

INSTRUCTION FOR USE OF PERSONAL PROTECTIVE EQUIPMENT

nitrylex® high risk

RD30001001-06

The instruction below should be used in conjunction with detailed information on the packaging.

Short description of the product

Examination and protective gloves, nitrile, powder-free, for single use, non-sterile


Full description of the product

Reference number : RD30001001-06
Raw material : nitrile
Cuff : beaded
Colour : orange
Shape : ambidextrous, fitting to the right and left hand
Size range : XS (5-6), S (6-7), M (7-8), L (8-9), XL (9-10), XXL (10-11)
AQL : 1.0
Quantity in packaging : 100 pcs. by weight
Shelf life : 3 years (from the date of manufacturing)

Storage instructions

It is recommended to store the gloves in dry place, in the temperature of 5-35°C and to protect them against direct sunlight.
Keep the gloves in a distance of not less than 1m from heating devices, sources of fire and ozone.
Do not keep in direct vicinity of solvents, oils, fuels and lubricants.

Food contact

Gloves are marked with food contact symbol  and comply with the requirements of Regulation (EU) No 10/2011, European Regulation (EC) No 1935/2004 and with Regulation (EC) No 2023/2006 on Good Manufacturing Practice. Gloves are suitable for handling the food and have been tested for Overall Migration Test acc. EN 1186:

Extraction conditions (tested for 1 h in 40°C)	Analysis results [mg/dm ²]	Test Result (limit < 10 mg/dm ²)
3% Acetic acid	3.99	Pass
10% Ethanol	0.95	Pass
20% Ethanol	1.47	Pass
50% Ethanol	2.64	Pass
Vegetable oil	Not detected (<2.0)	Pass

MD classification & compliance

Gloves are classified as class I according to Annex VIII of the Regulation (EU) 2017/745 and comply to standards:

EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2021, EN 1041:2008+A1:2013.

PPE classification & compliance

Gloves are category III Personal Protective Equipment as per Annex I of the Regulation 2016/425 and comply to standards:

EN 420:2003+A1:2009, EN ISO 374-1:2016, EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013, EN ISO 374-5:2016.

Notified Body responsible for EU Type Examination (Module B) and on-going conformity (Module D):

BSI Group The Netherlands B.V.

Say Building,
John M. Keynesplein 9, 1066 EP
Amsterdam, Netherlands

CE 2797

Declaration of Conformity and this instruction for use available under below web address:

<https://mercatormedical.eu>

Intended use

These are non-sterile examination and protective gloves for single use, intended for use in medical field to: protect patient and user from cross-contamination, conducting medical examinations, diagnostic and therapeutic procedures and for handling medical contaminated material. Gloves are classified as Medical Devices Class I and as a Personal Protective Equipment Category III, type B. Gloves designed to protect against substances and mixtures which are hazardous to health and against harmful biological agents. Gloves designed to protect against chemical risk according with EN ISO 374-1:2016 and microorganism (viruses, bacteria and fungi) risks according with EN ISO 374-5:2016. Their design and labelling corresponds to the requirements of the European Regulation 2017/745 on Medical Device and the European Regulation 2016/425 on Personal Protective Equipment. Gloves should be used solely according to their intended application.

Precautions and indications for use

Dry hands before taking the gloves out from the packaging. Before usage, inspect the gloves for any defect or imperfections. Use at least 1 pair of gloves for one patient and one procedure, these are disposable gloves. Do not let chemical substances get under the gloves through the cuff. If a chemical substance reaches the skin, wash it away immediately with plenty of water. If the gloves get punctured, torn or broken during their use, take them off and put on the new ones. Avoid using gloves dirty in the inside as they may cause irritation leading to skin inflammation or more serious damages.

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. The gloves should not be used in contact with open fire and to protect against any sharp tools. The gloves are not intended for welding, electric shock protection, ionizing radiation or from the effect of hot or cold objects.

The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in case where 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. This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.

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 chemical resistant gloves.

Components / hazardous components

Components used in making gloves may cause allergic reactions in some people. Some gloves may contain components known to be a possible cause of allergy for person allergic to them, who may develop contact irritation and/or allergic reaction. In case of an allergic reaction consult a doctor.

Disposal

Used gloves should be treated as a contaminated material, therefore local regulations regarding the disposal of such materials should be applied.






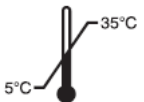

















Manufacturer

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31-327 Cracow, Poland
www.mercatormedical.eu

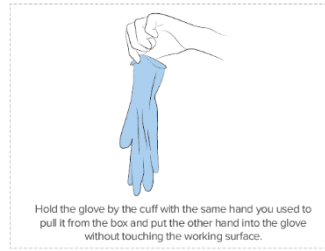
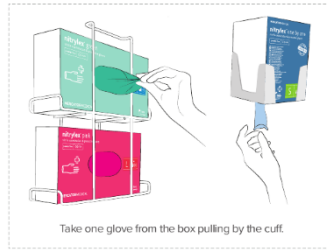
Permeation performance levels as per EN ISO 374-1:2016					
• Level 1 > 10 min • Level 2 > 30 min • Level 3 > 60 min • Level 4 > 120 min • Level 5 > 240 min • Level 6 > 480 min					
Test results acc. to EN 16523-1:2015		EN 374-4:2013	Test results acc. to EN 16523-1:2015		EN 374-4:2013
Chemical	Level	Degradation [%]	Chemical	Level	Degradation [%]
40% Sodium Hydroxide (K)	6	-66.1	1.5% Methanol in water	6	-20.3
n-Heptane (J)	1	18.7	0.1% Phenol	6	-3.7
50% Glutaraldehyde	6	-42.5	37% Formaldehyde (T)	6	-9.0
5% Ethidium Bromide	6	-33.8	96% Sulphuric Acid	0	100.0
70% Isopropanol	2	25.9	25% Ammonium Hydroxide (O)	1	31.6
Toluene	0	62.2	30% Hydrogen Peroxide (P)	5	26.9

EN 374-4: 2013 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

Test acc. to EN 374-2:2014 – Level 2 (ISO 2859)		Test acc. to EN ISO 374-5:2016	
Performance level	AQL	Protection against bacteria & fungi	Pass
Level 3	< 0.65	Protection against viruses	Pass
Level 2	< 1.5	EN ISO 374-5:2016 The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.	
Level 1	< 4.0		

Symbols used on the packaging			
	Medical Device		Keep dry
	Personal Protective Equipment		Keep away from sunlight
	Manufacturer		Temperature limitation 5-35°C
	Lot / batch number		Keep away from ozone
	Catalogue number		Product quality is not ensured if the package is damaged
	Expiry date		Recyclable packaging
	Date of manufacture		Package can be treated as municipal waste
	Indicates compliance with the requirements of Ukrainian market		Suitable for food contact (for details check the instruction for use)
			Nitrile gloves
			Powder-free gloves
			For single use only
			Non-sterile
			Designed to protect against to chemical risks acc. with EN ISO 374-1 (type B)
			Designed to protect against microorganisms risks acc. with EN ISO 374-5
			Consult instructions for use

■ HOW TO PUT THE GLOVES ON?



■ HOW TO TAKE THE GLOVES OFF?

