

MERCATOR high protect

RP30022202-06(2171)

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

Short description of the product

Nitrile household and protective gloves, powder-free, non-sterile, with long cuff and with a cotton lining inside

Full description of the product

Reference number	: RP30022202-06(2171)
Raw material	: nitrile
Cuff	: long
Colour	: dark blue
Shape	: anatomic, hand specific
Size range	: S (6-7), M (7-8), L (8-9), XL (9-10), XXL (10-11)
AQL	: 1.0
Quantity in packaging	: 1 pair (polybag); 24 x 1 pair (display)
Shelf life	: 5 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. It is recommended to protect gloves against humidity.

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 2 hours in 40°C)	Analysis results [mg/dm ²]	Test Result (limit < 10 mg/dm ²)
3% Acetic acid	< 3.0	Pass
10% Ethanol	< 3.0	Pass
95% Ethanol	3.3	Pass
Isooctane	< 3.0	Pass

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 A), EN ISO 374-2:2019, EN 16523-1:2015, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 388:2016.

Declaration of Conformity can be found under below web address:

<https://mercatormedical.eu/>

**Notified Body 0598 responsible for
Module B EU Type Examination
and Module D on-going Conformity:**

CE 0598

SGS FIMKO OY
Takomotie 8
00380 Helsinki, Finland

Intended use

These are non-sterile household and protective gloves, intended for food industry and processing, including the processing of animal products, plant products, as well as secondary processing (e.g. bakery, feed or confectionery industries) and spirits production. Gloves have the highest category of protection against chemical and for this reason they are also indicated for wide range of industry, where the worker exposes his hands to direct contact with chemicals. Gloves are classified as a Personal Protective Equipment Category III. Their design and labelling corresponds to the requirements of 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. When protection is limited to part of the hand only. 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. It can be different if the chemical is used in a mixture.

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

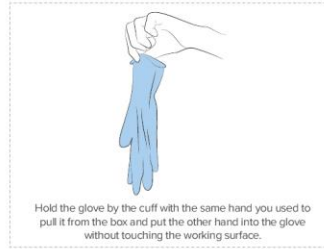
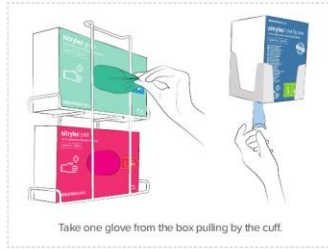
Used gloves can be contaminated with contagious or other hazardous substances. They should be disposed of in accordance with local regulation. Gloves should be buried or burned under controlled conditions.

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+A1:2018					
• 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 ISO 374-4:2019 Degradation [%]		
Chemical	Level				
99.9% Methanol (A)	1		82.4		
n-Heptane (J)	6		11.7		
40% Sodium Hydroxide (K)	6		7.5		
96% Sulphuric Acid (L)	2		93.9		
99% Acetic Acid (N)	2		92.9		
25% Ammonium Hydroxide (O)	4		38.5		
37% Formaldehyde (T)	6		31.3		
EN ISO 374-4:2019 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.					
Test results acc. to EN 388:2016		Test acc. to EN ISO 374-2:2019 – Level 2 (ISO 2859)			
Mechanical Resistance Test	Performance Level	Performance level	AQL		
Abrasion Resistance	3	Level 3	< 0.65		
Blade Cut Resistance	0	Level 2	< 1.5		
Tear Resistance	0	Level 1	< 4.0		
Puncture Resistance	1				
Cut Resistance	X				
Test acc. to EN ISO 374-5:2016					
Protection against bacteria & fungi	Pass				
Protection against viruses	Not tested				
EN ISO 374-5:2016 The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.					
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 gloves		Keep away from solar and fluorescent light		Presence of polymer coating on the inner surface of the glove
LOT	Lot / batch number		Temperature limitation / gloves store in temperature 5-35°C		Presence of cosmetic coating on the inner surface of the glove
REF	Catalogue number		Keep away from ozone		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		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
	Marking of type C chemical resistant gloves		Information in other languages inside		Do not use, if package is damaged
	Protective glove against mechanical risk (together with the performance levels achieved in each of the mechanical resistance tests)		Indicates compliance with the requirements of Russian market		Indicates compliance with the requirements of Ukrainian market

■ HOW TO PUT THE GLOVES ON?



■ HOW TO TAKE THE GLOVES OFF?

