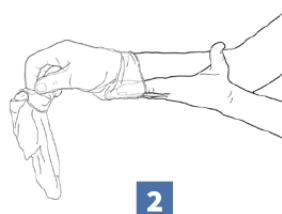
5

Fold back the outside surface of the glove you're putting on with bent fingers of your hand wearing the glove and put the glove on your other hand.



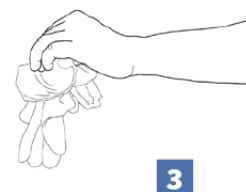
1

With your fingers grab one glove at the wrist height and pull it off, by turning the glove inside out



2

Hold the taken off glove in your hand wearing a glove and slide fingers of your bare hand between the glove and the wrist. Take off the other glove along the hand and later pull it over the glove you are holding with your fingers



3

Throw the removed gloves into a dust bin.

Taking off



Do not throw gloves into the toilet!



Do not touch your face while wearing gloves!