

MERCATOR latex comfort

RD10283001-05_0012

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

Short description of the product

Natural rubber latex examination and protective gloves, powder-free, non-sterile for disposable use

Full description of the product

Reference number	: RD10283001-05_0012 RD10284001-05_0012
Raw material	: natural rubber latex
Cuff	: beaded
Colour	: beige
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	: 1.5
Quantity in packaging	: 100 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 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 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. Test results are included in the table below.

MDR classification & compliance

Gloves are classified as class I according to Annex VIII of the Regulation (EU) 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 1041:2008+A1:2013.

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

Declaration of Conformity can be found under below web address: <https://en.mercatormedical.eu/>

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

CE 0598

**Module D on-going Conformity
Notified Body 0598**
SGS FIMKO OY
Takomotie 8
00380 Helsinki

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. 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. 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.

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. Gloves made from natural rubber latex may cause allergic reactions, including anaphylactic responses. In case of an allergic reaction, seek medical assistance immediately.

Disposal

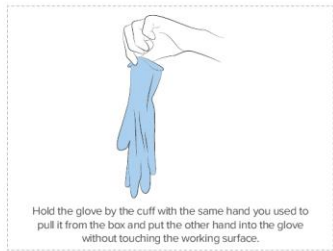
Used gloves can be contaminated with contagious or other hazardous substances. They should be disposed of in accordance with local regulation. Gloves should be buried or burned under controlled conditions.

Manufacturer

MERCATOR MEDICAL S.A.
ul. H. Modrzejewskiej 30
31-327 Cracow, Poland
www.mercatormedical.eu

Overall Migration Test with Food Simulant acc. to EN 1186						
Colour / Food Simulant & Test Conditions	Analysis result [mg/dm ²]					Test Result (limit < 10 mg/dm ²)
	3% Acetic acid 40°C, 2 hours	20% Ethanol 40°C, 2 hours	50% Ethanol 40°C, 2 hours	Olive oil 40°C, 2 hours	20% Ethanol 40°C, 2 hours	
Beige	5.4	4.2	4.2	7.3	< 1.0	Pass
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 ISO 374-4:2019 Degradation [%]	
Chemical					Level	
Sodium Hydroxide 40% (K)					3	
Sulphuric Acid 96% (L)					1	
Formaldehyde 37% (T)					5	
EN ISO 374-4:2019 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.						
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 374-5:2016 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		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 / batch number		Temperature limitation / gloves store in temperature 5-35°C		Presence of cosmetic coating on the inner surface of the glove	
	Catalogue number		Keep away from ozone		Presence of external texture on the glove	
	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		Gloves do not contain natural rubber latex	
	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		50 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		100 gloves by weight	
	Marking of type C chemical resistant gloves. One tested chemical shall be identified by their code letter under pictogram		Information in other languages inside		200 gloves by weight	
	Indicates compliance with the requirements of Russian market		Indicates compliance with the requirements of Ukrainian market		Do not use, if package is damaged	

■ HOW TO PUT THE GLOVES ON?



■ HOW TO TAKE THE GLOVES OFF?

