MERCATOR MEDICAL

ideall® grip+

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

Short description of the product

Powder-free nitrile protective gloves, with thicker walls and diamond textured, non-sterile.

Full description of the product

Raw material : nitrile

External surface : diamond textured, polymerized Internal surface : polymerized + chlorinated

Cuff : beaded
Colour : black / orange
Shape : ambidextrous

Size range : M (7-8), L (8-9), XL (9-10)

AQL : 1.5

Quantity in packaging : 50 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 $5-35^{\circ}\text{C}$ and to protect them against direct sunlight and fluorescent light. Recommended relative humidity in the room where the gloves are stored is $60 \pm 20\%$. 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 X 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	Analysis results	Test Result	
(tested for 2h in 40°C)	[mg/dm ²]	(limit < 10 mg/dm²)	
10% ethanol	2.6	Pass	
20% ethanol	3.1	Pass	
50% ethanol	8.5	Pass	
3% acetic acid	8.5	Pass	
olive oil	< 1.0	Pass	

PPE 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/produkty/rekawice/gospodarcze_i_ochronne/ideall-grip-orange

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EU Type Examination (Module B) Notified Body 2777 Satra Technology Europe Ltd Bracetown Business Park Clonee, Dublin 15 Dublin, Ireland

Module D on-going Conformity Notified Body 0598 SGS FIMKO OY P.O. Box 30 (Särkiniementie 3)

00211 Helsinki, Finland

C€ 0598

Intended use

These are non-sterile protective gloves with thicker walls and diamond textured, providing excellent grip and protection when working in oily and wet environment.

These gloves are intended for use when there is a need for protection against dangerous substances and infective agents. These are chemical resistant gloves classified as Personal Protective Equipment category III. The design and labeling of these gloves correspond to the requirements of the Regulation 2016/425 on Personal Protective Equipment. Gloves should be used solely according to their intended purpose.

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.

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 the case of an allergic reaction, seek medical assistance immediately.

Disposa

Used gloves 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 [%]			
n-Heptane (J)	2	42.3						
40% Sodium Hydroxide (K)	6	-34.7						
37% Formaldehyde (T)	6	28.6						
30% Hydrogen Peroxide (P)	4	19.9						

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			

EN 374-4:2013 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical. Symbols used on the packaging Do not re-use / gloves are Non-sterile gloves Powdered gloves intended for single use Do not use, if package is Keep away from solar and Powder free gloves damaged fluorescent light Temperature limitation / Keep away from moisture, Presence of polymer coating on gloves store in temperature 5store in a dry place the inner surface of the glove 35°C Raw material - natural rubber Presence of cosmetic coating on Keep away from ozone the inner surface of glove latex Presence of silk coating on the Catalogue number Lot / batch number inner surface of glove EU Authorised Representative, symbol should be accompanied Presence of external texture on EC REP Expiry date by name and address of the glove Authorised Representative Gloves protecting against Marking of gloves protecting chemical dangers with digit Gloves made from nitrile against bacteria and fungi. literal odes Marking of gloves protecting Gloves made from vinyl against viruses, bacteria and Antistatic gloves





ISO 374-1/Type B













fungi.

Marking o type A chemical resistant gloves. Six tested chemicals shall be identified by their code letter under pictogram.

Marking o type B chemical resistant gloves. Three tested chemicals shall be identified by their code letter under pictogram.

Marking o type C chemical resistant

Protective glove against mechanical risk (if applicable accompanied by 4 digit code of relevant performance

Food contact symbol (article is suitable for food contact, for details check the instruction for use)

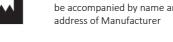
Indicates compliance with the requirements of Russian mar



Date of manufacture



Manufacturer, symbol should be accompanied by name and





Consult instructions for use



Package made from paper, qualify for recycling



Package is treated as municipal waste



Indicates compliance with the requirements of Ukrainian market





Gloves made from neoprene



Gloves made from polyisoprene



50 gloves by weight



100 gloves by weight



200 gloves by weight



Additional information on inner side of package