

MERCATOR gogrip



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EU DECLARATION OF CONFORMITY

Manufacturer: **Mercator Medical (Thailand) Ltd.**
88/8 Moo.12 Tambon Kampaengphet,
Amphur Rattaphum, Songkhla 90180 Thailand

Declare under its sole responsibility that protective gloves:

Brand	Type	Sizes	Packaging	Reference Numbers
MERCATOR GOGrip BLACK	Nitrile, powder free, black, diamond textured, for single use	S (6-7) - XXL (10-11)	a'100	RP30043002-06_0001
			a'50	RP30023002-06_0001
			a'4	RP30039002-06_0001

The products described above are in conformity with the provision of the PPE Regulation (EU) 2016/425 as a Category III product, Type B where such is the case, with standards EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 16523-1:2015+A1:2018 and EN ISO 21420: 2020

The products are subject of EU Type Examination (Module B) and Module C2 on-going Conformity under certificate No. 2777/25538-01/E00-00 issued by notified body:

SATRA Technology Europe Limited (Notified Body number 2777)
Bracetown Business Park, Clonee Dublin 15, Dublin, Ireland

This declaration is supported by the Quality System approval to ISO13485:2016/EN ISO13485:2016 and ISO 9001:2015 issued by:

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK

Date and place of issue:
24.12.2024, Thailand

Signed on the behalf of the Manufacturer:

Mr. Praneet Inthajak
Senior QA/RA Manager
Mercator Medical (Thailand) Ltd.



User instruction

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

Short description of the product

Nitrile protective gloves , powder-free, non-sterile for disposable use.


Full description of the product

Product Reference	: MERCATOR gogrip
Raw material	: nitrile
External surface	: diamond 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	: 1.5
Quantity in packaging	: 4 pieces, 50 pieces by weight, 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 Commission 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
Rectified Olive Oil	Pass

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, EN 16523-1:2015 + A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016, EN ISO 16350:2014. 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

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	
40% Sodium hydroxide (K)	6	-100.7%
30% Hydrogen peroxide (P)	3	-2.8%
37% Formaldehyde (T)	6	-18.2%
n-Heptane (J)	6	29.7%
25% Ammonium hydroxide (O)	1	-37%

Noted : EN ISO 374-4: 2019 Degradation results indicate the change in puncture resistance of the gloves after exposure to the challenge chemical

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	EN ISO 374-5:2016 The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.	
Level 1	< 4.0		

Test acc. To EN ISO 16350:2014	
Electrostatic Properties	Pass

Precautions and indications for use

Dry hands before putting the gloves on. Before usage, inspect the gloves for any defect or imperfections. 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 protective gloves where risk of injury to the wrist is considered to be minimal, gloves are shorter than EN ISO 21420 min. length requirement. The person wearing the electrostatic dissipative protective gloves shall be properly earthed e.g. by wearing adequate footwear. Electrostatic dissipative gloves shall not be unpacked, opened, adjusted or removed whilst in flammable or explosive atmospheres or while handling flammable or explosive substances. The electrostatic properties of the protective gloves might be adversely affected by ageing, wear, contamination and damage, and might not be sufficient for oxygen enriched flammable atmospheres wher additional assessments are necessary. Gloves are not intended for protection of electronic devices and protection against mains voltages.

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.





























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.

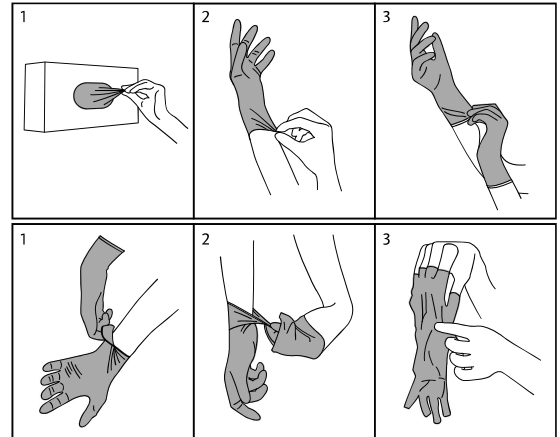
Disposal

Local regulations regarding the disposal should be applied.

Symbols used on the packaging

 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 a 3-digits code	 EN ISO 374-5 Glove protecting against bacteria, fungi and viruses	 Electrostatic dissipative protective glove
 Consult instructions for use	 Additional information on inner side of package	 Suitable for food contact
 Recyclable packaging	 Package can be treated as municipal waste	 Indicates compliance with the requirements of Ukrainian market
 Model number	 Lot / batch number	 Date of manufacture
 Expiry date	 Manufacturer	 Importer
 Catalogue number	 Packed 4 gloves	 Packed 50 gloves by weight
 Packed 100 gloves by weight		

How to put and take off



Manufacturer



MERCATOR MEDICAL (Thailand) Ltd.
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Amphur Rattaphum, Songkhla 90180,
Thailand

Importer



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