



nitrylex® orange

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

Short description of the product

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


Full description of the product

Raw material	: nitrile
External surface	: microtextured + fingertip textured, polymerized
Internal surface	: polymerized + chlorinated
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)
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 and fluorescent light. Recommended relative humidity in the room where the gloves are stored is 60 ±20%. 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 any type of food except for acidic foods and have been tested for Overall Migration Test acc. EN 1186:

Extraction conditions (tested for 2 h in 40°C)	Analysis results [mg/dm ²]	Test Result (limit < 10 mg/dm ²)
3% acetic acid	12.9	No Pass
10% ethanol	<1.0	Pass
20% ethanol	1.2	Pass
50% ethanol	2.1	Pass
Vegetable oil	<1.0	Pass

MDR classification & compliance

Gloves are classified as class I Medical Device as per Annex VIII of the Medical Device Regulation 2017/745 and comply to standards: EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2016, EN 1041:2008+A1:2013.

PPER 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 (Type B), EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013, EN ISO 374-5:2016.

Declaration of Conformity can be found under below web address: <https://mercatormedical.eu/products/gloves/examination-and-protective-gloves/nitrylex-orange>

EU Type Examination (Module B): Module D On-going Conformity:

Notified Body 2777
Satra Technology Europe Ltd
 Bracetown Business Park,
 Clonee, Dublin 15
 Dublin, Ireland

Notified Body 0598
SGS FIMKO OY
 P.O. Box 30 (Särkiniementie 3)
 00211 Helsinki, Finland



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. Their design and labelling corresponds to the requirements of the European Medical Device Regulation 2017/745 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 putting the gloves on. 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 with soap. 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. 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.

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 case where glove is equal to or over 400 mm – where the cuff is tested also) and relates only to the chemical tested and to the tested specimen. It can be different if the chemical is used in a mixture.

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

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 chemical resistant gloves.

Gloves are suitable for special purposes as they are examination gloves where risk of injury to the wrist is considered to be minimal, gloves are shorter than EN 420 min. length requirement.

Components / hazardous components

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, seek medical assistance immediately.

Disposal

Used gloves can be contaminated with contagious or other hazardous substances. They should be disposed of in accordance with local regulation. Gloves should be buried or burned under controlled conditions.

Manufacturer

MERCATOR MEDICAL S.A.
 ul. H. Modrzejewskiej 30
 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 Degradation [%]	Test results acc. to ASTM D 6978	
Chemical	Level		Chemotherapy drug and concentration	
n-Heptane (J)	2	51.4	Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	8.3
40% Sodium Hydroxide (K)	6	-36.1	Cisplatin 1.0 mg/ml (1,000 ppm)	240
37% Formaldehyde (T)	5	16.7	Cyclophosphamide (Cytoxan) 20.0 mg/ml (20,000 ppm)	240
30% Hydrogen Peroxide (P)	1	48.7	Cytarabine 100 mg/ml (100,000 ppm)	240
			Dacarbazine (DTIC) 10.0 mg/ml (10,000 ppm)	240
			Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm)	240
			Etoposide (Toposar) 20.0 mg/ml (20,000 ppm)	240
			Fluorouracil 50.0 mg/ml (50,000 ppm)	240
			Ifosfamide 50.0 mg/ml (50,000 ppm)	240
			Methotrexate 25 mg/ml (25,000 ppm)	240
			Mitomycin C 0.5 mg/ml (500 ppm)	240
			Mitoxantrone 2.0 mg/ml (2,000 ppm)	240
			Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm)	240
			Thiotepa 10.0 mg/ml (10,000 ppm)	38.0
			Vincristine Sulfate 1.0 mg/ml (1,000 ppm)	240

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		
Level 1	< 4.0		

Symbols used on the packaging

	Medical device		Personal Protective Equipment		Powdered gloves
	Do not re-use / gloves are intended for single use		Keep away from moisture, store in a dry place		Powder free gloves
	Non-sterile gloves		Keep away from solar and fluorescent light		Presence of polymer coating on the inner surface of the glove
	Lot / batch number		Temperature limitation / gloves store in temperature 5-35°C		Presence of cosmetic coating on the inner surface of the glove
	Catalogue number		Keep away from ozone		Presence of external texture on the glove
	EU Authorised Representative, symbol should be accompanied by name and address of Authorised Representative		Date of manufacture		Gloves made from nitrile
	Expiry date		Manufacturer, symbol should be accompanied by name and address of Manufacturer		Gloves made from vinyl
	Marking of gloves protecting against bacteria and fungi		Food contact symbol (article is suitable for food contact, for details check the instruction for use)		Raw material – natural rubber latex
	Marking of gloves protecting against viruses, bacteria and fungi		Package made from paper, qualify for recycling		50 gloves by weight
	Marking of type A chemical resistant gloves. Six tested chemicals shall be identified by their code letter under pictogram		Package is treated as municipal waste		100 gloves by weight
	Marking of type B chemical resistant gloves. Three tested chemicals shall be identified by their code letter under pictogram		Consult instructions for use		200 gloves by weight



ISO 374-1:2016/Type C



Marking of type C chemical resistant gloves. One tested chemical shall be identified by their code letter under pictogram



Indicates compliance with the requirements of Russian market



Additional information on inner side of package

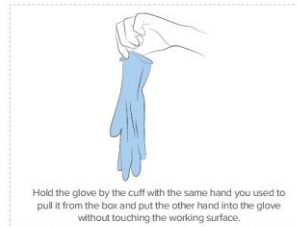
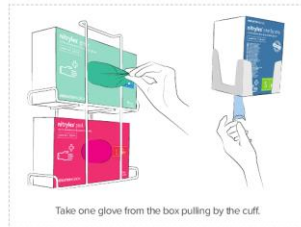


Indicates compliance with the requirements of Ukrainian market



Do not use, if package is damaged

HOW TO PUT THE GLOVES ON?



HOW TO TAKE THE GLOVES OFF?

