

# User Instruction

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

Product Reference	: nitrilex® strong
Raw material	: nitrile
External surface	: textured
Internal surface	: chlorinated
Cuff	: beaded
Colour	: black
Shape	: ambidextrous, fitting to the right and left hand
Size range	: S, M, L, XL, XXL
AQL	: 1.0
Quantity in packaging	: 100 pieces 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 European Regulation (EC) No 1935/2004 on materials, European Commission Directive 93/11/EEC and Council of Europe Resolution AP (2004) 4 and with requirement of Regulation (EC) No 2023/2006 on Good Manufacturing Practice. Result Summary: Test Requested Council of Europe Resolution AP (2004) 4

Extraction conditions (tested for 30 minutes in 40°C)	Test Result (limit < 10 mg/dm <sup>2</sup> )
3% Acetic acid	Pass
10% Ethanol	Pass
20% Ethanol	Pass
50% Ethanol	Pass
Rectified Olive Oil	Pass

It can be ensured that no substances are transferred to the food which may lead to an alteration of the food. Food disposable gloves are designed for short-term use and frequent changes. It's best to change your gloves regularly.

## MDR classification & 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 15223-1:2016, EN ISO 20417:2021.



CE Marking:

## PPE classification & compliance

Gloves are category III Personal Protective Equipment as per Annex II of the Regulation 2016/425 CAT III TYPE B on Personal Protective Equipment and comply to standards: EN ISO 21420: 2020, EN ISO 374-1:2016 + A1:2018 (Type B), EN ISO 374-2:2019, EN 16523-1:2015 + A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016.

EU Type Examination Certificate issued by: SATRA (Notified Body No. 2777)  
Checking of PPE manufactured:



SATRA Technology Europe Limited.  
Bracetown Business Park,  
Clonee, Dublin 15, Dublin,  
D15YN2P,  
Republic of Ireland

Declaration of Conformity and Instruction of Use with the information about the importer are available at: [www.mercatormedical.eu](http://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>120 min, Level5>240 min, Level6>480 min	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%

\* Permeation rate 5 µg/cm<sup>2</sup>/min, EN ISO 374-4:2019 degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

\*\* Permeation rate 7 µg/cm<sup>2</sup>/min, EN ISO 374-4:2019 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 EN 455-2

Test acc. To EN ISO 374-2:2019 (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		

EN ISO 374-5:2016 The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

## Intended use

These are non-sterile powder free nitrile examination and protective gloves for single use, intended for medical purpose that in worn on the hand to protect patient and examiners from cross contamination, conducting medical examinations, diagnostic and therapeutic procedures. Examination glove is intended for medical activities except surgery. Non-sterile powder free nitrile examination and protective gloves designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety. Intended for food contact purposes that donning to prevent the likelihood of food contamination during the preparation or handling and applies to every food handler. Gloves are classified as Medical Devices Class I. Their design and labelling correspond to the requirements of the European Medical Device Regulation 2017/745, the European Regulation 2016/425 CAT III TYPE B on Personal Protective Equipment and comply with the requirements of European Regulation (EC) No 1935/2004 on materials. 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.

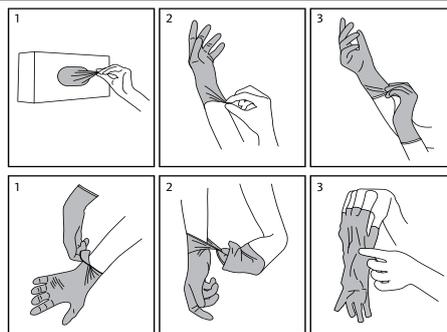
## Disposal

Local regulations regarding the disposal should be applied.

## Symbols used on the packaging

Medical Device	Personal Protective Equipment	Nitrile Gloves
Powder-free gloves	For single use only	Non-sterile
Product quality is not ensured if the package is damaged	Keep away from sunlight	Keep dry
Temperature limitation 5-35°C	EN ISO 374-1 Chemical protection gloves, accompanied by 3-digits code XYZ	EN ISO 374-5 Glove protecting against bacteria, fungi and viruses
Consult instructions for use	Additional information on inner side of package	Suitable for food contact
Recyclable packaging	Package can be treated as municipal waste	Lot / batch number
Date of manufacture	Expiry date	Manufacturer
EC representative	Importer	Catalogue number
100 by weight	Packed 100 gloves by weight	

## How to put and take off



## Manufacturer

MERCATOR MEDICAL (Thailand) Ltd.  
88/8 Moo 12, Tambon Kampaengphet, Amphur Rattaphum, Songkhla 90180,  
Thailand

## Authorized Representative

Mercator Medical S.A.  
Address: ul. H. Modrzejewskiej 30, 31-327 Krakow, Poland  
[www.mercatormedical.eu](http://www.mercatormedical.eu)