

santex[®] anatomic

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 / powdered, non-sterile, for disposable use

Full description of the product

Reference numbers	: RD10247060 – 090; RD11247060 – 090
Raw material	: Natural rubber latex
Cuff	: beaded
Colour	: creamy
Shape	: anatomic, hand specific
Size range	: 6.0; 6.5; 7.0; 7.5; 8.0; 8.5; 9.0
AQL	: 1.5
Quantity in packaging	: 2 x 50 pcs. by weight
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. 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.

MDR classification & compliance

Gloves are classified as class I according to Annex VIII of the Regulation (EU) 2017/745 and comply to standards: EN 455-1:2000, EN 455-2:2009+A2:2013, EN 455-3:2006, EN 455-4:2009, EN ISO 15223-1:2016, EN 1041:2008.



PPER classification & compliance

Gloves are category I Personal Protective Equipment as per Annex I of the Regulation 2016/425 and comply to standards: EN 420:2003+A1:2009.

Declaration of Conformity can be found under below web address:

<https://mercatormedical.eu/products/gloves/examination-and-protective-gloves/santex-anatomic-PF>

<https://mercatormedical.eu/products/gloves/examination-and-protective-gloves/Santex-anatomic-PP>

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 I. 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.

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.

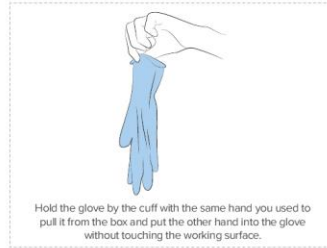
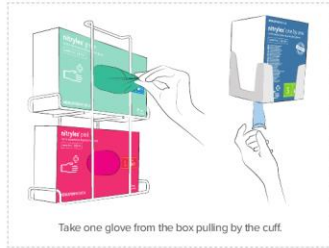
Manufacturer

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

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		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. One tested chemicals shall be identified by their code letter under pictogram		Additional information on inner side of package		Do not use, if package is damaged
	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?

