MERCATOR

nitrylex® high risk

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 with 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.
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.
Packaging suitable for transportation.

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 and have been tested for Overall Migration Test acc. EN 1186:

Extraction conditions (tested for 1 h in 40°C)	Analysis results [mg/dm²]	Test Result (limit < 10 mg/dm²)
3% acetic acid	<1.0	Pass
10% ethanol	<1.0	Pass
20% ethanol	<1.0	Pass
50% ethanol	<1.0	Pass
Vegetable oil	<1.0	Pass

MDR classification & compliance

Gloves are classified as class I according to Annex VIII of the Regulation (EU) 2017/745 and comply to standards:
EN 455-1:2000, EN 455-2:2009+A2:2013, EN 455-3:2006, EN 455-4:2009, EN ISO 15223-1:2016, EN 1041:2008.

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/

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

Notified Body 2797
responsible for EU Type Examination (Module B) and Module D On-going Conformity
BSI Group The Netherlands B.V.
Say Building,
John M. Keynesplein 9, 1066 EP
Amsterdam, Netherlands

CE 2797

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 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 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.

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

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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 which can be used on the packaging

MD	Medical device	PPE	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	Non-sterile gloves		Keep away from solar and fluorescent light	POLYMER COATED	Presence of polymer coating on the inner surface of the glove
LOT	Lot / batch number	35°C 5°C	Temperature limitation / gloves store in temperature 5-35°C	COSMETIC COATING	Presence of cosmetic coating on the inner surface of the glove
REF	Catalogue number	O_3	Keep away from ozone	TEXTURED	Presence of external texture on the glove
EC REP	EU Authorised Representative, symbol should be accompanied by name and address of Authorised Representative		Date of manufacture	NITRILE	Gloves made from nitrile
	Expiry date		Manufacturer, symbol should be accompanied by name and address of Manufacturer	VINYL	Gloves made from vinyl
ISO 374-5:2016	Marking of gloves protecting against bacteria and fungi		Food contact symbol (article is suitable for food contact, for details check the instruction for use)	LATEX	Raw material – natural rubber latex
ISO 374-5:2016 VIRUS	Marking of gloves protecting against viruses, bacteria and fungi	21 PAP	Package made from paper, qualify for recycling	50 by weight	50 gloves by weight
ISO 374-1/Type A	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 by weight	100 gloves by weight
UVWXYZ ISO 374-1/Type B	Marking of type B chemical resistant gloves. Three tested chemicals shall be identified by their code letter under pictogram		Consult instructions for use	200 by weight	200 gloves by weight
XYZ ISO 374-1/Type C	Marking of type C chemical resistant gloves. One tested chemicals shall be identified by their code letter under pictogram		Additonal information on inner side of package		Do not use, if package is damaged
	Indicates compliance with the requirements of Russian market		Indicates compliance with the requirements of Ukrainian market		

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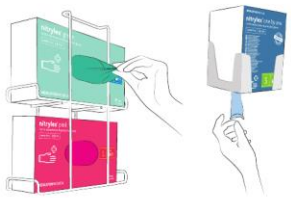
HOW TO PUT THE GLOVES ON?



Take one glove from the box pulling by the cuff.

Hold the glove by the cuff with the same hand you used to pull it from the box and put the other hand into the glove without touching the working surface.

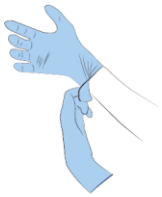
Stretch the glove on the right hand.

Take another glove from the box with the hand wearing a glove.

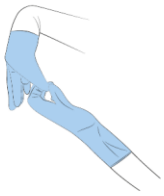
Put the glove on the hand and smooth it out.

Done!

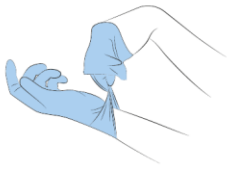
HOW TO TAKE THE GLOVES OFF?



Hold the glove with a finger of the other hand at the cuff.



Slide the glove down to mid-palm.



Hold the other glove by its outer edge.

When removing the gloves, turn them inside out.

Hold both gloves without touching the contaminated walls.

Removed gloves should be treated as healthcare waste.