User instruction

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

Short description of the product

Nitrile examination, powder-free, non-sterile for disposable use. Product Reference“Nitrylex Classic Long”.

Full description of the product

Raw material	: nitrile
External surface	: textured
Internal surface	: polymerized + chlorinated
Cuff	: beaded
Colour	: Blue
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 or customer required
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.

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)	Test Result (limit < 10 mg/dm²)
3% Acetic acid	Pass
10% Ethanol	Pass
Olive oil	Pass

MDR classification & compliance

Gloves are classified as class I Medical Device as per MDR 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.

PPE classification & compliance

Gloves are category III Personal Protective Equipment as per Annex II of the Regulation 2016/425 and comply to standards:
EN ISO 21420: 2020, EN ISO 374-1:2016+ A1:2018 (Type B), EN 374-2:2014, EN16523-1:2015, EN 374-4:2013, EN ISO 374-5:2016.

EU Type Examination Certificate issued by: SATRA (Notified Body No. 2777)

Checking of PPE manufactured:
CE 2777
SATRA Technology Europe Limited.
Bracetown Business Park.
Clonee.
D15YN2P.
Republic of Ireland.

Declaration of Conformity and Instruction of Use with the information about the importer are available at: www.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. Their design and labelling correspond 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 between mixtures and pure chemicals.

Degradation results indicate the change in puncture resistance of the gloves after exposure to the challenge chemical. The chemical penetration 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 ISO 21420 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 (Thailand) Ltd.
88/8 Moo 12 Tambon Kampaengphet,
Amphur Rattaphum,Songkhla 90180,Thailand.
www.mercator.co.th

Authorized Representative/Importer

Mercator Medical S.A.
Address: ul. H. Modrzejewskiej 30
31-327 Krakow, Poland
www.mercatormedical.eu

Permeation performance levels as per EN ISO 374-1:2016 Level1>10min , Level2>30 min, level3>60 min, level4>120min,Level5>240min, Level6>480m in Test results acc. to EN 16523-1:2015		EN 374-4:2013 Degradation [%]
Chemical	Level	
35% Ethanol	6	55.0
40% Isopropanol	6	68.7
10%Acetic acid	4	53.5
50% Benzalkonium chloride*	6	29.5
4% Chlorhexidine digluconate **	6	32.9
10% Phosphoric acid	6	14.0
40% Sodium hydroxide (K)	6	2.6
12% Sodium hypochlorite	6	22.7
50% Sulphuric Acid	6	21.1
5% Ethidium Bromide	6	32.9
3% Hydrogen peroxide	6	44.0
30% Hydrogen peroxide (P)	2	52.8
37% Formaldehyde (T)	5	20.0
50% Glutaraldehyde	6	22.9
0.1% Phenol	6	24.7

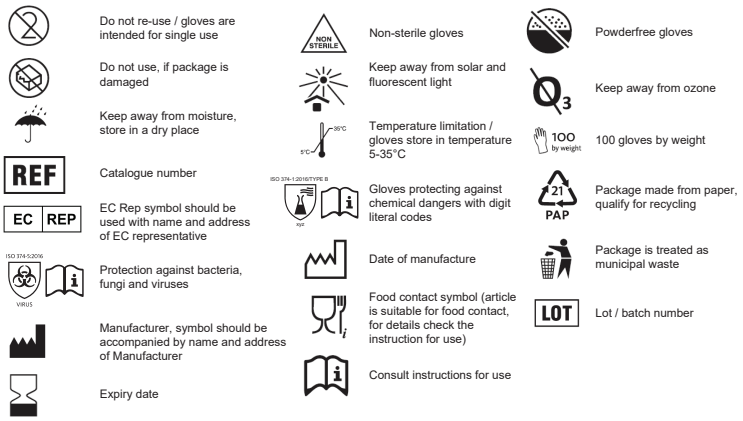
* Permeation rate 5 µg/cm²/min,EN374-4:2013 degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

** Permeation rate 7 µg/cm²/min,EN374-4:2013 degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

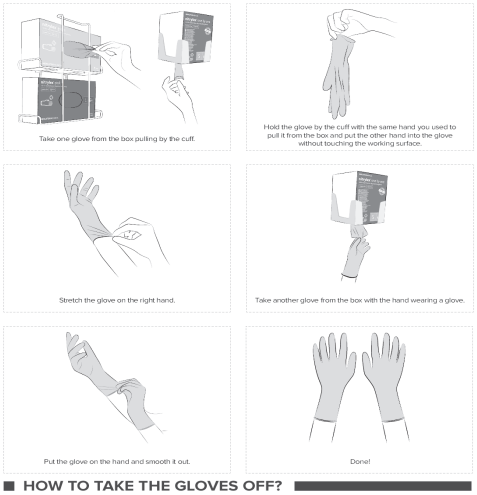
Noted : 1) Glove minimum length for Lab application accordance to EN455-2

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



HOW TO PUT THE GLOVES ON?



HOW TO TAKE THE GLOVES OFF?