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.

Full description of the product

Brand name	: nitrylex ® classic
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, 200 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 any type of food and have been tested for Overall Migration Test acc. EN 1186:

Extraction conditions (tested for 0.5 h in 40°C)	Test Result (limit < 10 mg/dm²)
3% Acetic acid	Pass
10% Ethanol	Pass
20% Ethanol	Pass
50% Ethanol	Pass
95% Ethanol	Pass
Isooctane	Pass

MD classification and compliance

Gloves are classified as class I Medical Device as per MDR 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 II of the Regulation 2016/425 and comply to standards:
EN ISO 21420: 2020, EN ISO 374-1:2016+ A1:2018 (Type B), EN ISO 374-2:2019, EN16523-1:2015 + A1:2018, EN 374-4:2013, EN ISO 374-5:2016.

EU Type Examination (Module B) and on-going conformity (Module C2) Notified Body: SATRA (Notified body No. 2777)
UKCA Type Examination Certificate issued by: SATRA (Approved Body No. 0321)

Checking of PPE manufactured:

CE 2777
SATRA Technology Europe Limited.
Bracetown Business Park,
Clonee, Dublin 15
Dublin, Ireland

UK CA 0321
SATRA Technology Centre Limited.
Wyndham Way, Telford Way,
Kettering, Northamptonshire,
NN16 8SD,
United Kingdom.

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, 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 to chemical risk according with EN ISO 374-1:2016+A1:2018 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 and included the PPE Regulation(EU) 2016/425 as brought into UK law and amended as a Category III product. 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. Gloves are suitable for special purposes as they are examination gloves where risk of wrist injury caused by chemicals is considered to be minimal. Length suitable for tasks that require hand protection. Glove minimum length in accordance to EN 455-2 standard.

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

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+ A1:2018		EN ISO 374-4:2019 Degradation [%]
Level1>10min , Level2>30 min, level3>60 min, level4>120min, Level5>240min, Level6>480min		
Test results acc. to EN 16523-1:2015+ A1:2018		
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

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

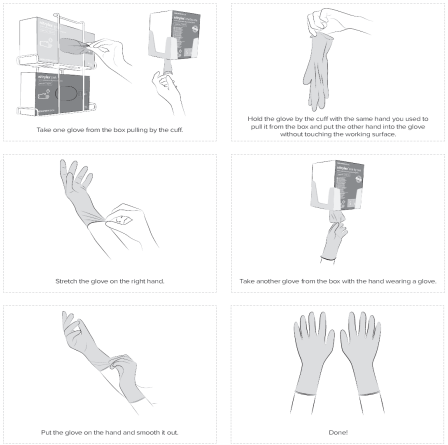
Noted : * Permeation rate 5 µg/cm^2/min.
** Permeation rate 7 µg/cm^2/min.

Test acc. To EN ISO 374-2:2019 – 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 : 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
- Personal Protective Equipment
- Manufacturer
- Authorized representative in the European Union
- Importer
- Lot / batch number
- Catalogue number
- Expiry date
- Date of manufacture
- Keep dry
- Keep away from sunlight
- Temperature limitation 5-35°C
- Keep away from ozone
- Product quality is not ensured if the package is damaged
- Recyclable packaging
- Package can be treated as municipal waste
- 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
- Indicates compliance with the requirements of Ukrainian market

HOW TO PUT THE GLOVES ON?



HOW TO TAKE THE GLOVES OFF?